THE ACCESS AND DELIVERY PARTNERSHIP

Empowered lives.
Resilient nations.

New Health Technologies for TB, Malaria and NTDs

Tuberculosis (TB), malaria and neglected tropical diseases (NTDs) are chronic infectious diseases, which have such significant impact on human and sustainable development that they are collectively defined as poverty-promoting.

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NEW APPROACHES AND PARTNERSHIPS TO TACKLE TUBERCULOSIS, MALARIA AND NEGLECTED TROPICAL DISEASES

Tuberculosis (TB), malaria and neglected tropical diseases (NTDs)[1] are chronic infectious diseases that impact human and sustainable development so significantly that they are collectively defined as poverty-promoting.

These diseases occur primarily in low- and middle-income countries (LMICs), and are usually concentrated in poor urban areas and remote rural areas. They disproportionately affect marginalized populations, and in many countries, they exacerbate marginalization through stigma. These diseases adversely impact child health and development, maternal safety and adult productivity. They kill and debilitate, and together account for 11.4 percent of the global disease burden.[2]

Nevertheless, of the 850 new therapeutic products registered in 2000–2011, only 37 (4 percent) were indicated for neglected diseases, including 25 products with a new indication or formulation, and eight vaccines or bi ological products. Only four *new* chemical entities were approved for neglected diseases (three for malaria, one for diarrhoeal disease), accounting for 1 percent of the 336 new chemical entities approved in that period. Furthermore, of the 148,445 clinical trials registered from the beginning of 2000 to the end of 2011, only 2,016 (1.36 percent) were for neglected diseases.[3]

The Government of Japan, in its **Global Health Policy 2011 – 2015**,[4] has called for new approaches and partnerships to tackle the grave global deficiencies in research, development and access to health technologies for TB, malaria and NTDs.

To cover the full spectrum of gaps and bottlenecks contributing to these deficiencies, the Japanese Global Health Policy employs a two-pronged health-systems approach. The first prong focuses on promoting innovation and research through the development of drugs, diagnostics and vaccines for TB, malaria and NTDs. The second prong aims at expanding the eventual access and delivery of these health technologies to populations in need.

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[1] The World Health Organization identifies 17 diseases as NTDs. These diseases share distinguishing features, including, most notably, their prevalence as some of the most common infections among people living in extreme poverty in sub-Saharan Africa, Asia, and Latin America and the Caribbean. These diseases are Buruli ulcer, Chagas disease, dengue/severe dengue, dracuculiasis (guinea worm disease), echinococcosis, foodborne trematodiases, human African trypanosomiasis (sleeping sickness), leishmaniasis, leprosy, lymphatic filariasis, onchocerciasis (river blindness), rabies, schistosomiasis, soil-transmitted helminthiases, taeniasis/cysticercosis, trachoma, yaws (endemic treponematoses). Source: WHO, *Working to overcome the global impact of neglected tropical diseases: First WHO Report on neglected tropical diseases*, WHO Geneva, 2010.

[2] WHO, *The Global Burden of Disease: 2004 update*, available at www.who.int/healthinfo/global_burden_disease/2004_report_update/en/index.html (accessed 30 January 2014)

[3] Pedrique et al., "The drug and vaccine landscape for neglected diseases (2000—11): a systematic assessment", *The Lancet Global Health*, Volume 1, Issue 6, December 2013, pp. e371 - e379.

[4] www.mofa.go.jp/policy/oda/mdg/pdfs/hea_pol_ful_en.pdf (accessed 16 January 2014)

The Government of Japan's initiative reflects renewed global attention to neglected diseases, and the global community's determination to eradicate them. This global resolve is evident in the January 2012 London Declaration on NTDs, which unites disease-endemic and donor countries with other key actors to address the infrastructural deficits that contribute to NTDs. [5]

The health-systems approach in Japan's Global Health Policy is consistent with the United Nations Development Programme's (UNDP) Strategic Plan for 2014-2017.[6] The UNDP Strategic Plan emphasizes sustainable human development, and outlines a vision in which UNDP works with countries to support their priorities and needs to eradicate poverty and significantly reduce inequalities and exclusion. The UNDP Strategic Plan calls both for income and for non-income measures, integrating best practices gleaned from sustainable development and human development approaches over the past two decades.

THE ACCESS AND DELIVERY PARTNERSHIP

The Access and Delivery Partnership is a five-year (2013-2018), approximately US$ 17.5 million project that aims to help LMICs enhance their capacity to access and introduce new health technologies for TB, malaria and NTDs. New health technologies are broadly defined as drugs, diagnostic tools and vaccines that are relevant for the prevention, treatment or cure of TB, malaria and NTDs, but are not yet available for market introduction or have not been introduced in LMICs.


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The introduction of new health technologies can place a weighty burden on existing health systems. These burdens may include new requirements for drug regulation, supply and distribution, and health personnel training. Accordingly, the Access and Delivery Partnership will focus on providing LMIC stakeholders with the necessary skills to develop the systems and processes required to effectively access new health technologies, and introduce them to populations in need.

[5] http://unitingtocombatntds.org/downloads/press/ntd_event_london_declaration_on_ntds.pdf (accessed 28 January 2014)
[6] www.undp.org/content/undp/en/home/librarypage/corporate/Changing_with_the_World_UNDP_Strategic_Plan_2014_17/ (accessed 28 January 2014)

The costs and pricing of health technologies, as well as the availability of funds to procure health technologies, vitally influence their affordability.

PHOTO CREDIT: UN/K. TASE

Led and coordinated by UNDP, the Access and Delivery Partnership is a unique collaboration among UNDP, the Special Programme for Research and Training in Tropical Diseases at the World Health Organization (WHO/TDR) and PATH. Working together, the partners will leverage the expertise within each organization to provide the full range of technical skills necessary to strengthen capacity in LMICs.

The Access and Delivery Partnership is one of two projects created under the Japanese Global Health Policy 2011 – 2015. The Access and Delivery Partnership emphasizes consultation, collaboration and implementation with partner-country governments and stakeholders, working to develop LMICs' capacities to access and introduce new technologies. The Global Health Innovative Technology Fund works with the Bill and Melinda Gates Foundation to make funds available to stimulate research and development of such technologies. Japanese pharmaceutical companies and specialized research and development institutions are engaged in this effort through global public-private partnerships and product development initiatives.

The Government of Japan invited UNDP, as the global intergovernmental agency with expertise in development, to serve as the facilitating and implementing partner for both the Global Health Innovative Technology Fund and the Access and Delivery Partnership.

AIMS AND OBJECTIVES

Even as the number of new health technologies coming to market for TB, malaria and NTDs slowly increases, their uptake in LMICs has been constrained by limited capacity. Three key determinants can influence LMICs' abilities to access and introduce new technologies:

Ensuring the appropriate linkages between innovation and access.

PHOTO CREDIT: UNDP/J. SCHYTTE

INNOVATION

Health technologies should be developed to meet the specific needs of populations in developing countries. Ongoing adaptive research is also needed to tailor new or improved products to developing country settings, and to ensure that developing country stakeholders have a voice in determining priorities.

AFFORDABILITY

The affordability of health technologies is influenced by their costs and pricing, as well as the availability of funds to procure them. It is also important to examine the implications of intellectual property rights and competition on the affordability of health technologies.

NATIONAL CAPACITY

Access and delivery depend on the adequacy of national-level health care infrastructure and resources. The policy and regulatory environments, basic infrastructure, adequate human resources, functioning primary and secondary health care delivery systems, and other factors are central to making existing treatments available and accessible.

The Access and Delivery Partnership provides technical and policy advice to LMICs with the aim of strengthening their capacity to access and introduce new health technologies. Ultimately, the partnership seeks to improve the access and delivery of new health technologies for TB, malaria and NTDs in LMICs. This will be achieved through a range of activities across the value chain of health services, in collaboration with government and other stakeholders in partner countries.

THE PARTNERS

THE UNITED NATIONS DEVELOPMENT PROGRAMME

With a presence in 177 countries and territories, UNDP is the United Nations' global development network, advocating for change and connecting countries to knowledge, experience and resources to help people build better lives. UNDP supports its partners in developing their own solutions to development challenges, and in developing national and local capacities that will help them achieve human development and the Millennium Development Goals. UNDP helps countries attract and use aid effectively, and promotes the protection of human rights and the empowerment of women in all its activities.[7]

THE WORLD HEALTH ORGANIZATION SPECIAL PROGRAMME FOR RESEARCH AND TRAINING IN TROPICAL DISEASES

The Special Programme for Research and Training in Tropical Diseases (TDR) is a global programme of scientific collaboration that helps facilitate, support and influence efforts to combat diseases of poverty. TDR is hosted by the World Health Organization (WHO), and is sponsored by the United Nations Children's Fund (UNICEF), UNDP, the World Bank and WHO.[8]

PATH


PHOTO CREDIT: UN/K. TASE

PATH is an international organization that drives transformative innovation to save lives and improve health, especially among women and children. PATH works to accelerate innovation across five platforms — vaccines, drugs, diagnostics, devices, and system and service innovations — that harness its entrepreneurial insight, scientific and public health expertise, and passion for health equity. By mobilizing partners around the world, PATH takes innovation to scale, working alongside countries primarily in Africa and Asia to tackle their greatest health needs. Working together with countries, PATH delivers measurable results that disrupt the cycle of poor health.

[7] www.undp.org/content/undp/en/home/operations/about_us/frequently_askedquestions/#undp (accessed 21 January 2014)
[8] www.who.int/tdr/about/en/ (accessed 21 January 2014)

THE STRATEGIC CONTEXT

The Access and Delivery Partnership has convened an expert group to provide strategic guidance on project implementation. The Advisory Group for the Access and Delivery Partnership comprises 10 members with multidisciplinary technical expertise, and experience in innovation and access to health technologies.

In its planning, execution, and monitoring and evaluation, the Access and Delivery Partnership is guided by four strategic objectives:

> Ensuring the appropriate linkages between innovation and access
> Promoting an enabling environment for innovation in developing countries
> Ensuring sustainable and affordable access to health technologies
> Enabling strategic South-South collaboration

Successful delivery of the project outputs relies on these strategic objectives to guide the project, effective partnerships at the regional and national level, and expert advice from all sectors implicated in the achievement of the project goals.

These strategic objectives can only be achieved in collaboration with national-level policymaking and implementing agencies in partner countries, in accordance with the obligations, responsibilities and partnerships in place at both the national and regional levels. These include interministerial competency overlaps, regional research partnerships, and intergovernmental regional political and economic commissions.

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ACTIVITIES

The Access and Delivery Partnership will not seek to create parallel structures that compete with or undermine existing public sector initiatives. Before undertaking activities, the Partnership will consult relevant stakeholders to identify the interventions appropriate for each partner country.

The Access and Delivery Partnership has identified a number of intervention points along the value chain with critical impacts on access and delivery of new health technologies. Potential areas for support include the development of a conducive policy and legal environment, effective disease control and drug regulatory systems, sustainable financing for public health innovation and procurement of health technologies, and proficient procurement and supply chain management. Project activities are thus aimed at delivering five key outputs:

Output 1: Coherent policy and legal frameworks for expedited access and delivery of new health technologies

Output 2: Enhanced capacity to identify and address country-specific health system needs for effective access and delivery of new health technologies

Output 3: Strengthened capacity to monitor and respond to safety issues associated with new health technologies

Output 4: 4a: Improved capacity to ensure sustainable financing for new health technologies
4b: Developed capacity for commercialization of health technologies to ensure appropriate pricing and adequate supply

Output 5: Enhanced capacity in supply chain and delivery systems

This attention to the entire chain of health service delivery is designed to create national health systems that are enabled for the efficient and effective uptake of new health technologies for TB, malaria and NTDs. A range of activities for each output may be undertaken in collaboration with partner countries.

Each output is described below, along with an indicative list of the government agencies and technical partners with whom the project may engage. The needs of each partner country under each output will vary, and implementation will be tailored to the specific needs and priorities of the partner country.

OUTPUT 1: Development of coherent policy and legal frameworks for expedited access and delivery of new health technologies

The development of an enabling policy and legal environment that addresses the intersections of public health and industrial and fiscal policies, including approaches to technological innovation and intellectual property rights, is integral to ensuring sustainable access to and delivery of affordable medicines and treatments. Many LMICs increasingly regard the development of local pharmaceutical production capacity and domestic research and development capacity in the public and private sectors as crucial for their development. An appropriate balance must be struck between policies that meet

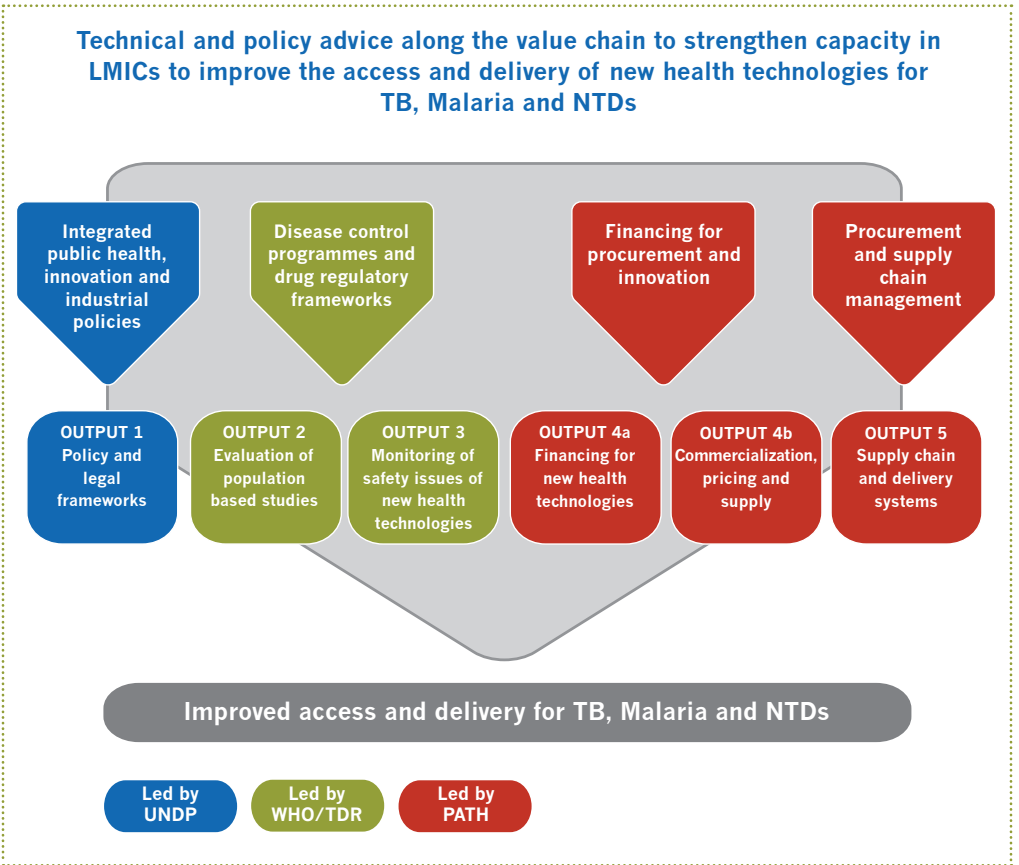

PHOTO CREDIT: UN/K. TASE

current needs, and policies that develop future capacities. The point of balance may vary according to the particular needs and priorities of a LMIC.

The focus of Output 1 will be strengthening capacities for the development and implementation of an integrated public health, innovation and industrial policy framework. Key national partners would include government authorities responsible for the various legal and regulatory environments, the pharmaceutical industry and civil society.

OUTPUT 2: Enhanced capacity to identify and address country-specific health system needs for effective access and delivery of new health technologies

Epidemiological surveillance systems are an integral part of a health care system; they provide health authorities a basis to make decisions about their priority health events, whether acute or long-standing. Ideally, functioning systems should be able to evaluate the impact of interventions on disease burden. This entails detecting and reporting bottlenecks and barriers causing inefficiencies or failure of interventions, and responding appropriately. The capacity of LMICs may need to be strengthened to optimize access and delivery of new technologies, as well as to identify solutions and options for overcoming implementation obstacles in health systems, disease control programmes and health care delivery.

Activities under Output 2 will focus on strengthening national capacities to use epidemiological population-based data to identify needs and enhance target populations' access to new health technologies. The main partners at the national level for this output would include government authorities responsible for disease control and surveillance, and the authorities responsible for operational research protocols. Research institutions from various sectors would also serve as partners.

PHOTO CREDIT: PATH/E. BECKER

OUTPUT 3: Strengthened capacity to monitor and respond to safety issues associated with new health technologies

Phase IV clinical trials are undertaken after a new pharmaceutical product has been brought to market. Their purpose is to gather data on the effect of the product in various populations, and to identify any side effects associated with long-term use. These clinical trials can strain the data management and surveillance systems of LMICs.[9] The burden they impose can have capacity implications, and may affect some countries' abilities to mobilize resources to sustainably expand and extend their capacity.

Output 3 focuses on strengthening the health sector's capacity to collate and analyse safety data related to newly introduced health technologies. Activities will focus on developing learning modules to train health care professionals in pharmacovigilance and the importance of reporting adverse drug reactions. Key partners under this Output would be the government agencies responsible for research protocols and public safety, the pharmaceutical industry and prescribing physicians from all sectors.

OUTPUT 4A: Improved capacity to ensure sustainable financing for new health technologies

Several global mechanisms — including the Global Fund to Fight AIDS, Tuberculosis and Malaria; the GAVI Alliance; and UNITAID — address financing challenges for specific disease areas. However, many countries do not have the capacity to develop policies and structures to ensure sustainability and self-sufficiency in financing the procurement of new health technologies. Capacities for financing research and development for TB, malaria and NTDs also remain problematic. Efforts should focus on supporting LMICs to integrate mechanisms that foster financial sustainability within

[9] Dr. Viraj Suvarna, "Phase IV of drug development", *Perspect. Clin. Res.*, 2010 Apr-Jun; 1(2): 57–60. PMCID: PMC3148611

the health system. Such mechanisms include tools like health technology assessments to inform coverage or pricing, inclusion into insurance benefit packages and the government resource allocation process.

Output 4a focuses on strengthening capacity for the development of processes that support sustainable financing for new health technologies, through review of existing resources and maximization of use of resources. The key national partners would be the government authorities responsible for finance and budgeting and science and innovation policies; academic research organizations; and knowledge management stakeholders.

OUTPUT 4B: Developed capacity for commercialization of health technologies to ensure appropriate pricing and adequate supply

Introducing new health technologies can be expensive, and LMICs may lack the resources to adequately quantify and qualify their needs with regard to pricing and sustainable supply of such technologies. While bodies such as the WHO provide reference tools for supply and procurement purposes, these tools cannot substitute for domestic capacity to ascertain needs and select new technologies to meet those needs.

Output 4b focuses on strengthening capacities in LMICs to ensure access to health technologies at appropriate pricing, such that supply meets demand. This may include support for the development of structured technology selection processes, as well as the development of a centralized mechanism or process for coordinating technology introduction. Key partners under this Output would be government authorities with responsibility for health technology selection, regulation, and supply; authorities responsible for infrastructure development, government procurement policies and disease control strategies; civil society stakeholders involved in procurement and supply of health technologies; and pharmaceutical and diagnostic device manufacturers.

PHOTO CREDIT: UN/N. FUJIWARA

OUTPUT 5: Enhanced capacity in supply chain and delivery systems

Health delivery systems that ensure quality commodities reach the end user require a well-designed and integrated supply chain. In many LMICs, bottlenecks in the planning, procurement and distribution functions disrupt public health programmes. These bottlenecks can occur at any point in the supply system, but the risk of disruptions or delays may be greatest when a new health technology is introduced. For example, it is more difficult to forecast a new commodity that has no usage data; sole sourcing the product may be necessary, but this may conflict with national procurement policies requiring competitive procurement. The new commodity may also require the procurement of other items to support its use (e.g. new diagnostic equipment will likely require consumable reagents, annual calibrations, special warranties and staff training on use).

Output 5 focuses on increasing integration and strengthening the supply chain disciplines, resulting in a system more capable of introducing new products without disruption. Key national partners would be the government authorities responsible for procurement policy, commodities planning, public sector procurement commodities storage and delivery, as well as civil society actors involved in health service delivery.

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