

**UNITING EFFORTS**  
FOR INNOVATION, ACCESS & DELIVERY



**DISCUSSION PAPER**  
**Landscape of funding and financing opportunities for access and delivery of health technologies for neglected diseases**

June 2020



From the People of Japan



**THE ACCESS AND DELIVERY PARTNERSHIP**

*New Health Technologies for TB, Malaria and NTDs*

**GHIT Fund**

Global Health Innovative Technology Fund

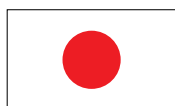


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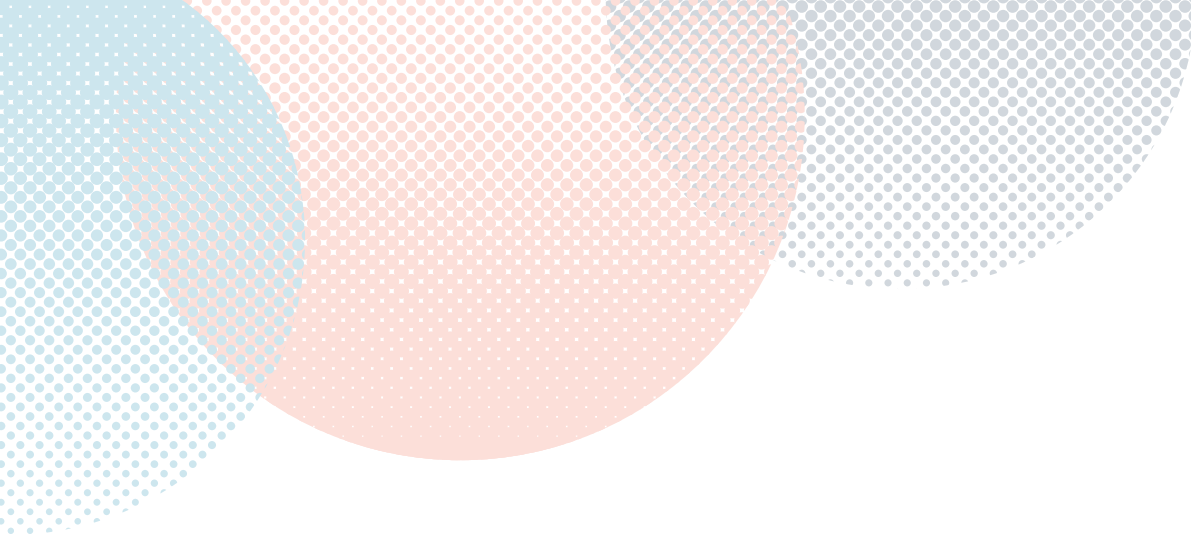


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**Acknowledgements:** This report was commissioned by Uniting Efforts for Innovation, Access and Delivery and its three core partners, the Government of Japan, the GHIT Fund, and the United Nations Development Programme (UNDP)-led Access and Delivery Partnership (ADP) – along with the World Health Organization (WHO), the Special Programme for Research and Training in Tropical Diseases (TDR) and PATH.

The document was written by independent consultant Rohit Malpani. The author would like to acknowledge the support, time and valuable contributions of the three partners of Uniting Efforts for Innovation, Access and Delivery and the experts who participated in interviews. A working draft of this paper was presented for discussion and feedback by the over 100 attendees at the Uniting Efforts for Innovation, Access and Delivery: Second Global Dialogue (Bangkok, 2–3 February 2020). For more information, including the list of participants, see: <https://www.unitingeffortsforhealth.org/globaldialogues>.

The views expressed in this publication are those of the author and do not necessarily represent those of the partners of United Efforts for Innovation, Access and Delivery.

**Suggested citation:** Malpani, R., *Landscape of funding and financing opportunities for access and delivery of health technologies for neglected diseases*. June 2020. Uniting Efforts for Innovation, Access and Delivery.

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# Acronyms and abbreviations

ADP	Access and Delivery Partnership
AU	African Union
BRICS	Brazil, Russian Federation, India, China and South Africa
COVID-19	Coronavirus disease
DAH	Development assistance for health
ESPEN	Expanded Special Project for Elimination of Neglected Tropical Diseases
EU	European Union
FDA	Food and Drug Administration (United States)
GDF	Global Drug Facility
GFF	Global Financing Facility
GHIT	Global Health Innovative Technology
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
HT	Health technology
IsDB	Islamic Development Bank
LMICS	Low- and middle-income countries
MSF	Médecins Sans Frontières
NEPAD	New Partnership for Africa's Development
NGO	Non-governmental organization
NTD	Neglected tropical disease
PDP	Product development partnership
PRV	Priority Review Voucher
PQ	Prequalification (WHO)
R&D	Research and development
STAG	Strategic and Technical Advisory Group (WHO)
TB	Tuberculosis
TDR	Special Programme for Research and Training in Tropical Diseases
UNDP	United Nations Development Programme
Uniting Efforts	Uniting Efforts for Innovation, Access and Delivery
VAT	Value-added tax
VL	Visceral leishmaniasis
WHO	World Health Organization



# Introduction

This landscape analysis, commissioned by Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts), provides an overview of existing strategies and needs to fund and finance access and delivery of health technologies for neglected diseases, opportunities to augment funding, and proposals to improve the efficiency of investments in line with the vision of the 2030 Agenda for Sustainable Development. For the purposes of Uniting Efforts, neglected diseases include tuberculosis (TB), malaria and neglected tropical diseases (NTDs).

The paper is structured in four main components:

- Overview of funding trends, including existing donors and funding mechanisms for neglected diseases
- A mapping of the elements and funding needs for an access and delivery strategy of health technologies
- Analysis of emerging funding and innovative financing opportunities
- Analysis of opportunities to improve the efficiency of investments

The report is focused on mechanisms that support or fund public sector interventions (supply and demand) and investments that improve access and delivery of health technologies, including the ability of the public health sector in low and middle-income countries (LMICs) to procure new health technologies. Measures that support, catalyse or fund private sector supply side interventions are not included except where such interventions are explicitly intended for adoption by the public sector.

The report is based upon desk research, key informant interviews (see Annex 1) and feedback from participants at the Uniting Efforts for Innovation, Access and Delivery: Second Global Dialogue (Bangkok, 2–3 February 2020).

## The impact of Coronavirus disease (COVID-19)

Research for this report was mainly conducted prior to the coronavirus disease (COVID-19) pandemic, and thus findings will need to be reconsidered in light of the impact of the pandemic on health systems and economies, and on the health of millions of people affected by neglected diseases worldwide. As of June 2020, when this paper was finalized, COVID-19 had already had an historic impact on economies and health systems worldwide, with uncertainty as to how the pandemic will evolve over the next 12 to 18 months, and how it will impact neglected diseases and health and well-being more broadly.

The rapid mobilization of efforts and investments in the research and development of COVID-19 therapeutics and vaccines hold important insights and lessons for neglected diseases. At the same time, for countries already affected by neglected diseases, the pandemic, and the upheaval it has created on health and economic systems, is likely to impact negatively programmes to prevent, diagnose and treat neglected diseases. Recent projections indicate that, as a result of COVID-19 restrictions, up to 6.3 million more people are predicted to develop TB between 2020 and 2025, and 1.4 million people are expected to die due to a lack of diagnosis and treatment.<sup>1</sup> In Africa, WHO has estimated that up to 250 million people could be infected by COVID-19, although the demographics of many African countries means mortality rates could be lower.<sup>2</sup> In the long term, the economic impact of the COVID-19 pandemic on all countries could negatively affect the resources that the public and private sectors can dedicate to address neglected diseases (and other health priorities), and further deprioritize the necessary investments on neglected diseases, making them even more neglected. Even as countries prepare and protect their populations from the COVID-19 pandemic, it will be crucial to adopt measures to mitigate any reversal in the progress towards the targets of ending the epidemics of TB, malaria and NTDs, as set out in the Sustainable Development Goals. Failure to do so

can exacerbate existing inequalities. Strategies that increase access and delivery of health technologies for neglected diseases, including investments in health systems, will also be essential to strengthen a response to COVID-19 and future pandemics in LMICs.

Against this scenario, Uniting Efforts partners are aligned in their continued efforts to promote an integrated approach that drives research and development (R&D) for new medicines, diagnostics and vaccines, combined with health systems strengthening to achieve universal health coverage (UHC). These are essential elements to secure sustained progress towards the 2030 Agenda. Therefore, the subject matter of this report and the discussion that Uniting Efforts partners are promoting on strategies to improve financing, including innovative financing mechanisms and opportunities for increasing synergies and efficiencies in existing and future investments across neglected diseases, is now even more necessary than when this paper was initially commissioned.

## Overview

Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts) is a global platform launched in 2019 aimed at bringing together and promoting dialogue among key stakeholders to accelerate and improve the innovation, access and delivery of medicines, vaccines, diagnostics and other health technologies for unmet health needs in LMICs. The focus of the initiative is to facilitate global dialogue and engagement among funders, innovators, product development partnerships and private sector, and governments and other access and delivery stakeholders in the field of tuberculosis, malaria and neglected tropical diseases (NTDs).

The platform was launched by three core partners: the Government of Japan, the United Nations Development Programme (UNDP)-led Access and Delivery Partnership (ADP) and the Global Health Innovative Technology Fund (GHIT Fund). As the **Welcome Statement to the Second Global Dialogue** highlighted, the three partners believe that “by working together in new ways, we can accelerate progress and better address persistent inequalities in health and transform the way that health technologies are developed, financed and delivered. We can work differently and more strategically, reducing silos and creating more space for collaboration and learning from one another. We must continue to build on this inclusive platform to ensure that lifesaving health technologies reach those who need them most. Only then can we achieve universal health coverage and deliver on the commitments embodied in Sustainable Development Goal (SDG) 3 and the 2030 Agenda”. For more information, please visit the **Uniting Efforts website**.







# Trends in funding and financing for health and neglected diseases

In 2016, worldwide investment in health care reached US\$8 trillion, of which an estimated 74 percent was financed by governments, 18.6 percent was out-of-pocket expenditure, 7.2 percent via private insurance, and 0.2 percent via donors.<sup>3</sup> Disparities as to where health expenditures occur persist. Between 2017 and 2050, nearly 70 percent of spending is expected to be in countries currently classified as high income, with only 0.6 percent of spending in LMICS.<sup>4</sup>

Government investment and out-of-pocket spending in LMICs for access and delivery of health technologies has increased significantly over the last decade. Out-of-pocket expenditure, which reached \$1.5 trillion worldwide in 2016, has a negative impact on the health and well-being of people living in poverty. According to the World Bank, households in developing countries spend half a trillion dollars annually – or over \$80 per person – to access health services, and such expenses hit the poorest hardest.<sup>5</sup>

Although donor assistance for health is less than 1 percent of overall health expenditure, it represents up to one quarter of all spending in low-income countries. In 2000, development assistance for health (DAH) (in 2018 dollars) was an estimated \$13.5 billion dollars, meaning overall DAH has nearly tripled over the last two decades.<sup>6</sup> Nevertheless, DAH has declined in recent years, totalling \$38.9 billion in 2018, or a reduction of 3.3 percent from 2017, and an annualized decline of 0.3 percent between 2013 and 2018.<sup>7</sup>

Over the last two decades, funding for access and delivery of health technologies to address HIV and AIDS, TB and malaria increased partly due to DAH – whether through bilateral contributions of donor governments or through multilateral contributions provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). Funding for immunization in low-income countries has been supported predominantly through Gavi, the Vaccine Alliance. In 2018, the top three areas of investment for DAH were: HIV and AIDS programming (\$9.5 billion), child and newborn health (\$7.8 billion) and reproductive and maternal health (\$4.7 billion). In contrast, \$2.1 billion was spent on malaria and \$1.6 billion was spent on TB; DAH for both diseases has increased over the last two decades but does not meet the actual need. While DAH totals for these areas of health are measured and reported annually, spending on access and delivery of health technologies to address the 20 WHO-priority NTDs is not systematically collected and published.

**Table 1 Selected DAH Funding by area of health for 2018 (in billions of United States dollars)**

HIV/AIDS	Child and Newborn Health	Reproductive and Maternal Health	Malaria	TB	NTDs
9.5	7.8	4.7	2.1	1.6	Data not available

Spending on NTDs has been historically low. Funding usually is provided through philanthropic and donor support and endemic government investment. Between 2008 and 2012, NTD spending was only 0.6 percent of DAH.<sup>8</sup> In 2015, WHO estimated that \$18 billion in total expenditure (for all interventions) would be needed to achieve its NTD road map by 2020, and yet, through 2018, less than \$200 million a year has been provided, a 94 percent shortfall.<sup>9</sup> At the time of publication, WHO was preparing to launch the WHO roadmap for NTDs 2021–2030, and the cost to deliver on that was not yet available, but it can be assumed that it is more than the \$18 billion of the last decade.

Annex 2 of this report provides an overview of existing data on current funders and available financing mechanisms and sources of funding for TB, malaria, and NTDs.



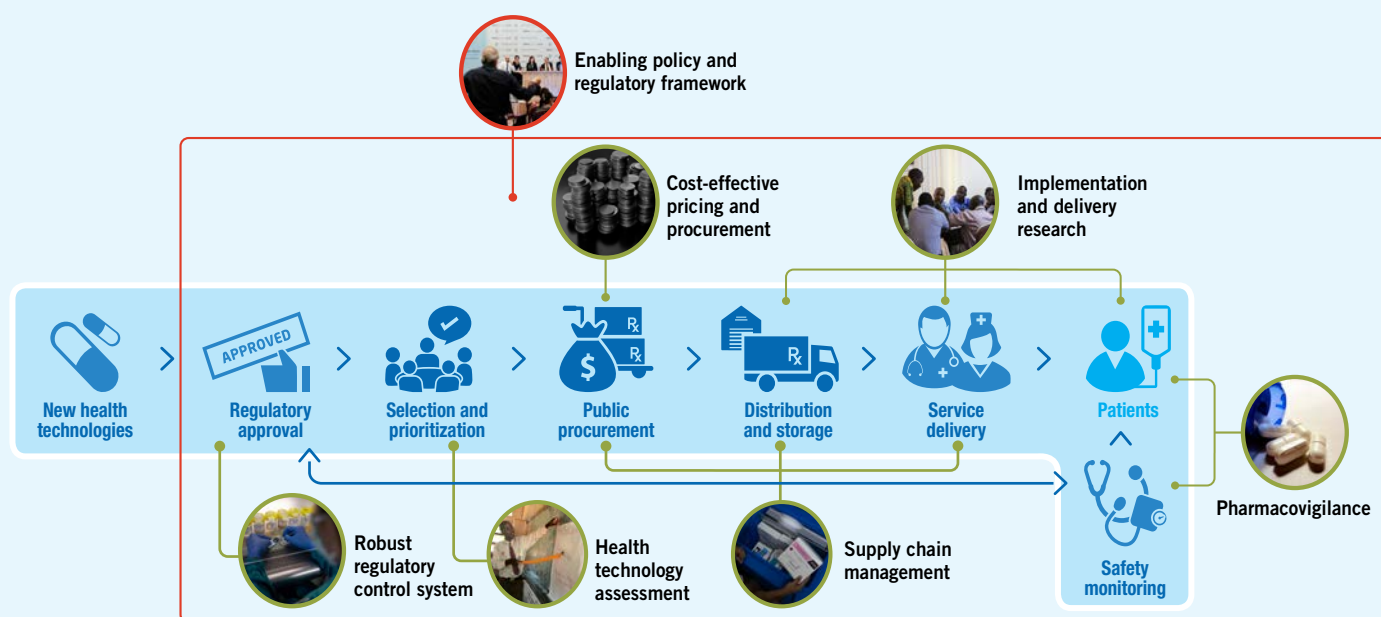
# Mapping access and delivery elements and funding needs

Successful adoption of health technologies that ensure populations in need are reached require predictable, sustained and strategic investments in access and delivery. Despite the collective efforts of governments, donors, development banks and non-state actors over the last two decades, funding needs for access and delivery endure for every neglected disease. Identification and mapping of the elements and the funding needs of a comprehensive access and delivery strategy of a health technology for neglected diseases are essential to improve access and delivery.

The ADP has mapped out the national-level interventions across the value chain of access and delivery that are necessary to introduce and rapidly scale up a new technology within a health care system. These steps are depicted in Figure 1.

For example, access and delivery of new health technologies requires regulatory approval through an appropriately resourced regulatory agency. Health technology assessments, already used in several high-income countries, also play an important role in improving selection of appropriate technologies<sup>10</sup> in LMICs, especially as the number of tools available for use against neglected diseases increases.<sup>11</sup> Appropriate product selection should be complemented by accurate demand forecasting, timely procurement and a supply chain that delivers technologies when and where needed. Implementation research is useful for a variety of purposes, including adapting test-and-treat models (or mass drug administration models) to unique country settings, and there should also be investment in pharmacovigilance to monitor adverse side effects and other safety signals. Laws and policies governing access and delivery must be updated to adhere to

**Figure 1:** ADP Value chain of access and delivery for health technologies



international standards, improve policy coherence and create enabling legal and regulatory environments, and adapt to the evolution of health technologies.

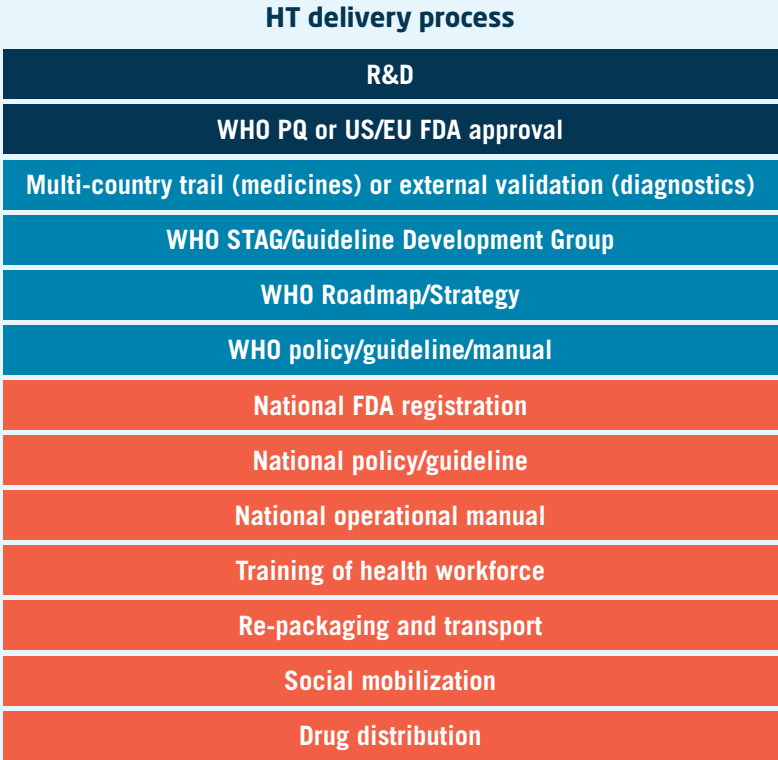
These investments in access and delivery in national health systems should be complemented by additional cross-cutting investments. One investment is encouraging community participation and demand creation. New technologies, especially those that replace the existing standard of care, run the risk of not gaining community acceptance and adoption unless communities are integrated into the selection of such technologies, including a full accounting of benefits and risks. Community participation and acceptance is also essential for scaling up treatment as many treatment models rely heavily upon community health workers, families and patients to compensate for weak health care systems. Community engagement also generates visibility of funding gaps, which can be transformed into public demands for resource mobilization. Even as communities bear a heavy burden, the training of health care workers at the national level is also essential. Health care workers require resources, expertise and capacity to integrate the use of new technologies (and the responsibility to diagnose and treat specific diseases) along with their existing responsibilities.

At the Uniting Effort Second Global Platform, a health technology delivery process illustrated by Dr. Kazuyo Ichimori and Dr. Aya Yajima – depicted the role and function of international institutions such as WHO, which makes important normative recommendations and provides key guidelines and tools relevant for access and delivery, including the WHO prequalification process and the WHO essential medicines and diagnostics lists (See Figure 2).

Although not all health technologies need to follow these steps to be available in countries and the order of the interventions is often diverse, the combination of both figures provides a useful overview and starting point to understand the complex and multifaceted processes and steps needed to improve access and delivery of health technologies, and the need for interventions at the national and global levels.

The concrete value chain and funding needs for access and delivery for health technologies for neglected diseases is likely to be different for each disease and technology (with important differences between drugs

**Figure 2: Health technology delivery process from research and development to drug distribution**



and diagnostics, for example), and will also vary by each country (and often within countries). This section of the report summarizes several common funding needs for neglected diseases and applies the following framework to assess funding needs across neglected diseases:

- a. What diseases, countries and populations have unaddressed funding needs?
- b. What are the access and delivery funding needs where health technologies have been introduced?
- c. What are the future funding needs that must be addressed for new or emerging health technologies?

## a. Unaddressed funding needs (diseases, countries, populations)

While domestic funding and DAH for TB and malaria does not match need, it is substantial, especially when compared to funding for most NTDs. Available funding for each NTD is different. Donor support has mainly been focused on NTDs that can be treated through administration of preventive chemotherapy medicines via mass drug administration. Mass drug administration programmes have affordable operating costs since such programmes apply simplified treatment models that are scaled up via non-specialized personnel and drug donations. Several NTDs – such as Chagas disease, visceral leishmaniasis (VL) and leprosy – have attracted some funding from donors though these programmes may attract less investment compared to those addressing other NTDs since operating costs are higher. NTDs such as yaws and scabies, which also depend on mass drug administration, do not have dedicated international programmes or systematic investment to galvanize the scale-up of existing treatments, although several endemic countries are making domestic investments, such as the efforts by Ghana to eliminate yaws.

Countries may not be able to obtain funds from available sources owing to ineligibility for donor funds and lack of spending of domestic resources on NTD access and delivery. A lack of a global fund for NTDs means that otherwise eligible countries may not obtain DAH or philanthropic contributions if they lack relationships with key bilateral donors. This raises questions of equity and fairness that have been addressed, however imperfectly, within global funding mechanisms for immunization or for HIV, TB and malaria.

Insufficient funding and financing for access and delivery of neglected diseases technologies can blunt efforts to control, treat and eliminate diseases. For example, while existing treatments for VL are not ideal, improved access to existing treatments and diagnostics could improve public health outcomes and reduce morbidity and mortality. VL persists in poor and remote areas in part due to limited health care and lack of access to medicines, including a lack of patient access to treatment centres. There are also significant barriers across the supply chain, including inadequate supply, stock management and forecasting, delays with registration and logistical challenges to distribution. These access and delivery barriers undermine availability and the cost of several VL medicines is still relatively expensive.<sup>12</sup> Innovation for new treatments, without investment in both sustainable access and health systems strategies, could mean health technologies will not reach patients or could be used sub-optimally, leading to inequities in health outcomes and resistance.<sup>13</sup>

Even within countries that are actively implementing NTD programmes, there are gaps in access and delivery that can lead to inadequate treatment coverage for certain population segments. This may be due to a lack of appropriate formulations – for example, provision of treatment to children or pregnant women. Even where cases have been detected there can be significant underreporting or inaccurate mapping, thereby limiting access to treatment. Cost recovery mechanisms that should pay for treatment may not reach certain communities, thereby leaving patients without treatment access if they cannot pay out of pocket.

Mass drug administration, while reaching many more people in need, does not provide comprehensive coverage. Distribution channels may exclude specific populations. School-based distribution can leave pre-school-aged children or out-of-school school-aged children without coverage, as well as pregnant women and other adults.<sup>14</sup> Drug donation programmes for use in mass drug administration often do not include adults and other sub-populations; therefore, if countries do not pay for NTD treatments beyond the ambit of donation programmes, there may be insufficient supply.

Within mass drug administration programmes, data that aggregates coverage data may have a tendency of masking inequities in availability, accessibility and acceptability of medicines. A qualitative study conducted across four countries (Cameroon, Ghana, Liberia and Nigeria) implementing preventive chemotherapy found many communities left behind owing to several causes.<sup>15</sup> This included a lack of coverage due to cross-border gaps in distribution. Other populations that were especially poor and stigmatized may have been hard to reach, including those affected by recent conflict and the Ebola outbreak (in the case of Liberia). There was exclusion of outsider communities, for example, migrants or people of a different religious background, – that was exacerbated by challenges in supply and delivery. Other groups were excluded from coverage because of ill-suited delivery channels, inability to reach target groups owing to timing of administration, or distribution strategies that did not consider infirmity or disability.<sup>16</sup>

### b. Access and delivery needs for existing health technologies

There are several needs that endure for technologies in use for neglected diseases. There are differences in the access and delivery needs for technologies required for TB and malaria, mass drug administration for NTDs, and test- and-treat programmes for NTDs. Table 2 below summarizes a few common needs and the underlying reasons those needs are important or remain unfulfilled.

**Table 2 Access and delivery funding needs for existing health technologies**

Access and delivery need	Underlying reason(s) on why it is important and/or need exists
Timely registration of new health technologies	<ul style="list-style-type: none"> <li>• Insufficiently resourced and functional national regulatory authorities</li> <li>• Delays by innovators to submit new products for regulatory approval</li> <li>• Diversity and lack of harmonization of regulatory requirements</li> <li>• Insufficient use of collaborative registration schemes</li> <li>• Challenges associated with registering novel combinations and formulations of new medicines intended for use only in LMICs</li> </ul>
Management of international supply, procurement and demand forecasting	<ul style="list-style-type: none"> <li>• Insufficient production to satisfy demand in LMICs</li> <li>• Poor procurement practice by national governments</li> <li>• Lack of engagement by communities and patients</li> <li>• Gaps in demand forecasting by governments</li> </ul>
Management of in-country supply and localized drug shortages	<ul style="list-style-type: none"> <li>• Updated population estimates</li> <li>• Poor supply chain management</li> <li>• Staff shortages</li> <li>• Delays in the supply chain</li> </ul>
Case finding	<ul style="list-style-type: none"> <li>• Gaps in report of diagnosed cases</li> <li>• Inadequate or unavailable diagnostic tools</li> <li>• Insufficient training and resources for health care workers</li> <li>• Lack of resources to implement test-and-treat programmes</li> </ul>
Distribution	<ul style="list-style-type: none"> <li>• Insufficient duration to ensure wide treatment coverage</li> <li>• Limited distribution methods that do not reach large numbers of people, especially in rural areas</li> <li>• Vulnerabilities of target populations and gender dynamics not considered</li> </ul>
Safety monitoring	<ul style="list-style-type: none"> <li>• Insufficient safety data not available prior to use</li> <li>• Approval of drugs based on limited data</li> </ul>

### c. Access and delivery funding needs for pipeline and new health technologies

The pipeline for neglected diseases has significantly changed, and new medicines, vaccines, and diagnostics to address neglected diseases will be submitted for regulatory approval in the next few years. These new products mean that access and delivery investments are crucial to ensure that impact is maximized. One study found 685 neglected disease (including HIV and AIDS) total product candidates as of August 2017, for which up to 128 expected product launches may emerge.<sup>17</sup> While most products in the pipeline address HIV and AIDS, TB and malaria, there are also multiple products in the pipeline for other NTDs, including Chagas disease (18 products), schistosomiasis (16 products) and leishmaniasis (14 products).<sup>18</sup> The growth of the pipeline reflects an increase in research & development (R&D) funding for neglected diseases. The G-FINDER report, which tracks overall spending on R&D for selected NTDs HIV and AIDS, TB and malaria, found that global funding for neglected disease R&D in 2018 had reached a new record high, totalling \$4.055 billion, or an increase of \$290 million (up 7.9 percent, with adjustments) from the previous year, which was the largest real annual funding increase on record.<sup>19</sup> Numerous product development partnerships (PDPs) dedicated to addressing R&D gaps for neglected diseases have also emerged, providing donors with a vehicle for their investment priorities. There has also been the introduction of new incentive programmes, especially the United States Food and Drug Administration (FDA) priority review voucher (PRV).

Additional funding needs for access and delivery may emerge as new health technologies are approved and introduced in countries. For example:

- *Manufacturing, supply and introduction of a new product.* New technologies to address NTDs may not be offered through product donations, and for those products emerging from PDPs, there are numerous questions as to how to ensure a sustainable supply for the product, and sufficient demand to ensure that such products can at least be offered on a non-profit, no-loss basis by a willing manufacturer. While there are multiple agencies and expertise to launch new TB and malaria products, there is insufficient guidance and international support to provide manufacturers and countries with a road map to launch new NTD products.
- *Government readiness to introduce a new product.* If a new health technology is not previously tested (e.g. during clinical trials) in a country, government policymakers may not be aware of or prepared for a new product.
- *Challenges with replacing an existing treatment or standard of care.* This may be difficult for several reasons. One challenge is that training for the use of a new drug, including for use in mass drug administration, may need to be significantly more extensive compared to training previously provided for introduction of a first-line drug. Since mass drug administration relies on highly simplified treatment algorithms, and in some countries, simplified record keeping, gaps will emerge unless adequate resources for training accompany the introduction of a new treatment. Other challenges include: cultural acceptance of new treatments after years (or decades) of using an existing treatment, side effects of new treatments used in communities that are not treatment naïve (and for which dangerous side effects can jeopardize the fragile trust that exists between health care providers and communities), and loss of a partner (or donor) that may have provided significant resources (including drug donations, training or funding) that may not be available for introduction of a new treatment.
- *Insufficient guidance for full integration into a health care system.* As new vertical programmes will not be possible for each new NTD test-and-treat programme, full integration within the existing health care system is essential. This requires implementation research to identify an appropriate model of care.
- The emergence of test-and-treat programmes for NTDs may create additional funding needs. Whereas mass drug administration can combine relatively small sums of funding and drug donations, new medicines or treatment programmes that apply test-and-treat models of care will be more resource-intensive since such programmes will require diagnosis, case identification and treatment, training and capacity-strengthening of health care workers to identify and treat cases, and a shift from a reliance on drug donations to procurement, which could result in higher expenditure.



# Emerging funding and innovative financing opportunities

This section provides options that are being used or proposed to augment resources for neglected diseases. Sources for funding will include DAH, as well as other sources that are equally important: domestic public funding and domestic and international private resources. Often these resources are combined or are used to catalyse or leverage other sources of funding or financing for health. This has created a gradient of approaches that range from traditional development assistance and domestic resource mobilization to conditional and catalytic funding, impact and socially responsible investment and commercial investment. While some of these approaches are intended to channel public funding into public sector delivery, others are intended to channel funds, whether public, blended or private, into private sector delivery. Finally, other mechanisms are intended to improve the ability of individuals to pay for health care in the public or private sector.

## The framing of financing and funding for access and delivery

Health is an investment, not a cost. An effective framing for investments in access and delivery of neglected diseases should accompany an appropriate financing mechanism and strategy. The following are three frameworks that could be used:

- International (donor) assistance has long been viewed as an act of charity, and occasionally a means of protecting global health security. An alternative framework is to present development assistance for neglected diseases as a form of solidarity, as has been seen with the COVID-19 pandemic.
- Expanded investment up front to address neglected diseases is a sound economic investment. Such investment translates into substantial savings for both the health care sector as well as improved productivity of affected populations, providing governments with a healthy return on investment.
- Control of neglected diseases is essential to meeting the Sustainable Development Goals and to achieve Universal Health Coverage and, where neglected diseases are endemic, must be included within an essential package of care.

In addition, advocates for expanded funding for neglected diseases should consider the relationship of climate change and the increased prevalence of neglected diseases that is anticipated. Rising temperatures will lead to a higher incidence of several neglected diseases, including malaria<sup>20</sup>, dengue<sup>21</sup> and leishmaniasis<sup>22</sup>. Prevention, diagnosis and treatment of neglected diseases could be considered a type of adaptation to climate change, and funding for adaptation to climate change should therefore be partially dedicated, where appropriate, to anticipate and address the health needs of affected countries and communities. The role that climate finance could play to generate and allocate new financial resources to combat neglected diseases is beyond the scope of this report.

**In terms of specific mechanisms and proposals for innovative financing, they can be classified as followed:**

### a. Grants for public sector provision of health care

There is currently no global fund for NTDs to pay for the introduction and scale-up of new health technologies. Existing global health funds have been successful in scaling up treatment access for a range of new health technologies, and such success could be expanded to NTDs. Existing global health funds could also become sources of funding to address access and delivery of NTDs (beyond current investment in TB and malaria). In particular:

- All three agencies (Unitaid, the Global Fund and Gavi) have collaborated to launch vaccine pilots for a malaria vaccine in Ghana, Kenya and Malawi.
- Unitaid provides funding for Chagas disease.
- While the Global Fund does not provide funding for NTDs, it has supported funding for co-infections of HIV, and most notably has provided limited funding and resources to address hepatitis C. The Global Fund has also demonstrated significant flexibility in responding to the COVID-19 pandemic, setting aside up to \$1 billion to fund a response to COVID-19 in recipient countries.<sup>23</sup> VL is an important opportunistic infection associated with HIV, with observation of an overlap between VL and HIV transmission. VL-HIV co-infection has been reported in at least 35 endemic countries. HIV-positive individuals are particularly vulnerable to VL, while VL accelerates HIV replication and progression to AIDS. A link has also been observed between female genital schistosomiasis (FGS) and HIV infection. It could be argued that any interventions to prevent FGS may also lead to a reduction in HIV infection risk. Thus, the Global Fund could fund schistosomiasis control programmes where appropriate.
- Gavi has not contributed to the funding of NTDs in part owing to the lack of effective vaccines to address NTDs, TB and malaria. However, this situation is changing because of: (a) a recommendation to Gavi to initiate funding for implementation of a rabies vaccine (post-exposure prophylaxis) starting in 2021; and (b) the malaria vaccine pilots with the RTS,S malaria vaccine. Gavi has also considered but not yet made an investment in a recently approved dengue vaccine. The pipeline of new TB vaccines (and potential improvements to the efficacy of the Bacillus Calmette–Guérin (BCG) vaccine<sup>24</sup>) may also expand the remit of Gavi for immunization against neglected diseases.

### ***Overseas development assistance (including milestone-based payments)***

The contributions of governments such as Belgium, Kuwait, Japan and the United Arab Emirates indicate that new donors may be willing to contribute DAH to address neglected diseases (see Annex 2). Funding from the BRICS (Brazil, Russian Federation, India, People’s Republic of China and South Africa) may also be available, although the BRICS have domestic NTD needs to address. Nevertheless, the BRICS may have an interest in investing in NTD elimination elsewhere, as trade, investment and travel between the BRICS and disease-endemic countries grows. In the People’s Republic of China, for example, while there have been important reductions in malaria and other NTDs over the last three decades, imported malaria and other parasitic infections have emerged or re-emerged as trade activities and travelling have increased, especially after the launch in 2013 of the Belt and Road Initiative and the presence of more than three million Chinese workers across Africa.<sup>25</sup> Beyond financial contributions, the BRICS might form partnerships and share expertise with other endemic countries and can help to mobilize resources by placing NTDs at the forefront of international discussions, including at G20 meetings.<sup>26</sup>

Another possible source of donor funds may be through milestone-based payments, or performance-based grants. These grants enable donors to fund projects through traditional channels while improving accountability. Funding is contingent upon the achievement of results rather than payment for inputs, thereby creating an incentive to avoid ineffective approaches as well as facilitating rapid adjustments.<sup>27</sup> While such grants can be awarded directly to governments, they are also provided to non-state actors, including non-governmental organizations and private sector companies.

Finally, endemic countries themselves can establish their own global health funds that can serve as a destination for bilateral donors to support efforts to scale up access and delivery to address neglected diseases. Zimbabwe has established a Health Development Fund with pooled funding (\$100 million per year) from several donors, including the European Union, IrishAid, the Swedish International Development Cooperation Agency, and the United Kingdom Department for International Development. The Health Development Fund supports the strengthening of health systems. Other developing countries could establish similar funds to attract bilateral development assistance for health to address neglected diseases.



## **Philanthropic contributions and consumer donations**

Historically, several major philanthropies have made substantial, impactful contributions towards access and treatment of neglected diseases. Increased effort to raise funds from local philanthropists in countries with significant accumulations of wealth that also have a high burden of diseases could be promising. For example, the India Health Fund, managed by the Tata Trusts with support from the Global Fund, was established to identify and pool \$150 million of philanthropic and private sector resources<sup>28</sup> to fund new innovations and programmes to address TB and malaria in India, with interventions intended for implementation within the public and private sectors.

Consumer donations can also be a separate vehicle to expand funding for neglected diseases, with such contributions tied to additional giving by corporations that serve as a channel for consumer donations. A well-known consumer donation programme for health is (RED), launched in 2006 to bolster corporate contributions to the Global Fund.<sup>29</sup> (RED) works with brands and organizations to develop (RED)-branded products and services that, when purchased, provide corporate giving to the Global Fund, with funding dedicated to countries with a high prevalence of mother-to-child transmission of HIV.<sup>30</sup> As of July 2019, (RED) had generated over \$600 million to support the Global Fund.<sup>31</sup>

M2030:Defeating Malaria Together is a new consumer donation vehicle dedicated to facilitating corporate donations. Incorporated in Singapore, it is focused on expanding funding for malaria, including to the Global Fund. Companies that partner with M2030 can use its brand for campaigns, or branding select products and services, in exchange for pledging funds to fight malaria.<sup>32</sup>

## **b. Loans for public sector provision of health care**

Loans play a central role in enabling countries to invest in key government priorities in the near term that provide long-term social and economic benefits. The World Bank reported in December 2019 that debt in emerging and developing economies had climbed to a record \$5 trillion in 2018, marking an endpoint of an eight-year increase that has been the “largest, fastest, and most broad-based in nearly five decades”.<sup>33</sup> The study noted that new risks had emerged with the debt build-up, including that the debt-to-gross domestic product ratio of developing countries has climbed 54 percentage points to 168 percent, and that such a debt build-up often preceded financial crises.<sup>34</sup> The COVID-19 pandemic is exacerbating risks associated with this debt build-up. The United Nations noted that “the COVID-19 pandemic could turn into a protracted debt crisis for many developing countries”<sup>35</sup> and the World Bank declared that “*public debt in emerging markets has surged to levels not seen in 50 years, ...many developing countries have increasingly taken on debt on non-concessional terms – from private lenders and non-Paris Club members.*”<sup>36</sup>

## **Development banks (including loan buydowns) and debt-to-health swaps**

Although the World Bank and the Islamic Development Bank (IsDB), for example, have provided loans and grants to address NTDs, there is an expectation that the World Bank may introduce additional support for NTDs at the country level – including support to address soil-transmitted helminths (parasitic worms) and schistosomiasis.

For many low-income countries, loans offered at market rates may not be feasible, and such loans to address NTDs may not be a priority for Ministries of Finance. Some development banks, such as the IsDB (through The Lives and Livelihoods Fund) have applied loan buydowns to introduce concessional rates (or to remove debt servicing payments entirely) to increase the likelihood that Ministries of Finance would apply for such funding.

One measure that has been used to reduce debt in low-income countries while also increasing funding for health priorities has been the use of debt-to-health swaps. A debt-to-health swap involves a creditor (whether developed country, emerging economy, or development bank) cancelling debts that are then converted in

the beneficiary countries into new funding for domestic health priorities. An example is Spain, in partnership with the Global Fund, which cancelled outstanding debts amounting to a total of 36 million euros (€) which will allow Cameroon to invest €9.3 million in HIV programmes, the Democratic Republic of the Congo to invest \$3.4 million in malaria programmes, and Ethiopia to invest \$3.8 million in initiatives to strengthen its health system.<sup>37</sup>

## **Diaspora bonds**

Another possible form of debt financing for governments are diaspora bonds issued by a country to its expatriates.<sup>38</sup> For a developing country, this can be attractive owing to the stability of diaspora bonds even during a debt or financial crisis and the support to a country's credit rating.<sup>39</sup> This type of financing is also appealing to the diaspora community as a means of providing structured assistance to a home country; moreover as creditors they may have less concern with debt service in the local currency of the recipient country.<sup>40</sup>

An estimated \$500 billion of cross-border remittances flows into emerging market economies annually.<sup>41</sup> Israel has issued diaspora bonds on an annual basis since 1951, while India has issued diaspora bonds at least three times in the last few decades.<sup>42</sup> Israel has raised at least \$32.4 billion in total, and India has raised \$11.3 billion (although it has not launched a diaspora bond since 2000).<sup>43</sup> Other countries, such as Ethiopia, Nepal, Nigeria and Pakistan have so far raised far less funding.<sup>44</sup> The World Bank has received requests from some twenty countries to develop financial products that target migrant workers, including Bangladesh and El Salvador.<sup>45</sup>

## **c. Domestic resource mobilization**

Most stakeholders point to increased domestic resource mobilization as the critical source of funding to expand access and delivery of new health technologies for neglected diseases. Nevertheless, the additional investment required can be difficult to obtain. Even when there is an annual budget line for specific NTD or TB programmes, governments may divert such funding to other priorities, possibly because while NTDs are associated with significant morbidity, many do not have high rates of mortality.

The most promising source of increased domestic funding for neglected diseases could be from the G20 countries and Nigeria. "Blue marble health"<sup>46</sup> refers to the finding that approximately one-half of the world's neglected diseases occur among the poor living in wealthy countries, and especially in the G20 countries and Nigeria.<sup>47</sup> At least one-half of major helminth infections occur in the G20 countries and Nigeria as well as a majority of cases of dengue, leishmaniasis, leprosy and Chagas disease.<sup>48</sup> In addition, approximately half of TB and malaria cases occur in these countries.<sup>49</sup> Yet the concept of "blue marble health" has not yet been included on the G20 agenda.

Donors have established other strategies to encourage domestic investment in LMICs:

## **Catalytic funding and co-funding**

Catalytic funding involves use of relatively modest grants from a facility to increase domestic resources for health. Catalytic funding can be used to introduce domestic government contributions and can also be used as leverage for contributions from development finance institutions, other forms of aligned external financing (e.g. philanthropic contributions), and private sector resources.

One catalytic fund for health is the Global Financing Facility (GFF), a trust fund first launched in 2015.<sup>50</sup> It is focused on catalysing investments in up to 67 countries, with a focus on women's, children's and adolescents' health and nutrition, including domestic government resources, as well as World Bank financing, philanthropic contributions and other private sector resources.<sup>51</sup> The GFF replenishment, held in 2018, raised \$1 billion (it had targeted \$2 billion).<sup>52</sup> The GFF could support specific investment cases targeting neglected diseases since there are clear linkages between maternal, child and adolescent health and specific neglected diseases.

Co-funding has been used by the Global Fund and Gavi with countries expected to expand progressively their contributions towards the shared goals of the funding agency and the government to address needs. The Global Fund has co-financing requirements designed to catalyse progressive increases in spending on health and gradual uptake of programme costs. This includes both a core co-financing requirement and a co-financing incentive. To encourage domestic investment, at least 15 percent of a country’s allocation may be a co-financing incentive that is available if countries make and eventually realize additional domestic commitments over the grant implementation period.

**Domestic earmarked taxes**

Endemic countries are not waiting for expanded support from donor governments, and are already mobilizing domestic funding through additional measures, such as placing special levies on specific goods or sectors or on income groups and applying the resources generated through these taxes for health-related purposes.<sup>53</sup> Some examples of existing programmes for which the taxes are applied to health care are included in Table 3.

**Table 3 Earmarked taxes to increase domestic resources for health**

Country	Description of health tax	Purpose of health tax
Chile	1% of value-added tax (the country has a total VAT of 19%) <sup>54</sup>	Fund health care provision
Philippines	“Sin tax” on tobacco and alcohol	Enrol people in universal health coverage and scale up non-communicable disease prevention services <sup>55</sup>
Ghana	An additional 2.5% on its existing value-added tax rate	Allocate to the National Health Insurance Scheme <sup>56</sup>
Gabon	1.5% levy on post-tax profits of companies that handle remittances and 10% tax on mobile phone operators	Apply to health care for low-income groups <sup>57</sup>
Zimbabwe	5% tax on airtime and data use (mobile phones)	Subsidize procurement of blood, blood products, pharmaceuticals and medical equipment

During the last decade, there have also been several proposals to introduce taxes on financial transactions, a type of excise tax imposed on trades of financial assets, including stocks, bonds and derivatives. Such a tax could raise government revenue (domestic revenue or development assistance for health) for use towards several objectives, including supporting access and delivery for neglected diseases.

**Local funding of neglected diseases**

Domestic investment to address neglected diseases is not just the remit of national governments. In many countries where both management of health care and budgets have been decentralized, local governments have the budgetary capacity to support access and delivery. One country where local governments have been persuaded to support such investments is Kenya, where health services are highly decentralized. Cities have also been identified as a possible source of funding and a partner to improve access and delivery for neglected diseases. This could be increasingly important since accelerating urbanization and the emergence of multiple megacities could accelerate the transmission of neglected diseases in crowded urban settings.<sup>58</sup>

## d. Investments to improve ability to pay (demand)

Financing can also provide individuals with greater purchasing power if health care is paid for out of pocket or through insurance-based models. Financial inclusion is one means to improve the ability of individuals to pay for health care where the public sector is unable to provide coverage. Financial inclusion within health care includes health savings accounts, health insurance, voucher schemes, loans and mobile money, all of which have the possibility of reducing the financial burden and vulnerability associated with health care payments. Microinsurance provides relatively low total coverage (e.g. up to \$1000 per year) to large numbers of people. To expand access to health insurance to individuals that are normally high risk, some funds make investments in insurance companies that provide coverage to people who otherwise are excluded from insurance markets. For example, LeapFrog Investments invests in a range of enterprises that help to expand access to insurance, including a prior investment in the insurance company BIMA, which provides coverage and low-cost insurance products to nine million people, 40 percent of which are in rural communities.<sup>59</sup>

One government-led approach is community-based health insurance, which has been implemented, for example, by the Government of Rwanda. Community-based health insurance in Rwanda involves prepayment plans for health care at the community level, and is intended to provide equitable, affordable health care and ensure that people avoid catastrophic health care costs.<sup>60</sup> Users can gain access to a wide network of public health care providers.<sup>61</sup> Revenue is dependent on premiums (66 percent), followed by government contributions (14 percent), co-payments (6 percent) and the Global Fund (10 percent).<sup>62</sup> Ghana also maintains a national health insurance scheme that provides equitable access to health care and financial coverage, including for malaria.<sup>63</sup>

## e. Private delivery and funding of private health care

There are numerous channels that have been introduced to expand access to health services in the private sector. These are outside the scope of this report (which is focused on strengthening and expanding public sector delivery) but they include: (1) corporate contributions, including investments in a company supply chain; (2) government-imposed levies or alliances between companies and governments; (3) pooled and impact investment funds; and (4) credit guarantees and social insurance to attract private capital to high-risk projects.

There are also several strategies that governments, philanthropies and private sector actors have introduced to generate new sources of funding for private sector delivery of health care, which may be eventually integrated and scaled up in the public sector. One such programme is development (or health) impact bonds. A development (or health) impact bond is a pay-for-performance mechanism. An investor provides funding in advance to a programme implementer to achieve a specific outcome. An independent evaluator measures the results of the programme. If the results hit a target that had been established, an outcome payer agrees to provide investors a return on the capital that they had invested up front that ensures that an investor is not merely engaged in lending.<sup>64</sup> There have been several bonds established for health care with most intended for prevention and most used in high-income countries, although there is some interest to apply these bonds in LMICs.<sup>65</sup> One highly publicized impact bond for investments in malaria in Mozambique failed to launch owing in part to a downturn in commodity prices that left companies with less money to invest, and with investors concerned about potential reputational damage for profiting off of a health crisis.<sup>66</sup> A second development impact bond, Kangaroo Mother Care, intended for implementation in Cameroon, was designed by its government for \$2.8 million and is focused on piloting a health practice in the private sector for premature babies that, if successful, could be scaled up throughout the public health care system.<sup>67</sup>



# Options to improve the efficiency of investments

This section aims at summarizing some of the options available or proposed to improve the efficiencies of existing or future investments. These are examples of interventions that governments, donors and other stakeholders can make to reduce costs, strengthen health care systems, and create other efficiencies that accelerate access and delivery of health technologies.

## Regulatory strengthening, collaboration and alignment

There are several efforts to simplify regulatory approval before a stringent regulatory authority and to facilitate registration across LMICs. Three mechanisms that help to expedite regulatory review in LMICs are the WHO Prequalification Programme<sup>68</sup>, the European Medicines Agency Article 58 of Regulation (EC) No 726/2004 mechanism<sup>69</sup> and the WHO Collaborative Procedure for Accelerated Registration<sup>70</sup>. Other mechanisms are intended to improve alignment or harmonize regulatory approval across national regulatory agencies. The African Medicines Regulatory Harmonization increases access to medicines in African countries by building medicine regulatory systems through harmonization of product application formats and technical requirements while also supporting capacity strengthening.<sup>71</sup> This is coordinated and supported by a partnership between the African Union (AU) and the African Union Development Agency (AUDA-NEPAD),<sup>72</sup> which includes the work supported by UNDP/ADP on the domestication of the AU Model Law<sup>73</sup> endorsed by African Heads of State and Government at the 26th African Union Summit (Addis Ababa, 17–30 January 2016).

## Pooled procurement

Pooled procurement combines several buyers into a single entity that negotiates and/or purchases a health technology on behalf of those buyers. Pooled procurement can be a tool to reduce prices, as countries can work together to purchase a greater number of doses collectively. Pooled procurement can reassure a producer that there will always be enough demand for at least one batch of a product, especially when demand tends to be either low, sporadic or unpredictable.

One pooled procurement mechanism for neglected diseases is the Global Drug Facility (GDF). The GDF has a mandate “to expand access to and availability of, high-quality TB drugs to facilitate DOTS (directly observed treatment, short course) expansion”.<sup>74</sup> The GDF provides a range of services that includes but extends beyond both supply management and demand forecasting to include technical assistance in TB drug management, monitoring of TB drug use and procurement of high-quality TB drugs and other key commodities at a relatively low cost.<sup>75</sup>

A pooled procurement mechanism might have a beneficial impact upon the NTD market. It could work with endemic country governments to engage in accurate demand forecasts and work with manufacturers to meet supply requirements. It can facilitate registration of new products and ensure that for those medicines for which there is usually insufficient demand, a minimum purchase size is maintained (even if the order is not fully used) so that manufacturers can produce a full batch. Recently there have been discussions between WHO, Médecins Sans Frontières, and other stakeholders to introduce a new leishmaniasis procurement facility, which could address a critical gap in expanding supply and delivery.

## Supply chain security and reduction of waste

There is often no mechanism in place to ensure that unused drugs (included donated medicines) are returned to a central medical store. Such a mechanism can ensure that unused medicines are not diverted to unintended uses such as livestock production, or that they can be used either by other age groups or in other regions or countries that may have insufficient supply. More generally, improved supply chain management can reduce wastage of medicines. The Breaking Transmission Strategy for four NTDs of the Government of Kenya seeks to reduce the wastage of medicines used for preventive chemotherapy from a 2018 rate of 40 percent to a global standard of 5 percent.<sup>76</sup>

## Improved drug packaging

Investments that improve drug packaging can have a dramatic impact upon the cost and ease of administration. For example, when malaria treatment changed from one drug taken once a day to a combination treatment with four doses over three days, the packaging was determined to be critical to not only protect against humidity but to be easily understood and acceptable to end users.<sup>77</sup> This helped people understand the need for taking a full course, even after feeling better. Researchers discovered how to represent visually the need to finish a course of treatment, which eventually included the use of symbols and colour coding.<sup>78</sup>

## Public and local production of health technologies

New medicines to treat neglected diseases (and especially NTDs) may not be sustainably manufactured if there is unpredictable demand and resources to pay for these medicines. Some stakeholders have suggested that public production could assure a continuous supply of a medicine and enable one or more governments to meet overall needs. Other stakeholders suggested that local production, in endemic countries with capacity and expertise, could encourage governments to purchase medicines on behalf of their population since it would also support local industry. Government investment in either public production or local production may also be a means to expand endemic government investments in neglected diseases.

Two examples of local production are DiaTropix, a Senegal-based rapid diagnostic test manufacturer, and Rephaiah Pharma, a Malawi-based manufacturer of essential medicines and medicines to treat NTDs. The Government of Kenya has expressed an interest to invest in local production of anti-venoms to satisfy regional demand.

## Integrated supply and delivery of neglected disease innovations

Integration of vertical NTD programmes into existing health care systems, disease elimination programmes or packages of care, is one route to scale up use of new neglected disease treatments without significant new investments. The Breaking Transmission Strategy of the Government of Kenya, noted above, seeks to control and eliminate four preventive chemotherapy NTDs: soil-transmitted helminths, schistosomiasis, lymphatic filariasis and trachoma. The strategy integrates NTD elimination programmes with investments in clean water, sanitation and hygiene. It also establishes an integrated approach across the four neglected diseases, including: procurement and distribution of drugs, community mobilization and sensitization, drug administration, training, and facilitation of reporting and digitization of data collection tools and records.<sup>79</sup>

## Access and delivery commitments in financing and incentive: the Priority Review Voucher

The Priority Review Voucher (PRV) programme, which was established in the United States under the direction of the United States Food and Drug Administration (FDA), is an incentive programme wherein a company, PDP or other entity that successfully registers a product with the FDA to treat certain neglected diseases is rewarded with a voucher that fast-tracks a subsequent product through the FDA review process. The voucher can be used by the recipient or sold to another entity and can be lucrative. One efficiency would be to introduce additional requirements as a condition of obtaining a PRV. This could include commitments such as seeking regulatory approval in high-burden disease endemic countries, affordable pricing or reasonable efforts to obtain inclusion on the WHO Essential Medicines List.

## Overall coordination of efforts

While there are several institutions that coordinate interventions for TB and malaria, the NTD field is unwieldy in that there are twenty diseases, and most are not easily associated with one another. Since resources remain scarce, avoiding duplication of investments is critical. Enhanced coordination of NTDs with additional resources to facilitate this coordination, will be critical to ensure full implementation of the next WHO Roadmap and to coordinate with other platforms. Another possible arena for cooperation could be among BRICS. Since those countries are both responsible for addressing a significant percentage of the overall burden of NTDs, have active programmes to address several NTDs, and have significant pharmaceutical capacity, they could work together to establish an international platform, much as BRICS have planned to address TB. Finally, generating accurate estimates of needs and expenditure by disease could help sustain and augment funding for access and delivery of neglected diseases over the next decade.





## Conclusion and recommendations

This landscape analysis has aimed at providing an overview of existing need in the financing of access and delivery of health technologies for neglected diseases, proposals to improve funding, and opportunities to increase efficiencies of investments. Some of these investments and strategies are relevant for neglected diseases and broader efforts to promote universal health coverage, as increasing funding and financing and facilitating efficiencies can contribute to strengthening access and delivery systems across diseases, geography and populations.

There are several areas of research and analysis that could be considered by the partners of Uniting Efforts for next steps:

First, there could be an analysis of the impact of COVID-19 on the funding and financing of neglected diseases and on the access and delivery of health technologies for neglected diseases. The COVID-19 pandemic has created an upheaval of countries' health care and economic systems, and its effects will last for years after the end of the pandemic. COVID-19 itself could become a neglected disease if it becomes a major respiratory virus pathogen in resource-poor countries that are unable to control it.<sup>80</sup>

Second, there could be further research and analysis that identifies concrete gaps and funding needs that undermine universal access to health technologies for neglected diseases. Since there are multiple diseases, countries and technologies, such research could initially focus on one or two diseases in one or two countries. This could generate a framework for analysis of access and delivery investment needs that could be applied widely to other countries and diseases and enable policymakers to allocate funding and resources to address gaps.

Third, additional data is needed to inform decision-making processes. The overall funding and financing available for access and delivery should be measured for each WHO priority NTD, TB and malaria. The G-FINDER survey, which has progressively improved its collection, analysis and publication of funding of research and development for neglected diseases, is an example of a good practice.

Fourth, governments, donors and other Uniting Efforts partners could identify options for improving the coordination and efficiency of international and domestic efforts to invest in access and delivery of neglected diseases. WHO and some governments have comprehensive strategies in place to address malaria, TB and NTDs. These strategies could be complemented by improved coordination between different platforms launched over the last decade, so that these efforts do not duplicate one another and instead support disease-endemic countries to build durable national programmes.

Fifth, additional research is required to identify novel sources of funding and financing. This research would consider: (a) the challenges and opportunities created by the COVID-19 pandemic; and (b) the intersection of climate finance (for adaptation) and funding and financing of access and delivery of neglected diseases.

As health technologies needed for the prevention, diagnosis and treatment for neglected diseases evolve and new technologies are available, it will require governments, donors and other policymakers and stakeholders in the neglected diseases community to identify sustainable financing strategies and stronger efficiencies that can harness proven strategies and thereby ensure that these new technologies reach the largest number of people in need.





# Annex 1

## Interviewees for Research Purposes

Name of Interviewee	Organizational affiliation
Martha Gyansa-Lutterodt	Government of Ghana
Sultani Hadley Matendebero	Government of Kenya
Janet Ginnard	Unitaid
Robert Matiru	Unitaid
Elisa Baring	The END Fund
Jed Beitler	Medicines Development for Global Health Limited
Ben Wills	Medicines Development for Global Health Limited
Cecilia Oh	United Nations Development Programme
Brenda Waning	Global Drug Facility
Julien Potet	Médecins Sans Frontières
Mike Frick	Treatment Action Group
Neil McCarthy	Medicines for Malaria Venture
Sandeep Juneja	TB Alliance
Michelle Childs	Drugs for Neglected Diseases Initiative
Thi Hanh Cao	Drugs for Neglected Diseases Initiative
Dave dela Cuesta	Development Finance International, Inc.
Dianne Tan	Development Finance International, Inc.



## Annex 2: Current Funders and Financing Mechanisms for Neglected Diseases

This annex provides an overview of existing funders and available financing mechanisms and sources of funding for TB, malaria and the 20 WHO Priority NTDs. There are significant differences when describing current funding mechanisms for malaria and TB as compared to NTDs. There are also differences in funding strategies for each of the 20 NTDs. While there are several sources tracking funding and financing for TB and malaria, data for funding and financing of the 20 NTDs is sporadic, incomplete and not tracked systematically on an annual basis by any one agency or research institution.

### Funding for Malaria

According to WHO estimates, total funding for malaria in 2018 was \$2.7 billion, compared with \$3.2 billion in 2017.<sup>81</sup> This translated into a shortfall of \$2.3 billion in funding in 2018.<sup>82</sup> Between 2010 and 2018, 70 percent of total funding for malaria control and elimination was provided through international sources.<sup>83</sup> Table 1 provides an overview of key international donors for malaria, whose total contributions equalled \$1.8 billion.

**Table 1 Key international donors for malaria programmes**

Donor	2018 contribution
United States	\$1.0 billion
United Kingdom	\$0.2 billion
Japan	\$0.1 billion
France	\$0.1 billion
Germany	\$0.1 billion
Other international donors (Bill & Melinda Gates Foundation, World Bank and others)	\$0.3 billion

Of the \$2.7 billion invested in 2018, nearly \$1.0 billion (35 percent) was provided through the Global Fund.<sup>84</sup> The other major multilateral donor was Unitaid, whose total portfolio was \$300 million in 2018.<sup>85</sup>

In 2018, governments of malaria endemic countries contributed 30 percent of total funding, reaching \$0.9 billion.<sup>86</sup> While endemic countries contribute to their own malaria control and elimination programmes, donor funding remains significant.<sup>87</sup> In low-income countries, donor funding represented 64 percent of total expenditure in 2018, and 43 percent of expenditure in LMICs.<sup>88</sup> According to 2016 figures, low-income countries and LMICS were only able to contribute \$3 and \$5 per malaria case respectively, compared to upper-middle-income countries, which spent \$175 per malaria case.<sup>89</sup>

## Funding for TB

According to WHO estimates, \$ 6.8 billion was available for spending on TB in 2019, compared to \$6.4 billion in 2018 and \$3.6 billion in 2007.<sup>90</sup> There was a shortfall of \$3.3 billion in 2019.<sup>91</sup> Most of the \$6.8 billion available in 2019 is from domestic sources, or \$5.9 billion (87 percent of the total).<sup>92</sup> This is primarily owing to investments made by BRICS countries, which account for 53 percent of available funding, with 95 percent of their expenditure emerging from domestic sources.<sup>93</sup> Outside of the BRICS, international donor funding remains critical, although international donor funding reported by national TB programmes fell from \$1.0 billion in 2018 to \$0.9 billion in 2019.<sup>94</sup> Donor funding accounted for 38 percent of funding in 25 countries with high-burden TB, excluding BRICS, and 49 percent of all funding available in low-income countries.<sup>95</sup> The single largest source of international funding (73 percent) reported by national TB programmes was the Global Fund,<sup>96</sup> which provided \$793.5 million for TB in 2018.<sup>97</sup> The cost of TB treatment remains high – the median cost per patient treated in 2019 was \$973 for drug-susceptible TB and \$6,430 for multi-drug resistant TB.<sup>98</sup>

## Funding for NTDs

Overall figures on spending by endemic countries on addressing NTDs have not been systematically collected. Spending by endemic countries should be analysed in BRICS separately from other endemic countries since BRICS are more populous, usually have greater domestic fiscal capacity to pay for health care priorities and receive little or no donor funding for health-related needs. NTDs are endemic in BRICS except for the Russian Federation.<sup>99</sup> Investments have grown substantially over the last decade, for example, Brazil launched a national integrated NTD plan in 2012 that was linked to the national plan for poverty reduction.<sup>100</sup> India, which accounts for more than 35 percent of the global NTD burden, is already implementing the world's largest programme against lymphatic filariasis.<sup>101</sup> India also has the most cases globally for 11 NTDs.<sup>102</sup> China eliminated lymphatic filariasis in 2007 and is now working towards the elimination of trachoma and schistosomiasis by 2030.<sup>103</sup> By 2020, the Government of China is contemplating elimination of rabies and leishmaniasis, and significant lowering of the prevalence of leprosy to less than one case per 100,000 people.<sup>104</sup> Soil-transmitted helminthiasis is also expected to decline by 20 percent in major endemic areas by 2020 as compared to 2015.<sup>105</sup> In South Africa, based on 2017 data, the country has zero percent coverage for schistosomiasis (with 2.55 million school children needing treatment), and 43 percent coverage for soil-transmitted helminths (or 7.04 million children out of a total of 16.41 million children requiring treatment).<sup>106</sup>

Uniting to Combat NTDs has published annual scorecards (the latest data available is from 2017) that provide treatment coverage and progress against five NTDs for endemic countries in Africa.<sup>107</sup>

### **Donor government funding for NTDs**

DAH for NTDs is provided primarily by two governments: the United States and the United Kingdom, while the Government of Japan has made substantial investments both in R&D to address neglected diseases and access and delivery. Table 2 provides a summary of investments by governments via DAH.

Several agencies or partnerships are building platforms to tackle access and delivery challenges. First, the **Access and Delivery Partnership (ADP)**, via investments by the Government of Japan, strengthens health systems and supports a variety of interventions on access at country and regional levels, as well as South-South exchanges and collaborations, to address NTDs, TB and malaria. ADP is a partnership led by UNDP, with WHO, TDR and PATH as core partners. Second, Unitaid announced a call for proposals to scale up new tools to diagnose and treat Chagas disease.<sup>108</sup> This effort includes contributions by the Government of Brazil towards a joint plan to scale up diagnosis and treatment of Chagas disease.

**Table 2 Government expenditure on DAH for NTDs**

<b>Government</b>	<b>Areas of investment and total investment figures</b>
United States	The United States invested \$986 million between 2006 and 2019, including an investment of \$100 million in 2019. <sup>109</sup> This funding includes investment in the following NTDs: lymphatic filariasis, blinding trachoma, onchocerciasis, schistosomiasis and soil-transmitted helminths.
United Kingdom	The United Kingdom committed to spend 360 million pounds sterling (£) between fiscal years 2017/2018 and 2021/2022. Spending in fiscal year 2018/2019 was spread across ten programmes. <sup>110</sup> From September 2019 to March 2022, the United Kingdom will invest £220m in the Accelerating Sustainable Control and Elimination of NTDs programme (ASCEND), <sup>111</sup> which targets lymphatic filariasis, onchocerciasis, schistosomiasis, trachoma and VL.
Japan	The Government of Japan has contributed to the Expanded Special Project for Elimination of Neglected Tropical Diseases (ESPEN). Since 2013, Japan has invested \$33 million in ADP and \$125 million in GHIT. <sup>112</sup>
Kuwait (Kuwait Fund)	The Kuwait Fund pledged \$4 million towards the elimination of NTDs in Africa. <sup>113</sup>
United Arab Emirates	The United Arab Emirates, in partnership with The END Fund and with the support of the Bill & Melinda Gates Foundation, United Kingdom Department for International Development and ELMA Philanthropies, launched the Reaching the Last Mile Fund, a 10-year \$100 million fund to address onchocerciasis and lymphatic filariasis. <sup>114</sup>
Belgium	In December 2018, the Governments of Belgium, Botswana and Mozambique, and other donors, committed \$45 million of a new \$150 million pledge to eliminate NTDs. <sup>115</sup> Belgium provided \$5 million, which was allocated to ESPEN. From 2017 to 2025, the Government of Belgium will invest a total of €27 million to eliminate sleeping sickness in the Democratic Republic of the Congo. <sup>116</sup>

### **Multi-stakeholder partnerships and pledges of commitments**

Commitments by governments, the private sector and others have also been fostered through multi-stakeholder partnerships, including the Onchocerciasis Elimination Program<sup>117</sup>, the Accelerate Trachoma Elimination Programme<sup>118</sup> and the Act to End Neglected Tropical Diseases/East.<sup>119</sup> The 2012 London Declaration on Neglected Tropical Diseases was a commitment by donor countries, endemic country governments and numerous stakeholders (development banks, philanthropies, pharmaceutical companies, product development partnerships and non-governmental organizations) to control, eliminate or eradicate jointly 10 NTDs by 2020, with the goal of improving the lives of over one billion people.<sup>120</sup> New commitments were expected to be announced in June 2020 in Kigali but the pledging event has been postponed owing to COVID-19, with discussions ongoing as to whether new commitments will take forward investments for mass drug administration programmes and also scale-up access to testing and treatment for different NTDs.

## Contributions of development banks, philanthropies, and non-state actors

The contributions of several development banks are summarized below in Table 3.

Table 3 Investments by development banks for NTDs

Organization	Area of investment and total investment figures
World Bank	Since 1974, the World Bank has committed \$160 million to NTDs in Africa through national and regional programmes including the Senegal River Basin Project and the Sahel Malaria and Neglected Tropical Diseases Project. <sup>121</sup> Following the 2012 London Declaration on Neglected Tropical Diseases, World Bank contributions were provided through different channels including: (a) \$120 million towards the goal of NTD control and elimination in low-income countries in Africa, including school-based deworming efforts <sup>122</sup> ; and (b) a grant to the Government of Angola to develop a national strategy to combat NTDs. <sup>123</sup>
Islamic Development Bank (IsDB)	In 2014, the Bill & Melinda Gates Foundation and the IsDB launched a \$2.5 billion of financing for a range of priorities, including funding to address malaria and NTDs, in low-income countries. This included a buy-down facility, financed in part by the Bill & Melinda Gates Foundation, to offset the cost of financing (debt-serving costs) that otherwise would be incurred. <sup>124</sup> The Islamic Development Bank eventually launched this facility as the Lives and Livelihood Fund, which is a multi-donor trust fund that enables low-income and LMICs to borrow funds on concessional terms. Between 20 percent to 60 percent of the funds provided through the Lives and Livelihood Fund are intended for health. <sup>125</sup>
Asian Development Bank	The Asian Development Bank launched a Regional Malaria and Other Communicable Diseases Threat Trust Fund, but no contributions from this fund addressed NTDs. <sup>126</sup>
OPEC Fund for International Development	In 2017, the OPEC Fund for International Development pledged to provide \$1 million to ESPEN to support the control and elimination of five NTDs amenable to preventive chemotherapy. <sup>127</sup>

Philanthropic contributions to address NTDs are summarized in Table 4 below.

Table 4 Philanthropic donors to address NTDs

Donor	Description of investment and total investment figures
Bill and Melinda Gates Foundation	In 2017, the Bill and Melinda Gates Foundation committed \$335 million of grants to support NTD programmes for drug development and delivery, including \$42 million for The Carter Center to eliminate Guinea worm disease. <sup>128</sup> The Gates Foundation is one member of the Reaching the Last Mile fund and allocated \$17 million to ESPEN in 2018. It has 218 active grants related to NTDs. <sup>129</sup> A description of several investments can be found <a href="#">here</a> .
The END Fund	In addition to the Reaching the Last Mile fund, The END Fund acts as an investment destination for other public, philanthropic and private contributors, whose contributions totalled \$29.5 million, listed <a href="#">here</a> . The END Fund distributed 220.3 million treatments in 2018 through 26 implementing partners, equally the treatment of 134 million people. <sup>130</sup> A summary of The END Fund's investments can be found <a href="#">here</a> .
Wellcome Trust	The Wellcome Trust provides contributions to NTD R&D. For snake bites, its total investment is £80 million <sup>131</sup> , which includes support for R&D, manufacturing and development of an evidence base, and measures to overcome regulatory challenges related to snake bites.

Donor	Description of investment and total investment figures
Fundacion Carlos Slim	The Carlos Slim Foundation supports R&D for Chagas disease and has contributed to Latin American efforts to eliminate onchocerciasis, including to The Carter Center from 2014 to 2018. <sup>132</sup>
Conrad N. Hilton Foundation	The Hilton Humanitarian prize (\$2 million) was awarded to the Task Force for Global Health in 2016, which focuses partly on elimination of blinding trachoma, river blindness and lymphatic filiarisis.
Children's Investment Fund Foundation (CIFF)	The Children's Investment Fund Foundation is one contributor to a \$105 million grant to address blinding trachoma. It has allocated, through 2019, up to \$20 million to The Carter Center and WHO to eliminate guinea-worm disease; and through 2020, has allocated \$30 million for national deworming programmes in Ethiopia and India.
ELMA Foundation	The ELMA Foundation contributes to The Carter Center, The END Fund and Sightsavers. A description of its investments can be found <a href="#">here</a> .

## Contributions by non-state actors, including private sector, NGOs and others

- Multinational pharmaceutical companies were core members of the original London Declaration on Neglected Tropical Diseases (2012) and previously stated that participating companies will meet a commitment to provide 14 billion treatments through 2020 to address ten NTDs, which the companies have valued at \$18 billion. Company donations are predominantly provided for mass drug administration while also providing donated or discounted drugs for treatment.

Large-scale drug donations for mass drug administration include contributions from the following companies: Johnson & Johnson, GlaxoSmithKline, Merck, Pfizer, EMD Serono, EMS and Eisai Co., Ltd.<sup>133</sup> Major donors integrate these drug donations into measurements of the overall impact of their contributions. USAID notes that for every \$1 it provides for NTD treatment, it can leverage \$26 in donated medicines, thereby providing \$19 billion in total value for NTD programmes through 2018.<sup>134</sup>

For test-and-treat programmes, at least three companies: Gilead Sciences, Inc., Sanofi S.A., and Novartis, have provided free or discounted drugs. Gilead Sciences has provided either discounted drugs or donations of a first-line treatment for VL, with an announcement of a donation of 380,000 vials of AmBisome in 2016 to support national plans to control and eliminate the disease.<sup>135</sup> Sanofi will donate a new treatment to address sleeping sickness – fexinidazole – that it has developed in partnership with the Drugs for Neglected Diseases initiative.<sup>136</sup> In 2015, Novartis renewed its pledge to WHO to end leprosy by extending its donation of multidrug therapy medicines to treat leprosy through 2020. This includes treatment donations valued at more than \$40 million and up to \$2.5 million to WHO to manage the donation and logistics, with an expected reach of 1.3 million patients.<sup>137</sup>

- NGOs such as Médecins Sans Frontières (MSF), The Carter Foundation and Sightsavers play a critical role in channelling funds provided by major donors for addressing NTDs, and likely spend their own funds to implement programmes. For example, an MSF project in Abdurafi, Ethiopia that provides diagnosis, treatment, community awareness and operational research to address kala azar and snakebite spends approximately € 1.7 million per year. This ensures treatment for an estimated 300 to 400 kala azar cases, with 1,000 snakebite cases admitted in the same clinic annually, and with about half of the admitted cases treated with antivenom therapy.
- Product Development Partnerships (PDPs), beyond development and securing regulatory approval of new technologies, now also engage in operational research, registration and building treatment programmes. PDPs – such as the Drugs for Neglected Diseases initiative, the Medicines for Malaria Venture (MMV), and the TB Alliance – are extending their programming to include support for access and delivery of

new technologies. This expansion is owing to several factors: (a) funders of PDPs have recognized and supported their expanding role to invest in access and delivery; (b) PDPs are more trusted than their drug company partners to make non-commercial decisions; and (c) PDPs can both innovate and fill gaps that other implementers, agencies or national governments do not, but which can be adopted and scaled up by governments. For example, over a decade ago, MMV piloted SMS for Life in the United Republic of Tanzania, which used basic short message service (SMS) technology to record anti-malarial stock levels at the point of care. The information was subsequently collated in a central database and used to display countrywide stock availability by district and health facility, thereby facilitating replenishment of stock where needed. The pilot was eventually scaled up in 2011 to cover all 133 districts in the United Republic of Tanzania.<sup>138</sup>

- There are a few emerging examples of funders for R&D supporting access and delivery of new health technologies. The European and Developing Countries Clinical Trials Partnership (EDCTP) launched a \$9 million call for proposals with WHO to support small grants for individual scientists that facilitate the translation of research results of medical interventions into policies and practices for national health programmes that strengthen health systems.<sup>139</sup>



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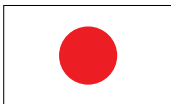
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