



THE ACCESS AND
DELIVERY PARTNERSHIP



From
the People of Japan



ACCESS AND DELIVERY PARTNERSHIP: TB, MALARIA AND NTD HEALTH TECHNOLOGIES FOR THOSE IN NEED

IMPACT STORIES

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01

A DECADE OF PARTNERSHIP

Since 2013, in partnership with the Government of Japan, the United Nations Development Programme (UNDP) has worked to strengthen policies, institutions, systems and capacities to increase people's access to life-saving health technologies – vaccines, medicines and diagnostic tools for tuberculosis (TB), malaria and neglected tropical diseases (NTDs) – diseases that disproportionately affect the poor.

The strategic approach of the UNDP-led Access and Delivery Partnership (ADP) is informed by two key lessons. First, even where innovative health technologies are developed, their introduction and use within national health systems are often constrained by country-specific bottlenecks and challenges. ADP focuses on identifying and strengthening the relevant human, technical and institutional capacities to address these challenges. Second, successful introduction and delivery of new health technologies also depends on coordination and coherence of domestic institutions. For this reason, ADP supports countries to strengthen policies and systems that drive country-led changes for sustainable and multisectoral approaches. Together, strengthened capacities with a coordinated multisectoral approach will enable sustained improvements in access to health and enhance progress towards universal health coverage (UHC), pandemic preparedness and human security.

Working with national, regional and global stakeholders, the core partners of ADP – UNDP, the World Health Organization (WHO), the Special Programme for Research and Training in Tropical Diseases (TDR) and PATH – have delivered results.

This report shares a collection of stories that put a spotlight on the impact that ADP is having on people's lives. These stories underscore the importance of the partnership between UNDP and the Government of Japan. This partnership strives towards a common goal, one that is reflected in the 2030 Agenda for Sustainable Development, the [UNDP Strategic Plan 2022–2025](#) and in Japan's new [Global Health Strategy](#): that of building resilience of national health systems and prioritizing universal health coverage as an important means towards achieving human security.

Photo: Annie Spratt on Unsplash



ADP core partner organizations

The four ADP partners each bring a unique set of expertise to the partnership, helping identify and strengthen capacity gaps in low- and middle-income countries (LMICs) in innovative and integrated ways.



UNDP is the leading United Nations organization fighting to end the injustice of poverty, inequality and climate change through its broad network of experts and partners in 170 countries. As the lead agency for ADP, UNDP manages and coordinates the partnership. UNDP supports the ADP focus countries on the development and introduction of national policy and legal and governance frameworks, and facilitates the digital transformation of health systems. UNDP also aids the establishment of multisectoral forums across government agencies and leads ADP's strategic focus on South–South learning and exchange.



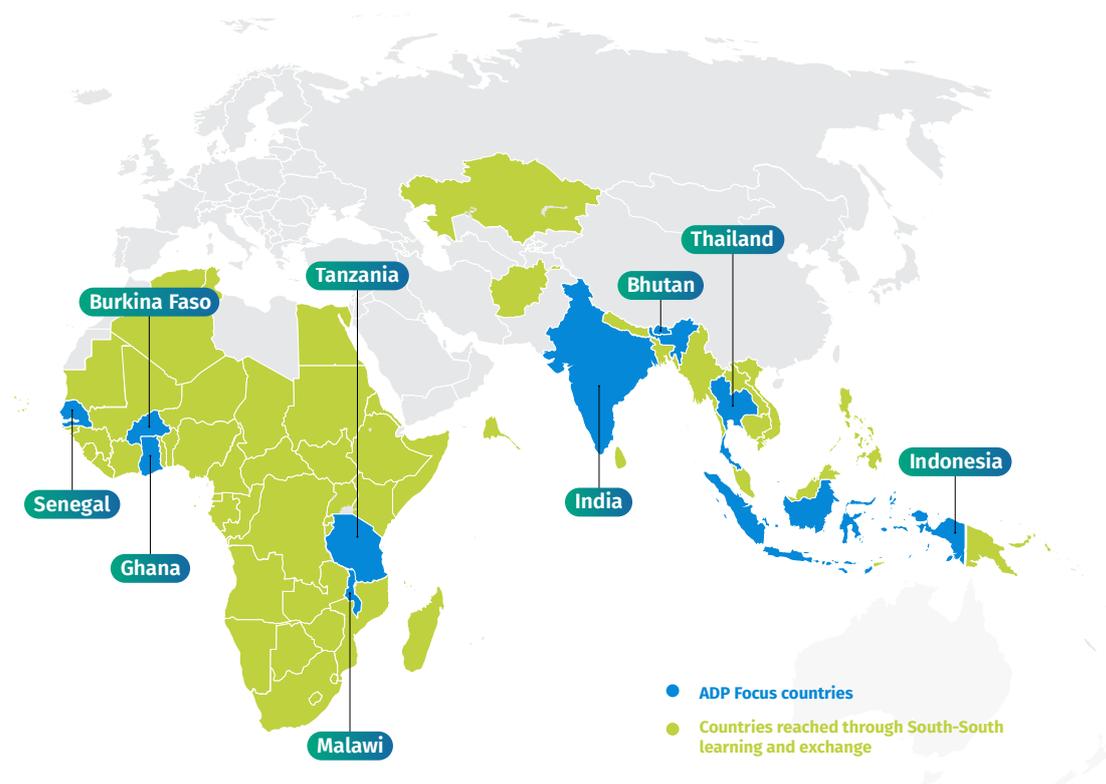
WHO is the directing and coordinating authority on international health within the United Nations system, working with 194 Member States in a shared commitment to achieve better health for everyone, everywhere. WHO supports the benchmarking of national regulatory authorities in ADP focus countries, promoting regulatory harmonization by addressing capacity gaps and facilitating coalition-focused approaches. Within ADP, WHO also helps strengthen processes for market surveillance and quality monitoring of health technologies.



TDR is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. It is co-sponsored by the United Nations Children's Fund (UNICEF), UNDP, the World Bank and WHO. Within ADP, TDR focuses on pharmacovigilance systems, including strengthening capacities for safety monitoring of new health technologies and related surveillance, reporting and data management capacities. TDR also supports national research institutions, disease control programmes and health researchers to systematically apply implementation research principles towards effective introduction and use of new health technologies.



PATH is an international non-governmental organization that drives transformative innovation to save lives and improve health, especially for women and children. Working with ADP focus countries, PATH supports sustainable evidence-based resource allocation processes, enabling LMICs to evaluate the implications of the introduction of new health technologies. Areas of focused technical support include institutionalizing priority-setting strategies as tools for informed health decision-making, and strategic approaches to 'value-based' planning, procurement and supply chain management.



ADP covers nine 'focus' countries and has reached over 60 countries through its South–South learning and exchange.

02

HELPING COUNTRIES ACHIEVE HEALTH AND HUMAN SECURITY

The 2030 Agenda for Sustainable Development acknowledges the human development impacts of TB, malaria and NTDs, and as such, calls for ending these epidemics by 2030 as a development priority. Despite progress in recent decades against these ‘diseases of poverty’, challenges have persisted in delivering promising new technologies to prevent, diagnose and treat them. The COVID-19 pandemic has further exacerbated these challenges. The Sustainable Development Goals Report 2022 paints a sobering picture of the reversal of gains against these diseases, threatening decades of progress in global health. Health systems and essential health services were severely disrupted, causing a drop in immunization coverage for the first time in a decade and a rise in deaths from TB and malaria.¹

TB, malaria and NTDs – diseases of poverty

TB, malaria and NTDs persist as diseases of poverty and inequality. They are disproportionately prevalent among the poorest and most vulnerable people and communities. Conditions associated with living in poverty, such as the lack of adequate housing, sanitation, access to safe drinking water and nutritious food, as well as access to health services, contribute to risk of exposure and increase the likelihood of transmission.

Each year, approximately 10 million people fall ill with TB, and 1.5 million of them die,² while malaria claims the lives of more than 600,000 people, with children under the age of 5 years old being the most vulnerable.³ In 2020, COVID-19 disruptions caused TB and malaria diagnoses to drop by 59 percent and 31 percent, respectively, and there were 1 million fewer people treated for TB and 45,000 additional malaria-related deaths.⁴

NTDs, an umbrella term covering a diverse group of tropical infections, continue to impact the lives of 1.7 billion people worldwide, causing approximately 200,000 deaths and the loss of 19 million disability-adjusted life years (DALYs) annually.⁵ There is a continuing and urgent need for safe and effective tools to prevent, diagnose and treat NTDs. The poorest households with the lowest level of education are twice as likely to have people infected with NTDs, which in turn perpetuates the already high level of human, social, economic and financial burdens. Sub-Saharan Africa is particularly affected, with over 500 million people at risk of NTD infection. In 2019, over 360 million cases of NTDs were reported in this region, causing a total loss of almost 5 million DALYs.⁶

Addressing TB, malaria and NTDs requires equity-based health infrastructure that will support wider health and well-being for all, and include the provision of basic needs, such as clean water and sanitation. At the same time, this health infrastructure must adopt prevention and control measures, such as vector control and ensuring access to diagnosis and treatment. Increased and enhanced access to health services for TB, malaria and NTDs can be regarded as a benchmark of progress towards UHC.

¹ United Nations, ‘The Sustainable Development Goals Report 2022’, New York, 2022, <https://unstats.un.org/sdgs/report/2022/The-Sustainable-Development-Goals-Report-2022.pdf>.

² World Health Organization, ‘Tuberculosis’, 14 October 2021, <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>.

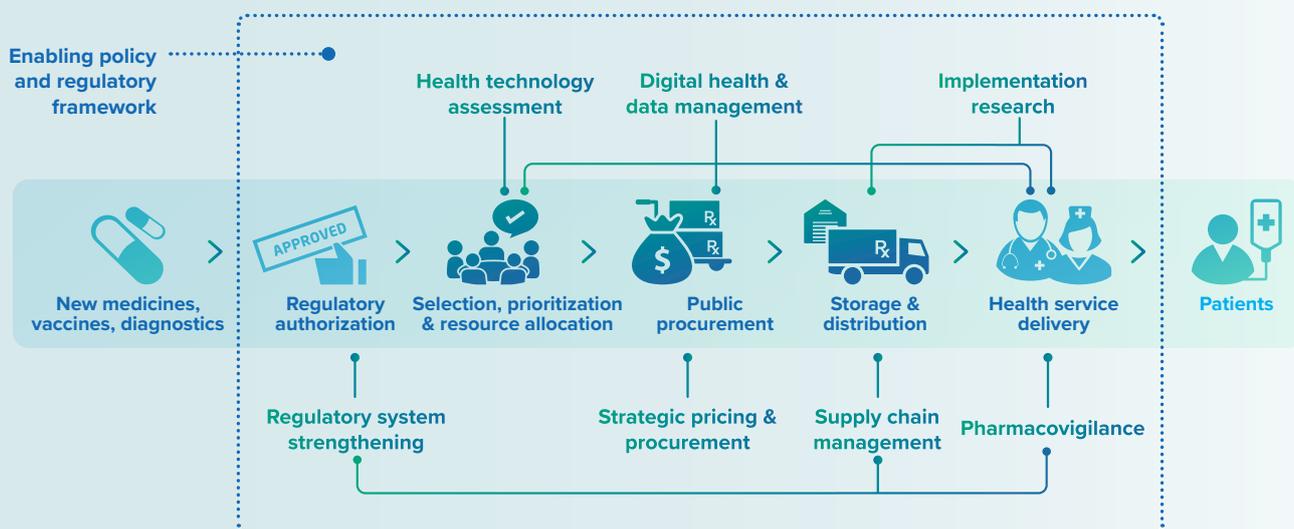
³ World Health Organization, ‘Malaria’, 26 July 2022, <https://www.who.int/news-room/fact-sheets/detail/malaria>.

⁴ Global Fund to Fight AIDS, Tuberculosis and Malaria, ‘The impact of COVID-19 on HIV, TB and malaria services and systems for health’, 13 April 2021, <https://www.theglobalfund.org/en/updates/2021/2021-04-13-the-impact-of-covid-19-on-hiv-tb-and-malaria-services-and-systems-for-health/>.

⁵ World Health Organization, ‘Neglected tropical diseases’, https://www.who.int/health-topics/neglected-tropical-diseases#tab=tab_2.

⁶ Prevalence and DALYs data from the Institute for Health Metrics and Evaluation, University of Washington, ‘Global Burden of Disease study 2019’, <https://vizhub.healthdata.org/gbd-results/>.

ADP supports governments and stakeholders to strengthen their health systems, encompassing policies, processes and capacities along the value chain of access and delivery.



Responding to this, UNDP and the Government of Japan joined forces in 2013 in a strategic partnership to combat TB, malaria and NTDs, through two interlinked and innovative projects. [The Global Health Innovative Technology \(GHIT\) Fund](#) stimulates innovation and research for the development of new health technologies for TB, malaria, NTDs and other diseases, while ADP focuses on enabling and strengthening capacities in LMICs to access and deliver the new products as they become available.

The GHIT Fund invests in the discovery and development of medicines, diagnostics and vaccines for neglected diseases, through its support for partnerships that bring together Japanese organizations with global actors in research and development (R&D) initiatives. ADP brings together four core partners – UNDP, WHO, TDR and PATH – in a unique collaboration to support governments and other stakeholders to strengthen national health systems. ADP partners help LMICs to ‘connect the dots’ from the development of policies and laws, to building human and institutional capacities, to systems and processes to ensure access to and delivery of health technologies.

The partnership between the GHIT Fund and ADP enables an innovative and synergistic approach that combines accelerated health technology R&D and product development with focused capacity and systems development to ensure their timely access and delivery in countries. This integrated approach is vital to achieving UHC and, in turn, human security. It is also strategically aligned with the 2030 Agenda for Sustainable Development and the Sustainable Development Goals, which call for a broad systemic approach to tackle the epidemics of TB, malaria and NTDs.

Despite differences in national contexts, common challenges can be identified across different health systems. ADP has identified capacity gaps that persist in LMICs, and focuses on strengthening these capacities to enable the multiple institutions and mechanisms to work together to effectively introduce and improve access to health technologies for patients in need.

“Together, GHIT and ADP demonstrate that by investing in both research and development and health systems, we can drive faster progress on equitable access to care, end the COVID-19 pandemic and prepare for future health emergencies.”

– Senator Keizo Takemi and
UNDP Administrator Achim Steiner⁷



ADP promotes a whole-of-government approach aimed at strengthening the entire value chain of access and delivery, from enabling policy and legal frameworks, implementation research, regulatory approval, procurement and supply chain management to, ultimately, service delivery and patient safety monitoring. Working with country stakeholders across this broad range of sectors and disciplines, ADP interventions help countries prepare for and accelerate the introduction and scale-up of new health technologies.

The COVID-19 pandemic has unleashed cascading health and development crises, which further underscores the critical importance of ADP’s support to build strong and resilient national health systems. The ADP approach has already helped strengthen the foundation for national COVID-19 responses in a number of countries and has supported the development of policies and tools that have been adapted to meet urgent health system demands of COVID-19. Importantly, these efforts also contribute to pandemic preparedness in the future.

The support from the Government of Japan for both the GHIT Fund and ADP demonstrates its strategic vision and foresight on health and human security, and the need for strong, resilient health systems for sustainable human development.⁷

⁷ Keizo Takemi and Achim Steiner, ‘COVID-19: Nobody is safe until everyone is safe’, *The Japan Times*, 4 December 2020, <https://www.japantimes.co.jp/opinion/2020/12/04/commentary/world-commentary/covid-19-nobody-safe-everyone-safe/>.

03

MAKING A DIFFERENCE TO PEOPLE'S LIVES IMPACT STORIES

Multisectoral planning for roll-out of new health technologies

ADP's experience has shown that consistent multisectoral coordination across government agencies – from health and regulatory authorities to finance, industry, investment and science and technology agencies – can enable institutions to effectively address gaps in policy and capacity. In recognition of the need for coordinated action to ensure access to and delivery of health technologies, ADP supports the establishment or strengthening of relevant multisectoral fora in its focus countries.



Contributing to the RTS,S malaria vaccine introduction in Ghana and Malawi



Health workers with the Ghana Health Service organize a community immunization session where the RTS,S vaccine is delivered alongside other routine vaccines. Photo: Ghana Health Service

Malaria continues to threaten millions of people around the world. Africa bears a disproportionate share of malaria cases — making up 95 percent of all malaria cases and 96 percent of deaths. Children under 5 years old are among the most vulnerable, accounting for 80 percent of the malaria deaths in the region.⁸

Fortunately, a powerful new tool is available in the fight against malaria: a vaccine called ‘RTS,S’, which offers protection against *Plasmodium falciparum*, the deadliest and most prevalent malaria parasite.

Studies have demonstrated that the vaccine prevents up to 39 percent of malaria cases overall, and 29 percent of severe cases.⁹

In October 2021, WHO made the landmark recommendation for widespread use of the vaccine in children in sub-Saharan Africa and other regions.

This recommendation was informed by the findings of the Malaria Vaccine Implementation Programme (MVIP), which conducted pilot programmes in

Ghana, Kenya and Malawi to assess the feasibility of administering the the four-dose RTS,S vaccine.

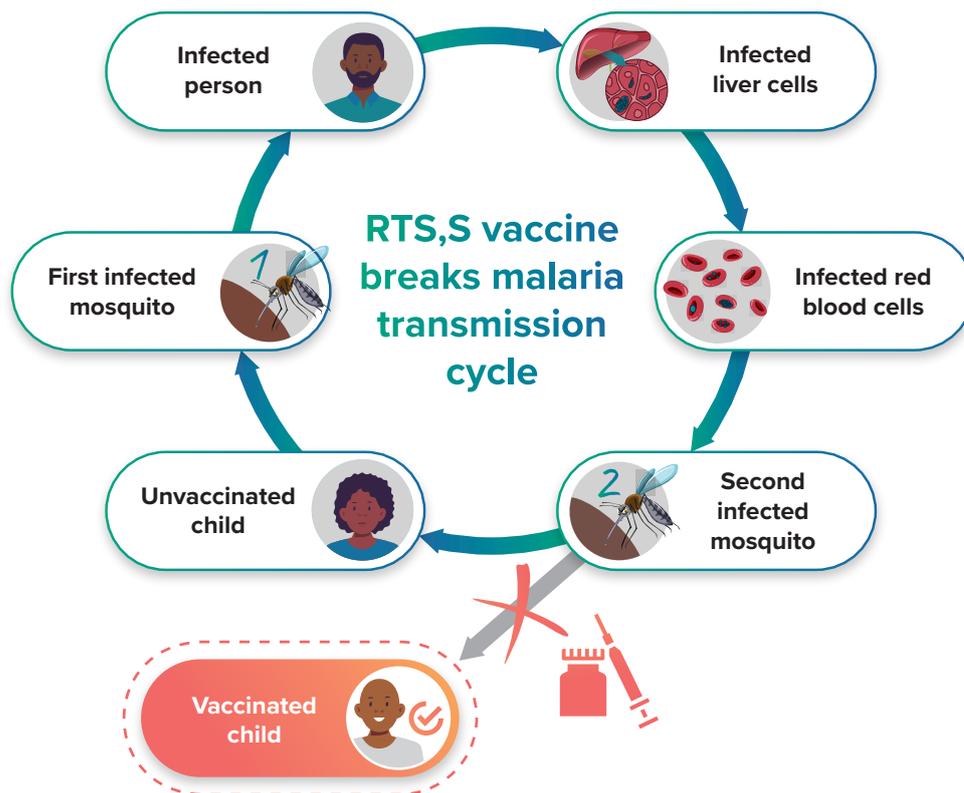
The MVIP coordinated the introduction of the vaccine through routine national immunization programmes in the three countries, implemented under the leadership of the ministries of health of Ghana, Kenya and Malawi.

As a contribution to MVIP’s efforts, the Access and Delivery Partnership (ADP) provided targeted technical assistance in Ghana and Malawi that aimed at facilitating the effective introduction of the new vaccine.

In Ghana, the Sustainable Access and Delivery of New Vaccines in Ghana (SAVING) Consortium, led by the University of Health and Allied Sciences, was established to assess and address capacity gaps in the national institutions that play key roles in the introduction and delivery of new health technologies in the country. The pilot roll-out of the RTS,S vaccine provided an opportunity to put in place integrated planning and multisectoral coordination between the key national institutions.

⁸ World Health Organization, ‘Malaria’, 26 July 2022, <https://www.who.int/news-room/fact-sheets/detail/malaria>.

⁹ World Health Organization, ‘Malaria: The malaria vaccine implementation programme (MVIP)’, 2 March 2020, <https://www.who.int/news-room/questions-and-answers/item/malaria-vaccine-implementation-programme>.



Source: Adapted from a figure in Fidel Zavala, 'RTS,S: the first malaria vaccine', *The Journal of Clinical Investigation*. 2022;132(1):e156588.

ADP is supporting the SAVING Consortium to bring together national stakeholders, including the Ghana Food and Drugs Authority, the Ministry of Health and the Ghana Health Service, to adopt an implementation research approach combined with capacity-building, to solve implementation and operational barriers to the effective introduction of the new malaria vaccine across the country.

ADP also supported the creation of a digital communication platform for the consortium, which enables members to remotely engage in integrated planning, coordination and capacity-building.

“Within each country, the ADP approach is bringing different institutions together to address common implementation challenges, said Professor Margaret Gyapong, Director of the Institute of Health Research at the University of Health and Allied Sciences.

“In Ghana – through the ADP-supported SAVING Consortium – we are building implementation research capacity for pharmacovigilance [drug safety] and related areas to ensure that challenges to access and delivery of new health technologies are identified and addressed.”

“We have been supported in various ways to review our national medicines policy and implementation plan, and to strengthen capacities to monitor and respond to safety issues,” added Prof. Gyapong.



Prof Margaret Gyapong. Photo: edctpforum.org

In Malawi, ADP built on the pharmacovigilance mechanisms developed for the RTS,S vaccine by the national malaria vaccine programme to help expand the drug safety monitoring systems across the wider health system. And as part of its broader support to strengthening the regulatory system, ADP has worked with the Pharmacy and Medicines Regulatory Authority to establish a national pharmacovigilance centre, bolster its safety monitoring, and improve reporting channels and tools for health care providers.

If successfully introduced and scaled up in Ghana and Malawi, the vaccine will have the potential to avert over 1 million cases and prevent almost 4,000 deaths per year among children under the age of 5.¹⁰ If it were to be scaled up across sub-Saharan Africa to reach children living in areas of high malaria transmission, the vaccine has the potential to avert up to 33 million cases¹¹ and 96,400 deaths¹² annually.

“The implementation of wide-scale use of RTS,S can pose significant challenges for national malaria programmes,” explained Dr. Corinne Merle, a scientist with ADP partner TDR.

“The lessons learned from Ghana and Malawi will be invaluable for other countries to address these challenges and prepare for the mass introduction of the vaccine.”

“ADP’s activities to monitor vaccine safety and strengthen implementation research capacities of ministries of health will help facilitate vaccination scale-up.”

As the introduction of the vaccine ramps up across the continent, ADP will be widely sharing the lessons from Ghana and Malawi’s experiences with other national malaria programmes.

The lessons learned from the RTS,S vaccine roll-out by MVIP will also be useful to inform the planning and implementation of other vaccine programmes, including for the COVID-19 vaccines in LMICs across the world.



Dr. Corinne Merle.
Photo: International AIDS Society/Steve Forrest/Workers’ Photos

Further information

- ✓ SAVING consortium: <https://savingconsortium.org/>
- ✓ WHO, ‘Malaria vaccine implementation programme’: <https://www.who.int/initiatives/malaria-vaccine-implementation-programme>
- ✓ WHO, ‘Malaria vaccine: WHO position paper – March 2022’, *Weekly Epidemiological Record*, 2022, 97 (09): 60–78: <https://www.who.int/publications/i/item/who-wer9709-61%E2%80%939380>
- ✓ WHO, ‘Over 1 million African children protected by first malaria vaccine’, 21 April 2022: <https://www.who.int/news/item/21-04-2022-over-1-million-african-children-protected-by-first-malaria-vaccine>
- ✓ WHO, ‘WHO recommends groundbreaking malaria vaccine for children at risk’, 6 October 2021: <https://www.who.int/news/item/06-10-2021-who-recommends-groundbreaking-malaria-vaccine-for-children-at-risk>

¹⁰ Based on incidence data from the Institute for Health Metrics and Evaluation, University of Washington, ‘Global Burden of Disease study 2019’, <https://vizhub.healthdata.org/gbd-results/>.

¹¹ Ibid.

¹² World Health Organization, ‘Full Evidence Report on the RTS,S/AS01 Malaria Vaccine: Background paper’, WHO, Geneva, September 2021, <https://cdn.who.int/media/docs/default-source/immunization/mvip/full-evidence-report-on-the-rtss-as01-malaria-vaccine-for-sage-mpag-%28sept2021%29.pdf>.

Protecting children from schistosomiasis in Tanzania



ADP is helping to ensure that preventive medication for NTDs such as schistosomiasis reaches children in vulnerable areas.
Photo: Natasha Scripture/UNDP

Schistosomiasis – also known as ‘bilharzia’ or ‘snail fever’ – is a parasitic disease carried by freshwater snails.

It is one of the most widespread NTDs, with huge socio-economic and health burdens. Estimates show that almost 240 million people around the world required treatment for schistosomiasis in 2019.¹³ The vast majority of these infections occur in sub-Saharan Africa, where over 172 million children under 5 are at risk of infection.¹⁴

Insufficient hygiene and activities such as swimming or fishing in infested water make children especially vulnerable to infection. The disease is also more common in poor communities without adequate access to safe drinking water and sanitation.

In Tanzania, more than 50 percent of the population are at risk of contracting schistosomiasis, primarily in the lake basin regions of Lake Victoria, Lake Tanganyika and Lake Nyasa. It is estimated that as many as 6 million children under the age of 5 in Tanzania are at risk of schistosomiasis infection. In 2019, 53,316 children under 5 were found to be infected, accounting for 1,086 DALYs.¹⁵

Abdominal pain, diarrhoea and blood in the stool or urine are common symptoms of schistosomiasis. The effects on children can be dire – causing anaemia, stunting and impaired learning. Thankfully, the effects are usually reversible with treatment.

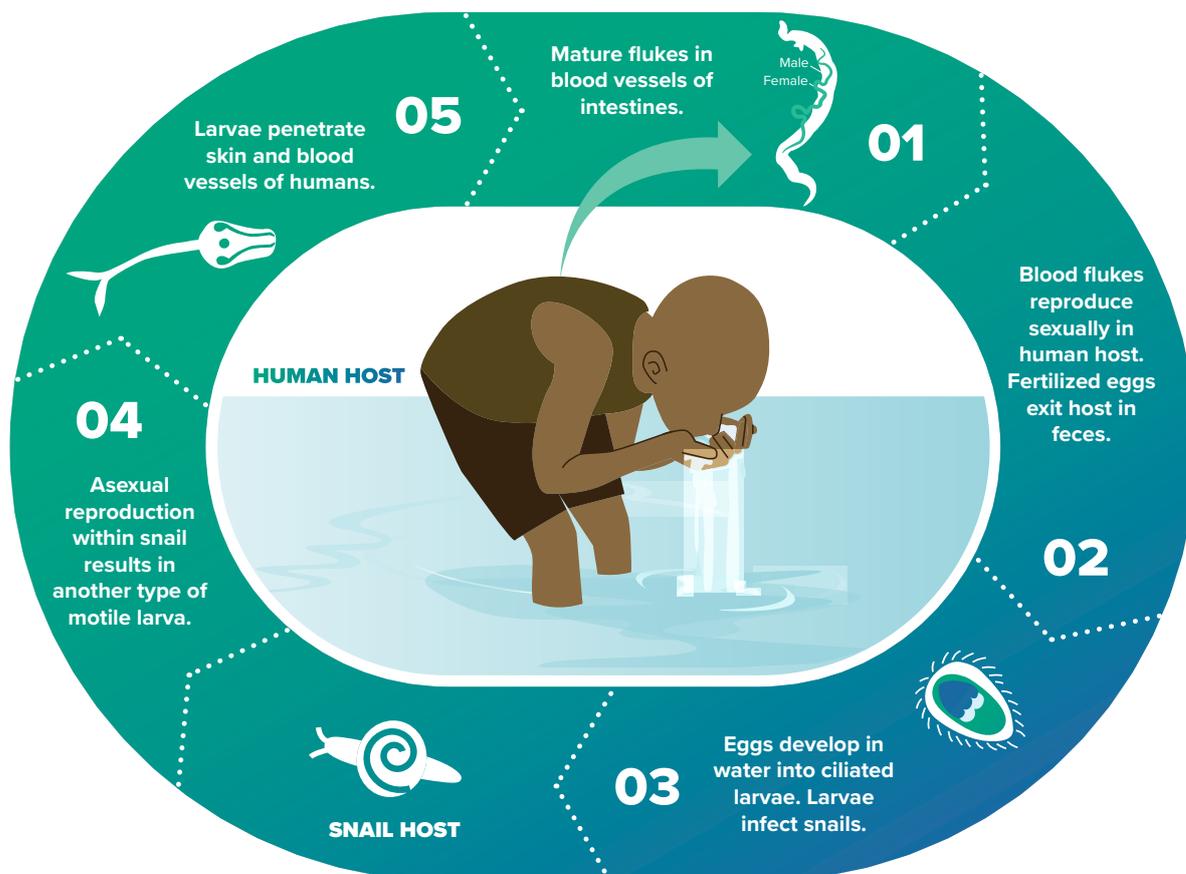
The primary method for controlling schistosomiasis, as recommended by WHO, is periodic and targeted large-scale treatment (referred to as mass drug

¹³ World Health Organization, ‘Schistosomiasis: Key facts’, <https://www.who.int/news-room/fact-sheets/detail/schistosomiasis>.

¹⁴ Figure is based on data from WHO (Maternal, newborn, child and adolescent health and ageing data portal: [https://www.who.int/data/maternal-newborn-child-adolescent-ageing/indicator-explorer-new/mca/under-five-population-\(thousands\)](https://www.who.int/data/maternal-newborn-child-adolescent-ageing/indicator-explorer-new/mca/under-five-population-(thousands))); and ‘Schistosomiasis: Status of schistosomiasis endemic countries’: https://apps.who.int/neglected_diseases/ntddata/sch/sch.html) and the Institute for Health Metrics and Evaluation, University of Washington, ‘Global Burden of Disease Study 2019’: <https://vizhub.healthdata.org/gbd-results/>.

¹⁵ Institute for Health Metrics and Evaluation, University of Washington, ‘Global Burden of Disease study 2019’, <https://vizhub.healthdata.org/gbd-results/>.

Schistosomiasis life cycle



Source: Adapted from a figure by Pearson Education, Inc., publishing as Benjamin Cummings (2004).

administration) of at-risk populations with the medicine praziquantel. Mass drug administration for the prevention of NTDs is one of the most cost-effective interventions in global public health.

For many years the Government of Tanzania has implemented such large-scale population treatment campaigns, often distributed at schools. However, children under the age of 5 at risk of schistosomiasis in Tanzania have not been covered by the mass treatment campaigns due to the lack of a suitable treatment formulation for their age group.

The GHIT Fund has provided funding support to the Pediatric Praziquantel Consortium for the development of a potential treatment option suitable for younger children, including infants and toddlers. The treatment – arpraziquantel – is currently in preparation for the required regulatory approvals and is expected to be available for use in 2024.

In advance of the treatment becoming available and being recommended for use, ADP is helping Tanzania to prepare for its timely introduction

and delivery by strengthening relevant national capacities. This is in recognition of the fact that even when a new health technology has been developed, ensuring effective introduction and delivery to patients requires a combination of policy and regulatory measures, coupled with effective procurement and supply chain management at the national level.

To achieve this, ADP is working closely with stakeholders across different sectors, including the Ministry of Health, the National Institute for Medical Research (NIMR) and WHO, and is supporting the Strengthening Capacity of the Health System to be Ready for Delivery and Uptake of the Pediatric Praziquantel Formulation for Schistosomiasis (STEPPS) project in Tanzania.

“Schistosomiasis infections among children under 5 years of age is a public health concern in Tanzania. It’s imperative that we are ready to introduce arpraziquantel effectively and in a timely manner, as soon as it is approved and available,” said Dr. Paul Kazoyoba from NIMR. “At the National

Institute for Medical Research, we have engaged with development partners, as well as decision- and policymakers, for a multisector approach to achieve this.”

To establish the precise magnitude of schistosomiasis infection among children under 5 years of age, especially in regions where data are lacking, an epidemiological study is being conducted by NIMR with support from the Tackling Infections to Benefit Africa partnership. This information will be used to estimate initial quantities of the drug to be procured, and related costs.

Among the notable achievements of the STEPPS project has been the identification of an appropriate delivery model—through the existing countrywide de-worming programme.

In addition, more than 300 health workers from across 20 districts have been trained on the

use of a safety monitoring and response system for adverse drug reactions associated with praziquantel. And the efficiency and reliability of the supply chain for NTD medicines have been improved through the development of tools and guidelines that have strengthened the capacity of 3,000 community health workers who conduct the large-scale treatment campaigns.

The STEPPS project is also working to raise community awareness of schistosomiasis infection among young children, and of the potential availability and importance of uptake of the pediatric formulation.

The efforts of ADP to help Tanzania successfully control schistosomiasis are ongoing. Once the goals are attained, it is hoped that lessons learned will be instructive for other countries in the region and beyond.



Photos: Natasha Scripture/UNDP

Further information

- ✓ Pediatric Praziquantel Consortium: <https://www.pediatricpraziquantelconsortium.org/>
- ✓ Pediatric Praziquantel Consortium, ‘The Pediatric Praziquantel Consortium Announces Positive Phase III Results for Arpraziquantel To Treat Schistosomiasis’, 16 November 2021: https://www.pediatricpraziquantelconsortium.org/sites/ppc/files/2021-11/Ped_PZQ_Phase_III_results_press_release_Consortium_FINAL.pdf
- ✓ JAGntd and GHIT Fund, ‘Webinar Series 3: Country’s Perspective: Introduction of Pediatric Praziquantel for Schistosomiasis in Tanzania’, 18 November 2021: https://www.youtube.com/watch?v=UNuTO6x0A38&list=PLGQCDAHEeq-Y96srduc_LzeGo_9nrhRz&index=4
- ✓ WHO, ‘Ending the neglect to attain the Sustainable Development Goals: A road map for neglected tropical diseases 2021–2030’, 28 January 2021: <https://www.who.int/publications/item/9789240010352>

Enabling policy frameworks

An enabling policy environment is key to the timely introduction of new health technologies. ADP has prioritized support for the development of harmonized national policy and regulatory frameworks that enable the various health system functions – from the selection, prioritization and use of health technologies to the procurement, supply chain management and delivery systems – to work in tandem and increase access to quality-assured, safe and effective health technologies across Africa.



Increasing access to quality-assured, safe and effective health technologies across Africa



Harmonizing regulatory systems and improving regulatory efficiency, which will speed up access to COVID-19 vaccines and other health technologies across Africa, has taken on greater urgency during the COVID-19 pandemic. Photo: Braño on Unsplash

The high disease burden and mortality rate from preventable diseases on the African continent is attributed in part to inadequacies in national health systems, and to the lack of access to safe, quality-assured and efficacious medicines and other health technologies. The increasing demand for health technologies warrants urgent focus and investment in their effective regulation.

In many countries, there are still limited capacity and resources to approve medicines and other health technologies in a timely manner and to ensure adherence to quality, safety and efficacy standards. Another persistent challenge is weak, outdated or varying national policy frameworks. This can lead to differences in application requirements across countries, which result in researchers and manufacturers navigating multiple regulatory systems to register the same health technology.

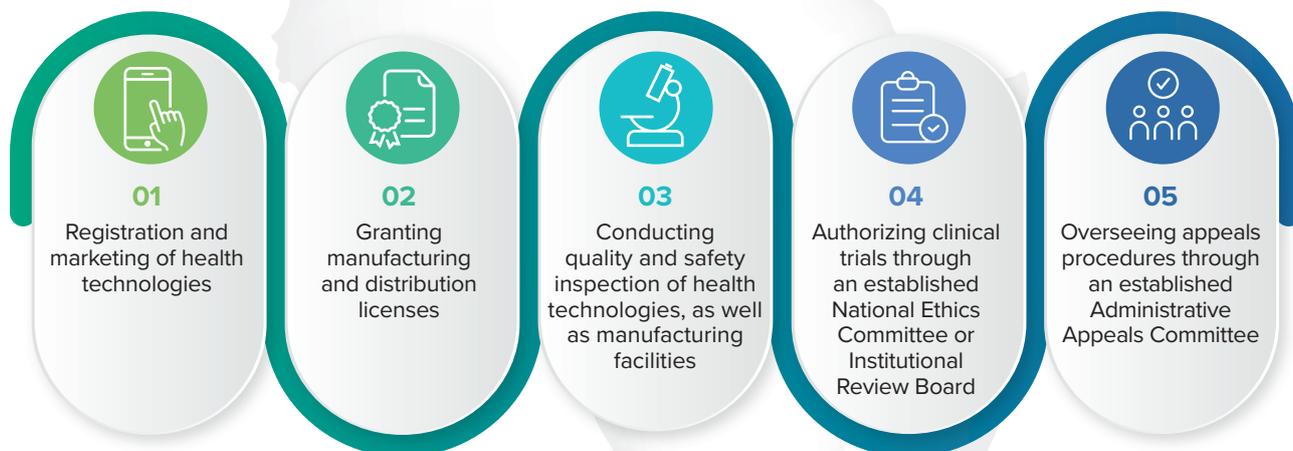
Harmonized policy frameworks can provide a foundation for effective regulation, as well as being a force for increased collaboration. Recognizing this, ADP has supported the development and ongoing implementation of the [African Union \(AU\) Model Law on Medical Products Regulation](#). So far,

19 countries have domesticated the law in part or in full.

The AU Model Law, endorsed by the AU Member States in 2016, serves as a template for countries to strengthen and align their regulatory frameworks, which is critical to improving the predictability and efficiency of regulatory approvals. The law is one of two key pillars of the African Medicines Regulatory Harmonization initiative, which aims to remove regulatory barriers that hinder patient access to health technologies in Africa through regional harmonization and capacity-strengthening. Regional harmonization initiatives of this kind have been shown to reduce duplication of regulatory reviews, facilitate mutual recognition and accelerate access, expediting the delivery of new health technologies.

ADP provided expert legal advice and technical support throughout the process of developing the AU Model Law. ADP support also extended to legal advice and technical support for the proposed establishment of the African Medicines Agency (AMA). As the specialized regional technical agency, the AMA is expected to play a major role

Summary of regulatory functions covered under the AU Model Law on Medical Products Regulation



Source: Adapted from Africa Union Development Agency-New Partnership for Africa's Development, 'AU Model Law for Medical Products Regulation', AUDA-NEPAD, Midrand, South Africa.

in providing regulatory guidance and technical assistance to AU Member States, as well as promoting the use of the AU Model Law to facilitate regulatory and legal reforms at continental, regional and national levels.

The COVID-19 pandemic has given these issues even greater urgency. Harmonizing regulatory systems across Africa and improving regulatory

efficiency help ensure faster access to COVID-19 vaccines and related health technologies.

ADP has long partnered with the African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), and have worked together to promote the development of the AU Model Law and, since its adoption in 2016 by African Heads of State and Government at the AU



Photo: @matteoguedia on Freepik

Summit, its domestication within the national legal and regulatory frameworks of AU Member States.

To date, four countries have reported completing the domestication process, while others are in the midst of ongoing national processes, including national consultation processes and, in some cases, draft laws or bills are undergoing legislative processes for adoption.

ADP continues to actively collaborate with AUDA-NEPAD to increase the number of countries working towards domestication of the law and to provide ongoing technical assistance to navigate through the process.

In Ghana and Senegal, for example, ADP has supported the organization of national stakeholder consultations, as well as legal and policy reviews, and the process of legal drafting is currently under way.

A Guidance Document developed by AUDA-NEPAD, with ADP support, aims to improve understanding of key concepts, and provides guidance on how to draft legislation with a chapter-by-chapter analysis of the AU Model Law, offering useful drafting suggestions.

Together, these efforts are helping countries to align their regulatory laws to the AU Model Law and not only facilitate effective regulation but also advance the goal of harmonizing regulatory systems across the region.

“A harmonized legal and regulatory environment will enable the effective operation of the continent-wide AMA. As such, domestication of the AU Model Law by AU Member States will be a crucial step towards such regulatory harmonization.”

said Dr. Margareth Ndomondo-Sigonda, Head of Health Programme and the African Medicines Regulatory Harmonization initiative, AUDA-NEPAD. “The COVID-19 pandemic has shown us how important this is, and we hope this awareness will translate into greater focus on this issue. We look towards our continued partnership with ADP to further mobilize AU Member States in their domestication processes. With the Guidance Document, we are also responding to the needs of AU Member States who may require some technical assistance in adapting the provisions of the AU Model Law to suit the national needs and priorities.”



Dr. Margareth Ndomondo-Sigonda
Photo: AUDA-NEPAD

Further information

- ✔ AUDA and ADP, ‘A guidance document for domestication of the African Union Model Law on Medical Products Regulation’, 2021: <https://www.nepad.org/publication/guidance-document-domestication-of-african-union-model-law-medical-products>
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Regulatory systems strengthening

National regulatory authorities protect public health by ensuring the quality, safety and efficacy of health technologies. This is done through a wide range of functions, including the assessment of health technologies before their introduction and use in the country; promotion of adequate manufacture, storage and distribution of medicines; prevention of substandard and falsified products; and provision of information to health professionals and patients for rational use of medicines. Developing a strong national regulatory system is, therefore, a critical component of a national health system.

ADP provides support, through WHO, to LMICs to strengthen capacities of the national regulatory authorities (NRAs). The technical assistance aims at bringing NRAs up to benchmarked international standards and best practices, and is vital in ensuring the quality, safety and efficacy of health products.



Strengthening national regulatory authorities to ensure safe and effective health technologies



WHO evaluators discuss with officials from the Thailand Food and Drug Authority during an assessment mission in June 2021. Photo: WHO

Improving access to medicines and other medical products is a critical public health priority and a fundamental requisite for UHC. The national regulatory system assesses and monitors the safety, quality and efficacy of all medical products introduced into a country, including medicines, vaccines, blood and blood products, and medical devices such as in-vitro diagnostics, among others. However, WHO has estimated that fewer than 30 percent of the world's regulatory authorities have sufficient capacities to perform all of the required functions to ensure medicines, vaccines and other medical products are safe and effective.

Where medical products are of substandard quality, or are improperly produced, stored or transported, or where they are falsified, used incorrectly or abused, they pose significant risks to public health, and can lead to hospitalization or death.

Over the last several decades, the WHO Regulatory Systems Strengthening programme has developed and refined a robust model of technical support that involves the assessment of regulatory systems and functions using a standardized tool – the Global

Benchmarking Tool (GBT) – and the formulation of institutional development plans (IDPs) that are designed to assist countries in implementing effective regulatory oversight. IDPs provide a blueprint to inform and guide government investments and the provision of technical assistance by WHO and other development partners. Coupled with the GBT indicators, the IDPs also provide an objective baseline to monitor and encourage progress.

Working with ADP in recent years, the NRAs in a number of ADP focus countries have attained a high level of capacity improvement, as indicated by WHO's benchmarking process.

The NRAs in Ghana, India, Indonesia, Tanzania and Thailand have achieved maturity level 3 (against a highest of level 4) for their vaccine regulatory systems. Two of the countries – Tanzania and Ghana – have achieved maturity level 3 for both their medicine and vaccine regulatory systems.

Maturity level 3 confirms a stable, well-functioning and integrated regulatory system is in place.

Timeline of ADP supported countries operating at maturity level 3



This means that these countries have made considerable improvements in recent years, following WHO's guidance based on assessments made by the GBT, to ensure medical products within their health systems are of good quality and safe, and produce the intended health benefits.

Notably, Tanzania and Ghana are the first two countries in Africa to achieve this milestone.

Most recently, Thailand also achieved this milestone in September 2021. Over the years, the Thailand Food and Drug Authority (FDA) has enhanced its regulatory system for vaccines to meet increasing

domestic demands, especially for the 10 vaccines provided to children in its Expanded Programme on Immunization. The improvement also reflects Thailand's aspiration to be a trusted authorization body to allow for export of domestically produced vaccines, contributing to the regional and global vaccine supply. Accelerated efforts are ongoing in the country to expand the Thailand FDA's increased maturity level to medicines and other medical products.

Additionally, ADP is currently supporting the development and implementation of IDPs for NRAs in Bhutan, Burkina Faso, Malawi and Senegal.

Further information

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Medicines and vaccine safety

The introduction and use of new health technologies invariably encounters previously unanticipated events and/or adverse reactions. Certain side effects may only emerge once the products have been used by a heterogenous population over a period of time. This underscores the importance of a functional system to detect, assess, understand, manage and prevent adverse effects. ADP, through TDR, has supported NRAs, disease control programmes and health providers to strengthen related tools and technical capacity, and to implement best practices for pharmacovigilance.



Driving out drug-resistant TB in Indonesia



A patient at a hospital in Jakarta, Indonesia examines an x-ray of their lungs. Photo: Fauzan Ijazah/UNDP

Despite significant progress, TB continues to claim an estimated 1.5 million lives each year, making it the second most deadly infectious disease behind only COVID-19.¹⁶ In Indonesia, TB is one of the top causes of death, with nearly 100,000 people dying in 2020.¹⁷

TB is caused by a bacterium, *Mycobacterium tuberculosis*, which infects the lungs. In recent years, new strains have emerged that are resistant to existing treatments (known as drug-resistant TB or DR-TB). DR-TB is a debilitating and life-threatening condition that requires longer and more intensive treatment.

TB can leave patients and their families in catastrophic financial hardship. Even though the government provides free TB tests and medicines at public facilities across Indonesia, it has been shown that loss of income and out-of-pocket expenses (such as travel, follow-up visits, hospitalization and food supplements) can amount to around US\$169 for each TB patient. Such costs can be up to 14 times greater for DR-TB patients, at US\$2,342 each, due to the greater severity of the disease, length of treatment and the resulting loss of income.¹⁸

The barriers to effective diagnosis and treatment of DR-TB are multidimensional and influenced by social factors. They include TB-related stigma,

¹⁶ World Health Organization, 'Tuberculosis', 14 October 2021, <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>.

¹⁷ World Health Organization, 'Tuberculosis profile: Indonesia', 3 October 2022, https://worldhealthorg.shinyapps.io/tb_profiles/?_inputs_&entity_type=%22country%22&lan=%22EN%22&iso2=%22ID%22.

¹⁸ Susan van den Hof, David Collins, Firdaus Hafidz, Demissew Beyene, Aigul Tursynbayeva and Edine Tiemersma, 'The socioeconomic impact of multidrug resistant tuberculosis on patients: results from Ethiopia, Indonesia and Kazakhstan', *BMC Infectious Diseases* 2016; 16(1): 470, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5011357/>.

which often impedes people from accessing testing or treatment services, as well as issues related to mental health, poverty, housing and unemployment.

Indonesia's national TB programme is making significant progress responding to the threat of DR-TB. In 2017, Indonesia achieved 100 percent national coverage by establishing 360 DR-TB treatment facilities and 2,300 DR-TB satellite sites across all 34 provinces.

In 2020, WHO recommended an all-oral treatment for DR-TB, which lasts for around 9–11 months. This new regimen is shorter, easier to administer and more effective than the conventional DR-TB treatment, which can take up to 24 months and also requires daily injections.

But the new treatment regimen remains a challenge for many patients. On top of financial hardship, the treatment can have a range of side effects, including

nausea, drowsiness, depression, psychosis, kidney impairment and hearing loss.

Much remains to be done. From January to September 2022, there were 8,042 patients with confirmed cases of DR-TB, and approximately only 54 percent of them received treatment,¹⁹ likely because of the barriers posed by the range of economic and social challenges associated with DR-TB.

ADP has contributed to the TB response efforts in Indonesia, especially through its support to set up surveillance systems that ensure the safe scale-up of new TB medicines.

Between 2014 and 2016, ADP supported the national TB programme, the National Drug and Food Control Agency and public hospitals to enhance their ability to detect and properly manage unwanted side effects of bedaquiline, a



A patient with DR-TB taking his daily treatment. Photos: Fauzan Ijazah/UNDP

¹⁹ Based on data presented at the Ministry of Health's quarterly review meeting in September 2022.



new medicine that is part of the shorter treatment regimen for DR-TB. This included the training of nearly 200 health care providers and pharmacists for ‘active safety monitoring’, which is the active and systematic clinical and laboratory assessment of patients while on treatment, to detect, manage and report suspected or confirmed adverse drug reactions.

In 2021, ADP supported a comprehensive situation analysis of DR-TB drug safety monitoring, from which the national TB programme developed an action plan aimed at bolstering weak points in the monitoring system. Lessons learned will be useful for other national TB programmes adopting the shorter, all-oral treatment regimen.

ADP has also worked with the Ministry of Health on strengthening other related systems, including those supporting the selection and purchase of quality, affordable medicines, and health systems



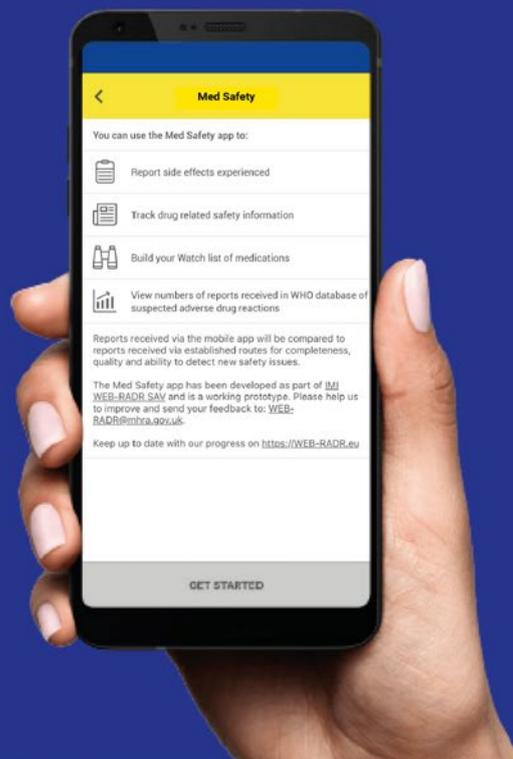
Participants at a workshop on pharmacovigilance, organized by ADP in Bogor, Indonesia in April 2015. Photos: UNDP

research that addresses gaps in TB programme implementation. Technical support from UNDP to strengthen the Ministry of Health’s financial management information system, human resources and reporting contributed to the success in securing grants from the Global Fund to Fight AIDS, Tuberculosis and Malaria from 2018 to 2023 for the country’s HIV, TB and malaria response.

Further information

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Innovation for drug safety monitoring in Malawi and Ghana



Photos: Ghana Food and Drugs Authority

Advances in modern medicine have transformed the way in which diseases are controlled, extending life expectancy and improving health and well-being of all. However, adverse reactions do occur, and can be the cause of illness and disability, even death. This is especially the case for newly introduced health technologies, which must be closely monitored.

Systems are put in place to detect, assess and manage adverse reactions. Often referred to as ‘pharmacovigilance’, such systems are a critical component of effective national regulatory systems, clinical practice and overall public health programmes in countries.

Effective pharmacovigilance systems require, among other things, numerous and high-quality reports, and in many countries, underreporting and delays are common. To help address this, ADP is actively promoting the use of low-cost and easily accessible digital solutions.

In Malawi, ADP has supported the creation and installation of a digital solution for patients to report adverse reactions to medicines and vaccines – a

process accelerated after the onset of the COVID-19 pandemic.

In 2021, with ADP’s support and funding, Malawi introduced Medsafe 360. With this tool, patients and health care workers can report suspected adverse drug events using a mobile phone with SMS capability. Medsafe 360 reduces delays in reporting, as it is quicker than using the traditional paper forms. Notably, it does not require smartphone capability or an internet connection to function. Users can simply dial or message *360# for free to submit reports.

The use of Medsafe 360 is timely, because the introduction of new health technologies, such as the new treatments for DR-TB and the new vaccines for malaria and COVID-19, always requires close safety monitoring.

According to Cecilia Sambakunsi, a Medicine Inspection Officer at the Malawi Pharmacy and Medicines Regulatory Authority, ADP has been a key stakeholder in strengthening the pharmacovigilance system in Malawi.



Cecilia Sambakunsi.
Photo: LinkedIn

“ADP has provided both technical and financial support towards building capacities of the key personnel at the national pharmacovigilance centre and also health care workers,”

said Ms. Sambakunsi. “In terms of MedSafe 360, ADP has provided funding for development, introduction and evaluation of the tool.”

ADP has also supported the digitization of drug safety surveillance in Ghana, through the introduction of the Safety Watch System, a national electronic management system for individual case safety reports, and most recently, MedSafety, a mobile application that facilitates fast and direct community reporting of possible adverse drug reactions. Together, the systems increased related reporting by over 30 percent between 2016 and 2019.

The MedSafety app, which is implemented by the Ghana Food and Drugs Authority, is designed to encourage reporting by patients and health care professionals of harmful, unexpected side effects of health technologies, including medicines and vaccines. It includes safety information and allows users to receive personalized product-specific news and alerts.

It was developed with support from ADP, the WEB-RADR (Recognising Adverse Drug Reactions) project, the United Kingdom Medicines and Health Products Regulatory Agency and the Ghana Ministry of Health.²⁰

Speaking at the launch of the app in June 2019, Delese Mimi Darko, Chief Executive Officer of the Ghana Food and Drugs Authority, said:

“The Med Safety app today is our new, faster way to report safety issues of medical products, to promote patient safety anytime and anywhere – because you always have your phone with you.”



Delese Mimi Darko.
Photo: Ghana Food and Drugs Authority

The MedSafety App has contributed to a reduction in the cost of monitoring and reporting adverse reactions and has improved communication between the Food and Drugs Authority and clients. An ADP-supported survey of users (mainly health workers) revealed an overwhelmingly positive response to the app, and identified key areas for improvement. The results will be published in a peer-reviewed journal in 2022, and findings will help with scaling up the app in Ghana. It will also provide information for the implementation of similar applications in other countries.

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²⁰ Ghana Food and Drugs Authority, MedSafety flyer, 2019.

Implementation research

Large-scale deployment of health technologies can encounter a range of challenges in access, delivery and use, particularly given the resource-limited health systems of many LMICs. Failure to address unique local barriers affects the effective uptake of new medicines, diagnostic tests and vaccines. Through TDR, ADP has supported national research institutions, national disease control programmes and health researchers to collaboratively apply implementation research approaches to identify and address such barriers.



Breaking the chain of yaws infection in Ghana



Students at a school in West Akim, Ghana line up to be screened for skin lesions and tested for yaws. Photo: Nii Armah Solomon

“I had a small boil last month, and it became big this month. It is sometimes painful and distracts me in school, so I got some medicines from the drugstore. But it is not going away,”

said Godfrey Tamate, a 14-year-old student at Topease Methodist School in West Akim municipality, Ghana.

“I have had the sore for more than two years now. I use hot water and an ointment from the drugstore, but it’s still there. I wasn’t taken to the hospital,” said 16-year-old Samuel Achia.

What Godfrey and Samuel had was a chronic infection of the endemic treponematoses bacterium, commonly known as ‘yaws’. It is a disfiguring and debilitating disease that targets the skin,

cartilage and bones. The disease mainly affects children under the age of 15 years and those in remote communities. If left untreated, it can cause lifelong disability.

Yaws—classified by WHO as an NTD—is primarily found in warm, humid climates. It is currently known to be endemic in 15 countries, including Ghana.

The WHO yaws eradication strategy calls for rounds of total community treatment (or mass drug administration, which involves treating entire populations) and total targeted treatment (treating cases and their contacts), to identify cases, then treat and cure them, putting a stop to ongoing transmission.

Since 2019, ADP has supported the National Buruli Ulcer Control and Yaws Eradication Programme of the Ghana Health Service in its efforts to

eradicate yaws. This has been through support for implementation research and strengthening of national capacities for community-based mass drug administration using the antibiotic azithromycin, which cures yaws after a single dose.

Implementation research – a systematic approach to understanding and addressing localized barriers to effective and quality implementation of health interventions, strategies and policies – is a key pillar of the ADP approach to support countries to introduce and scale up new health technologies.

At the start of 2020, as part of preparatory-phase activities, a 30-day endemicity mapping survey was conducted in the West Akim district of Eastern Ghana to collect relevant information from affected communities. The survey involved interviews with local leaders and community members about where and when yaws was occurring.

“The first step is to map out the endemic communities. If everybody is treated at least once, there is little chance that the disease will continue to spread,” said Dr. Samuel Agyeman Boateng, West Akim Municipal Director of Health Services.

Important operational challenges, including those related to the effective use of rapid diagnostic tests and sample collection, and the need for community mobilization to prevent gender- and stigma-related barriers, were identified.

The survey also established a baseline by identifying and mapping endemic and non-endemic communities in the municipality and helping to target interventions down to the subdistrict level.



Photos: Nii Armah Solomon

Since eradication efforts require extensive planning and multiple phases of activities, ADP supported the training of front-line and community-based health workers to build relevant capacities. Health workers from the National Buruli Ulcer Control and Yaws Eradication Programme and regional NTD focal persons received training on case identification and reporting, as well as on monitoring adverse effects of the treatment.

According to Dr. Nana Konama Kotey, Programme Manager at the National Buruli Ulcer Control and Yaws Eradication Programme, Ghana Health Service, the eradication of yaws in Ghana holds great promise:

“Eradication of yaws will have a significant impact on the lives of the people of Ghana – it has the potential to be transformational and will definitely improve public health.”

During 2022, the National Buruli Ulcer Control and the Yaws Eradication Programme is intensifying efforts to continue total targeted treatment in selected districts, as this approach enhances surveillance and represents a key tool in the eradication of yaws.



Dr. Nana Konama Kotey.
Photo: Nii Armah Solomon

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Strengthening health systems through research



Photo: TDR

Even the most promising health interventions can encounter obstacles and fail to produce the desired results when used in unique local settings. A range of unpredictable variables come into play, such as socio-behavioural factors, logistical challenges, financial limitations and extreme environmental conditions.

Implementation research is becoming an increasingly critical tool for health practitioners to ensure the greatest likelihood of success.

Implementation research identifies bottlenecks and, importantly, the solutions to enhance health care service delivery while strengthening overall health systems. This form of research can help determine whether health interventions such as vaccines, drugs, medicines, policies and practices are effective in real life, beyond the laboratory or clinical trial setting.

ADP has advanced the use of implementation research across different levels of the health system, through health workforce training and the development of an innovative learning resource called the [Implementation Research Toolkit](#).

Initially developed by TDR in 2014, the Toolkit is a self-learning tool offering health care service

providers, researchers and administrators a comprehensive guide on the design and planning of implementation research projects, including formulation of research questions, development of funding proposals, data collection and analysis, and sharing of research findings.

ADP supported enhancements to the Toolkit, which included its conversion into a bilingual (French and English) online version. In 2022, a new module was added to strengthen the capacity of researchers to incorporate an intersectional gender perspective in implementation research projects and related proposals. The Toolkit is also in the process of being fully digitized, with updated functionalities optimized for virtual and hybrid learning, to maximize its reach.

Beneficiaries of the Toolkit and training have included disease control programme implementers, district and central hospital personnel and academics. Participants from Malawi and Ghana share their experiences below. They continue to be part of a broad network of researchers and benefit from technical exchanges with their counterparts across countries and regions – which, in turn, will enhance implementation research approaches and contribute to future enhancements of the Toolkit.

“The Implementation Research Toolkit has helped me fully understand and distinguish implementation science and quality improvement projects. I have been able to review our biochemistry department using the data monitoring tips in the tool. Using this data, we are trying to improve performance and participation in external quality control with NHLS [the National Health Laboratory Service]. Secondly, the Implementation Research Toolkit has helped me with identifying and engaging stakeholders with critical roles and influence to implementation of our QIPs [quality improvement processes]. This has promoted and improved linkages between the laboratory and the clinical section.

Florence Filisa, Head of the Biochemistry Laboratory,
Kamuzu Central Hospital, Lilongwe, Malawi



“Participating in the implementation research course, using the Implementation Research Toolkit, equipped me with analytical skills in implementing health interventions. With every health intervention being provided to the community, I am able to think of the end from the beginning.

Dr. Sheena Kaunda, Senior Medical Officer at
Chikwawa District Hospital, Malawi

“We are now able to look at project outcomes not only in terms of the biological impacts, but we are now able to look at the process itself in terms of implementation determinants and implementation outcomes that inform the quality of implementation. Now when we engage with partners, we are paying more attention to the implementation process just to make sure that it is also of good quality.

Steve Manyozo, Epidemiologist, Kamuzu University of
Health Science, Malawi



“The implementation research training helped to apply a structured process to identify bottlenecks and barriers – the problem – in the health system, especially in the area of neglected tropical diseases. We were able to successfully develop and implement an interventional study. The implementation research training also helped in identifying and engaging appropriate stakeholders, and identifying potential funding sources for our interventional studies in the region.

[The training] has enhanced my day-to-day activities of identifying problems in the routine service delivery system and being able to use my acquired skills to solve some of the problems in the service. I am now an expert in IR, gained the knowledge, skills and experience, and am able to use IR to conduct research and win international research grants for projects.

Adam Abdul Razak, Regional Health Research Coordinator, Bono Regional Health Directorate, Ghana Health Service



“The training in implementation research and mentorship were crucial to designing and conducting my Master’s research work. The long-lasting impact of my training in implementation research is worth mention. I am currently applying my knowledge and skills in conducting implementation research to design a study to understand the gaps and facilitators to the implementation of maternity protection regulations in the informal economy of Ghana.

Faustina Twumwaa Gyimah, PhD candidate and recipient of a TDR postgraduate scholarship, Ghana



“As a health systems development officer and health research officer based at the Policy Planning Monitoring and Evaluation Division of the Ghana Health Service, the implementation research training has systematically sharpened my understanding to demonstrate evidence and highlight alternative recommendations in the act of engaging larger communities.

Samuel Mayeden, Health Systems Development Officer and Health Research Officer, Policy Planning Monitoring and Evaluation Division, Ghana Health Service

GHANA

More information

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Value-based procurement policies and practices

Introducing new health technologies into the health system can bring procurement and distribution challenges. ADP, through PATH, works with governments to enhance effectiveness of the procurement and supply chain systems in LMICs. Procurement policies can have significant impact on the ability to efficiently access health technologies and commodity supply chains – as the technology landscape evolves, national procurement policies will need to reflect the new requirements. Value-based planning and procurement approaches can help maximize the impact of limited resources. ADP has thus focused on increasing awareness of strategic approaches for ‘value-based’ planning and procurement as a means to help governments balance increasing health needs, safeguard the availability of much-needed health technologies and contain rising costs.



Procurement dashboard for equitable access to COVID-19 diagnostic tests



Demand for diagnostic tests for COVID-19 has been unprecedented, creating significant procurement challenges for LMICs.
Photo: Guido Hofmann on Unsplash

The COVID-19 pandemic triggered demand for diagnostic testing at an unprecedented scale. Decision makers in LMICs have faced particularly tough challenges accessing relevant information on quality metrics to inform selection, procurement and deployment decisions as a key part of their strategic pandemic response efforts.

Early in 2020, while diagnostics manufacturers were still struggling to ramp up production capacity of COVID-19 tests to an adequate level, the constrained supply and high demand pushed prices to prohibitive levels for many countries. Soon after, the market was flooded with hundreds of COVID-19 diagnostics tests, spanning different technology platforms and with varying performance and availability, making it increasingly challenging for local and national decision makers to decide which tests to purchase and use. This was a key gap, as ensuring that high-quality tests are available and accessible to LMICs is vitally important in supporting a robust and equitable response to the pandemic.

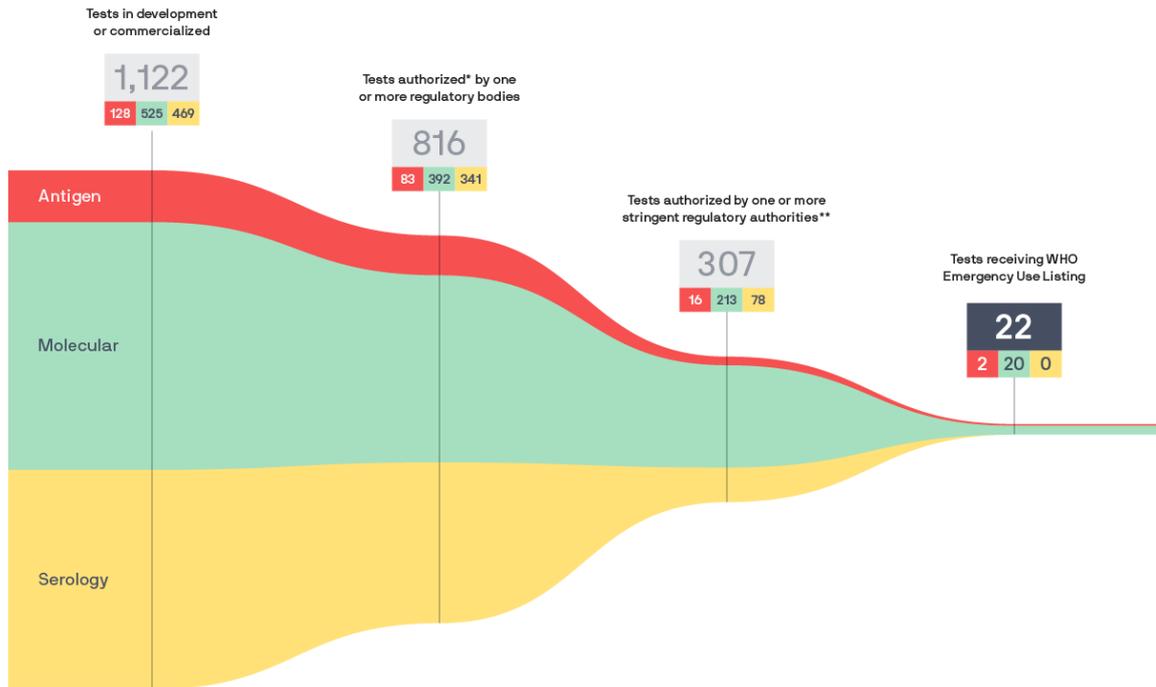
Recognizing this, several inter-agency collaborations and initiatives were established to support LMICs in gaining access to affordable and quality tools for the COVID-19 response, including the [Access to COVID-19 Tools \(ACT\) Accelerator](#), the [Diagnostic Consortium for COVID-19](#) (involving the Global Fund to Fight AIDS, Tuberculosis and Malaria, the Stop TB Partnership's Global Drug

Facility, the Pan American Health Organization, UNDP, United Nations Children's Fund, Unitaidd/ Clinton Health Access Initiative and WHO), [WHO's development of product selection considerations for COVID-19 diagnostics](#) and more. While these efforts continue to make important progress, the need for greater transparency and access to information at regional and local levels is equally important to ensure equitable outcomes.

In response to this gap and need, the PATH Diagnostics Program developed a set of six interactive COVID-19 diagnostic dashboards. Each of the dashboards aggregates and visualizes publicly available information on available COVID-19 diagnostic tests, addressing specific needs of national governments, procurers, funders and policymakers, and helping them to navigate the complex and congested marketplace to better support their COVID-19 responses.

Given the inherent challenges for procurement officials in LMICs to secure quality-assured COVID-19 diagnostics in a timely manner, in 2021 ADP partner PATH developed the [COVID-19 Diagnostics Procurement Resource](#), a tool specifically designed to support country-level procurement decisions. The interactive dashboard consolidates key data and parameters needed to make informed decisions about the technical specifications, performance, regulatory status and supply of individual COVID-19 diagnostic tests.

Global supply of COVID-19 diagnostic tests



Source: Neha Agarwal, 'Making sense of COVID-19 diagnostics', PATH, 23 November 2020, <https://www.path.org/articles/making-sense-covid-19-diagnostics>.

The interactive dashboard provides users with access to aggregated public data on an increasing number of COVID-19 diagnostic tests. The data can be easily filtered by country-specific regulatory status and with key test specifications to identify products that meet highly specific procurement needs and requirements.

The dashboard seeks to provide information that is most useful for in-country diagnostics procurement officials and includes, where available, indicative purchase pricing of tests and distributor information.

Going forward, the resource is continually updated to incorporate further relevant products and associated data. Further efforts to promote the resource and collect feedback from key stakeholders are also planned to support continuous improvement.

COVID-19 Diagnostics Procurement Resource

Filter by test approval / availability:

- Geographic Region: Africa, Americas, Europe, South East Asia, Western Pacific
- Country/Sub-region: All, Australia (TGA), Brazil (ANVISA), Burkina Faso, Canada (Health Canada), EU and UK (CE/MD), Ghana, India (CDSCO), Japan (PMDA), Korea (KFDA)

Filter by test characteristics:

- Approved Use (Lab vs. POC): [Dropdown]
- Instrumentation required?: [Dropdown]
- User (Professional vs. Self-test): [Dropdown]
- Independent Evaluation: [Dropdown]
- Acceptable Sample Type: [Dropdown]
- Available Distribution Channel: [Dropdown]
- Time to result (min): [Slider]
- Length of Cold Chain Stability (mo): [Slider]

Manufacturer	Test name	Approved Use (Lab vs. POC)	Independent Evaluation	Acceptable Sample Type	Instrumentation required?	Available Distribution Method	Hover for additional information
Abbott Diagnostics	BiaxPlex COVID-19 Ag 2 Card	Point-of-care, Laboratory	No	Nasal swab	Null	TSP	Is indicative purchase pricing available? No
Abbott Diagnostics	BiaxPlex COVID-19 Ag Card	Point-of-care	Yes	Nasal swab	Null	TSP	Is indicative purchase pricing available? No
Abbott Diagnostics	BiaxPlex COVID-19 Ag Card 2 Home Test	Point-of-care	No	Nasal swab	Null	None identified	Is indicative purchase pricing available? No
Abbott Diagnostics	BiaxPlex COVID-19 Ag Card Home Test	Point-of-care	No	Nasal swab	Null	None identified	Is indicative purchase pricing available? No
Abbott Diagnostics	INFLUENZA Mobile App and BIAxPlex COVID-19 Ag	Null	Yes	Nasal swab	Null	None identified	Is indicative purchase pricing available? No
Abbott Laboratories	BinaxNOW COVID-19 Ag Rapid Test Device - Nasopharyngeal	Point-of-care	Yes	Nasopharyngeal swab, Nasal swab	Null	TSP, UNICEF, JHU/CEP	Is indicative purchase pricing available? No
Abbott Laboratories	BinaxNOW COVID-19 Ag Rapid Test Device - Nasal	Point-of-care	Yes	Nasopharyngeal swab, Nasal swab	Null	TSP, UNICEF, JHU/CEP	Is indicative purchase pricing available? No
Access Bio, Inc.	CarteScan COVID-19 Antigen	Point-of-care	No	Nasopharyngeal swab	Null	AMSP	Is indicative purchase pricing available? No
Alisa Biotech	Alisa COVID-19 Antigen Rapid Test	Point-of-care	No	Nasopharyngeal swab, Oropharyngeal swab, Nasal	Null	TSP	Is indicative purchase pricing available? No
Alisa Link (Beijing) Technology Co Ltd	NOVA Test SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)	Point-of-care	No	Nasopharyngeal swab, Nasal swab	Null	TSP	Is indicative purchase pricing available? No
BD Biosciences	SARINATE COVID-19 Antigen RDT	Point-of-care	No	Nasopharyngeal swab	Null	TSP, private	Is indicative purchase pricing available? No

The COVID-19 Diagnostics Procurement Resource allows users to filter by an array of characteristics and parameters

Further information

- ✓ ADP, 'COVID-19 Diagnostics Procurement Resource': <https://adphealth.org/covid-19-diagnostics-procurement-resource/>
- ✓ PATH, 'COVID-19 Diagnostics Dashboards': <https://www.path.org/programs/diagnostics/covid-dashboard-covid-19-diagnostics-dashboard/>

Digital health

The COVID-19 pandemic has accelerated digital transformation in the health sector in many countries. For example, the use of digital technologies played a crucial role in the roll-out of the COVID-19 vaccination programmes in a number of countries. Beyond vaccines, digital tools show promise as a means to increase efficiency, resilience and sustainability of health systems. ADP has supported national efforts to identify digital interventions and tools that are appropriate, cost-effective and sustainable to address broader health system challenges. These efforts have also included policy support and technical assistance for strengthening policy frameworks, governance structures, data management and health workforce capacities.



Digital solutions for improved vaccine access



Health workers in Indonesia use the SMILE cloud-based digital system for vaccine management. Photo: UNDP Indonesia

Vaccines are widely regarded as one of the greatest advances in global health and development, protecting children and communities from deadly and disabling diseases. As has been well demonstrated by the COVID-19 pandemic, vaccines are also critical to the prevention and control of infectious diseases, and a cornerstone of global health security.

Digital tools have shown great promise in enhancing the efficiency of vaccination systems in LMICs. ADP is actively supporting countries to identify and adopt the appropriate digital solutions.

In 2014, the Government of India, with support from UNDP and Gavi, the Vaccine Alliance, embarked on a journey to digitize its vaccine supply chain network through the [Electronic Vaccine Intelligence Network \(eVIN\)](#). Since then, the cloud-based system has made significant contributions to the immunization programmes in India.

The system strengthens the vaccine supply chain by digitizing information on vaccine stocks and storage temperatures. eVIN has transformed the entire vaccination system in India, from vaccination registration and scheduling to monitoring and tracking of possible side effects, strengthening cold chain and logistics management, generating real-time reports and producing vaccine certificates.

Artificial intelligence and big data analytics also support decision-making and targeting of the most vulnerable for vaccination. It has been successfully implemented for vaccine stocks at all 28,000 storage centres across the country.

The eVIN experience has shown that digitized information systems are critical for driving the rapid, safe and equitable deployment of vaccines, which in turn can enhance health system preparedness and resilience. ADP has collaborated with UNDP India to facilitate South–South technical cooperation and transfer of technical know-how to other LMICs to enable accelerated uptake.

ADP has also supported the documentation of digital good practices, strategies and lessons learned to improve policymaking and planning for the introduction of new vaccines, particularly for countries exploring digital solutions to support distribution of COVID-19 vaccines.

In Indonesia, beginning in 2018, ADP partnered with UNDP Indonesia to support the Ministry of Health and the national immunization programme with a pilot cloud-based digital system, based on eVIN, under the name [Sistem Monitoring Imunisasi Logistik secara Elektronik \(SMILE\)](#). The pilot's success has led to its rapid scale-up to 10,000 primary health centres in 34 provinces across the country.

The COVID-19 pandemic attested to the critical role of the digital vaccine systems in India and Indonesia. The earlier investments in digital vaccine management and delivery systems in both countries enabled the swift pivoting of the systems to manage and deliver COVID-19 vaccines once they were available. They provided the essential foundation on which the much larger, population-wide COVID-19 vaccination programmes could be formed.

In India, the COVID Vaccine Intelligence Network (CoWIN) facilitates all aspects of the vaccination process, including registrations, immunizations, appointments management, and issuing of digital vaccine certificates. Since its launch in January 2021, the CoWIN system has registered 1.1 billion people (84 percent of the country’s total population) for COVID vaccination and been used to deliver 2.04 billion doses, resulting in over 855 million people being fully vaccinated (two doses) as of July 2022.²¹

Indonesia COVID-19 vaccination time series

2021 Q1



2021 Q4



2022 Q3



The SMILE digital vaccine system enabled the rapid and efficient distribution of COVID vaccines across the Indonesian archipelago of 6,000 inhabited islands. See <https://public.flourish.studio/visualisation/10906026/> for an animated graphic showing the vaccine coverage progress from Q1 2021 to Q3 2022.

²¹ Real-time data are available on the CoWIN website: <https://dashboard.cowin.gov.in/>.

SMILE has also been adapted to support COVID-19 vaccine delivery in Indonesia, facilitating the administration of 429 million vaccine doses and the full vaccination of 171 million people (as of July 2022).²²

The experiences of India and Indonesia in repurposing eVIN and SMILE, respectively, for inventory management and delivery of COVID-19 vaccines offer valuable lessons for other countries. ADP has helped to facilitate the transfer of knowledge and technical know-how to other LMICs.

One of the first recipients of the transfer of technical know-how was Bhutan, which successfully set up its Bhutan Vaccine System and immunized its population against COVID-19 at a remarkable speed, including by providing the first dose of vaccine to 99 percent of children aged 12–17 over a four-day span in September 2021.

Under the Bhutan Vaccine System, 719,000 people (93 percent of the total population) have been registered, 2.1 million doses have been administered, and 671,000 people have been fully vaccinated with two doses (as of July 2022).

The successful vaccination drives and high vaccination coverage, aided by the operational and systemic efficiencies provided by the digital systems, have greatly benefited Bhutan, India and Indonesia, and helped enable quick economic recovery.

Looking ahead, ADP will continue its support to countries to identify and implement digital solutions for vaccine delivery. This is complementary to the global UNDP approach towards support for national COVID-19 vaccine deployment plans, which focuses on three core elements: digital solutions for vaccine delivery and systems-strengthening; integrated data analytics to support decision-making for vaccine equity; and greening of COVID-19 vaccination.

Further information

- ✓ UNDP, 'Improving vaccination systems – eVIN': <https://www.in.undp.org/content/india/en/home/projects/gavi1.html>
- ✓ Ministry of Health and Family Welfare, 'Co-WIN Global Outreach Program': <https://www.undp.org/india/projects/improving-vaccination-systems-evin>
- ✓ SMILE Indonesia: <https://elearning.smile-indonesia.id/>
- ✓ UNDP, 'Indonesia recognizes digital champions on health and vaccination drive through SMILE', 9 August 2022: <https://www.undp.org/indonesia/press-releases/indonesia-recognizes-digital-champions-health-and-vaccination-drive-through-smile>
- ✓ UNDP, 'Building Digital Public Goods: takeaways from India's COVID-19 vaccine implementation programme', 1 February 2022: <https://www.undp.org/digital/blog/building-digital-public-goods-takeaways-india%E2%80%99s-covid-19-vaccine-implementation-programme>
- ✓ UNDP, 'Support to Vaccine Equity | Beyond Recovery: Towards 2030', 17 June 2021: <https://www.undp.org/publications/support-vaccine-equity-beyond-recovery-towards-2030>
- ✓ UNDP, 'A New Digital System Drives Bhutan's COVID-19 Vaccination Success', 30 July 2021: <https://www.asia-pacific.undp.org/content/rbap/en/home/presscenter/pressreleases/2021/a-new-digital-system-drives-bhutan-s-covid-19-vaccination-succes.html>
- ✓ UNDP, 'The digital COVID vaccine system in Bhutan that ensures no one is left behind', 1 October 2021: <https://undpbhutan2012.medium.com/the-digital-covid-vaccine-system-in-bhutan-that-ensures-no-one-is-left-behind-7d1ac0a98979>
- ✓ UNDP, 'Indonesian President highlights the importance of vaccine temperatures ahead of COVID-19 immunization drive', 19 November 2020: <https://www.id.undp.org/content/indonesia/en/home/presscenter/pressreleases/2020/Indonesian-President-highlights-the-importance-of-vaccine.html>

²² Real-time data are available on the SMILE website: <https://vaksin.kemkes.go.id/#/vaccines>.

Uniting Efforts: Linking innovation, access and delivery for a common goal

For too long there has been a lack of attention to and funding for the development of new health technologies needed to address many of the neglected diseases that disproportionately affect the world's poorest people. And when medicines, vaccines and diagnostics are developed, they often do not reach those communities who need them most. The current global context of multiple crises presents a further challenge for greater investments in neglected diseases.





Photo: Uniting Efforts for Innovation, Access & Delivery

R&D funders, innovators, governments, civil society and other actors involved in the innovation, access and delivery of health technologies all have critical roles to play in meeting this challenge.

Uniting Efforts for Innovation, Access and Delivery is the global platform bringing together these key stakeholders with the objective of promoting dialogue and cooperation for new tools and strategies that will simultaneously inform both the R&D and innovation process, and access and delivery initiatives. The platform is a joint initiative of the Government of Japan, the UNDP-led ADP and the GHIT Fund.

Uniting Efforts aims to provide a global forum to define a common vision towards 'health technology delivery preparedness' for neglected diseases and patients in LMICs.

The continuing unequal access to COVID-19 vaccines in LMICs illustrates the need to ensure that global cooperation efforts in the development of health technologies and investments in robust health systems to deliver them must come together to achieve equitable and timely access. Consolidating an agenda for action across the major stakeholders within the continuum of innovation, access and delivery will be a critical contribution towards the achievement of both UHC and pandemic preparedness.

A priority issue addressed by Uniting Efforts is the need for sustainable financing to ensure access to and delivery of health technologies. Neglected diseases have long been left behind when it comes to domestic and international funding. In 2020, Uniting Efforts launched the Discussion paper on the Landscape of Funding and Financing Opportunities for Access and Delivery of Health Technologies for Neglected Diseases. The paper documented increasingly downward trends in financing for NTDs, and identified a range of innovative and sustainable financing strategies.

Following up on the recommendations, Uniting Efforts partners are collaborating with the Department of Control of Neglected Tropical Diseases at WHO on a toolkit for developing investment cases aimed at improving financing options for addressing NTDs.

The Ministry of Health in Ghana has agreed to pilot an investment case of three priority diseases in the country: leprosy, onchocerciasis and lymphatic filariasis. The investment case will help provide the economic and development rationale for investing in evidence-based and cost-effective interventions with regard to these priority NTDs in the country. The investment case will also be an important advocacy tool to generate new resources and help the government, donors and

other partners prioritize financing that is aligned with national priorities.

In the current context of reduced global health funding, the national investment case will be an important means to identify and unlock new financing opportunities, including domestic sources. The pilot investment case in Ghana will also provide a model that can be adapted and replicated in other countries, to drive informed financing decisions related to neglected diseases, and contribute to the implementation of the WHO NTD Roadmap 2021–2030.

The lack of planning and well-defined policies, as well as coordination among different actors, has been identified as a major challenge hindering access to and delivery of health technologies. Uniting Efforts is undertaking analysis aimed at distilling lessons to improve the planning for access and delivery in the early stages of the R&D process. A survey of leading funders, innovators and stakeholders in LMICs will inform the review of access policies and practices within R&D processes, and identify lessons and good practices for an end-to-end integration of access strategies.

The goal of this work is to inform the community of funders, product developers and access stakeholders about the diverse approaches that can be adopted to integrate access considerations throughout the R&D process. There is an obvious and common interest in enhancing the ability of product developers, funders and access stakeholders to better understand how access goals can be met. It is anticipated that the good practices and success factors identified will

generate an agenda for concrete measures to effectively connect innovation processes with on-the-ground realities for access and delivery.

Another area that Uniting Efforts is working on is the procurement and supply of NTD health technologies, as this has been recognized as an area that is highly fragmented. Uniting Efforts is looking at the lessons that can be learned from the procurement and supply of technologies for other global health challenges, such as HIV, TB and malaria, and how they can be applied to NTDs.

“We know that the global community can come together very quickly for the common good; we have seen this happen with the development of COVID-19 vaccines. We now need to make sure that access and delivery considerations are also embedded in the R&D process. We need to invest in access and delivery to ensure a seamless transition from R&D to delivery.”

“The Uniting Efforts platform affords us a new way of working together in alignment from the beginning. The GHIT Fund will continue to work with UNDP and the Government of Japan on this important mission.”

– Dr. Osamu Kunii,
Chief Executive Officer at the GHIT Fund

Further information

- ✔ Uniting Efforts for Innovation, Access and Delivery: <https://www.unitingeffortsforshealth.org/>
- ✔ Uniting Efforts, ‘Discussion Paper on the Landscape of Funding and Financing Opportunities for Access and Delivery of Health Technologies for Neglected Diseases’, 6 November 2020: <https://adphealth.org/resource/68/discussion-paper-landscape-of-funding-and-financing-opportunities-for-access-and-delivery-of-health-technologies-for-neglected-diseases/>
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- ✔ Uniting Efforts, ‘Challenges and opportunities for innovation, access and delivery of health technologies: Why a global dialogue? Background paper’, 30–31 January 2019: https://static1.squarespace.com/static/5be0631d620b8515f3a9e8a4/t/5c427d0c0e2e7224cf/e7f342/1547861266545/Backgrounder_Uniting+Efforts_18+January.pdf

04

INVESTING IN HEALTH AND HUMAN SECURITY

As the world faces multiple interconnected crises – in health, environment and security – the collective global commitment to ‘leave no one behind’ is more important than ever.

The lessons from the COVID-19 pandemic are becoming increasingly obvious: the record pace set in the R&D of the multiple COVID-19 vaccines was not accompanied by structures and frameworks to enable timely and equitable access in all countries. This understanding is critical for the design of an improved response to COVID-19 and to prevent future pandemics.

The continuing partnership between the GHIT Fund and the UNDP-led ADP is well positioned to respond. The strategic aim of the partnership has long aimed at an integrated approach that links accelerated R&D and product development with capacity support on the ground to ensure access and delivery to those in need. ADP’s focus on strengthening institutional and technical capacities of national health systems and supporting national responses to COVID-19 and other outbreaks and pandemics are, in fact, two sides of the same coin: each drives access to and delivery of affordable and quality-assured health technologies towards the achievement of UHC and progress towards human security.

It is vital that national health systems are enabled to provide continued essential services for the population even during a crisis. A well-functioning health system remains the strongest enabler of UHC, and a critical means of reducing inequalities. Put simply, the measures taken now to strengthen overall health systems resilience, including through ADP’s work, will contribute towards sustainable human development. This aligns with the UNDP Strategic Plan 2022–2025 and the UNDP HIV and Health Strategy 2022–2025, both of which acknowledge the need to build resilient and sustainable health systems as the foundation for achieving the mutually reinforcing goals of health, sustainable development and human security.

The lasting impact of the COVID-19 pandemic will likely remain centre stage. The pandemic put health systems under tremendous stress, reiterating the underlying need for enhanced capacities to perform essential health functions.

The ADP’s focus on strengthening health systems to ensure enhanced access to and delivery of new health technologies is more critical today than ever. Underpinning ADP’s strategic focus in the future will be:

Strengthening disease control for TB, malaria and NTDs

ADP is sustaining and advancing its long-standing commitment to supporting national disease control programmes against TB, malaria and NTDs. Maintaining the most critical prevention activities and care services is essential to reduce the indirect impact of the pandemic and other health crises on poor and other vulnerable populations.

Supporting national pandemic preparedness

The COVID-19 pandemic has reversed decades of progress on poverty, health care and education in some settings, jeopardizing gains towards the Sustainable Development Goals. Given the current need to ensure delivery of and equitable access to safe and effective COVID-19 tests, vaccines and antiviral treatments, ADP is supporting countries to ensure their timely deployment through integrated planning, multisectoral coordination, strengthened regulatory capacity and supply chain improvements. ADP has helped countries to pivot quickly to respond to the pandemic, and this provides the basis for further support on pandemic preparedness.

Promoting digital health

The COVID-19 pandemic has accelerated digital transformation of health systems, including through improved models of health service delivery. ADP will focus its support to countries on strengthening digital health policy frameworks, governance structures and health workforce capacities to ensure local ecosystem readiness, and identifying digital health interventions that are appropriate, cost-effective and sustainable. ADP will continue to strengthen supply chains through digitization, enhance drug safety monitoring through the use of digital applications, and scale up digital health tools and telehealth systems to promote equitable access to essential health services.

Uniting Efforts for Innovation, Access and Delivery

Uniting Efforts has become a global platform to promote country preparedness for innovation, access and delivery of new health technologies. The platform will provide a means of fostering innovative partnerships to promote effective global and national collaboration across the innovation, access and delivery value chain. Uniting Efforts is poised to play a critical role in promoting the new approach, acknowledging that global health security is essential for realizing human security and sustainable development. This approach acknowledges the need for strengthened and resilient national health systems, and global cooperation on prevention and preparedness for future outbreaks and pandemics.

“We must not ignore the important lessons of the COVID-19 pandemic: strengthened capacities to access and deliver new health technologies are equally important as advances in R&D and product development to driving effective and sustainable responses to public health priorities – from the COVID-19 pandemic to maintenance of essential health services. This validates the Government of Japan’s support for both the GHIT Fund and for ADP, as interlinked and complementary projects; investing in R&D alongside health systems-strengthening ensures greater on-the-ground impacts.”

“We hope that a new phase of the GHIT Fund and ADP partnership – building on the 10 years of results and achievements – will continue to amplify the strategy of integrating innovation, access and delivery of health technologies, with the goal of achieving universal health coverage and human security.”



– Dr. Osamu Kunii, Chief Executive Officer, GHIT Fund, and Dr. Mandeep Dhaliwal, Director, HIV, Health and Development Group, UNDP

