

ISSUE BRIEF

Strategies to Improve the Procurement of Health Technologies for Neglected Tropical Diseases

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Draft for comments

Introduction

Neglected Tropical Diseases (NTDs) are diseases of poverty that impose a devastating human, social and economic burden on more than 1.6 billion people worldwide, predominantly among the most marginalized populations of developing countries in Africa, Asia and the Americas.¹ Despite progress made in the past 10 years,² there remains a need for improvement in the responses to address these diseases, including establishing efficient procurement and financing pathways to increase access to newly developed health technologies. Twenty diseases are designated as priority NTDs by the World Health Organization (WHO), but prevention and control strategies differ from one disease to another. According to the WHO NTD Road Map 2021–2030,³ some NTDs are targeted for eradication (for example, Dracunculiasis), some for elimination (lymphatic filariasis and trachoma, for example), and some for control (leprosy, for example), with each strategy requiring different interventions.

Advancing research and development, and the subsequent access to, and delivery of, medicines, diagnostics and other health technologies for NTDs, is limited by several factors, including fragmented demand, limited funding, and ineffective procurement and supply systems. The needs, challenges and opportunities related to the improvement of procurement strategies for the 20 different NTDs are multiple and diverse and depend on the nature of the disease, the available health technologies and the specific country or context.

This Issue Brief provides a summary of an analysis commissioned by Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts). It aims to help a broader level of stakeholders understand the status of financing and procurement of health technologies for NTDs, and to leverage lessons learned on the use of procurement mechanisms for other diseases, with a view to assessing their relevance to the NTD context and making proposals for improvements. This document is a draft in progress for comments and aims to provoke reflection and stimulate dialogue to identify priority interventions and directions that can lead to better and sustainable procurement systems for NTD health technologies.

Uniting Efforts for Innovation, Access and Delivery

Recognizing the urgency of developing new, life-saving treatments for neglected diseases and getting them to people in need, the Government of Japan, the UNDP-led Access and Delivery Partnership (ADP) and the Global Health Innovative Technology (GHIT) Fund launched Uniting Efforts for Innovation, Access and Delivery (Uniting Efforts) in 2019. It aims to accelerate and improve the innovation, access and delivery of health technologies for unmet health needs in low- and middle-income countries, through dialogue and partnerships. Analysis of funding and financing opportunities to improve access to and delivery of health technologies, published by Uniting Efforts in 2020, recommended, among other things, the need to "identify options for improving the coordination and efficiency of international and domestic efforts to invest in access and delivery of [health technologies for] neglected diseases". A key tool for improving coordination and efficiency is the strengthening of procurement strategies for health technologies, and this analysis was commissioned as a follow-up.

For more information about Uniting Efforts, visit https://www.unitingeffortsforhealth.org.

Overview of current procurement mechanisms for NTDs

There are currently two main pathways to procure health technologies for NTDs: (1) product donation programmes from pharmaceutical companies; and (2) direct purchase by or for national NTD programmes.

1. Product donation programmes

Donation programmes are the key procurement mechanism for several NTD health technologies in many low- and middle-income countries. In the last 30 years, pharmaceutical companies have established programmes to donate 17 different medicines for NTDs. As a result, important global health advances have been made in the elimination and control of several diseases, such as lymphatic filariasis, onchocerciasis, trachoma, trypanosomiasis, leishmaniasis, schistosomiasis and intestinal parasites.^{4, 5}

Through the WHO Global NTD Programme, WHO manages the majority of donated NTD medicines and a limited number of diagnostic tests based on well-established partnerships with pharmaceutical companies. Pharmaceutical manufacturers donate their products to WHO, which in turn makes medicines available to NTD programmes at the country level. Donations are regulated by a series of memoranda of understanding signed by WHO and the manufacturers, following an assessment of the quality of medicines. In one single year (2017), the WHO donation

programme for NTDs delivered 1.762 billion treatments to 1 billion people across five preventive chemotherapy diseases (lymphatic filariasis, onchocerciasis, soil-transmitted helminthiasis, schistosomiasis and trachoma). The United States Agency for International Development (USAID) and the United Kingdom Foreign, Commonwealth and Development Office (FCDO) (prior to 2023) also procure NTD medicines and diagnostics for use in a number of low- and middle-income countries.

WHO plays a major role in the supply chain management cycle for donated health products, particularly for the NTDs amenable to preventive chemotherapy. It facilitates quantification (forecasting and supply planning) as well as timely review and processing of requests. The main roles of WHO are to coordinate with endemic countries and pharmaceutical companies and ensure that quantities of requested medicines are appropriate, and effectively and rationally distributed. WHO also coordinates logistical arrangements with pharmaceutical companies and global freight forwarders to ensure that safe, quality-assured health products are made available easily and equitably and are readily accessible to populations. These WHO-led coordination and management efforts have had a noticeable impact on eradicating, eliminating and controlling some NTDs, with the latest reports showing that 49 countries have eliminated at least one NTD.

Most of the donated NTD health products are limited to preventive chemotherapy and Mass Drug Administration (MDA) programmes, leaving other NTD diagnostics and medicines outside their scope. In addition, the sustainability

of donation programmes relies on the will and capacity of pharmaceutical manufacturers to donate the products, and logistical and financial support from governments, donors and partners. Moreover, donations are not free; there are costs and management implications for countries and partners. Furthermore, although donations have helped to achieve some NTD targets, they are not enough to meet the public health need in some specific cases. The praziquantel donation for schistosomiasis is a good example of this situation. Merck currently donates 250 million tablets a year of praziquantel for specific MDA programmes, primarily targeting school-age children in Africa, leaving a coverage shortfall for adults and preschool-age children. It also does not account for testing and treatment needs. As a result, the current donation may only result in 30 percent coverage of global needs instead of achieving the stated target of 75 percent.6

While some pharmaceutical companies have made longterm commitments to donate NTD medicines, there is no clarity about how new technologies will be procured, and some pharmaceutical companies are moving away from donation strategies. While the donation model has been a cornerstone of NTD control and elimination efforts, some pharmaceutical companies and product developers, particularly small to medium-sized enterprises and notfor-profit developers, do not have the capacity to donate products and are seeking strategies to sell to countries and donors. Therefore, there is a need to explore alternative models that would allow national NTD programmes to benefit from access to health technologies with improved efficacy and impact.

Major advantages of the donation programmes are as follows:

- The donation programmes are mature and relatively well coordinated with resources available (products, funds, expertise, logistics).
- There are ongoing memoranda of understanding with manufacturers and long-term commitments to make health technologies available for some NTDs until the elimination or the control of the disease.

Challenges include the following:

- Distorted effect of creating national programmes driven by the availability of donated products rather than needs.
- Donations are usually product-, intervention-, diseaseand population-specific and do not cover the procurement needs of all NTD health technologies and populations.

• While there are long-term commitments to donate certain products until elimination has been achieved, the availability of donations for other products and diseases remains an open question.

2. Direct purchase

The other main procurement mechanism for health technologies for NTDs is direct purchase for use by national NTD programmes and projects. Purchasing is conducted by the national NTD programmes and government procurement agencies or counterparts including donors, local or international non-governmental organizations (NGOs) and other partners — on behalf of the country or to use in national implementation. Directly procured health technologies supplement the donation programmes in some cases and can include those technologies on the National Essential Medicines List, as well as any technology that is a priority for the government or the purchasers, including those not available as donated products.

The direct purchase procurement mechanisms identified in the analysis can be classified as one of two types: (1) one-shot purchases; and (2) long-term agreements (LTAs). One-shot purchases have the benefit of quick availability and delivery of necessary health products for the specific need and moment. However, they can be challenging, as countries and payers are negotiating alone, and they might not offer sufficient financial incentives for product developers and suppliers to commit to supply in appropriate terms and conditions to facilitate access. Procurement and purchasing mechanisms using LTAs appear to be more advantageous and suitable for NTDs, as they offer more guarantees to suppliers and manufacturers. They have been used by several implementing NGO partners (e.g. Sight Savers, Crown Agents, Christian Blind Mission, etc.) to support their NTDs activities; however, they do not seem to be consistently applied by all national governments.



Some advantages of the direct purchasing programmes are as follows:

- Direct purchasing can cover all of the NTD health technology needs, consistent with the specific needs of the population in the country.
- Countries have ownership.

Challenges include the following:

- Direct purchasing by a country NTD programme may not offer enough financial incentives for product developers and suppliers, particularly for low-volume or new products (Volumes for one country may be too small.)
- There is a risk of price variability for the same product. (For both one-shot purchases and LTAs, the price may differ between countries depending on their volumes and negotiations.)

Lessons from other disease areas

One frequent example arising from experiences of largescale procurement of health technologies for diseases such as HIV, tuberculosis (TB), malaria and COVID-19, as well as from procurement of vaccines for the Expanded Program on Immunization through UNICEF/GAVI, The Vaccine Alliance, is the use of Pooled Procurement Mechanisms (PPMs). For the purposes of this paper, pooled procurement refers to a formal arrangement where multiple countries and purchasing authorities combine their financial and non-financial resources to create a single entity responsible for purchasing health technologies on behalf of the participating countries. Although the advantages of PPMs have been highlighted by many, 7 they have not been widely used for NTD health technologies, except for a few exceptions, including the work of the Pan American Health Organization (PAHO) Revolving Fund for some NTD technologies.

Some advantages of PPMs are as follows:

- They can provide volume assurances for manufacturers and enhance the bargaining power of purchasers, therefore allowing for more pro-access terms, including lower prices and sustainability in the supply.
- They reduce uncertainty and increase predictability and volumes, due to the capacity to aggregate forecasts and demand, among other advantages.
- They can incorporate financial mechanisms that can increase sustainability and ability to purchase.
- They can also include quality, anti-corruption, transparency and accountability safeguards that can ensure quality standards of the health technologies procured, and address potential misuse of funding, avoid procurement fraud and improve the value for money.

Some of the challenges of PPMs include the following:

- Establishing a functional PPM requires significant catalytic financial and technical resources to set up standard operating procedures and processes to successfully operationalize procurement transactions (supplier prequalification, data on disease burden and procurement needs, forecasting and supply planning, etc.), conduct capacity-building of end users or purchasers, and establish a monitoring and evaluation system with robust performance indicators.
- Running a functional PPM requires significant political will to coordinate demand among countries, harmonize national laws and regulations, including regulatory and procurements laws and policies, and negotiate affordable prices and overall terms with different manufacturers.
- Setting up a PPM in itself is not enough; it requires a sustainable financing strategy to generate resources to purchase the health technologies.
- PPMs can be viewed as a threat to national sovereignty and weaken a country's procurement capacity if not well designed.



Examples of PPMs for other diseases and health needs

PAHO procurement funds

PAHO has two PPMs: the Strategic Fund, which procures essential medicines and strategic health supplies, including some health technologies for NTDs, and the Revolving Fund, which focuses on vaccines. The Strategic Fund leverages financial resources contributed by member countries, which are then used to procure health technologies that member countries in the region need. Since its creation in 2000, the Strategic Fund has worked with countries and institutions that have signed a participating agreement to offer support and capacity-strengthening services for priority health products. The Strategic Fund 2021 annual report⁸ notes that the Fund procured over 110,000 diagnostic tests for NTDs, including those for Chagas disease, leishmaniasis and leptospirosis. After more than two decades of existence, it now serves 51 participating entities from 34 states and territories and has become a successful model of a regional or cross-border PPM.

Global Fund to Fight AIDS, Tuberculosis and Malaria

The Global Fund to Fight AIDS, Tuberculosis and Malaria is another highly illustrative example of how global partnerships can use PPMs — partnered with financial commitments — to increase availability of and access to specific life-saving health technologies. In 2009 the Global Fund established a PPM which currently has annual spending of US\$1 billion and serves partners in 63 countries, representing around 55 percent of the Global Fund's procurement systems, the others being national procurement mechanisms and use of contracted Procurement Services Agents. The Global Fund's Supply Operations Department has enhanced interfaces for supply and demand management by establishing an online tool known as 'Wambo', through which PPM orders are managed. Wambo allows in-country procurement teams to search for, compare and purchase transparently priced, quality-assured products needed for HIV, TB and malaria programmes.

Stop TB Partnership's Global Drug Facility

Since its creation in 2001, the Stop TB Partnership's Global Drug Facility (GDF) has grown into a one-stop procurement and supply mechanism providing a unique package of services that combine strategic procurement of TB products and coordination of market-shaping activities. GDF is the largest supplier of quality-assured TB treatments, including first-line drugs, second-line drugs, pediatric formulations, and diagnostics. It is a unique TB procurement mechanism that provides targeted technical assistance, innovative supply management tools and institutional capacity-strengthening to countries for accelerated uptake of new TB products.

USAID Global Health Supply Chain – Procurement and Supply Management

The Global Health Supply Chain – Procurement and Supply Management (GHSC-PSM) is the main mechanism through which procurement of USAID-funded health technologies is coordinated for several diseases, including malaria, HIV/AIDS and TB. The GHSC-PSM also provides technical assistance to improve the efficiency, reach and sustainability of in-country supply chains and is supported with funding from the United States President's Emergency Plan for AIDS Relief (PEPFAR), the President's Malaria Initiative (PMI), USAID's family planning and reproductive health programme and USAID's maternal and child health programme.

The GHSC-PSM implementing partners oversee the supply chain management (SCM) of US government-funded health commodities, building on previous programmes such as the Supply Chain Management Systems for PEPFAR or DELIVER for the SCM of malaria commodities. It organizes various procurement platforms itself or subcontracts Procurement Services Agents while remaining accountable for the entire SCM of procured health products. In addition to its main procurement pathway, the GHSC-PSM has developed a protocol for targeted local procurement when it is in line with its market analysis. For example, laboratory commodities and essential medicines are some of the items commonly procured at the local level. Local sourcing and procurement continue to be a key component of providing the best value to USAID and its partners by lowering the landed costs of products and shortening lead times to meet demand.

CDA Foundation's Global Procurement Fund

The Global Procurement Fund (GPRO) was founded in 2017 by the CDA Foundation to improve access to medicines and diagnostics and help countries to eliminate hepatitis through a sustainable funding mechanism, with two main objectives: (1) to achieve competitive prices through economies of scale: the GPRO pools orders from member countries/territories and uses international competitive bidding to purchase products at negotiated prices. According to the GPRO,⁹ the pooled procurement results in lower prices than most countries/territories can negotiate on their own; and (2) to promote quality: all products available through the GPRO are authorized for use by WHO pre-qualification or FDA tentative approval.

Africa Medical Supplies Platform

The Africa Medical Supplies Platform (AMSP) was set up by the African Union for the procurement of COVID-19 products. In addition to all the advantages of PPMs already discussed above, the AMSP also brings a regional advantage, just like PAHO, including political support from the regional bloc of countries, having been created by the African Union, for Africa and with the financial backing of an African financial Institution, which addresses the question of domestic investment, and the Africa Export-Import Bank (Afreximbank). The AMSP is an e-commerce platform that connects medical suppliers with medical providers, eliminates middlemen and ensures that products in its catalogue meet quality standards. Purchasing through the AMSP is restricted to governments, national health systems, NGOs and donor organizations. The AMSP aims to leverage Africa's bulk purchasing power to secure supplies and stabilize prices by pooling orders and ensuring transparency so that African countries can equitably compete for goods.

The following important issues that have a bearing on the procurement of NTD health technologies also came up during the literature review, the survey and in discussions with key informants:

- The multiplicity of NTDs and their individual uniqueness make it difficult to have a single procurement system for the medicines, diagnostics, vaccines and other supplies needed. When newly developed, the market for these heterogeneous health technologies is characterized by supply chain risks such as demand fragmentation, inefficient procurement, high per-unit product costs, and inaccurate or delayed forecasting and supply planning.
- Insufficient domestic and donor funding dedicated to NTDs, due to a lack of political will and a lack of visibility of NTDs as being of public heath significance, leads to non-prioritization in comparison to other priority infectious and non-communicable diseases.
- A lack of intra-sector and cross-sector coordination between the different stakeholders and between countries creates a lack of visibility of what country is directly procuring which product, from where and for what interventions. Assessing actual global needs has been one of the biggest challenges to understanding the direct purchasing model. Often, multiple entities, including local, regional and national authorities, international organizations and NGOs, are involved in procuring and providing similar products for NTDs without necessarily coordinating. This lack of awareness regarding the activities of other actors and lack of coordination can result in duplication and inefficient resource allocation.

Discussion points

Effective strategies are needed to increase access to NTD health technologies, especially for newly developed health technologies that are costly and less accessible, including functional and efficient procurement mechanisms. Existing procurement strategies for NTDs — donations and direct purchase — are important and necessary, but PPMs emerge as a promising approach that could not only increase access to health technologies for NTDs but also act as an incentive for research and development.

The WHO NTD Road Map acknowledges the promise of pooled procurement as a fundamental component in strengthening health care systems for both medicines and diagnostic tests:

"Closing the gap in the availability of medicines by securing access to quality-assured products at affordable prices for all NTDs is fundamental. Integrated supply and logistics can ensure efficient management, for example by reducing duplication and the costs of parallel supply chains and benefiting from pooled or coordinated procurement. An integrated platform might be set up to accelerate access to new NTD medicines."

PPMs are not new, and, as this Issue Brief illustrates, there are existing successful models that could be extended to NTDs, and lessons learned applied for future NTD procurement. This Issue Brief poses the following questions for discussion: **Can and should existing pooled procurement institutions and mechanisms be leveraged to integrate technologies for NTDs into their strategic plans and priorities?** The WHO NTD Road Map 2021–2030 calls for integration as one of the paradigm changes. This integration cannot occur only at the country implementation level but also needs to be reflected in global efforts.

The idea of integrating NTDs into existing PPMs is not new, and discussions about expanding the scope of some of the global initiatives to include NTDs have been explored before. In view of this, is there an opportunity to open (re-open) the discussions on how NTDs could be integrated into existing PPMs with well-established operating systems and funding?

An in-depth feasibility study on the potential integration of NTDs into existing PPMs could be useful to inform the design of procurement models and procedures, ideally with a pilot involving a specific NTD product and select PPMs. Several key factors can contribute to successful PPMs, which would be worthy of further study: (1) prioritization of the diseases/health technologies; (2) the availability of dedicated funding; (3) policy and legal coherence; and (4) collaboration and coordination among countries, including consolidated demand forecasting.

It is important to recognize that applying PPMs to NTDs is not a straightforward, standardized approach that can be universally applied. Instead, it is a multifaceted, diverse and context-dependent undertaking encompassing

various components, structures, operational levels and product types. Understanding this complexity is crucial for effectively implementing and tailoring pooled procurement strategies to the specific needs and circumstances of each NTD and context.

Almost all the successful PPMs have or have had funding support to purchase health technologies, including catalytic funding at the beginning to set up the processes and mechanisms. This is seen clearly with the Global Fund and the PAHO Strategic Fund. The CDA Foundation, which set up the pooled procurement funding for hepatitis products, cited the lack of such catalytic funding as one of the major barriers to success. Securing catalytic funding is a challenge for NTDs. Most of the existing global health funds linked to procurement of health technologies target specific diseases prioritized by global donors, and NTDs are generally not included in the list of priority diseases. As a result, procurement for NTDs has largely relied on the donation model or self-procurement/direct purchase by national governments and partners. Addressing this funding gap and ensuring dedicated resources for NTD procurement are crucial steps towards strengthening the pooled procurement approach for NTDs. The WHO Global NTD Programme, Uniting Efforts and other partners, including GLIDE, are working on innovative financing strategies for NTDs that will be needed in addition to any procurement strategy. For example, WHO and Uniting Efforts are supporting the creation of a toolkit for national NTD investment cases. 11

Establishing policy and legal coherence at national, regional and international levels is also essential to facilitate pooled procurement, including allowing international or regional agencies to participate in local tenders, as well as strengthening regulatory systems to contribute to the availability of quality health technologies for NTDs. The implementation of coordinated regional regulatory policies and strategies, such as the African Union Model Law for Medical Products Regulation, 12 and the establishment of regional agencies such as the African Medicines Agency can greatly enhance access to NTD health technologies. These initiatives promote harmonization and streamline regulatory processes, contributing to more efficient and effective procurement, distribution and availability of NTD health technologies throughout the region and beyond.

Finally, improved coordination among various actors involved in health technology procurement is a crucial step towards achieving consolidated demand forecasting and efficiencies. Successful procurement mechanisms for NTD health technologies necessitate collaboration and cooperation among countries and a diverse set of

stakeholders. By working together, countries can make significant progress towards improved and sustainable procurement pathways for NTD health technologies.

The initial step towards this goal would involve convening key stakeholders to foster open and candid discussions on the challenges and opportunities identified, in alignment with the WHO NTD Road Map. Coordination efforts can occur at different levels, including local, regional and national. However, for comprehensive impact, there is a need for overarching coordination at the global level, ideally spearheaded by WHO and supported by all partners.

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Endnotes

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