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Aggregating Demand for Pharmaceuticals is Appealing, but Pooling Is Not a Panacea

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EXECUTIVE SUMMARY

As low- and middle-income countries reduce their reliance on donor aid, they are increasingly obliged to assume some degree of financial responsibility for donor projects. This challenge will be particularly complex in the procurement of health commodities. In recent decades, recipient countries have benefitted from donor-aggregated demand and pooling mechanisms, negotiated prices, purchasing, and delivery of commodities. However, as countries shift away from donor support, their challenge will be finding a way to aggregate demand in order to achieve the benefits that the pooled purchasing arrangements of vertical health programs now provide. As a first step in tackling this challenge, much can be learned from a diverse group of pooled procurement initiatives that have developed over the past 40 years in high-, middle-, and low-income countries.

This note reviews the rationale and functions of these initiatives, notes their potential benefits and barriers, and draws lessons regarding how best to incorporate pooled pharmaceutical purchasing models into the design and implementation of health financing reforms in countries in transition. We first provide a brief background on the procurement challenges faced by countries in transition. In section 2, we provide an overview of different types of pooling initiatives, highlighting the key features of each. Leveraging our research and key interviews, we outline the real and potential benefits of pooling in section 3, and the most pressing barriers that organizations or countries will face as they seek ways to aggregate demand in section 4. In section 5 we discuss some of the issues that countries and development partners should address when considering pooled procurement initiatives and make two recommendations: (1) countries and development partners should conduct further research on the merits of pooled procurement, and (2) they should develop a straw model of a pooled procurement governance structure that could be tested using a series of pilots.

1. CHALLENGES OF COUNTRIES IN TRANSITION

As low- and middle-income countries (LMICs) transition away from aid for health and other sectors, they face increasing financial pressures on domestic budgets.[1] Donors and multilateral institutions are seeking ways to sustain funding for the programs they have developed by increasing co-financing requirements and establishing policies on how to taper off funding. At the same time, countries are increasingly establishing their own priorities, which may not be aligned with those of donors.

One area where transition will be particularly challenging is in the procurement of medicines, as countries have benefitted from donor-aggregated global demand—in the form of pooled arrangements executed by the Global Fund and GAVI, for example—to select products, negotiate prices, and purchase and deliver drugs and commodities. However, donors have often delivered commodities through parallel systems, not investing in in-country capacity for making informed procurement decisions through strengthening local institutions and supply chains in anticipation of the aid transition.[2]

With donor departure, countries are left with three choices for procuring commodities once procured by donors: countries can procure independently; procure through current donor mechanisms where this is allowed for a short period post-graduation; or develop new cross-border pooled mechanisms for procurement, either from scratch or by leveraging existing donor mechanisms.

In the absence of donor-aggregated demand and established relationships with suppliers, countries (especially small countries) could be vulnerable to high or variable prices for the small volumes they would purchase and could face limited product selection if they purchase independently. Furthermore, without strong local regulation, countries may have inadequate quality assurance compared to the global standards imposed by donors,[3] thus threatening the quality of their drug supply.

Procuring through existing mechanisms, such as UNICEF's Supply Division or GAVI, is an attractive option for countries in transition as the infrastructure already exists, demand is already aggregated into a large patient pool across borders, and these mechanisms have a history of negotiating with manufacturers for a wide range of quality-assured products. However, existing mechanisms are limited to the public sector in select countries, and options for procurement when countries are no longer aid-eligible are generally viewed by donors as a temporary stopgap solution until countries can procure themselves. Those countries that are able to use existing mechanisms for this stopgap may choose not to for several reasons, including country co-financing is already directed to local mechanisms/procurement; legislative issues; preferences for local manufacturers; corrupt deals among local parties; legal and regulatory barriers; and governments' political preferences.[4]

The third option—developing a new cross-border pooling mechanism—would require political will, funding, and an operating model that takes into account barriers countries will likely face. With their technical expertise, infrastructure, and long-cultivated supplier relationships, donor organizations could help develop such a model, as could other cross-border pooling mechanisms which will be discussed in more detail in Section 2.

Given the challenges of the first two options, the third option could be attractive for countries in transition. As a starting point, this note chronicles the rationale and functions of pooled procurement mechanisms that have been developed in high-income countries (HICs) and low- and middle- income countries (LMICs) in the past 40 years.

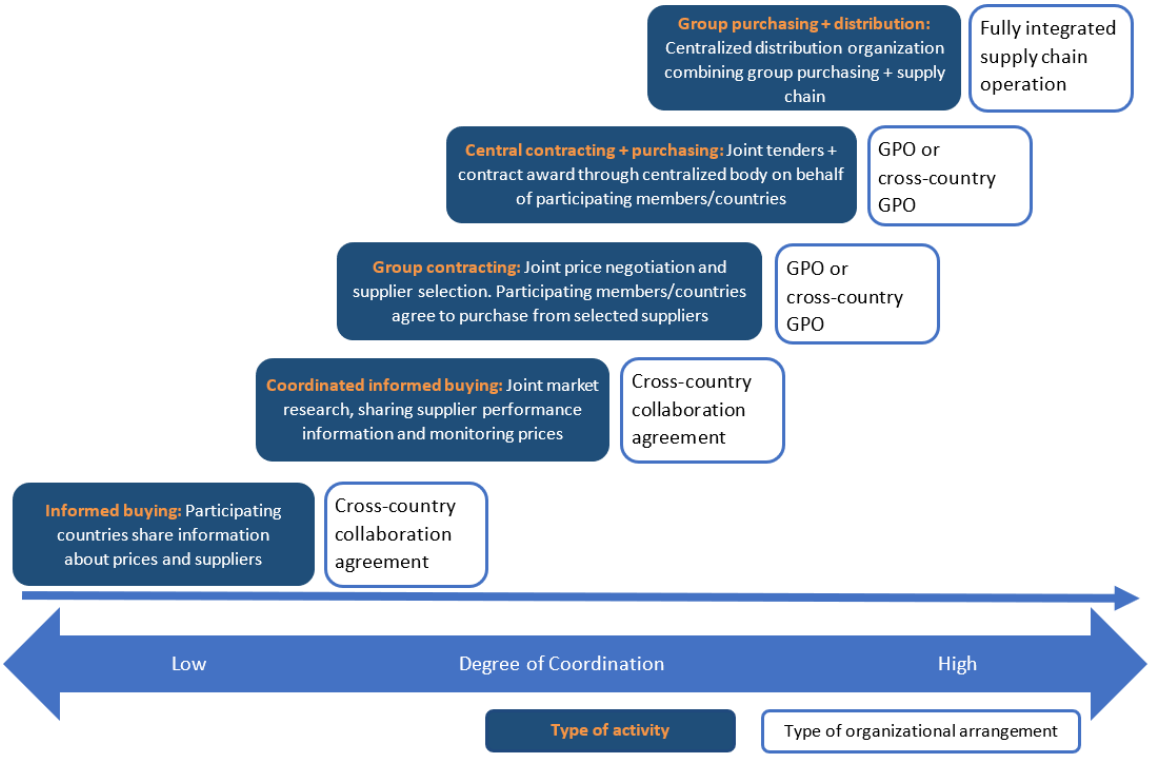
2. TAKING STOCK OF POOLED PROCUREMENT MECHANISMS

What is pooled procurement?

There are a number of ways in which demand can be aggregated, ranging from less formal agreements on information sharing to formalized governance structures where entities or countries negotiate, contract, and purchase together.

Various terms describe the act of buyers "pooling" resources or bargaining power in the health sector to obtain pharmaceutical products, but there is not one standardized term.[5] Figure 1 outlines the different *types of activities* countries/payers coming together may wish to carry out as well as the *types of organizational arrangements* for doing so. In this figure, the horizontal axis represents the degree of coordination among participating pooling members. It is important to note that pooling can take place *within* or *across* borders. Box 1 defines the *types of organizational arrangements* and provides examples explained in detail later in this section.

Figure 1. Different pooling activities and types of organizational arrangements



*Adapted from Espin et al. 2016

Cross-country collaboration agreements

In recent years, loose collaborations for information sharing or negotiating prices have developed in multiple regions. One in a high-income setting is "BeNeLuxA," a collaboration between Belgium, Netherlands, Luxemburg, Austria, and more recently Ireland, which aims to reduce the price of orphan drugs. It recently negotiated its first successful price deal on a drug for spinal muscular atro-

BOX 1. DEFINITIONS

Within borders

Group purchasing organization (GPO): A group purchaser that aggregates purchasing power of multiple buyers (pharmacies, hospitals, long-term care facilities) to negotiate supply contracts from which buyers can purchase commodities; operations paid by administrative fees linked to purchases (common in the US, e.g., Health Trust; nascent in LMICs, e.g., MedSource)

Fully integrated supply chain operation (FISCO): Sometimes legally a GPO, a FISCO is an outcomes-focused procurement and distribution operation that manages a wide range of activities that can include negotiating prices, contracting with suppliers, managing distribution and logistics, repackaging products, and balancing members' supplies (increasingly common in the US, e.g., LeeSar; nascent in LMICs, e.g., mPharma)

Across borders

Cross-country collaboration agreements: A signed agreement between countries to collaborate and share information on various aspects of procurement such as sharing/jointly negotiating prices, joint market research, and sharing supplier performance information[5] (e.g., BeNeLuxA)

Cross-country group purchasing organization (cross-country GPO): A GPO that aggregates the purchasing power of multiple buyers (typically ministries of health) across *borders* (e.g., PAHO Revolving Fund)

phy.[6] BeNeLuxA has initiated pilots to conduct horizon scanning for new products; mutually recognize and jointly conduct health technology assessment; exchange policies and best practices; and improve price transparency across borders.[7] Similar European initiatives include the European Union (EU) Joint Procurement Agreement, the southern European Valletta Declaration, and the joint Baltic Partnership Agreement.[5,8] In the LMIC context, the South East Asia region recently initiated a project for collective procurement of antidotes.[9]

These collaborations have partially been enabled by newly formed legal frameworks, such as the public procurement framework for the EU that was revised in 2014 to enable cross-border procurement, allowing for and outlining the applicable laws and responsibilities of member states wishing to procure jointly.[5] While the outcomes of these projects are currently limited to a few specific joint evaluations, horizon scanning initiatives, and few purchasing decisions, further development of enabling legal frameworks could pave the way for more cross-country collaborations in the future.

Group purchasing organizations (GPOs) and cross-country GPOs

GPOs were first introduced in the United States in 1910 with the aim of consolidating bargaining power of multiple buyers and have evolved over the past century. Given the complexity of the American health system, we will not detail the US GPO landscape. More interestingly, some LMICs are testing the GPO model, such as Kenyan MedSource, which works with suppliers to negotiate lower prices for medicines and supplies, and provides a platform for its members (private Kenyan pharmacies, hospitals, and clinics) to buy supplies at pre-negotiated prices.[10]

Similarly, cross-country GPOs were set up as early as the mid-70s with the primary goal of clubbing

countries together to decrease prices, as well as to supply a more reliable stream of medical commodities. We reviewed publicly available information on six of the largest cross-country GPOs and provide a summary of these in table 1 (more detailed descriptions of these initiatives can also be found in the appendix).

TABLE 1. Key Features of Cross-Border GPOs

GPO	Member Countries	Products	Funding Source	Lending/Other Conditions	Pricing	Contracting Mechanism	Support Services Provided	Challenges
PAHO Revolving Fund (1977)[11]	41 Latin America and Caribbean countries	Vaccines, syringes, and related supplies	Fee charged to members as a percent of the purchase price: 3% for capital account; 1.25% for operations	Countries access shorter (60-day payback) credit	Single global price	Central contracting	-Technical cooperation pillar to regional immunization program (e.g. national plans, demand forecasts, national budget lines, vaccine legislation) - Ensures access to high-quality WHO prequalified vaccines -Supports financial sustainability of national immunization programs -Creates economies of scale that enable bulk purchases at lowest price	Affordability: Higher prices for newer vaccines limit national operational budgets -Evolving global vaccine market ⟶ limited competition and higher prices
PAHO Strategic Fund (2000)[12]	33 Latin America and Caribbean countries	Medicines, kits for diagnosis and monitoring equipment, vector control	Same as above	Same as above	Aims for single price	Central contracting	- Supply chain management - Capacity building - Procurement plan development - Technical support in quality assurance - Reference prices	- Varying national quality/registration; procurement/ financial calendars; treatment preferences; politics; budgetary constraints - Fund sometimes used ad-hoc by countries
UNICEF Vaccine Independent Initiative (VII) (1991)[13,14]	14 Pacific Islands + Kenya, Chad, Niger, Capo Verde, Laos, Côte d'Ivoire, Nigeria, Uzbekistan	Vaccines	Donor funds (BMGF, GAVI, UNICEF)	Countries assigned borrowing ceiling and granted interest-free payback period of 30-60 days	Varies by supplier and country	Central contracting	- Assists with country VII plans for future procurement needs - Plans shipments and purchases - Owns and manages cold storage facility in Pacific Islands	- Small market in hard-to-reach geographic areas with high costs for transport and storage - Limited countries included due to selection based on likely ability to repay loans
UNICEF VII Expanded (2015)[14]	Same as above	Essential commodities - focus on nutrition, LLIN, essential meds	Donor funds (BMGF, GAVI, UNICEF)	Same as above	Varies by supplier and country	Central contracting	Same as above, plus contract support	High demand for procurement of new technologies exceeds financial capacity
Gulf Cooperation Council (1978)[13]	Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE	Various products including for infectious and NCDs	Member contribution, revenue from tenders, drug registration	Members must buy >60% of vaccines from GCC - Suppliers must have a local agent in Saudi Arabia for tendering	Single price	Group contracting	Group contracting and procurement	- Members demand specific European and American suppliers which keeps some prices high - Serves a small (predominately Saudi) market
Organization of Eastern Caribbean States (OECS) Pharmaceutical Procurement Scheme (PPS) (1986)[15]	10 Caribbean states	Various products from OECS essential meds list	9% surcharge to member states	Monopsony does not allow for purchasing outside PPS	Single price	Central contracting	- Continuing medical education training - Technical assistance - Common formularies - Medicine utilization studies - Quality assurance	- Late payments - Managing donations - Purchases outside the PPS - Supplier influence - Local forecasting capacity weak

A few achievements are common among these cross-country GPOs. First, many have a history of negotiating single, low prices (especially for vaccines), achieved through multi-source bidding of generics that often keeps competition high. Second, revolving funds that allow countries to borrow money in advance for orders and pay back interest-free later smooth over procurement cycles and reduce the risk of stock outs. Third, the technical support that the GPOs provide in addition to procurement services has contributed to capacity building in-country. To supplement this technical support (detailed in table 1), the UNICEF VII and expanded VII have developed ideas-exchanging networks (the Vaccine Procurement Practitioners Exchange Forum and the Medicines Procurement Practitioners Forum, respectively) for self-procuring countries to exchange information on pricing, budgeting, forecasting, legal issues, and more.[16] While these achievements are noteworthy, many of these GPOs have been developed over the course of decades and have expanded only minimally due to a variety of legal, regulatory, and political constraints which will be discussed further in section 4.

Fully integrated supply chains (FISCO)

Alongside GPOs, another model that has emerged recently in the United States and could be relevant to the LMICs market is the fully integrated supply chain operation (FISCO), which combines both procurement and supply chain-related activities. A FISCO serves multiple member pharmacies or hospitals and provides a variety of services, such as contract negotiation, procurement, centralized warehousing and distribution, and logistics management.[17]

This concept in its general form could be used to describe Ghanaian-born mPharma, a small vendor-managed inventory service with ambitious growth plans. mPharma is responsible for forecasting, sourcing, procuring, financing, distributing, and owning the inventory liability of pharmaceutical products for its 250 member pharmacies, which serve 25,000 patients monthly. It maintains efficiency by using a standardized drug formulary, concentrating its operations (including newly opened storage facilities and vehicles) in urban areas, and rebalancing stock across members as needed.[18] At the time of writing, mPharma only served private pharmacies, was in the process of acquiring Kenya's second-largest pharmacy chain,[19] and aimed to grow much larger—expanding also into the public sector. If it can scale, the mPharma model has the potential to improve the efficiency of supply chains and distribution through streamlining and consolidating parallel systems.

3. ADVANTAGES OF POOLING—REAL AND POTENTIAL

Pooled procurement requires a market. Specifically, there must be a market with (i) large enough volumes; (ii) a supplier that can supply such volumes, and (iii) a buyer that commits to purchasing those volumes. For (ii) and (iii) to work, it is critical for there to be *trust* between buyers and suppliers. With a market, pooled procurement has the following real or potential benefits:

Bulk purchases

For a wide range of products in a wide range of markets, manufacturers and suppliers offer volume discounts. The most obvious potential benefit of pooling for buyers is obtaining a lower price per unit through the mechanism of higher volume purchasing.

Monopsony power

Any buyer offering to buy in volume can obtain a price discount. However, if the buyer is one of many, the supplier has only a limited incentive to lower its selling price. The organization of buyers into a

pooled procurement agreement reduces the competition among the buyers. In the extreme, when all buyers join in a single pool, that pool has monopsony power and can negotiate a lower price for the given product at *any* given volume. Even when the pool organizes and aggregates only a portion of total demand for a product, the pool could, in theory, acquire monopsony power and negotiate lower prices. CGD's recent empirical analysis of pharmaceutical prices suggests that monopsony power can reduce the price paid by a pooled procurement agency by as much as 50 percent.[20,21]

Well-paid expert procurement specialists

A pooled procurement agency, by virtue of the cost savings it generates, can afford to employ well-paid experts, monitor them closely to prevent corruption, and use them to improve the efficiency of the procurement process in several ways. First, the experts can participate in the drug registration process assuring that the market for each drug is as competitive as possible. Second, the experts' knowledge of pharmaceutical technology can prevent some of the more obvious incidents of low quality or high cost procurement. Third, expert staff can facilitate the procurement agency's interactions with global or regional quality assurance institutions such as WHO or a regional health technology assessment agency, thereby protecting the quality of purchased pharmaceuticals.

Faster access to drugs

The lag between a new efficacious drug's loss of patent protection and its availability in a low- or middle-income country can be as long as 10 years.[22] The existence of a pooled procurement agency offering to buy in bulk and to facilitate drug registration and approval could potentially shorten this lag, with benefits for all pool members. (For drugs that are already registered and approved, the use of centralized framework agreements that allow participating entities to call orders has been proven in Tanzania to reduce the lead time of drugs reaching facilities, thus reducing the threat of stockouts.[50])

Self-financing

To the degree that a pooled procurement agency can reduce the cost and increase the quality of pharmaceutical purchasing, it should be viewed as self-financing. To be effective, the agency must attract high-quality staff and pay them well enough so that, with proper checks and balances, they are immune to corruption. For a low- or middle-income country aspiring to use domestic resources to finance wider health coverage, the savings in pharmaceutical procurement costs and the avoidance of expensive, occasionally fatal, and always politically inconvenient procurement scandals are benefits that should convince a minister of finance that the agency is essentially self-financing.

4. BARRIERS TO JOINT PROCUREMENT

Having reviewed the above pooling mechanisms, we found that there are also a number of recurring barriers which countries in transition are likely to face as they move away from receiving donor aid and look to explore new mechanisms for pooled procurement, list below.

Legal frameworks sparse or limited in scope

Mutually recognized legal frameworks can be a powerful tool for integration,[23,24] and have helped to enable many of the procurement initiatives mentioned in this note. In the absence of legal frameworks, there is a lack of clarity around applicable laws for new initiatives, the types of contracts allowed, and the responsibilities of different parties within that initiative. National laws, as simple as

BOX 2. EAST AFRICAN COMMUNITY

The East Africa Community (EAC) has taken recent strides towards better coordination and harmonization across five of its member states (Burundi, Kenya, Rwanda, Tanzania, and Uganda) in order to become more self-reliant, including in pharmaceutical procurement. In 2012 the EAC was the first pilot region of the African Medicines Regulatory Harmonization (AMRH) Initiative, which aims to remove barriers blocking access to quality medicines with a focus on strengthening governance and regulatory systems, and harmonizing medicine registration systems. When the project closed at the end of 2017, it was found that several achievements improved countries' technical capacity and coordination. These include the introduction of a common technical document that helped to decrease the average drug approval time from 24 to 12 months and was used over 10,000 times during the five-year project period. Over the course of the project, 62 applications were received for joint regional assessment and registration, of which 15 products were recommended for joint registration. Fourteen GMP inspections were conducted with 11 certificates issued.[35]

In addition to the AMRH project, EAC members introduced a legal common market protocol in 2019[36] that includes a non-discrimination clause for public procurement among member states. With this legislation, the EAC seeks to redefine "local" procurement as "regional," and propel the use of local (e.g., regional) manufacturers. Having observed that local products are sometimes cheaper in rural areas and experience less stock-outs compared to internationally procured products, the EAC has also assessed the compliance of local manufacturers to GMP and is providing technical assistance needed for manufacturers to be brought up to that standard. As these initiatives progress, the EAC hopes for regionally specialized manufacturers that can provide products to multiple countries.[25]

countries requiring a shipment before payment and distributors requiring a payment before shipment, could inhibit the set-up of pooled procurement. The EU has successfully implemented a legal framework that clarifies some of this ambiguity,[5] and the East Africa Community (EAC)[25] (box 2) has begun doing the same. Any new initiative would similarly have to consider whether the legal context allows the type of collaboration proposed, and if it does not, the feasibility of developing such frameworks.

Lack of regulatory harmonization

Regulatory misalignment and the lack of technical capacity to address this could also hinder pooling efforts. Misalignment can occur in different national quality standards, lengthy registration processes, and varying adherence to good manufacturing practices. The African Medicines Regulatory Harmonization (AMRH) initiative, which aims to streamline product registration and strengthen regulatory capacity in a number of regional economic communities, is tackling some of these barriers in some LMICs (box 2).[24] Other regional harmonization projects have struggled. For example, the Southern Africa Development Community (SADC) first discussed pooled procurement in 1999, but implementation has been stalled in part because of a lack of mutually recognized registration.[26]

Uncertain cash flow

Some of the cross-country initiatives outlined in table 1 have been financed in part by revolving funds,

which require an initial capital investment by donors or members that is then replenished through a purchasing fee.[27] Revolving funds are beneficial because they allow members to immediately receive orders and make payments (interest-free) during a given window after commodities are received, smoothing over supplies and mismatched budgeting cycles. However, donors' and countries' limited willingness to make the initial capital investment has hindered the expansion of these funds. For example, UNICEF VII's expansion was approved for a capital account up to $100mm contingent on donor contributions, but was only able to raise $35mm.[14] As countries transition, revolving funds could be considered a potentially useful tool for ensuring a continuous flow of medicines and minimizing stock-outs.

In addition to being useful at the cross-country level, revolving funds could also be considered for use by national procurement agencies or GPOs serving individual pharmacies that could have an even greater need for advanced payments and tactics to minimize stock-outs. However, faced with multiple pressures on domestic financing and unpredictable donor funding, governments many not prioritise setting aside money for a revolving fund.

The politics of pricing

There are two debates around pricing for pooled procurement: whether there should be a single (low) price, and whether there should be price transparency. (See box 3 for an explanation of how we define prices for purposes of this section.)

Historically, cross-country GPOs achieved a single price for *generic* products because there was enough product competition and bargaining power to keep prices low. Countries are increasingly facing demand for a wider variety of health commodities, which often include innovative, *on-patent* products, including oncology products widely marketed in HICs.[28,29] While there can also be product competition that brings down prices for on-patent products—for instance, with therapeutic equivalents—keeping a single, low price can be increasingly difficult in the face of fewer products and information about a locally applicable, affordable, value-based price.[29–31]

The price transparency debate is a bit more complicated. Let's imagine a perfectly competitive pharmaceutical market that is characterized by a single, directly observable price which is no greater than the marginal cost of production and available to any buyer. From this, it is tempting to conclude that making the price transparent would be sufficient to reduce the price to a small fixed amount above marginal cost for all buyers. However, recent research casts doubt on this inference for two reasons.

First, the fact that prices for a given product are opaque is likely to be the result, not the cause, of high market concentration (where one or a handful of producers control the overall market). The monopoly power afforded by high market concentration allows a profit-maximizing supplier to charge prices above marginal cost to all its customers and to differentiate the price charged according to each individual buyer's willingness to pay, with lower prices charged to the most price-sensitive. Suppose a group of LMICs pool their procurement for that product, so that all pay the same price, but the price is known only to pool members—a secret from other buyers. In this case, the price selected by the profit-maximizing monopolist will be a weighted average of the prices it would have charged to each of the countries in the group—and lower than the prices paid by MIC buyers. Now suppose that the formerly secret average price paid by this LMIC pool is revealed to the world. The profit-maximizing monopolistic pharmaceutical manufacturer is likely to fear that richer countries will ask for the same relatively low price, and will therefore raise its price to the LMIC pool, reducing its sales and its profits in that pool in order to protect its (presumably higher) profits in the MIC markets.

Second, the secret average price paid by the pool—while smaller than the price that would have been paid by the most price-resistant member of the group—will be larger than the price that would have been paid by the most price-sensitive member. Knowing this is the case gives the most price-sensitive buyer an incentive to strike a separate bargain outside the pool, and thus threatens the political cohesion of the pool. One option would be for pool members to accept to remain individually ignorant of the unit prices paid by other members of the pool.

These observations suggest that pooled procurement arrangements will be most politically stable from a pricing perspective if (a) the purchase price (or prices) remains secret within the pool, not transparent to other buyers; (b) when a purchase is at a single price, the buyers in the pool have similar degrees of price sensitivity for the specific products in the pool; and (c) when price-sensitivity differs among members, the procurement pool assigns a different price to each of its members, thus allowing highly price-sensitive pool members to pay a lower price than do less price-sensitive members within the same pooled procurement.

According to a recent WHO report, theoretical arguments on whether medicines prices increase or decrease in the face of transparency are inconclusive (the authors recommend price transparency on the grounds of good governance, not as a means of improving access).[32] Establishing whether to use a single price and/or price transparency for any pooling mechanism should be grounded in evidence regarding what these policies can achieve. (Transparency can also enable collusion because it "can result in unnecessary dissemination of commercially sensitive information, allowing firms to align their bidding strategies and thereby facilitating the formation and monitoring of bid rigging cartels. Transparency may also make a procurement procedure predictable, which can further assist collusion."[51]).

Conflicting competition among manufacturers

Some countries have a strong preference for local manufacturing. They justify this by claiming that local manufacturing brings down prices (particularly in rural areas),[23] simplifies procurement and supply chains, reduces lead times, and enables countries to boost their economy and move towards self-reliance. Governments also sometimes rely on them for central cold storage and internal distribution;[3] as a result, local producers often enjoy preferential treatment.[21] At the same time, donors have a clear preference for buying quality-guaranteed products often sourced from India, and have been reluctant to buy locally given that most manufacturers do not meet GMP standards.[23] Establishing a local or regional pooling mechanism could allow for fair and competitive tendering and bidding among multiple manufacturers/suppliers, but could be met with resistance from governments, Indian manufacturers, local manufacturers, and donors who all have competing preferences.

BOX 3. THE RETAIL PRICE

The prices discussed in this section are ex-manufacturer prices. Equally important, but not necessarily related to the ex-manufacturer price is the retail price—the sum of the ex-manufacturer price and the mark-ups for various services after the product enters the country including those for import, duties, central storage, distribution, and so on.[33] These mark-ups can account for as much as 60 percent of the total price paid by the patient.[34] Given that the consumer pays the retail price, maximizing the efficiency of both the ex-manufacturer price and the mark-ups has an important effect on the price the patient ultimately pays.

DISCUSSION

Developing a way to support the sustainability of procurement in transitioning countries by finding a means to aggregate demand for pharmaceutical products in the same way that vertical health programs do now (the Global Fund, GAVI, etc) will be challenging. As previously mentioned, countries buying independently or through an existing donor mechanism are perhaps not long-term solutions, so it is worth considering the lessons learned from the pooling mechanism outlined in this note to evaluate whether developing a new pooling mechanism or one adapted from existing donor mechanisms is possible. Given that aggregating demand for pharmaceutical products is a large and complex topic, there are a number of factors in addition to the challenges listed in section 4 that should be considered in planning for the sustainable future of procurement.

First, by aggregating the demand of multiple buyers, pooled procurement is often believed to reduce prices by achieving economics of scale and increased bargaining power; improve quality assurance and access to medicines; reduce or eliminate corruption; rationalize choice; and reduce transaction and operating costs.[37] Section 3 discussed some of these real and potential benefits in more detail, alongside some empirical evidence, but this evidence remains limited. Additionally, grey literature often recommends "success factors" for pooled procurement, such as country ownership, equity among members, use of an independent agency and transparent competitive tender, stability of funding, uniform regulation, and flexible and gradual development.[38] There is also mixed empirical evidence[39–41] that these claims are actually correct, and that these success factors are truly critical. Given the pooling arrangements reviewed in this note, it is clear that pooling initiatives can be fundamentally and operationally different, which means that the benefits of pooling and success factors needed are also likely to vary.

Second, in the LMIC context, different considerations and options should be taken into account for procurement and supply chain within the public and private sectors. Large pooled purchasers such as the Global Fund have been designed to integrate with or operate alongside the public sector. While public sector procurement and supply chains in some countries are complex— partially due to parallel supply chains introduced by donors[42]—some countries have well-functioning public procurement modalities that should continue to be strengthened as donors depart. For example, in the southern state of Tamil Nadu in India, the Medical Supplies Corporation procures on behalf of 80mm people and regularly undercuts the private sector's procurement prices (so much that the private sector once blocked them from opening retail chains for fear of being undercut). Similarly, Sri Lanka's State Pharmaceuticals Corporation has a track record of getting good prices—particularly for generics—since the 1970s, as evidenced by a significantly lower share of out-of-pocket expenditures compared to neighbouring countries.[43] In both cases, a political commitment to effective public procurement has been instrumental in their success.

On the other hand, in the absence of access to the public sector, the private sector has often purchased drugs and supplies independently. However, investment in private sector clinics and pharmacies in LMICs is increasing,[44] as is interest in pooling demand of those facilities. MedSource in Kenya is working to tackle this issue. It negotiates prices on behalf of its members and allows them to buy at negotiated prices. Another company offering even more services for private pharmacies is mPharma. In the four African countries where it works, there are 15,000 independent pharmacies that do not have a way of collectively purchasing; mPharma's model allows pharmacies to only purchase what they actually sell at pre-agreed rates, making it attractive to cash-strapped pharmacies that might otherwise experience stock-outs. The "start-up" nature of these businesses makes them nimble and

may offer an opportunity to evolve their business models to suit local contexts. If a new pooling mechanism were to be built, it should consider engaging with these companies and perhaps even applying the efficiencies achieved by them to the public sector in some type of partnership model. It could also benefit from a North-South learning exchange with US GPOs, which have expertise in negotiating prices, achieving efficiency, and entering new markets.

Third, and related, MedSource and mPharma are two of several pharmaceutical distribution start-ups, a few of which CGD recently chronicled in a blog, and many more of which were studied in a recent Impact for Health landscaping analysis. These companies offer a broad range of services to assist with the challenges of health product distribution, including visibility, price, availability, and quality—similar to the challenges that pooling mechanisms aim to address. Few conclusions can be drawn about the companies' impact on these aims because they are all so new, having been established in the past five years. Regardless, they do present an interesting alternative to the more "classic" pooling mechanisms described throughout this paper and might have the potential to also achieve lower prices and better access using an entirely different business model.

Last, donor departure exacerbates the challenges of procuring two separate types of products—those for communicable and those for non-communicable diseases—and will increase pressure on governments to make difficult decisions about how to allocate scarce resources. For communicable diseases, there is a risk of backsliding on progress made by donor programs focused on these diseases and the Sustainable Development Goals. At the same time, LMICs are facing an epidemiological transition towards non-communicable diseases and rising demand for universal health coverage including high-cost non-communicable disease treatments. Any pooling mechanism would have to account for these competing demands and prioritize the products procured.

Given the issues and challenges discussed in this note and the thin empirical evidence on whether pooling achieves its potential benefits, we first recommend further context-specific research on whether pooling is beneficial, in what contexts, and for which stakeholders.

Despite the lack of empirical evidence on pooling, donor transition is happening now and it may not be reasonable to wait until perfect evidence is available on what type of pooling mechanism works best. Thus, in addition to further research, we recommend exploring the design of a new pooling mechanism. A group of stakeholders including the architects behind the already-existing pooling mechanisms discussed in this paper could assist in exploring the accelerated development of one or multiple new mechanisms that integrate demand and tackle some of the barriers outlined in this paper. If a straw model were to be developed, we recommend considering the following key elements:

- ***Level of coordination*** for pooling (Figure 1), ranging from low-coordination information sharing to high-coordination FISCO.
- ***Geographic level*** of pooling, that is, local/national level (pharmacy chains), regional level (EAC), or global level (cross-country GPO/FISCO)
- Type of ***product(s)*** to be pooled, which could be standardized using a formulary or bundled into "episodes of care" (e.g., WHO guidelines do not allow malaria treatment without testing, but no one buys tests and treatment together)
- ***Pricing structure*** that is evidence-based and relevant to local context
- ***Role of current market players*** including donors, wholesalers, domestic manufacturers, and suppliers

- Engagement of the ***public and private sector***
- ***Legal and regulatory*** framework, and whether they allow for what is designed
- ***Source and structure of financing,*** which could include revolving funds, direct country financing, or other innovative financing mechanisms
- ***Type of entity being used, created, reformed, replicated, or expanded,*** which could include Amazon/a new e-platform, a (cross-country) GPO, a "start-up," a current procurement financing mechanism (e.g., the Global Fund), EAC regional pooling
- Other potential ***barriers to collaboration*** including political interests, logistical practicalities (financial and procurement calendars), language barriers

Designing a straw model could start with convening donors, policymakers, suppliers, and public and private sector representatives to evaluate/sketch the items listed above and be followed by a feasibility study to refine the proposed model(s) and set the groundwork for developing a pilot program. Further consideration should be given to which organization(s) would be accountable for convening stakeholders and designing such models/pilots.

CONCLUSIONS

As donors depart from countries transitioning towards middle-income status, there is an urgent need to find a better solution to aggregate their changing demand for pharmaceutical products as they shift towards self-reliance. The innovative procurement initiatives that have been developed over the past 40 years offer a variety of lessons to learn from and platforms to expand on, even though the empirical evidence base of the effectiveness of these initiatives is limited. New initiatives should be explored that seek to benefit all stakeholders and be ready to tackle the rigid collaboration barriers they might face.

APPENDIX. CROSS-BORDER GPOS

PAHO Revolving Fund (est. 1977) and PAHO Strategic Fund (est. 2000)

The oldest cross-country GPO, the PAHO Revolving Fund (RF) is a technical cooperation mechanism that, among other activities, centrally procures vaccines and related supplies on behalf of 41 countries in Latin America and the Caribbean.[11] The RF has a well-established common fund of working capital from which members can purchase products using their assigned line of credit. Annually, WHO-approved suppliers/producers bid for supply needs proposed by countries to the RF and a selection of the best bids is accepted at a fixed price (but does not guarantee volumes). By buying in bulk, the RF takes advantage of economies of scale. Many members of the RF order 100 percent of public vaccines from the RF, but the large economies (Brazil, Colombia, and Mexico) typically only order those they do not produce locally.[41] Since its inception, the RF has been one of the technical cooperation pillars for the expanded program of immunization in the region

Built on the success of the RF, PAHO's Strategic Fund (SF) is a technical cooperation mechanism that aims to build national-level capacity in medicine supply management, demand forecasting, procurement programming, and procurement planning. It provides not only pooled procurement of medicines (for communicable, non-communicable, and neglected tropical diseases), kits for diagnostics and monitoring, and equipment and vector control products, but also wide-ranging technical support and a capital account similar to that of the RF. It aims to achieve a single price, where feasible, for all 33 of its Latin American and Caribbean members.[12] Some high demand products with the SF (e.g. for HIV and TB) are entered into long-term agreements with a supplier, fixing a price for the duration of the agreement.[28] The SF is revamping its strategy; its growth plans for the future include expansion of the capital account and expansion towards new products (mostly for NCDs).[45]

UNICEF Vaccine Independence Initiative (est. 1991) + Expanded VII (est. 2015)

The Vaccine Independence Initiative (VII) procures vaccines for a number of mostly Pacific Island and a few African countries. The VII has a small capital fund from which members can finance orders up to a set ceiling based on annual forecasted purchases and capacity of the fund. Should a country default on the payment, the VII bears the risk by covering funding through its capital fund without affecting the country's standing. Prices for products from the VII vary by manufacturer and country, but are driven by manufacturers rather than being structured in formal tiers.[16]

In 2015, UNICEF VII expanded to all essential commodities based on growing demand for other products. Its aim was to raise more capital and initially focus on ready-to-use therapeutic foods/nutrition, long-lasting insecticidal nets requests, essential medicines, and required supplies.[14]

Organization of Eastern Caribbean States Pharmaceutical Procurement Scheme (est. 1986)

The Organization of Eastern Caribbean States' (OECS) Pharmaceutical Procurement Scheme (PPS) is a monopsony GPO serving nine small Caribbean states. The PPS procures based on its standardized essential medicines list,[47] and is financed with a surcharge to member states.[15] The PPS pre-qualifies suppliers which then enter into a restricted international e-tender; once a supplier is selected the PPS enters an 18-month framework agreement with a fixed price whereupon suppliers can ship directly to member states.[46] Being a monopsony has increased bargain power for the PPS, and the arrangement claims to have improved quality assurance, price transparency, and harmonization of formularies.[48]

Gulf Cooperation Council Pooled Procurement (est. 1978)

The Gulf Cooperation Council (GCC) Purchasing Programme serves six Gulf States' ministries of health and twelve public hospitals in Saudi Arabia; its permanent secretariat is Saudi Arabia. As a small market, the GCC procures exclusively from high-cost American and European producers due to member states' demands,[49]the Twentieth World Health Assembly, in resolution WHA 28.66, stated the need for the World Health Organization (WHO according to a standard formulary.[26] For the GCC, all pre-qualified suppliers must have an agent or local partner in Saudi Arabia to participate in the tendering process; tender documents are then sold at $1,300–$4,000 through the local representative to the supplier. If all suppliers return with bids that are high compared to the last year, another round of bidding occurs. Similar to the PAHO RF, accepted tenders set the price but do not require purchase of specified volumes; the binding agreement occurs when countries and suppliers contract directly.[41]

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