MEDICINES BUYERS CLUBS

Collaborative approaches to increase access to affordable and quality-assured medicines

Koray Parmaksiz

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Introducing collaborative approaches to increase access to medicines

"Welcome to the Dallas Buyers Club!"

That is how Ron Woodroof, a real-life figure portrayed with an Oscar-winning performance by Matthew McConaughey, introduces the launch of a new medicine warehouse and dispensary during the AIDS crisis in 1980s United States.

The eponymous movie is about how Ron Woodroof, a bigoted, homophobic, drug-addicted electrician and rodeo cowboy from Texas who, upon discovering his limited time to live due to an HIV infection, grapples with the challenges of increasing access to medicines. He takes on the US Food and Drug Administration (FDA) and *Big Pharma* to make unauthorized medicines accessible to address the unmet need of other HIV patients in the state and wider country. Although he succeeds for a while, and even manages to extend his own life expectancy against all odds with seven more years, he loses the legal battle against his powerful opponents and has to shut down business. This movie painfully illustrates the harsh reality of constrained access to medicines.

Constrained access to medicines

As the example above highlights, medicines play a crucial role in preventing illness, curing disease and protecting health. Development of new medicines gained momentum during the 20th century with the first clinical use of penicillin against bacterial infections in 1941, followed by streptomycin against tuberculosis in 1944, and chloroquine against malaria around the same time period (Management Science for Health, 2012). These, and many other discoveries that followed revolutionized medical care and significantly contributed to improve global health.

However, not everyone has benefitted equally from these developments. Ensuring access to affordable and quality-assured medicines has been an enduring challenge. According to World Health Organization (WHO) estimates, nearly two billion people worldwide have constrained access to *essential medicines*, which are defined as "medicines that satisfy the priority healthcare needs of the population" (Hogerzeil, 2006, p. 371; World Health Organization, 2017c). They are seen as medicines that need to be accessible at all times in functioning public healthcare systems. Essential medicines are broadly defined because which specific medicines are essential is country-dependent and therefore, selecting those medicines remains the responsibility of each country (Laing et al., 2003). Another broadly defined concept is *access*. It encompasses availability, affordability, accessibility, acceptability (i.e., adoption) and quality of medicines (Wirtz, Kaplan, et al., 2016). Constrained access therefore refers to essential medicines that are either not available, too expensive, inaccessible, unacceptable or of poor quality (Ozawa et al., 2019).

Although there has been a lack of recent comprehensive surveys assessing access to medicine globally, a survey carried out between 2007 and 2012 found that essential medicines were only available in 57% of the public sector and 65% of the private sector health facilities in low- and middle-income countries (LMICs) (MDG Gap Task Force, 2013). In addition, essential medicines for chronic conditions were significantly less available compared to essential medicines for acute conditions, both in public (36% vs. 53.5%) and private sector (54.7% vs. 66.2%) (Cameron et al., 2011). A more recent study that looked into the availability of essential medicines for chronic diseases in five developing countries found that availability ranged from 16% to 49% between the countries (Vialle-Valentin et al., 2015). But also, high income countries are not immune to constrained access of essential medicines (Krikorian & Torreele, 2021). For example, constrained access to essential insulin

treatment has been recorded in European countries and in the United States (Beran et al., 2016). A growing shortage of antibiotics and other essential medicines in recent years in the Netherlands provides another example of the global scope of this problem (van der Geest, 2024b).

This thesis explores the implementation and functioning of two collaborative approaches that have been promoted and adopted to increase access to affordable and quality-assured medicines[1]: pharmaceutical track & trace systems and pooled procurement mechanisms. While these approaches have been promoted as potential solutions to increase access to affordable and quality-assured medicines, the conditions under which they work, as well as their development has received little attention in academic literature. Increasing our understanding about these elements, however, is important as many of such initiatives never become operational or fail before reaching their intended goals. In this thesis I try to fill the knowledge gap on these collaborative approaches. But before I expand further on these, we first need to understand what causes constrained access to medicines, and the resulting consequences thereof.

Reasons for constrained access to medicines

Multiple factors contribute to constrained access of essential medicines. The Lancet Commission on Essential Medicines Policies identified five core challenges affecting essential medicines policies (Wirtz et al., 2017):

1. Lack of adequate and sustainable financing to buy essential medicines;
2. High prices of medicines jeopardizing affordability;

[1] In this thesis, I use medicines to refer to pills, powders, liquids, inhalers, vaccines or other substances that are used to prevent or treat an illness or injury – unless otherwise specified.

3. Uncertain or poor quality medicines;
4. Inappropriate use; and
5. Mismatch between development of new medicines and burden of disease in LMICs.

Governments, especially in some LMICs, often have insufficient financial capacity to procure medicine in the right quantities at the right place and time. In such cases, patients often face the burden of out-of-pocket expenditure to buy medicines through private sector channels. Poor quality medicines, categorized as substandard medicines (i.e., authorized products that fail to meet quality standards) and falsified medicines (i.e., products that deliberately misrepresent their identity, composition or source) also negatively affects government's effort to achieve universal health coverage (UHC). Substandard and falsified medicines waste money, prolong or aggravate disease and undermine public confidence (Pisani et al., 2019). In addition, inappropriate use of medicines results in overspending while also reducing the efficacy of medicines. For example, increased antimicrobial resistance caused by non-adherence to antibiotic regimens. Finally, manufacturers mainly invest in the development of new medicines that are profitable. As a result, the needs of LMICs with limited financial capacity and different disease burdens are often overlooked or neglected.

This list of challenges, however, is not comprehensive. In addition to challenges regarding affordability, quality, acceptability and development of new medicines, challenges can also be related to accessibility, availability or other contextual factors. Scarcity of health facilities, pharmacies or medical professionals reduce the patient's accessibility to medicines, while a lack of technical capacity, trained staff or infrastructure to procure, store and distribute medicines might reduce the availability of medicines. In addition, certain contextual factors that are not related to or solvable within the health domain, such as natural

disasters, conflicts or wars can also hinder the on-time delivery of health products, and therefore constrain access.

Thus, poor access to essential medicines is often caused by a combination of factors. All of these factors have varying but interdependent root causes, which further complicate the process of finding adequate solutions to prevent or solve these problems (Bigdeli et al., 2013). How would you, for example, tackle constrained access in a scenario where patent restrictions create an unmet demand because new medicines become unaffordable for governments to reimburse, while a lack of health services in combination with low consumer awareness drive patients to buy poor quality medicines from street markets that have no regulatory oversight or enforcement? Would you start knocking on the door of the pharmaceutical industry? Perhaps pay a visit to the overstretched medicine regulator? Or demand politicians to expand health services? Maybe increase awareness among patients? Or tighten enforcement and increase penalties for illegal street vendors? As you can imagine, all these issues are interdependent, and solving them requires a collaborative effort spanning multiple domains, including political, economic, regulatory and industrial actors.

Consequences of constrained access to medicines

A lack of access to essential medicines can have serious consequences in terms of public health and wealth. It can also create distrust amongst citizens in the healthcare system and the government in general. I will discuss these consequences in turn.

Lack of access of essential medicines at the level of the health facility results in patients not receiving the right treatment when needed. Patients might have to seek for alternative, sometimes inferior treatment options. Shortages in combination with unmet demand might also push

patients outside the regulated supply chain, providing falsifiers and criminals an opportunity to fill this gap (Pisani et al., 2019; Wingrove, 2024). At best, poor quality medicines might fail to cure people and prolong the illness. At worst, they might aggravate the illness and kill people. Shortages of medicines can also impede efforts to prevent diseases and outbreaks. A shortage of vaccines, for example, might hamper a population's herd immunity leading to disease outbreaks and exposure to serious health risks for the most vulnerable. Additionally, shortages of antimicrobials might promote antimicrobial resistance. Antimicrobials such as antibiotics, antifungals or antivirals are specifically developed and dosed to kill a pathogen. Shortage of an antimicrobial might lead to uncompleted treatment regimens, overuse of alternative antimicrobials or substandard antimicrobials. All of these result in some of the pathogens to survive, mutate, reproduce and spread further as drug-resistant infections (Shafiq et al., 2021; World Health Organization, 2017d).

The lack of access to medicines also has serious economic consequences, both on the individual and population level (Atif et al., 2021; World Health Organization, 2017d). In countries with insufficient insurance coverage, patients have to incur the costs of their treatment out-of-pocket. This is especially problematic in countries where there is a relatively low density of health facilities, where patients might need to travel long distances to visit medical professionals. When medicines are not available during such visits, patients might need to return another time to receive their treatment. This often means another missed day of work, without income, while also incurring transportation costs once again. In countries with higher percentages of insurance coverage, constrained access to medicines might have more macro-economic effects. The bill of an unhealthy population caused by delayed treatment has to be paid by (public) insurance companies, which in turn are recovered from the insured or taxpayers.

Finally, lack of access can also undermine the population's trust and

confidence in health workers, the overall healthcare system and the government in general. Patients might question the health worker's credibility and competence when the doctor or nurse is not able to treat the patient adequately (Bigdeli et al., 2013). Moreover, patients that are repeatedly denied appropriate care due to unavailability of treatment might lose trust and confidence in the (public) healthcare system, and try to look for alternative, sometimes unregulated treatment options. This might also generate distrust in the government, who are responsible for organizing a well-functioning public healthcare system. Certainly, the opposite might hold true as well: a general distrust in the government may extend to distrust in the public healthcare system (Blendon 2006).

Historical overview of global efforts to increase access to medicines

So, at this stage you might wonder: What has been done to tackle these problems and fight its consequences? Coordinated efforts to improve access to medicines globally, started only half a century ago. In the following section, I distinguish among three categories of key efforts to combat constrained access that have been taking place: putting access on the global agenda, translation of efforts into practical output and embedding efforts within organizational structures. Moreover, I elaborate on the resistance efforts of the pharmaceutical industry in response to these developments, as they have a significant influence on the effects of these measures. The efforts below co-exist and are interdependent, relying on each other and the actions of other actors.

One of the key events that propelled access to medicines on the global health agenda took place in 1975. In Resolution WHA28.66, the World Health Assembly (WHA) requested the WHO Secretary-General to assist Member States in the procurement of affordable and quality-assured

essential medicines for their national healthcare systems (World Health Organization, 1975). The adoption of the resolution was prompted by recently decolonized countries struggling with their healthcare systems due to high costs of branded medicines. (Greene, 2010). During that same time period, there was a strong global effort to prioritize primary healthcare, in which essential medicines were playing a crucial role (Krikorian & Kapczynski, 2010). Agenda setting efforts continued in the following decades, when, for example, the importance of access to essential medicines was further emphasized during the Alma Ata Declaration of 1978. Essential medicines were identified as one of the eight key components of primary healthcare (Wirtz et al., 2017).

The United Nation's publication of the Millennium Development Goals (MDGs) in 2000, and the Sustainable Development Goals (SDGs) in 2015 were instrumental in providing policy direction, attracting funding and allocating resources to improve health globally. While MDG-8E aimed to, "in cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries", SDG3.8 took this a step further by declaring "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a target to achieve by 2030 (Bigdeli et al., 2014; Wirtz et al., 2017).

In 2007, the World Health Assembly adopted another resolution (WHA60.20) called "Better Medicines for Children". This resolution underlined the need to "identify appropriate dosage forms and strengths of medicines for children, and to encourage their manufacture and licensing" (World Health Organization, 2007, p. 2). This led to the WHO's first Model List of Essential Medicines for Children later that year (Wirtz et al., 2017), which I will explain further in the following section.

The second category refers to the translation of efforts in the form of guidelines, lists, reports or policies to ensure better access to quality-assured medicines. These documents have been developed to prioritize needs and funds to allocate resources as efficient as possible.

Written records of pharmaceutical standards and preparatory guidelines, known as *pharmacopeia*, trace back to ancient Egypt 3000 BC. Over centuries, this knowledge expanded across cultures with contributions from Chinese, ancient Greek, Persian, Arab and European civilizations (Fullerton Cook, 1946; Eban, 2019; Wiggins & Albanese, 2019). Current examples of internationally recognized pharmacopeias that contribute to ensuring access to quality-assured medicines include US Pharmacopeia (USP)[2], European Pharmacopoeia and the International Pharmacopeia issued by the WHO (Rägo et al., 2014).

Another influential guideline was introduced by the WHO two years after the adoption of the 1975 WHA resolution: the first essential drugs list – now Essential Medicines List (EML) – of 205 items. The list was intended as a model list for Member States to provide guidance to develop their own national list of essential medicines and use their financial resources as efficiently as possible. It was intended that Member States would adjust the medicines list according to their own national health needs. The medicines listed on the WHO EML are expected to be available at all times in national health systems. The WHO updates this list every two years, and medicines are selected based on disease prevalence and public health relevance (World Health Organization, 1977, 2023). So far, the WHO has published 23 Model Essential Medicines Lists and 9 Essential Medicines List for Children. Their long-lasting impact becomes apparent when you realize that 90% of the LMICs adopted at least one version of their national medicines list and had developed a national medicines policy by 2013 (Wirtz et al., 2017).

During the 1985 Nairobi conference on rational use of medicines – requested by the Nordic countries and the Netherlands during the WHA the year before – the *Revised Drug Strategy* was developed. This strategy puts further "emphasis beyond selection, onto procurement,

[2] As a personal disclaimer, I held a position as a research fellow in Quality of Medical Products at the USP Quality Institute during the first two years of my PhD trajectory (2019-2021).

distribution, rational use, and quality assurance for the public sector" (Bigdeli et al., 2014; Laing et al., 2003; Wirtz et al., 2017). Since then, the WHO has published countless guidelines, strategies and policies to increase access to quality and affordable essential medicines. More recent examples include *A Model Quality Assurance System for Procurement Agencies* in 2007 (World Health Organization, 2017a) and *WHO Guideline on Country Pharmaceutical Pricing Policies* in 2020 (World Health Organization, 2020b). In addition, numerous demand- and supply-side tools and approaches – including pooled procurement and logistical technologies such as pharmaceutical track and trace systems – have been developed to increase access to medicines (Kettler et al., 2020).

To drive translation efforts forward, these efforts needed to be embedded into organizational structures – the third category. In 1981, four years after the first EML, the prioritization efforts were further formalized and institutionally embedded when the WHO Action Programme on Essential Drugs (later called the Department of Essential Medicines and Health Products) was established. Its main goal was to assist Member States in the development of national drug policies based on essential medicines and to work towards rational use of medicines. Around the same time, over 50 consumer groups and public interest groups came together to form Health Action International (HAI). Their goal was to counterbalance the growing power and influence of multinational pharmaceutical companies and expand access to essential medicines (Reich, 1987). Since then, HAI has been actively involved in advocating for improved access to essential medicines during numerous WHAs and campaigns (Krikorian & Kapczynski, 2010). The lack of access to essential medicines during the AIDS epidemic in the 1990s led to a plenitude of global health and funding organizations, such as the Global Drug Facility (GDF), the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF),

Clinton Health Access Initiative (CHAI), the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Alliance for Vaccines and Immunizations (GAVI). These organizations were set up to diminish funding disparities between high-income countries (HICs) and LMICs, and increase access in LMICs for specific diseases (e.g., HIV, TB, Malaria) or products (e.g., vaccines, diagnostics, pediatrics) (Bigdeli et al., 2014; Wirtz et al., 2017). Once generic HIV/AIDS medicines became affordable and more widely available by Indian manufacturers, Member States asked the WHO to assist them in assessing the quality of those medicines. In response to this request, the WHO set up the Prequalification of Medicines Programme (PQP) in 2001. PQP was initially set up to assess the quality of HIV/AIDS, TB and malaria medicines. Now, it prequalifies a wide variety of essential medicines, diagnostics, vaccines, active pharmaceutical ingredients (APIs), manufacturing sites and laboratories (Bigdeli et al., 2014; 't Hoen et al., 2014).

These developments, however, were not welcomed with open arms by all parties. The pharmaceutical industry and certain industrialized HICs have met some of these developments with resistance by repeatedly expressing their opposition to the concept of the essential medicines lists, the WHO Action Programme on Essential Drugs and infringements of intellectual property rights.

The pharmaceutical industry opposed the introduction of essential medicines and the Essential Medicines List from the beginning. The industry was worried that the development of the EML would restrict their marketing operations (Krikorian & Kapczynski, 2010). Their representatives were concerned that the concept of EML would also be adopted in higher income countries, limiting the variety of products on the national lists of HICs, and hurt their profits for their new and existing product portfolios. Therefore, their opinion has been that the EML should only be intended for the public sector of the

poorest nations (Laing et al., 2003). Similar worries were expressed towards the WHO Action Programme on Essential Drugs, when industry feared interference with their marketing operations by rules and regulations imposed by the WHO (Wirtz et al., 2017).

To protect their interest, the pharmaceutical industry developed another strategy. Around the time of the Nairobi conference and the development of the *Revised Drug Strategy* in 1985, pharmaceutical industry members united their interest in a lobby group to put intellectual property rights – giving the creator exclusivity rights to use their idea or product during a specific time period – on the agenda of the General Agreements on Tariffs and Trade (GATT) framework, the predecessor of the World Trade Organization (WTO) (Krikorian & Kapczynski, 2010; World Trade Organization, n.d.). This resistance of the industry contributed to introduction of the Trade Related Intellectual Property Rights (TRIPS), an international legal agreement between the members of the WTO in 1994. From this moment onwards, this agreement provides technology products, including medicines, a minimum of 20-year patent protection (Bigdeli et al., 2014). However, the TRIPS agreement has faced severe criticism by public interest groups for its role in restricting access to medicines. After *CIPLA* – an Indian generic drug maker – announced to make generic HIV treatment available for $1 a day (as opposed to $10,000 to $15,000 a year charged by originator companies), global public outrage towards *Big Pharma* soared over their failure to make essential medicines accessible to patients during the AIDS epidemic (Eban, 2019; 't Hoen et al., 2014). In response to public pressures, the TRIPS agreement was revised during the Ministerial Conference of the WTO in 2001 with the adoption of the DOHA Declaration. The DOHA Declaration provides countries certain flexibilities in bypassing patent protection to achieve better access to essential medicines with a compulsory license. In practice, however, these flexibilities have not been used often due to retaliatory threats in terms of trade sanctions by

countries hosting pharmaceutical companies ('t Hoen et al., 2018; Wirtz et al., 2017).

Despite these resistance attempts, the efforts made by the global health community in the past 50 years, both mentioned and unmentioned, have undoubtedly contributed to increasing access to quality and affordable medicines worldwide. Although recent studies are lacking, the number of people with access to essential medicines increased from 2.1 billion people in 1977 to over 4 billion in 2003 (Quick, 2003). The problem, however, is far from solved. It remains a complex, multi-actor and persistent problem with nearly two billion people lacking regular access to essential medicines, while 13.6% of essential medicines in LMICs are estimated to be substandard or falsified (Ozawa et al., 2018; World Health Organization, 2017c). Converting (often) rigid and normatively prescribed global-level solutions to local-level practices has remained challenging. Partially as a result of insufficient funding and resources, inadequate regulatory and governance structures or lack of expertise in countries and partially as a result of global dynamics and incentives structures that favor economic benefits over maximizing public goods.

In the remainder of this thesis, I will be focusing on two collaborative approaches that have been adopted and promoted to increase access to quality and affordable medicines: pharmaceutical track and trace systems and pooled procurement mechanisms (Huff-Rousselle, 2012; Nemzoff et al., 2019; Pisa & McCurdy, 2019). Implementing these approaches requires a collaborative effort involving multiple stakeholders, often with diverging interests, as they must be tailored to suit the local context. However, little is known about how they work in practice. In the following sections, I will elaborate further on these aspects. I will provide a more in-depth explanation of what these approaches are, how they operate, what makes them work and to what

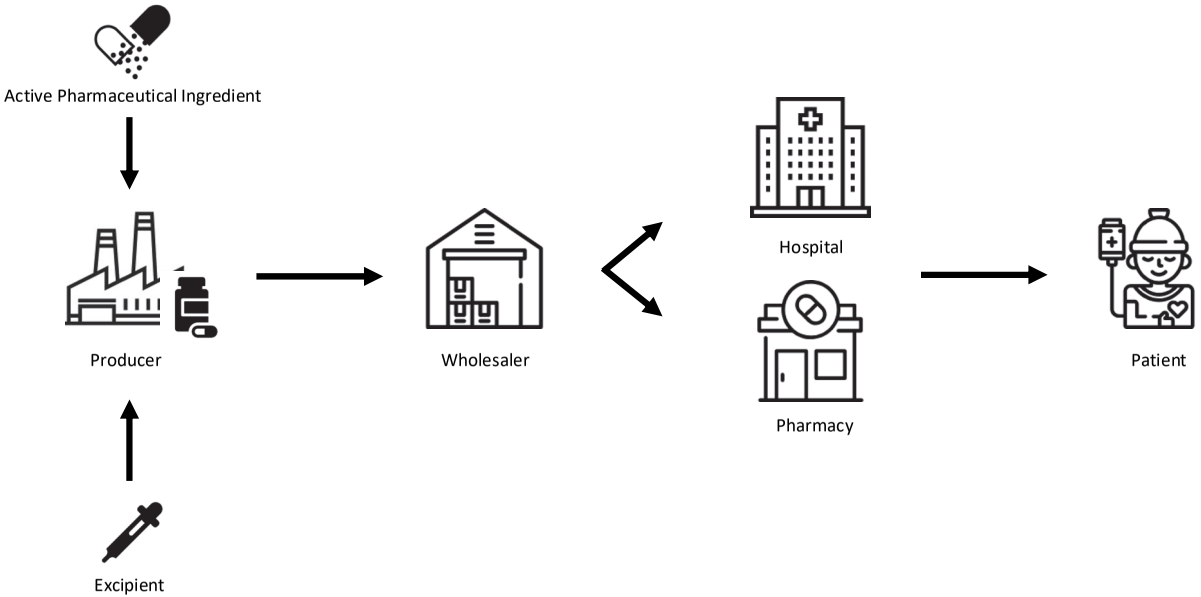
extend they contribute to increase access to affordable and quality-assured medicines.

Pharmaceutical supply chain

Medicines do not magically appear when needed. They pass through a so-called pharmaceutical *supply chain*, which can be defined as "the ecosystem of organizations, people, technology, activities, information, and resources that have to come together to ensure the delivery of the product from the point where it is manufactured to the end-patient in a cost-effective way" (Yadav, 2015, p. 142). If there are no good supply chain management practices in place, it can create bottlenecks that delay or obstruct medicines to reach their endpoint in time. This has serious consequences for access. Because of the multiplicity of actors, organizations and information involved, supply chains are often complex and opaque, creating inefficiencies and vulnerability to corruption, diversion or theft (Pisa & McCurdy, 2019).

In its most simple form, pharmaceutical supply chains operate as shown in Figure 1: raw materials (active pharmaceutical ingredients and excipients) are manufactured into finished pharmaceutical products; these finished products are distributed through distributors and wholesalers; and medicines are dispensed to patients through pharmacies or hospitals.

Figure 1. Schematic representation of the pharmaceutical supply chain. Adapted from Parmaksiz et al. (2020).



In reality, however, pharmaceutical supply chains are much more complex than illustrated here. For example, a US pharmaceutical manufacturer might produce their pharmaceuticals at a manufacturing site in India that receives their active pharmaceutical ingredient (API) from a Chinese supplier and their excipients from Brazil. These finished products might be destined to a wholesaler in Germany, shipped through Singapore, resold by the German wholesaler for a higher price to another wholesaler in Kenya, and procured by the National Medical Stores in Uganda, before they are finally transported to a rural hospital in Arua.

It is natural if this journey made you feel a bit dizzy. However, journeys like this are not uncommon for medicines. Add up the fragmentation caused by a lack of coordination between government and global partners, poor integration of disease-specific vertical programs creating parallel supply chains (Pisa & McCurdy, 2019), and generally well-intended but unwittingly causing "more-harm-than-good" donations[3] (Bero et al., 2010), and a country's pharmaceutical supply chain starts looking like a spaghetti bowl. What makes these supply chains even more complex is that it often remains unknown where a medicine package has travelled before it reaches its endpoint. When there are suspicions about the authenticity or quality of a product, tracing back its footprints in the supply chain to find the source of the problem becomes a resource-intensive and time-consuming task for regulators and customs officials that can take multiple months.

This complexity is amplified by the discrepancy between global level incentives for the pharmaceutical industry and national-level mandate

[3] Medicine donations, especially after crisis situations, often fail to comply with guidelines in terms of the recipient's needs, quality assurance, shelf-life, packaging, labeling, and information management. Beyond not meeting local requirements, the donations can impose additional costs on recipient countries for their disposal.

of regulators. Pharmaceutical manufacturers, distributors and wholesalers often operate globally with a large number of profit-seeking middlemen, who do not necessarily operate in the interest of the public good. Regulators, however, are responsible for regulating products within the borders of their country on a national level. Often under-resourced national regulatory authorities might therefore experience difficulties regulating and tracking products over international borders. Even within national borders, the multiplicity of actors involved in the production, trade, transportation, dispense and regulation of pharmaceutical products in combination with a lack of accountability systems is not conducive. It is often unclear where one actor's responsibilities starts and another's ends (World Health Organization, 2017d).

To tackle this problem, global measures that focus on international collaboration between regulators is imperative. Various examples of such regulatory harmonization initiatives exist. Some are geographically linked such as the European Medicine Agency (EMA), the Gulf Central Committee for Drug Registration (GCC-DR), and the East African Community Medicines Regulatory Harmonization (EAC-MRH) programme, while other collaborations are based on similar levels of technical capacity such as the Access Consortium (regulatory agencies from Australia, Canada, Singapore, Switzerland, United Kingdom). The work of these regulatory collaborations ranges from information sharing on suppliers and products, and harmonizing regulatory standards, to joint dossier assessment for medicine registration, joint inspections of good manufacturing practice (GMP) and post-marketing surveillance. Although regulatory harmonization initiatives exist to increase information and work sharing, and reduce duplication of efforts and resources, tracing poor quality medicines in the supply chain remains challenging due to the complexity described above.

Pharmaceutical track and trace

So far, I have made an effort to explain the complexity causing opaque and fragmented supply chains. The development of other collaboration initiatives such as new technologies, however, provides promising opportunities to increase supply chain transparency. One such technology that I will focus on in this dissertation is the *pharmaceutical track and trace system*. Various potential benefits have been attributed to it such as real-time tracking of products, accurate inventory management, targeted product recalls, reduction of medication errors and minimizing theft (Klein & Stolk, 2018; Pisa & McCurdy, 2019). Such track and trace systems in itself are not new. Various industries such as logistics, agriculture and aviation have been using some form of tracking for the past couple of decades (Kelepouris et al., 2006; Musa et al., 2014). The application to the pharmaceutical sector, however, is relatively new.

What are pharmaceutical track and trace systems? In essence, *tracking* refers to the ability to follow a product throughout the pharmaceutical supply chain at all times, while *tracing* refers to knowing the historical pathway a product has taken to reach its current location (Koh et al., 2003). They can have various uses and outcomes, depending on the technology that is being used. An earlier review (Mackey & Nayyar, 2017) identified five main categories of track and trace technologies that are currently being used or explored: mobile, radio frequency identification (RFID), advanced computational methods (i.e., machine learning), online verification, and blockchain technology. Online verification technologies have mainly been used to inform the end-user (i.e., patient) about the authenticity of the website they are buying their products from. The technologies include website seals and authorized domain names. Although online verification technologies can be a first barrier to protect patients from poor quality medicines, they do not

allow for tracking and tracing products through the supply chain. Advanced computational methods and blockchain technology, on the other hand, are promising solutions to track and trace products in real time (Mackey & Nayyar, 2017; Sylim et al., 2018). However, their development and application to pharmaceutical track and trace systems is currently still in their infancy and has yet to be applied successfully in practice. Other, more mature technologies, such as RFID and mobile are currently more appropriate for tracking and tracing pharmaceuticals. RFID uses radio waves to communicate between the tag, attached to the product packaging, and the reader (Altunkan et al., 2012; Mackey & Nayyar, 2017). Mobile technologies make use of the scanning capabilities of smartphones. For this thesis, I prefer to expand this characterization by including handheld scanners that are used with a similar purpose by focusing on the portability aspect of *mobile*, rather than a specific focus on mobiles phones. These mobile technologies track and trace a product by scanning a unique product identifier (e.g., Datamatrix, QR code, barcode) on the medicine package.

Regardless of the technology, there have been mainly two approaches to organize track and trace systems in practice (Pisa & McCurdy, 2019; World Health Organization, 2016). One is called the *point-of-dispense check* system, which validates the uniquely assigned code during the manufacturing process on the medicine packages at the point where the medicine is dispensed to patients (e.g., pharmacy or hospital). This system enables authentication, but not tracking. The other one, referred to as *full track and trace* or *end-to-end*, operates based on cross-checking every movement of the package during every transaction between the buyer and the seller in the supply chain. It does this by matching sales and purchase notifications in a central digital database. This system allows for tracking and authenticating the product throughout the entire supply chain.

Although track and trace systems have been widely adopted in other sectors, the implementation of such technological systems has not reached its full potential in the field of medicines. Various factors have contributed to this. First, supply chains are very complex, as we are already aware by now. What makes it even more complex is that within a country, often multiple parallel supply chains for different diseases or programs exist. Integrating these supply chains into one track and trace system is very arduous. Second, each country has different laws and regulations to regulate medicines. Therefore, no one-size-fits-all solution exists for track and trace systems. These systems need to be adapted to and embedded in local contextual situations. Third, its implementation and operation are collaborative efforts that involve many stakeholders. Forcing or incentivizing suppliers or other key actors in the supply chain to adhere to track and trace systems can also pose significant challenges. If the costs of adhering to the system do not outweigh its benefits, suppliers and other middlemen are likely to sell their products to other markets with less stringent regulatory conditions.

In theory, track and track systems reduce complexity of supply chains by making them more transparent. However, we do not know if they work in practice, and what is needed to make such systems work within a national context. Rather than focusing on the technological aspect of track and trace systems, this study will focus on the underlying political and economic factors that play a role in its implementation and functioning. I will also seek to find answers to additional questions such as what preconditions and drivers are needed to implement such systems? What work is needed to bring actors together and incentivize them to adopt and adhere to the system? And once track and trace is implemented, what is it capable of in terms of increasing access to affordable and quality-assured medicines?

Pooled procurement

Although track and trace systems have a great potential to make the regulated supply chain more transparent – spoiler alert – they do not guarantee product quality, because the system has no inherent quality mechanism built-in. If poor quality products enter the supply chain at the stage of the manufacturer or importer, these products can reach the patient without detection. Put differently: *garbage in, garbage out!* Similarly, track and trace systems have no way of guaranteeing affordability of the product because they have no direct effect on the price of the products passing through the supply chain.

After this realization, I shifted my (research) focus on the question of how to guarantee affordable, quality-assured medicines to enter the supply chain? One of the ways to achieve this is by procuring the right products. This new focus also provided me another opportunity to study a collaborative approach through a governance perspective. Essentially, procurement refers to the operation of obtaining products or services. This can be done in various ways. The buyer can directly approach a supplier to negotiate a price, and buy the products or services directly from that particular supplier. This is often done when the buyer needs a product or service that is only supplied by one supplier, such as patented products. Another procurement method, which is often legally mandated in public procurement laws, is tendering. In this method, the buyer sets out tenders for competitive bidding, which can be either open (all suppliers can participate) or restricted (in which only prequalified suppliers can participate).

Procurement generally consists of the following cycle: identification of needs, specification and selection of products; forecasting and quantification of demand; determining the procurement method (e.g., direct procurement and tendering); awarding the contract and issuing the purchase order; monitoring the delivery; and receipt of

the order and use of products, before starting the procurement cycle again with identification of needs (Management Science for Health, 2012; Rao et al., 2006; Seiter, 2010).

Public procurement is not unique to the health sector. There are, however, certain conditions that make procurement of medicines fundamentally different compared to other types of products or services.

First, there is an urgency of need for medicines. This means that procurement needs to be very accurate in terms of time and quantity – too many or too early, and you create wastage, too few or too late, and you have shortages. Neither one of these options is desired, and both options can have great financial, political and public health consequences. Related to this is the fact that most medicines have an expiration date and are often susceptible to environmental factors. Therefore, procurement of medicines is not a singular event, but a recurring cycle that needs accurate demand forecasting and planning in addition to appropriate transportation and storage conditions.

Second, new medicines and technologies are usually protected by intellectual property rights, such as patents. This means that patented products are only allowed to be manufactured by the patentholder for at least 20 years from the application date. It might still take several years before the medicine enters the market for medical use – if it gets through clinical trials at all. Once it gets on the market, however, these patents are sometimes extended by making minor changes to the molecule, also known as *evergreening* (Silverman et al., 2019). As a result, the supply side of the innovator-product market is often very concentrated, heavily skewing negotiating power in favor of the supplier.

Third, production of medicines is subject to stringent rules and regulation. This might limit the total supplier base and cause high entry barriers for potential new supplier or manufacturers,

restricting market competition. In countries with weaker regulatory oversight, however, the market might be flooded with suppliers of unknown or poor quality products. This is particularly alarming for medicines because the quality of the product cannot be assessed by the prescriber or the consumer. When medicines fail to cure sick people, the initial tendency is to blame the illness rather than question the quality of the medicine. This can have serious consequences for the medicine market because higher quality products come at a cost, as our earlier research has shown (Pisani et al., 2019). If left undisturbed, this information asymmetry can result in cheaper and often inferior quality (i.e., substandard and falsified) products driving out the more expensive and higher-quality products, in time. This phenomenon is often referred to as *market for lemons*[4], as first introduced by the Nobel Prize winning economist George Akerlof in 1970 (Akerlof, 1970; Silverman et al., 2019).

Against this backdrop, many buyers face difficulties with procurement of medicines. A buyer can range from a single health facility to multiple countries. Buyers might have a market size that is too small to generate sufficient negotiating power or attract suppliers to supply or produce for that particular market. Another difficulty might be related to limited resources and technical capacity. Buyers might not have the financial capacity to buy medicines in the right quantities at the right time. In addition, buyers might have a lack of sufficient, dedicated and qualified staff to carry out procurement in a way that maximizes availability of quality health products for the lowest possible cost.

[4] George Akerlof used the term 'market for lemons' in the context of the used car market. In the American language, lemons are used as slang for bad quality cars, while peaches are used for high quality cars. A market for lemons occurs when information asymmetry between the seller and the buyer results in adverse selection, where lower priced lemons drive out higher priced peaches (Akerlof, 1970).

One solution to tackle these difficulties is through *pooled procurement*. Pooled procurement can be defined as "a collaboration initiative that consists of two or more buyers, or a third-party organization that procures on behalf of its participating members" (Parmaksiz et al., 2022, p. 2). Pooled procurement, which has over 170 variations and synonyms in literature referring to the same approach (Schotanus, 2007), operates based on the monopsony principle, in which there is a single buyer in the market, as opposed to a monopoly in which the market is dominated by a single seller. Notable examples of pooled procurement mechanisms on a global level include the Global Fund for medicines, along with GAVI for vaccines. On an inter-country level, examples include the Gulf Cooperation Council (GCC), the Pan American Health Organization Revolving Fund (PAHO RF) and the Organisation of the Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS) (Nemzoff et al., 2019). At the national level, centralized procurement policies have been implemented in, for example, China (Zhu et al., 2023) and Mexico (Adesina et al., 2013), while subnational pooled procurement efforts can be seen in Indian states such as Tamil Nadu and Bihar (Chokshi et al., 2015). More recent efforts to establish pooled procurement mechanisms include initiatives of the East African Community (EAC) and the African Union's supranational pooled procurement initiative (Jerving, 2024).

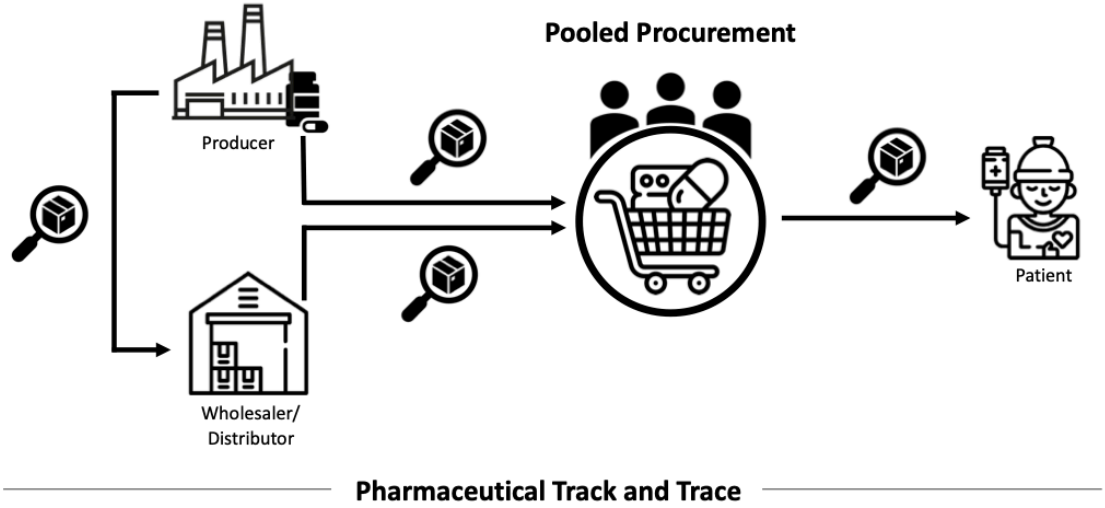
The pooled procurement approach, however, is not exclusive to the procurement of medicines. Various other industries, such as military defense (Gray, 2023), aviation (Khalaf, 2008), retail (Smit, 2018), hospitality (Polychronakis & Syntetos, 2007), catering (Smit, 2013), and oil and gas (Hancock, 2023) have set up such pooled procurement mechanisms by consolidating the procurement of products and services to increase negotiating power and lower prices. Pooled procurement mechanisms have also been promoted or implemented for various other reasons such as improving procurement efficiency

(Domfeh, 2021), increasing demand forecast accuracy (USAID Center for Accelerating Innovation and Impact, 2014), enhancing quality standards (e.g., by harmonizing regulations or sharing staff, laboratories and technical capacity) (Espín et al., 2016), or increasing availability and supply sustainability of medicines by incentivizing, sustaining and expanding the supplier base (DeRoeck et al., 2006). However, it remains unclear how such mechanisms are set up, what work is needed to realize that, how they function within the context of the health sector and how they develop over time.

Pooled procurement mechanisms can be described as symbiotic relationships. They are formed or joined based on the idea that each participating member should generate a net benefit from the collaboration (i.e., mutualism). This does not mean that the benefits have to be identical. A small country, for example, might achieve price reductions of essential medicines induced by demand aggregation as a result of pooling their procurement with a substantially larger country. The landlocked, larger country, on the other hand, might benefit from lower transportation costs because it can make use of the port of the smaller neighbor country. Also, some hospitals, for example, might join to increase their technical capacity and expertise, while specialized clinics might join the same mechanism to maximize their financial gains. More often than not, however, these benefits are distributed unevenly, threatening the longevity of the mechanism. As much as these mechanisms are organizational collaborations, they are also social and relational. And therefore, inevitably political. It involves goals, aims, interests, needs that requires active and continuous work in terms of negotiation and alignment. However, to gain a better understanding of the areas that need alignment and the factors affecting this alignment-process, further study in the context pooled procurement for medicines is required.

Pooled procurement mechanisms come in different structural forms. Schotanus (2007) has identified three main forms: piggy-backing, lead buying and third-party. In this context, *piggy-backing* refers to one member, often the largest, sharing their individual supplier-agreement, allowing the other members to benefit from similar contractual terms. *Lead buying* refers to a mechanism where one of the members, often the most resourceful, is assigned to take the role as procurement agent. Finally, *third-party* refers to a mechanism where the procurement task of a mechanism is outsourced to an external, often specialized, procurement agency. I will apply this typology to the context of pooled procurement of medicines to explore the questions which structural forms are typically adopted, and for what reasons? How do they differ in terms of characteristics, and the way they are set up? Figure 2 provides a schematic overview of the relationship between the two collaborative approaches explored in this dissertation (i.e., track and trace, and pooled procurement).

Figure 2. Schematic representation of the relationship between pharmaceutical track & trace and pooled procurement.



As discussed, full track and trace systems help to make supply chains more transparent. This is depicted with the magnifying glass. Before the product enters the supply chain, it needs to be produced or stocked by the suppliers (i.e., manufacturer, wholesaler, and distributor). Then, these health products need to be procured. This is where pooled procurement comes into play. The buyers, ranging from a single health facility to a country, come together and unify their purchases in a pooled procurement mechanism. Depending on buying structure, more actors or middlemen, might be included in the supply chain before it reaches the patient. If it is a pooled procurement mechanism of hospitals or pharmacies, the patient can access the health commodity from them directly. If it is national level procurement agency, it generally passes through regional or district-level warehouses, before it goes to healthcare organizations and the patient. In summary, pooled procurement mechanisms allow buyers to procure the right product, for the right price, and the right quality, at the right time, at the right place. Track and trace systems register all these interactions between actors, and ensure that those exact products, safely reach the patient.

Theoretical perspectives

To understand how collaborative approaches, such as track & trace systems and pooled procurement mechanisms, are created, I will zoom in on the collaborative process. What is needed to initiate and organize these collaborations? How do actors interact? What factors play a role? To explore these questions, I will draw upon theoretical insights from collaborative governance literature. Setting up these approaches, I will argue, is not a singular event, but a process that evolves over time. To study these dynamics and developmental processes, I will mainly draw upon lessons from organizational life cycle literature.

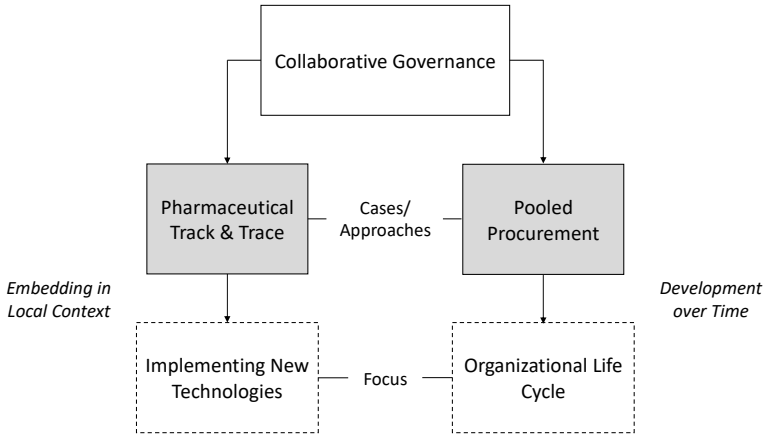


Figure 3. Overview of theoretical perspectives applied in this dissertation.

But first, what is a collaboration? In everyday language, it commonly refers to a process where two or more people work together to achieve a common goal. Ansell and Gash (2018) defined a collaboration as a "high intensity mode of interaction that nurtures mutual interdependence and joint action while preserving the autonomy of collaborating parties" (p. 16). Collaborative governance studies, therefore, concentrate on the interaction processes and structures between the actors within those collaborations (Emerson et al., 2012). Following Emerson et al. (2012), I do not restrict collaborative governance to formal, state-initiated arrangements. In this study, state-initiated, as well as collaborative approaches initiated by NGOs or intergovernmental organizations, such as the WHO, will be explored.

Much has been written about collaborative governance in the last decades in an attempt to identify key features of the collaborative process (Ansell & Gash, 2008; Bryson et al., 2006; Emerson et al., 2012). In this dissertation, I will be focusing on three core processes of collaborative governance:

- The system context and drivers;
- The collaborative process and multi-actor interactions; and
- The outcomes and adaptations.

In the following sections I will further explore and specify which conditions, factors, characteristics and values might be relevant for setting up and sustaining the two collaborative approaches examined in this study (i.e., pharmaceutical track & trace systems and pooled procurement mechanisms).

The system context and drivers

Collaborations do not take place in a void. They interact with and are shaped by various political, economic, legal, environmental and other systemic factors. Emerson et al. (2012) draw attention to this system context in which collaborations take place. They underline that this context is dynamic and has an influence on the collaboration during its entire lifecycle. Bryson et al. (2006) add that cross-sector collaborations are more likely to occur during turbulent environments or sector failures, in which preliminary attempts to solve the problem within a sector have been tried and failed.

These systemic factors bring forth certain essential *drivers* that affect an actor's incentive to participate. These drivers include uncertainty (around defining "wicked" problems and finding appropriate solutions individually), interdependence among actors, leadership to initiate the collaboration, and consequential incentives – in the sense that inaction might have a negative impact – are influential in initiating engagement between actors. These consequential incentives can emerge either internally from problems, needs or opportunities within the participating actors, or externally from crises or threats (Emerson et al., 2012).

Ansell and Gash (2008) accentuate the influence of inter-relational drivers, which they term as starting conditions. These can be seen as *a*

priori incentives for engagement between actors, and are influenced by the prehistory of collaboration or conflict between actors, and the existing imbalances in power, resources, and knowledge. Actors, ranging from an individual to multiple people representing larger entities, are motivated by personal aims prior to engagement. Huxham and Vangen (2013) point out that those aims can be explicit, unstated or hidden. Additionally, they characterize aims as fluid in the sense that they can be multiple, conflicting and subject to change over time.

The collaborative process

The core of the multi-actor interactions take place within the collaborative process. Although multi-actor interactions and the collaborative process are often intertwined in collaborative governance literature, I deliberately distinguish these processes in order to emphasize the work and efforts carried out by actors to drive the collaborative process forward.

Certain factors seem to play an important role in organizing and structuring the collaborative process. Sometimes referred to as institutional design, these involve protocols, organizational structures and "rules of the game" in which collaboration takes place. More specifically, factors such as the inclusivity of the collaboration, availability of alternative venues, and the transparency of the collaborative process need to be determined and/or formulated (Ansell & Gash, 2008; Bryson et al., 2015; Emerson et al., 2012). These are concerned with questions such as: who is allowed to participate? How are problems resolved? And are decisions based on consensus or majority-vote?

Leadership is another relevant factor as it influences the initiation, mediation, facilitation and mobilization of resources for the collaborative process (Ansell & Gash, 2008; Emerson et al., 2012). Leadership can be either formal, based on allocated title, role or position, or informal, based on prestige, credibility, expertise or skills. One actor can hold multiple roles, just like multiple actors can also fulfil the same

role. In this dissertation, the exploration of leadership will not be limited to the scope of individual actors. It will encompass individuals, organizations or government units, for example, that fulfil those leadership roles.

Emerson and Nabatchi (2015) stressed the significance of two additional factors that influence the structuring of the collaborative process: the importance of sharing and leveraging resources to facilitate collaborations, and transferring and co-creating knowledge, which they perceive as the *currency* of collaborations.

Other factors, however, are more pertinent to inter-personal dynamics. Emerson and Nabatchi (2015) use *principled engagement* to describe the interaction processes concerned with bringing actors together and initiating engagement. It evolves along the lines of four phases: discovery (i.e., presenting interests, concerns and values), definition (i.e., developing shared purposes, concepts, language, expectations, and assessment criteria), deliberation (i.e., open negotiation and discussion processes aimed at resolving conflicting interests and reaching relative alignment), and determination (i.e., agreeing on operations and organizational design of the collaboration).

Reaching common ground and relative alignment on goals, purposes and operations simultaneously shapes and is shaped by inter-personal factors, such as attaining mutual understanding, shared commitment to the process, internal legitimacy, face-to-face dialogue and trust-building. Inter-personal dynamics can be reinforced by intermediate outcomes such as small wins for the participating actors (Ansell & Gash, 2008; Bryson et al., 2015; Emerson & Nabatchi, 2015; Voets et al., 2021). The extent to which these factors are successfully achieved is contingent on the presence and intensity of the drivers discussed in the previous section.

Outcomes and adaptions

As previous scholars have argued, collaborations are formed to respond to a demand or problem that participating actors cannot solve individually. Within those collaborations, actors participate to pursue and realize individual goals. The collaborative process, aimed at achieving relative alignment by converging individual goals into shared goals, leads to specific actions. These actions are agreed upon strategies that have been articulated to reach the shared goals of the actors. In turn, the execution of those actions results in specific outcomes. These outcomes can be both successful and unsuccessful in terms of reaching the predetermined common goals. One of the key areas identified by Bianchi, Nasi and Rivenbank (2021) for advancing our knowledge involves enhancing our understanding of designing and implementing collaborative governance initiatives within various contexts. They specifically draw attention to the need to explore the influence of culture, history and traditions on the success or failure of such collaboration initiatives. In addition, the actions can generate indirect or unintended consequences, which should not be overlooked (Emerson & Nabatchi, 2015). This process, however, is not static. It is a dynamic and iterative process that leads to adaptations. Especially because those actions, like the collaboration itself, need to be tailored, embedded and adapted to the local contextual environment of the actors, which – in itself – is dynamic. This type of work is also referred to as *articulation work* (Star & Strauss, 1999). This means that those actions – technologies (i.e., track and trace systems) or (pooled procurement) mechanisms in the case of this dissertation – are likely to transform during adaptation in order "to deal with the unanticipated contingencies that arise" (Gerson & Star, 1986, p. 266). Analysis of this process is often overlooked, which undermines the successful reproducibility of innovations within specific contexts. Hence, I will not only focus on the systemic factors, the drivers, the collaborative processes and inter-personal dynamics, but also on the

material actions, outcomes, their adaptations to their local contextual environments and learnings from comparative analysis of success and failure.

Development over time

Although collaborative governance acknowledges the dynamic, cyclical and iterative nature of the collaborative process (Emerson & Nabatchi, 2015), it provides limited emphasis on its development over time. Time is mostly seen as a currency; an investment actors make during the collaborative process (Ansell & Gash, 2008), like planting seeds, watering the soil, checking its pH levels and adding fertilizers requires investment of time. However, time can also be seen as a dimension or medium in which something happens or develops. Like the growth and flourish of a garden takes place over time, not simply because plants need time to grow but because the garden is a complex environment where interactions with other plants, soil, animals, and weather conditions play a crucial role in shaping its evolution. I argue that both the cyclical and iterative nature of processes, as well as their temporal development are valuable in understanding how such collaboration initiatives are created, implemented, embedded, operated and sustained. To fill this gap, I will draw upon insights from organizational life cycle literature. This literature will enable me to gain a deeper understanding of the development over time and identify the general stages through which such collaboration initiatives typically evolve.

Since the second half of the last century, organizational life cycle scholars have endeavored to identify patterns and theories on how organizations tend to develop over time. Lippitt and Schmidt (1967) were one of the first to write about a three-staged model of organizational development consisting of birth, youth and maturity. Other scholars have made adaptations to these stage-models by relabeling stages or identifying additional stages in the organizational life cycle process

(D'Aunno & Zuckerman, 1987; Miller & Friesen, 1984; Quinn & Cameron, 1983). Despite differences in focus and study contexts, these models share certain fundamental elements of the developmental process: all collaborations emerge, grow and mature. If alignment between members within a collaboration is threatened, however, they might also enter the decline stage (Miller & Friesen, 1984), where the progress might stagnate or even result in the collapse of the collaboration. Transitioning into decline, however, may not follow a linear path. It can happen at any stage of the development. Pooled procurement mechanisms are an interesting site for studying life cycles of collaborative processes as many of these mechanisms fail (McDonnell et al., 2021; Barton & Berger, 2022b). Therefore, I will focus on these mechanisms to study the temporal dimension of collaborative governance.

Research questions

My main objective in this dissertation is to contribute to increasing access to affordable and quality-assured medicines. I aim to do this by focusing on the implementation and functioning of two collaborative approaches: pharmaceutical track & trace systems and pooled procurement mechanisms. To guide the empirical work of my dissertation, I have formulated three central research questions:

1. *What are the preconditions for the emergence of collaboration initiatives?*

The first research question explores how these collaboration initiatives emerge. It seeks to investigate what preconditions drive their implementation and adoption process by identifying systemic factors (e.g., political, economic, industrial or legal) and essential elements that must be taken into account to realize these collaboration initiatives successfully within their specific local contextual environments.

2. *How do collaboration initiatives develop over time?*

The second research question focuses on the temporal dimension of the collaboration initiatives. It particularly concentrates on one of the collaborative approaches (i.e., pooled procurement mechanisms), and explores how such mechanisms change over time, what general stages can be identified, and describes what the essential processes within each identified developmental stage are.

3. *What work is needed to implement and sustain collaboration initiatives?*

The third research question zooms in on the work and effort required to create, implement, embed and sustain collaboration initiatives over a longer period of time. It also pays attention to inter-personal dynamics and the often overlooked, mundane work that goes into engaging, motivating and aligning actors to drive the initiatives forward.

Methodological approaches

This dissertation is based on a variety of qualitative methodological approaches. It combines various data collection methods including (semi-structured) interviews, literature reviews, theoretical insights, document analysis, and observations.

At first, I set out to explore ways to ensure the public's access to cost-effective, high-quality medicines. After investigating supply chain processes, I realized that these mostly depended on the quality of products used and the efficiency of the production, supply and procurement processes (**Chapter 2**). Next, as I tried to learn more about how to procure medicines in resource-limited settings, I compiled all published information on how to collaboratively procure medicines, such as

what types of pooled procurement mechanisms exist? What are the most essential steps to procure medicines jointly? How many personnel and money are needed to set up and sustain pooled procurement mechanisms? (**Chapter 3**).

After realizing that many essential steps seemed to be missing, underemphasized or scattered in existing sources, I decided to develop a general *Pooled Procurement Guidance* document on how I think that pooled procurement ought to work, and how its developmental process ideally should take place over time (**Chapter 4**). To test its validity, I applied my guidance to successful and failed examples of pooled procurement mechanisms, while considering various different organizational structures and types. I purposefully paired successful examples with failed ones because lessons from failed examples are often overlooked or omitted from academic studies (**Chapter 5**). Finally, I had the opportunity to verify my guidance from close range by engaging with one specific inter-country pooled procurement mechanism spanning four years. Throughout this study, I kept a particular focus on the work and efforts required to align interests and overcome disagreements between countries to drive the mechanism forward. This long-term study, conducted alongside my other studies on pooled procurement, allowed me to explore the interaction between theory and practice. This was a reflexive and recursive process in the sense that findings from this study informed and contributed to developing my theoretical notions, which, in turn, were put into practice and further validated within the context of this study (**Chapter 6**).

Probably the best way to summarize my methodological underpinnings is by using the following car analogy: I began by analyzing the supply chain processes of a car. Next, I examined what parts a car is made of, followed by developing a general blueprint for building one. I then tested this blueprint by comparing multiple assembly processes across various vehicle types. Finally, I applied this blueprint to conduct an in-depth examination of the assembly process for a specific car over

an extended period of time. A more detailed description of the study designs and specific methodologies used throughout this dissertation can be found in the respective chapters.

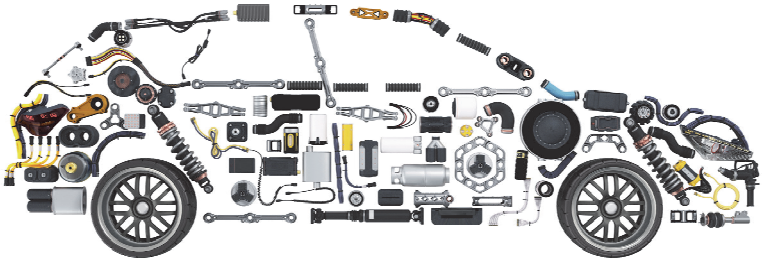


Figure 4. Decomposition of a car's elements and processes.

Thesis outline

The remainder of this dissertation consists of five empirical chapters, and one concluding chapter. Each empirical chapter has been published or submitted as an academic article, and focuses on various aspects of the two collaborative approaches.

Chapter 2 – *What makes a national pharmaceutical track and trace system succeed? Lessons from Turkey* – explores the implementation process of the pharmaceutical track and trace system in Turkey with a particular focus on the underlying political and economic drivers. It sets out to understand why Turkey succeeded to implement the first full track and trace system in the world, where other, more technologically advanced countries have been struggling. What problems was it trying to solve? Which actors were instrumental and why? And how did it affect the access to affordable and quality-assured medicines?

Chapter 3 – *A systematic review of pooled procurement of medicines and vaccines: identifying elements of success* – presents the findings of our systematic literature review on the implementation and functioning of pooled procurement mechanisms for medicines and vaccines. It focuses on describing the processes as well as summarizing lessons on outcomes of pooled procurement mechanisms.

Chapter 4 – *From promise to practice: a guide to developing pooled procurement mechanisms for medicines and vaccines* – builds on insights and gaps identified in Chapter 3 to develop a comprehensive *Pooled Procurement Guidance*. For each key actor involved, it provides a structured overview of the elements and processes that are essential to set up and sustain pooled procurement mechanisms, while also describing how such mechanisms evolve over time.

Chapter 5 – *Does structural form matter? A comparative analysis of pooled procurement mechanisms for health commodities* – provides a comparative analysis of four pooled procurement mechanisms that differ in structural form (i.e., inter-buyer vs. third-party mechanisms), using the Pooled Procurement Guidance, developed in Chapter 4. We purposefully selected and paired successful and failed examples of inter-buyer (i.e., the Organisation of the Eastern Caribbean States & the Pacific Island Countries) and third-party mechanisms (i.e., the Global Drug Facility & the Asthma Drug Facility) in order to understand how they differed in terms of characteristics and developmental process.

Chapter 6 – *Towards regional access to medicines: the development of the East African Community pooled procurement mechanism* – zooms in on the developmental process of the East African Community pooled procurement mechanism over a longer period of time. It uses the Pooled Procurement Guidance to provide insight into the individual country needs, their alignment processes and continuous negotiations, and the

work that is required to drive the mechanism forward.

Chapter 7 – *On the emergence, development and sustainability of collaborative approaches* – highlights the key empirical findings, provides answers to the research questions, reflects on their implications for theory and practice, and suggests a research agenda for future research on improving access to affordable and quality-assured medicines.

2

What makes a national pharmaceutical track and trace system succeed? Lessons from Turkey

This chapter was published as:
Parmaksiz, K., Pisani, E., & Kok, M. O. (2020). What makes a national pharmaceutical track and trace system succeed? Lessons from Turkey. *Global Health: Science and Practice*, 8(3), 431–441.

Abstract

Background: Track and trace systems are increasingly being implemented as a technological solution to secure pharmaceutical supply chains. Turkey was the first country to implement a full pharmaceutical track and trace system throughout the entire regulated domestic supply chain. This article explores the emergence and functioning of this system and the consequences for substandard and falsified medicine with a focus on the underlying political and economic factors.

Methods: This study uses an explanatory case study approach that combined interviews with purposefully selected key informants and document analyses.

Results: The main drivers for implementing the pharmaceutical track and trace system in Turkey centered on the elimination of reimbursement fraud and the prevention of falsified medicine in the regulated supply chain. Although stakeholders experienced both physical and software-related problems in implementation, the alignment of incentives of all stakeholders with the power of the state, along with leeway for adaptations, ultimately resulted in a successful process. This track and trace system provides a clean regulated supply chain, minimizes reimbursement fraud, facilitates fast market recalls, and can flag likely medicine shortages. Staff previously engaged in pharmacy inspections now concentrate on ensuring production quality, which reduces the risk of substandard medicines.

Conclusions: In Turkey, four factors drove the successful implementation of pharmaceutical track and trace: the political determination to eliminate reimbursement fraud, a large pharmaceutical market dominated by a single payer, medicine reimbursement being contingent on

verified dispensing and prescription, and flexibility to adapt the system according to the needs of stakeholders during implementation.

Introduction

Track and trace systems are logistical technologies that enable localizing and following a product throughout a supply chain (Mackey & Nayyar, 2017); they are used in many sectors, including aviation and retailing (Mackey & Nayyar, 2017; Musa et al., 2014). In 2012, Turkey became the first country in the world to implement a full track and trace system to secure its domestic pharmaceutical supply chain. A growing number of countries are now following suit. Argentina and Saudi Arabia are among the countries that have already put such a system in place, while other countries, including China, the United States, and European Union (EU) member states, are currently in the process of implementation (Pisa & McCurdy, 2019; Roth et al., 2018; World Health Organization, 2016).

For pharmaceuticals, two track and trace systems dominate. The first, known as a *point-of-dispense check* system, validates medicine packages at the points where they are dispensed to patients (e.g., pharmacy or hospital) with the code assigned during the manufacturing process. Other transactions (e.g., between wholesalers and distributors) are not systematically recorded (World Health Organization, 2016). The European Medicines Verification System, implemented by the EU in February 2019 as part of the Falsified Medicines Directive, provides an example (Pisa & McCurdy, 2019). This system allows for verifying the authenticity of the product, but not for tracking the product throughout the supply chain (Mackey & Nayyar, 2017; Pisa & McCurdy, 2019). The second track and trace system, often referred to as full track and trace, validates a medicine package at every stage of its journey through the supply chain. This system is in use in Turkey (Pisa & McCurdy, 2019). Although the full track and trace system is more complex to implement, it provides additional potential benefits to those of the point-of-dispense check system. These benefits include real-time tracking

throughout the entire supply chain, stock management for timely detection and prevention of stock-outs, targeted product recalls, and reduction of reimbursement fraud, theft, and medication errors (Hara et al., 2017; Klein & Stolk, 2018; Mackey & Nayyar, 2017; Pisani et al., 2019; Rotunno et al., 2014).

Recent studies show that the opportunity to enter the pharmaceutical supply chain differs between substandard and falsified medicines. Substandard medicines, which are defined as authorized products that fail to meet quality standards, enter the supply chain through manufacturers who might sacrifice quality to maximize profits (World Health Organization, 2017d; World Health Organization, 2017b). Falsified medicines, which have a deliberately misrepresented identity, composition, or source, are often introduced by criminals who see a market opportunity when shortages of quality and affordable medicine occur in the regulated market (Pisani et al., 2019; World Health Organization, 2017b).

Turkey began with a point-of-dispense check system known as *Ilaç Takip Sistemi* (ITS) in 2010, before introducing full track and trace in 2012 (Rotunno et al., 2014; World Health Organization, 2016). From the start, all medicines sold in Turkey had to be equipped with a DataMatrix code, which is a 2-dimensional barcode. A DataMatrix code contains information on the Global Trade Item Number, a serial number, an expiration date, and a batch number, which enables tracking the history and location of each medicine through the supply chain (Cordon et al., 2016; MoH Turkey, 2017b).

Implementing new technologies

In this case study, we draw upon insights into the implementation of new technologies, which are based upon the rich literature on technological innovation. First, technological changes do not take place in a

vacuum; they are embedded in dynamic and complex systems and are shaped by social, political, and economic factors. Therefore, when analyzing the implementation and functioning of new technologies, one must consider the context in which they are embedded (Cresswell & Sheikh, 2013; Hamilton, 2016; Rip & Kemp, 1998).

Second, initiation or successful implementation of technological change is often contingent on the determination of key actors to solve a perceived problem. The process of problematization and the emergence of a relative consensus about the nature of a problem are important first steps in aligning the incentives of all parties playing a key role in implementing the new technology (Callon, 1984).

Third, implementation and innovation are intimately and reciprocally connected, which means that innovations transform during implementation (May, 2013). As a result, the technology that ultimately gets implemented often deviates from the initial plan. These adaptations, which are often omitted in retrospective accounts about the success of a technology, enable a certain system or technology to operate successfully within its specific context. Overlooking these adaptations undermines the successful reproducibility of technological innovations. In addition, adaptations enable different actors to assign different roles to the technology that are not limited to the official function of the technology (Law & Callon, 1992). This results in unforeseen outcomes of the technology that are valuable to capture in order to reach its full potential.

Although Turkey was the first country to implement a full track and trace system, neither how the country achieved this significant feat nor what made it possible has been closely investigated. The aim of this study was to gain insight into political and economic factors that drove the implementation of the pharmaceutical track and trace system in Turkey. We paid special attention to the consequences of the system for substandard and falsified medicines. Insights from our study may provide valuable knowledge to other countries aiming to implement

pharmaceutical track and trace systems and may contribute to the understanding of implementing large technological systems in the health sector.

Methods

Study design

For this qualitative case study, document analysis and semi-structured interviews were carried out. We used an explanatory case study approach, the main purpose of which was "to explain how and why some conditions came to be" (Yin, 2014). Such an approach allows for investigating underlying factors that are often too complex to be captured by surveys or other quantitative measures alone (Baxter & Jack, 2008). We believe that a detailed understanding of the implementation and adaptation of the pharmaceutical track and trace system will provide valuable insights into the complexities involved in implementing such large-scale health technologies.

Study participants

The study participants were 16 purposefully selected key informants. Selection was based on their knowledge and expertise in political and economic factors influencing the emergence, implementation, and functioning of ITS. The aim of purposeful sampling is to increase depth and richness of the collected data by identifying and selecting information-rich cases from different perspectives (DiCicco-Bloom & Crabtree, 2006; Palinkas et al., 2015). We sought to involve stakeholders across the supply chain, together with independent experts, to achieve a comprehensive evaluation of the pharmaceutical track and trace system in Turkey. Backgrounds of study participants are shown in Table 1.

Category of participant	#
Pharmaceutical manufacturers	2
Wholesalers	1
Healthcare providers	1
Ministry of Health/regulators	3
Technical agencies	
International organizations	1
Software developers	2
Associations/unions	3
Reimbursement agencies	2
Academics	1

Table 1. Category and number of participants in the study, N=16.

Data collection methods

To prepare for interviews and to triangulate findings, we reviewed relevant policy documents that helped us understand the emergence, implementation, and functioning of ITS, such as regulations on recall (MoH Turkey, 2015), labelling, package leaflets, tracing of human medicinal products (MoH Turkey, 2017a, 2017b), and ITS guidelines (MoH Turkey, 2009).

Semi-structured interviews were carried out between March and April 2018, using an interview guide.[5] We obtained written informed consent for interviews and requested permission to audio-record them. Three respondents refused to be audio-recorded, so detailed notes were instead taken during these interviews. Participants were anonymized using identification numbers that were stored separately from the study data. Interviews were conducted both in English and Turkish and lasted between 60 and 120 minutes.

[5] The interview guide can be found online in the article's supplementary material. See: https://doi.org/10.9745/GHSP-D-20-00084

Data analysis methods

A constant comparative method of analysis was carried out. This method involves an iterative process, in which newly collected data in the form of interviews were triangulated with existing data from previous interviews, studies, or reports obtained during literature research to inform subsequent data collection and verify findings (Boeije, 2002). First, the semi-structured interviews were recorded and transcribed verbatim. Then, if necessary, they were translated into English. Interviews were coded using a coding structure jointly developed by the research team. This structure was based on political and economic factors enabling market opportunities for substandard and falsified medicine, along with factors facilitating or obstructing the implementation and functioning of track and trace systems.[6] Emerging themes and the analysis were discussed during six weekly team meetings, until consensus was reached. NVivo (12.0.0) was used as the qualitative data analysis software.

Results

Historical developments and pricing policies

To provide the contextual background, we asked participants to reflect on the historical developments of the health sector and the pharmaceutical industry in Turkey. Until the early 2000s, Turkey experienced several problems in the health sector, including insufficient insurance coverage, poor health outcomes such as life expectancy and maternal mortality, and relatively low governmental health expenditure.

In addition, Turkey had three state institutions, which are known by their Turkish abbreviations SSK, BAĞ-KUR, and Emekli Sandığı, providing

[6] The coding structure can be found online in the article's supplementary material. See: https://doi.org/10.9745/GHSP-D-20-00084

health insurance to different employment-based groups. These institutions operated independently, which resulted in high fragmentation of service provision and restricted access to health services (Atun, 2015; T.C. Sağlık Bakanlığı Tedavi Hizmetleri Genel Müdürlüğü, 2001):

> *At that time about half of Turkey's population, 50% was covered under SSK, and the number of hospitals those people could use was only 120. For the whole of Turkey, can you imagine? Half of the population in Turkey is doomed to only 120 hospitals.* [Academic]

After the national elections in 2002, the Justice and Development Party came into power in Turkey. This was the first time a political party with religious roots came into power as a single-party government since the establishment of the constitutionally secular Republic of Turkey. Therefore, they had to establish political legitimacy among their citizens and the international community. The government made a strong commitment to universal health coverage as a way of establishing political legitimacy among the country's citizens and in the international community. The government subsequently introduced the Health Transformation Program in 2003 with the aim to increase insurance coverage and financial risk protection.

After 2006, the government merged the three state institutions providing health insurance to form a single-payer institution, called *Sosyal Güvenlik Kurumu* (SGK) (Sosyal Güvenlik Kurumu Kanunu, 2006). Insurance coverage provided by SGK increased access to health services in Turkey considerably, resulting in a significant increase in public health expenditure. In response, the government introduced price-cutting measures, such as reference pricing in 2004 and global budgeting between 2010 and 2012. Despite these measures, manufacturers continued to supply the Turkish market, mainly because increased access to health services increased the overall volume of sales, creating a substantial pharmaceutical market that manufacturers were not willing to give up:

> *There was not such a thing as convincing. The state is not obliged to convince. The customer is king. "I pay the money; I determine the conditions." Turkey has such an advantage. I buy more than 80% of the market. They say: "If you are willing to give [medicines] under these conditions, then you can give them. Otherwise, I'm sorry, go sell them in another country, don't sell them to me."* [Multinational manufacturer]

Respondents were asked if downward price pressures incentivized manufacturers to cut corners, resulting in substandard medicines. Both manufacturers and the Ministry of Health (MoH) emphasized that the production or import of substandard medicine in the Turkish market was very unlikely because Turkey has well-defined legislation and regulations, including Good Manufacturing Practices (GMP), inspections, laboratories, and a pharmaceutical track and trace system. According to respondents, this strong regulatory framework minimized the possibility of substandard products on the market, while enabling rapid detection.

Pharmaceutical track and trace

An MoH official explained that before the introduction of the pharmaceutical track and trace system in 2010, quality assurance of medical products was mainly based on market surveillance and inspections. When pharmacists, health professionals, or others reported suspicions about a product, the MoH might sample that product for testing. This largely reactive system was time and resource intensive.

Despite the successful pricing policies to reduce medicine prices, the state experienced significant losses due to fraud around 2007. Although falsification and theft contributed to these losses, all respondents indicated that the main reason for the implementation of the pharmaceutical track and trace system in Turkey (i.e., ITS) was the presence of *reimbursement fraud* or *barcode scamming*. Prior to ITS, pharmacies had to

cut out the barcode of each product sold and put it behind the invoice. The invoice would then be sent to SGK for reimbursement. However, this system was vulnerable to fraud, as seen in the following example:

> *I know your national identity number. I am a doctor and I am writing the prescription to you, but you don't know that I am writing it. I give this prescription to the pharmacy. And the pharmacy doesn't sell the drug but sells the barcode. It prints the barcode on the offset and sticks that barcode behind that prescription or the invoice and sends it to SGK. Takes the money, but there is no transaction or trade. I mean, nobody sells anything, but gets the money from SGK. It is not a fraud to people; it is a fraud to the government.* [Technical agency official]

Respondents mentioned the existence of "printing houses" exclusively printing these falsified barcodes to be reimbursed by SGK. This fraud was estimated to account for $1 billion annually (Smith, 2016; Ünal, 2015).

Implementation of ITS

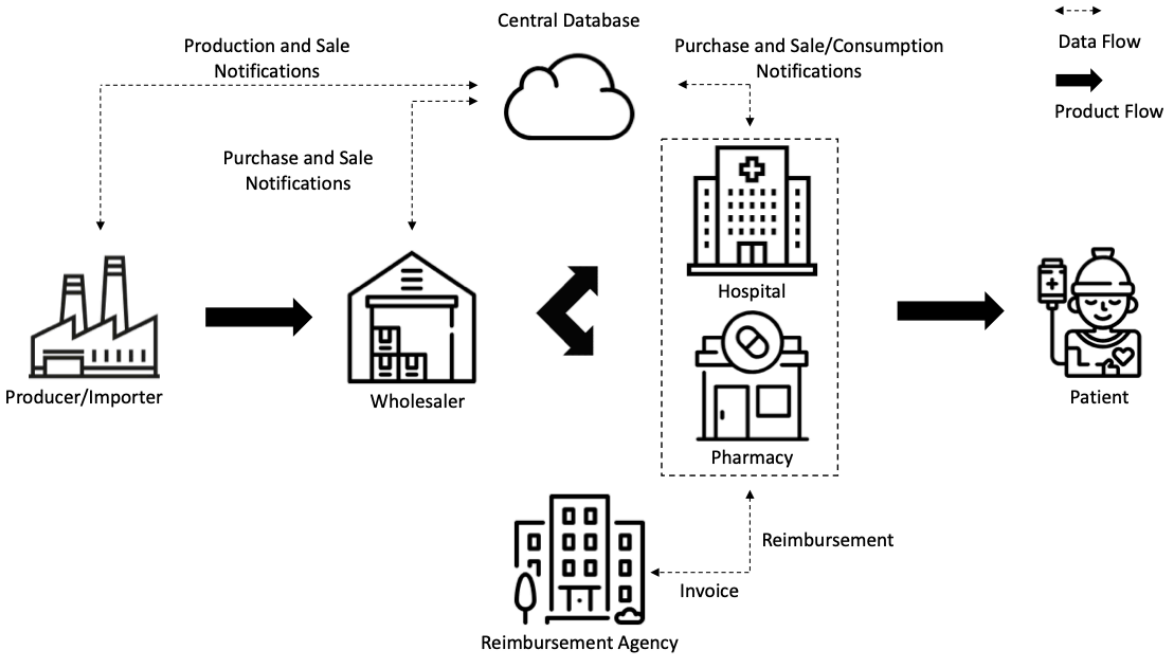
To prevent reimbursement fraud, the government decided to implement ITS. The first discussions on ITS occurred in 2007, but it took three years to convince and prepare stakeholders. The implementation took place in two phases to reduce implementation problems. A few months prior to the implementation of the first phase, a short pilot study was done with a small number of pharmacies. Then, phase 1, which focused on the manufacturers and pharmacists, was introduced in 2010. These two stakeholder groups, which are the front- and tail-end of the pharmaceutical supply chain, were obliged to make sales notifications, but wholesalers were not yet included in the system. Respondents mentioned that the phase 1 system, which corresponded to a point-of-dispense check system, remained vulnerable to introduction of falsified medicines at points in the supply chain where transactions were not tracked.

The initial implementation of phase 1 was problematic because of the way in which the software was developed. A single software engineer who had little experience in building enterprise systems was given the responsibility to create the software. The system crashed shortly after phase 1 was launched in 2010 and the system then had to be rebuilt from scratch by another person. Respondents indicated that the political will and determination of senior political figures were the main driving forces for this project to succeed:

> *The undersecretary general called me to SGK, I was shopping in my sportswear at that time. He told me: "Okay, it is not important, come here!" I was running in the hall of SGK and I opened the door of the meeting room. I was sweating, in sportswear and I saw that two ministers, two undersecretary generals, two vice presidents, a lot of big guys were in the meeting room. I was shocked. The undersecretary general said: "This is the person I mentioned." I sat between two ministers and they asked: "The system crashed, what should we do?" I told them: "First, accept it. In front of the news, in front of the media, first accept it and postpone it." They said: "This is politics, we cannot do that. You have 10 days, please make it work." This is the Eastern culture.* [Technical agency official]

Phase 2 was implemented in 2012. It can be described as full track and trace, encompassing all actors within the domestic regulated supply chain. It was based on cross-checking movements of a product between each actor by comparing sales and purchase notifications. After phase 2, maintenance and development of ITS came under the responsibility of another company and MoH. The data on the medicines were pooled in a centralized database managed by the MoH. A schematic representation of the ITS workflow is shown in Figure 5.

Figure 5. Simplified schematic representation of the workflow of the full pharmaceutical track and trace system used in Turkey.



Reaction to ITS

When ITS was first introduced, the expectations on its feasibility varied widely between different actors. Government institutions, including MoH and SGK, were convinced that the system would succeed, and that it would cut fraud and thus expenses in the national health system. Manufacturers, however, did not think it was feasible. No other country had successfully executed national track and trace, and manufacturers were especially skeptical that it could be achieved in the very limited timeframe envisaged by Turkish politicians:

> *There was a thing like: "Well, it won't be implemented here anyways. It will fail. Let's act as if we are complying to it, it won't work anyways."* [Multinational manufacturer]

Industry was unhappy about having to bear the costs of compliance. One manufacturer estimated that his company invested around $5 million in adding track and trace to their production and distribution flow, and that amount did not account for production losses. Another manufacturer said that the costs were around $100,000 per conveyor belt. An additional concern of manufacturers was the lack of adequate equipment:

> *We invited the Germans and Italians, who were good in machines. We talked to them. When we first bought it, we were buying dreams. (...) The ones who were able to convince you the most, you picked, because there was nobody that could show you [how it would work].* [Multinational manufacturer]

The wholesaler, who shared these initial doubts and skepticism, explained that they invested around 100 million Turkish Liras to implement this system across Turkey.

The merger of the three state payers into a single health insurer provided the state with consolidated buying power covering around 95%

of the market, which was sufficient to incentivize the pharmaceutical industry to implement the system. Manufacturers also saw a benefit in reducing access to the market for medicine falsifiers, thus protecting income and value.

The pharmacists included in our study indicated that they were most concerned about the increased workload because each product had to be individually scanned. Forgetting to do so could have serious consequences for the pharmacists during inspections.

With all these different interests, the challenge of aligning personal and institutional incentives was far greater than any technological challenge, as an MoH official pointed out:

> *I can get four people from India who can build this system in a short amount of time. The most crucial part is aligning all stakeholders with the support of the government.* [MoH official]

Implementation and adaptation

Despite the phased implementation, stakeholders experienced many implementation problems, both physical and software related. In phase 1, issues with software development and realistic planning of the implementation process were experienced by manufacturers, wholesalers, and pharmacists. Additionally, a manufacturer explained that physically adapting the production lines to print and scan DataMatrix codes turned out to be challenging:

> *We experienced a lot of problems. The ink got wiped because it did not dry properly. Also, when the conveyor belt was a bit skewed, the scanner could not read the DataMatrix [code].* [Multinational manufacturer]

Existing production lines in factories were not designed to be adapted, while new production lines were not yet developed. In addition, manufacturers experienced problems with sales notifications. Originally, the DataMatrix code on each secondary medicine package—the packaging enclosing the primary packages (e.g., blister or bottle)—had to be scanned individually, which took time and resources. Therefore, manufacturers introduced a *minimum-order-quantity system*, in which wholesalers were obliged to purchase medicines in fixed amounts. This system allowed manufacturers to scan the DataMatrix code on the tertiary packaging (i.e., the shipping-level packaging surrounding the secondary packaging).

Similarly, changes were made to logistic units (MoH Turkey, 2017a). The industry realized that the serial shipping container code was more appropriate than the serialized global trade item number, which MoH initially proposed. However, respondents pointed out that MoH was willing to modify the system accordingly:

> *The things that the authority sees from above and the reality we work in at the operational level are different. … We realized these things by experience. Therefore, things that were written down in theory evolved towards the reality of daily life in the end. Otherwise, if they did not change, if the ministry of health did not take our feedback into consideration, this system would be a nonoperative system.* [Multinational manufacturer]

The wholesaler experienced similar implementation problems. Scanning the DataMatrix codes and adapting conveyor belts proved challenging. Also, staff needed to be trained to use the system appropriately. Most of the problems experienced by pharmacists related to software malfunction. When the system was inaccessible, pharmacists

were not able to sell their products to patients. The problems were more acute in hospitals, where scanners were often in short supply. Additionally, hospitals buying common medicines in bulk found it difficult to scan individual prescriptions because the DataMatrix codes were not affixed to the packages of pills given to the patients but were only on the outer (or secondary) packaging, which was often thrown away before medicines were dispensed as individual patient prescriptions. As a result, hospitals were making consumption notifications instead of sales notifications (MoH Turkey, 2009).

Although MoH was open and collaborative in adapting the system according to the needs of those involved during implementation, solving practical problems remained largely the responsibility of stakeholders.

Outcomes of ITS

Respondents indicated that implementing ITS has had five main positive outcomes. First, reimbursement fraud is highly unlikely to happen in the current system. Successful fraud would require the participation of a long chain of people, raising the risk and reducing the reward for fraudsters. Reimbursement agency officials added that fraud cannot be reduced to zero but only minimized to a certain level, which is believed to have currently been achieved.

Second, ITS has largely eliminated falsified medicines in the regulated domestic supply chain. According to respondents, it is currently close to impossible to sell falsified medicines to patients in pharmacies and get reimbursement from SGK. Medicines cannot be "injected" into the supply chain at any stage other than by the manufacturer or importer. The only possibility for selling falsified products to patients is through out-of-pocket payments. However, since SGK provides comprehensive coverage to almost the entire population, citizens have no incentive to look outside the regulated supply chain or buy products out-of-pocket. Respondents underlined that Turkey's health financing

system, which reimburses pharmacists for verified dispensing and prescriptions, is central to the success of ITS. If pharmacists do not scan the DataMatrix code at dispensing, which serves to verify the authenticity of the product, SGK will not pay them for the product. In the case of a prescription medicine, SGK also verifies the authenticated product with the patient's medical prescription before paying the pharmacist.

Third, respondents said that ITS has optimized the recall process for products that are degraded or show unwanted side effects. ITS enables quick and targeted recalls of specific products. The sale of suspect products can also be blocked within the system by MoH officials (MoH Turkey, 2015), which prevents further dissemination of poor quality medicines and potentially significantly reduces public health harm caused by them.

Fourth, a mobile application of ITS, which was launched in 2014, allows citizens to scan the DataMatrix code of products. Citizens can immediately check the legitimacy of the product and obtain additional information, such as the expiry date, price, and recall status. Also, side effects can be entered in the application, which facilitates the collection of pharmacovigilance data.

Fifth, since ITS registers sales throughout the supply chain and eventual dispensing by outlet, the system allows for close monitoring of medicine stocks by health authorities, as well as providing inventory control for manufacturers, wholesalers, and pharmacies.

Although ITS has had many positive outcomes, respondents noted that ITS does not guarantee product quality. If a product has poor quality at manufacture or import, it will continue through the supply chain; careful tracking also does not protect against degradation. However, by reducing time spent on pharmacy inspections, ITS allows the transfer of human resources to other quality assurance functions:

> *Before ITS, we had 3,000 inspectors [checking pharmacies]. After ITS, we have 100 inspectors. The other ones, we didn't*

> *fire them, the other ones are used inside a new department which is GMP compliance, GDP [Good Distribution Practice] compliance and they are taking more samples from the market. They are going to the manufacturing sites and inspecting for substandard products. They are inspecting the active pharmaceutical ingredients. Now, they have time to inspect these things.* [Technical agency official]

Although quantitative data are not available, respondents reported that the tracking capability of ITS in combination with sufficient and qualified human resources has significantly increased the possibility of detecting substandard and falsified medicine.

Future adaptations to ITS

Respondents suggested two potential improvements to ITS. First, the scope of products given a DataMatrix code should increase. Currently, almost all medicines under the responsibility of MoH are obliged to carry a DataMatrix code, and internet sales are prohibited. However, some products, such as intravenous and radiopharmaceutical products, active pharmaceutical ingredients, and personalized medicines compounded in the pharmacy, are excluded from the DataMatrix code requirement. In addition, products such as vitamins and dietary supplements that are overseen by the Ministry of Food, Agriculture, and Livestock are not included in ITS. Respondents pointed out that falsification currently takes place with over-the-counter products rather than prescription medicine because inspections and regulations are less rigid. Although the majority of patients are aware that quality cannot be guaranteed, some products such as weight loss products, sexual products, or dietary supplements are sometimes purchased on the internet.

Second, an MoH official mentioned that ITS data could be used more effectively to prevent shortages and stock-outs. Although the current

system is largely reactive, MoH aims to implement a proactive alarm system that provides a warning when the supply of a certain product goes below a specific threshold in a particular area. Such warnings will enable the system to procure medicine more rapidly and to prevent drug shortages more successfully.

Discussion

Several countries and regions have attempted to introduce full pharmaceutical track and trace systems. Turkey was the first to succeed. This study aimed to elucidate the factors underpinning the success of this technological innovation. We find that the drivers of success were more political and economic than technological.

China, which has considerable experience and capability in implementing large technological programs in its health sector, suspended plans to introduce pharmaceutical track and trace in 2016 after facing considerable resistance from medicine manufacturers. Industry was concerned that the linear barcode system proposed instead of a Data-Matrix code would create a large footprint on the medicine package to capture the required data. Further, there was concern that the requirement that all barcodes be printed only by the government would result in a burdensome and costly procedure for manufacturers (GS1, 2015). As discussions with stakeholders continue, the target data for implementation has been pushed back to 2022.

The United States provides another example in which difficulty in adequately aligning incentives for all key actors has led to slow adoption of full traceability. Industry has not fully complied with the phased implementation foreseen in the 2013 Drug Supply Chain Security Act. Implementation of the act is expected to take a full decade (GS1 US, 2018; Pisa & McCurdy, 2019).

How was Turkey, a middle-income country with no great tradition of technological innovation, able to succeed where others stumbled? The most critical element was the combination of a widely recognized problem and political determination to solve it.

The winners of the 2002 elections in Turkey sought to establish political legitimacy through programs that delivered benefits to a broad swath of citizens. One of these benefits was universal health coverage delivered through a single-payer state institution. When high levels of fraud threatened the sustainability of this coverage, politicians threw their weight behind an ambitious technological solution within an improbably tight timeframe.

The state controlled access to a large and expanding pharmaceutical market, and manufacturers who wanted to sell into that market had to play ball. A generous benefit package greatly reduced out-of-pocket spending on medicines. Together with a prohibition on internet sales of prescription products, the benefit package removed any incentive for patients to purchase products from the unregulated supply chain. At the same time, the reimbursement system obliged pharmacists to bow to the will of the government; if they did not, they would not get paid. Together, these factors allowed for the widespread adoption of the system.

The successful implementation of the system was underpinned by another key factor: a willingness of the government, which was driving the process, to support flexible and adaptive solutions to problems identified during implementation. These work-arounds were not just technical; like all adaptive implementation, they also had a social component, encompassing human actions and relations (May, 2013). The Turkish state mainly focused on facilitating the social component, while other actors took responsibility for implementing the technical components of ITS.

Turkey's centralized database allowed for verifying reimbursement data because its track and trace database was linked to the database of SGK, the single-payer state-owned reimbursement agency. This process enabled reducing fraud dramatically (Rotunno et al., 2014). Centralized databases

rely heavily on the presence of sufficient technical capacity at the central level. If this capacity is lacking, outsourcing the development of the system to a software company, as in Turkey, might solve the problem, as long as security and privacy concerns of stakeholders are addressed (Pisa & McCurdy, 2019). In environments without political power emerging from a single-payer institution, the reimbursement landscape might be fragmented. The reimbursement agencies within a fragmented market, as well as the pharmaceutical industry, might oppose sharing and centralizing their competitive data more strongly (Barlas, 2011; Kang & Lee, 2013). In these circumstances, setting up a distributed database that gives stakeholders more authority over their data might be more feasible. However, disadvantages of distributed databases include difficulty in governing and adapting the system because ownership of the data is not centralized (Pisa & McCurdy, 2019; Rotunno et al., 2014).

To our knowledge, this study is the first to evaluate the emergence, implementation, and outcomes of ITS in Turkey, while focusing on the underlying political and economic factors. Since Turkey is the first country in the world to implement a full track and trace system, the implications of this study might be of particular interest to countries aiming to implement similar track and trace systems, including the EU member states, China, and the United States.

Limitations

The findings of this qualitative study could be strengthened through triangulation with quantitative data on the quality of medicine in the Turkish pharmaceutical market, the implementation costs of ITS, and the effect of ITS on public health. However, attempts to verify estimates provided by respondents with quantitative data from government or other formal sources proved unsuccessful. Future studies on the cost effectiveness of ITS might provide valuable insights.

For some categories of participants, we interviewed only a single key informant. However, triangulation of data provided by respondents

from different sectors (e.g., manufacturers, wholesalers, technical agencies) in combination with further triangulation from literature increases our confidence in the validity and reliability of our study data.

Recommendations

The outcomes of our study show three main implications for countries aiming to implement pharmaceutical track and trace systems. First, a track and trace system should be seen as a means to an end, rather than a goal in itself. To function, it must be underpinned by well-defined legislation and regulatory capacity, including laboratories and frequent GMP and GDP inspections. Without these, there is a risk of "garbage in equals garbage out." In that case, track and trace may simply deliver a secure supply chain for poor quality products.

Second, the incentives of all the stakeholders need to be aligned to successfully adopt the system. The role of the state should not be underestimated. It should both facilitate the implementation process with its political power, as well as provide sufficient leeway to adapt the system according to the needs of stakeholders. Countries lacking powerful political leadership might expect greater resistance to implementing pharmaceutical track and trace systems from stakeholders. This resistance is especially likely from stakeholders that bear the burden of upfront investment in technology and those that might benefit from gaps in the supply chain.

Third, countries/regions should aim to implement a full track and trace system. Although the benefits of track and trace systems are not universal and rely on the nature of the pharmaceutical system of the implementing country, point-of-dispense check systems, which exclude wholesalers and other middlemen, preclude some of the more important benefits of full track and trace. They do not provide data to flag regional shortages. Further, because they do not allow for traceability of products throughout the supply chain, such partial systems limit the

ability to recall products. As a result, falsified products might circulate in a market for months without detection (World Health Organization, 2016). This situation is especially true in the EU's complex single-market supply chains. Although the European Medicines Verification System has added an antitampering device to the outer medicine package to prevent unlawful repackaging, non-reimbursed or over-the-counter products will remain vulnerable to falsification. Most importantly, in EU member states lacking closed supply chains, patients might buy products online that are less likely to be verified and may even be excluded from verification. Although accreditations, domain name verifications, and logos for online pharmacies exist, their effectiveness can still be undermined by a lack of consumer awareness, vulnerability to misuse, unavailability of certain types of products at accredited online pharmacies, and the attractiveness of cheaper options (Buckley & Gostin, 2013; Fittler et al., 2013; Mackey & Nayyar, 2016).

Conclusion

Although track and trace systems are sometimes presented as reproduceable technical solutions to quality assurance in the supply chain, this study shows that the main drivers of success for ITS in Turkey were highly dependent on the presence of a specific set of circumstances. These included political determination induced by reimbursement fraud, political power emerging from a single-payer institution that generated a substantial pharmaceutical market, reimbursement for verified dispensing and prescription, and flexibility to adapt the system according to the needs of stakeholders during implementation.

Despite ITS's success in providing a clean regulated supply chain, it represents only part of the solution. ITS can only operate effectively if it is embedded in a pharmaceutical market where all legislative and regulatory components are in place.

3

A systematic review of pooled procurement of medicines and vaccines: Identifying elements of success

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Abstract

Introduction: Pooled procurement of health commodities has increasingly been promoted as a solution to reduce prices, increase availability, and achieve more efficient procurement processes. However, little is known about what is required to implement pooled procurement mechanisms successfully and how they function under specific circumstances. Therefore, the aim of this systematic review is to synthesize empirically grounded insights by identifying the elements that are essential for setting up and operating pooled procurement mechanisms of medicines and vaccines.

Methods: Our review was based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. We searched PubMed, Scopus and Web of Science for empirical studies on pooled procurement of medicines and vaccines using various search terms. Publications were assessed based on predetermined eligibility criteria.

Results: Our initial search yielded 1596 publications, of which 44 were eventually included in our review. Most of the included articles focused on pooled procurement mechanisms that operated on a sub-national level (43%), procured a variety of products (38%), and were set up with the goal to contain costs (64%). The review identified several elements that are essential for pooled procurement mechanisms to function. We organized these elements around three key actors in the mechanism: buyers, the pooled procurement organization, and suppliers. To participate in pooled procurement, buyers need a sufficient level of technical capacity, financial capacity and compatible laws and regulations. To carry out pooled procurement, the pooled procurement organization needs sufficient financial capacity, technical capac-

ity, and independent operations. To supply the mechanism with health commodities, suppliers need sufficient incentives, such as a sufficient market size and a prompt payment mechanism.

Conclusion: Pooled procurement mechanisms are very diverse. They differ in characteristics and organizational structures and are set up to achieve a variety of goals. While certain essential elements are more likely to increase successful implementation and functioning of pooled procurement mechanisms, the organizational structure must be aligned with the goals of the mechanism, and adapted to the local contextual environment.

Introduction

Providing access to affordable, quality-assured medicines remains an enduring challenge with complex roots, including global economic structures that reward monopolistic behavior; information asymmetry due to a lack of transparency around prices and costs; chronic under-investment in health systems; and corruption (Pisani et al., 2019; Seiter, 2010).

One approach, known as *pooled procurement*, has specifically been promoted to address several problems related to constrained access to affordable, quality-assured medicines, such as small market size of the buyer, limited technical capacity and human resources, and insufficient incentives to manufacture or supply specific medicines or vaccines (Espín et al., 2016; Management Science for Health, 2012; Nemzoff et al., 2019). In essence, pooled procurement (also referred to as joint, bulk, group, centralized, cooperative or collaborative procurement) can be defined as a collaboration initiative of buyers that consolidate their purchases (Management Science for Health, 2012; Pazirandeh & Herlin, 2014). Pooled procurement mechanisms have been implemented to achieve a variety of goals, including price reductions induced by demand aggregation (Karjalainen, 2011; Nollet & Beaulieu, 2005; Trautmann et al., 2009), improvement of procurement efficiency and quality standards by sharing technical capacity and human resources (Espín et al., 2016; Huff-Rousselle, 2012), increasing availability and securing supply sustainability by incentivizing suppliers and as a result increasing supplier competition (DeRoeck et al., 2006; Huff-Rousselle, 2012).

The history of pooled procurement mechanisms for medicines on the global health agenda dates back to the late 1970s. In 1978, the World Health Assembly (A31.32) underlined that collective purchasing might substantially reduce costs of medicines (World Health Organization, 1978). Around the same time, the first inter-country pooled procurement mechanisms, including the Gulf Cooperation Council (GCC)

and PAHO Revolving Fund (RF), were set up to purchase medicines and vaccines collectively (Nemzoff et al., 2019). Propelled by the global moral outrage during the AIDS epidemic in the late 1990s, the era of global health organizations, such as the Global Fund to Fight Aids, Tuberculosis and Malaria (Global Fund), the Global Drug Facility (GDF), the President's Emergency Plan for AIDS Relief (PEPFAR), and GAVI started at the beginning of century (Wirtz et al., 2017). These global health organizations started providing access to affordable and quality medicine based on pooled procurement principles.

Pooled procurement has been seen as successful in the context of global, disease-specific, third-party organization programs, such as the GDF, Global Fund, and PEPFAR (Management Science for Health, 2012). Based on the achievements of these global health organizations in consolidating demand and reducing prices and partly driven by recipient countries transitioning from donor funding, pooled procurement mechanisms are currently being promoted in other settings, such as inter-country and buyer's mechanisms (Huff-Rousselle, 2012; McDonnell et al., 2021; Nemzoff et al., 2019). More recently, the COVID-19 pandemic has increased the adoption of pooled procurement mechanisms. Buyers in Europe (McEvoy & Ferri, 2020), Africa (Munshi, 2020), the Americas (Pan American Health Organization, 2021) and at the global level the Covax initiative (Eccleston-Turner & Upton, 2021) have pooled together to procure vaccines and personal protective equipment in the fight against COVID-19.

Previous reviews of pooled procurement mechanisms have mainly focused on outcomes. For example, Seidman and Atun (2017) looked at cost savings achieved by pooled procurement mechanisms operating at various levels (e.g., sub-national, national and inter-country). None of the papers included in their review reported on reduction of stock-outs or increased availability of health products as a result of pooled procurement. Huff-Rousselle (2012) described a wider variety of outcomes of inter-country and global level pooled procurement

mechanisms, including cost savings, quality improvement, reduced corruption, more efficient procurement processes and increased access to medicines. The article also provided detail on various elements that have been essential in the operation of the selected pooled procurement mechanisms that this review focused on.

However, pooled procurement mechanisms are not a simple, uniform, one size fits all solution; indeed, they do not always even address the same problem. These mechanisms are complex, diverse, multi-component and context specific, varying in structural form, operational level, and product type. Also, these mechanisms require active work and effort by the actors involved to align the various motivations, goals and design. The expansion in the adoption of pooled procurement, and choices about the most appropriate mechanism and structure, should be based on a clear understanding of these factors. Yet to our knowledge, no attempt has been made to synthesize learning from existing academic enquiry into this diversity of pooled procurement mechanisms.

The current review focuses on processes as well as summarizing learning about outcomes. We searched empirical studies that focus on medicines or vaccines for evidence on the motivations, goals, actors, characteristics and elements that are required to implement and operate pooled procurement mechanisms. To our knowledge, this is the first review that focuses on empirical studies to identify essential elements for successful implementation and functioning of pooled procurement mechanisms for medicines or vaccines.

Analytical framework

For the purpose of this study, we define pooled procurement as a collaboration initiative that consists of two or more buyers, or a third-party organization that procures on behalf of its participating members (Huff-Rousselle, 2012; Nemzoff et al., 2019). To guide the analysis of the empirical studies, we developed a general analytical framework.

Within this analytical framework, we identified the key actors and their roles in the pooled procurement mechanism.

Key categories of actors

The pooled procurement mechanism is the structure that enables key categories of actors to interact and carry out the procurement at a certain moment in time. These key actor categories within the pooled procurement mechanism are:

- The **buyers**, ranging from healthcare organizations (e.g., primary healthcare facility, hospital) to countries. If an external funder is involved, the role of the buyer is split between the financial buyer (i.e., funder) and the physical beneficiary (i.e., recipient) (Ripin et al., 2014);
- The **pooled procurement organization**, which is set up to carry out the actual procurement. It can be seen as a focal institution that is tasked with the role of aligning the interests of different actors in the mechanism such as buyers and suppliers;
- **Suppliers**, which are the manufacturers, wholesalers and distributors that provide products to the pooled procurement mechanism.

The functioning of pooled procurement mechanisms is not only shaped by these key actors and their interactions, but also by the evolving world in which processes are embedded. These mechanisms need to be adapted to, embedded in, and appropriated to the local context.

Operational models

Pooled procurement covers a variety of operational models. Based on previous studies and documents, we have identified some of the important characteristics of these operational models, including their structural form, operational level, type of products to be pooled, motivations and goals of the pooled procurement mechanism.

The structural form of a pooled procurement mechanism can vary from a third-party organization procuring on behalf of its buyers, such as the GDF, to a more buyer's owned mechanism that operates more collaboratively, such as the pooled procurement mechanism of the Organisation of Eastern Caribbean States (OECS) (Bakker et al., 2006; Kenis & Provan, 2009; Schotanus & Telgen, 2007).

Pooled procurement mechanisms can take place on sub-national, national, inter-country and global level, procuring medicines ranging from single source (e.g., patented products), single disease (e.g., TB, HIV, Malaria), single product type (e.g., vaccines, orphan medicines, pediatrics) to multi-products (e.g., essential medicines) (Nemzoff et al., 2019).

As mentioned above, pooled procurement mechanisms have been implemented to achieve a variety of goals, including price reduction, increase availability, improve procurement efficiency and share technical capacity. Actors involved in the pooled procurement mechanism can have multiple motivations to participate and goals to achieve. This can become a barrier, especially if key actors are trying to achieve conflicting goals.

Developmental stages

Setting up and implementing pooled procurement mechanisms is a process over time. This process can be categorized into a few general stages: the pooled procurement mechanism as a promising solution, the creation of the mechanism, the start of operations, and the maturing stage of the mechanism. For the pooled procurement mechanism to evolve from one stage to another, key categories of actors that are involved in the mechanism have to align their interests, motivations and goals both within and between each actor category. They also have to ensure that they remain aligned with any major changes in context. When alignment is or becomes impossible, progress or implementation ceases, and the mechanism collapses; this can occur at any stage of development. The life cycle of a pooled procurement mechanism is not always linear. Some mechanisms are disrupted by changing

conditions and fall back to earlier stages. Others end after a long and fruitful life.

Methods

The systematic review was based on the methodology described in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Moher et al., 2009).[7]

Search strategy

We started with reviewing three scientific databases (PubMed, Scopus and Web of Science) in August 2020 to find key empirical publications on pooled procurement of medicines and vaccines. We searched for publications containing the search terms: pooled; joint; bulk; group; co-operative; collaborative or centralized along with procurement or purchasing. This was combined with medicine; medicines; pharmaceutical; pharmaceuticals; drug; drugs; vaccine or vaccines. Boolean operators were applied to combine search terms and truncation was used with the search terms to capture as many search results as possible.[8] Zotero (5.0) was used as a reference management software to organize references and check for duplications. We did not limit our publications with a specific time range in an attempt to capture as many publications on pooled procurement mechanisms as possible. We focused on peer-reviewed articles, as we set out to provide an overview of the academic literature. Another reason why we excluded gray literature documents was because these documents often did not provide a detailed description of their methodology, making it difficult to assess their eligibility.

[7] The PRISMA checklist can be found online in the article's supplementary material. See: https://doi.org/10.1186/s12992-022-00847-z

[8] The specific search terms can be found online in the article's supplementary material. See: https://doi.org/10.1186/s12992-022-00847-z

Inclusion criteria	Exclusion criteria
Peer-reviewed publications on pooled procurement of medicines or vaccines	Non-peer-reviewed publications or publications of pooled procurement around other type of products or taking place in other sectors
Publications that focus on primary data collection, or on the analysis of existing datasets	Editorials, perspectives, literature studies, commentaries and opinions
Publications that focus on existing or failed pooled procurement mechanisms	Pooled procurement simulations or modelling studies
Publications that focus on pooled procurement mechanisms operating on a sub-national level or higher	Micro-level pooling of <10 health facilities or hospitals. Our focus is mainly in understanding the functioning of pooled procurement mechanisms that aim to increase access, affordability and quality benefitting a larger population than the particular micro-level pool of health facilities and the target population it serves
Publications that are published in English	Publications in other languages
Full text availability of the publication	Full text unavailability of the publication

Table 2. Overview of the inclusion and criteria.

Then, the first author scanned the title and abstract fields, based on the inclusion and exclusion criteria described in Table 2. This was followed by reading the full texts of the remaining publications. To mitigate potential bias, three co-authors independently assessed a selection of 19 articles that were doubtful during initial screening on their relevance to our study objective. We had differing views on three publications. After discussion among the co-authors during team meetings, we reached consensus on the inclusion of the articles in our review. As our data analysis was nearly ending, the three databases were re-searched on July 20, 2021 with the same search terms for additional articles that were published since our last search in August 2020.

Data analysis and synthesis

We analyzed the publications included in our study, using NVivo 12 as our data analysis software. Analysis and synthesis were aided by insights we obtained during the development of our general analytical framework. We identified and extracted several characteristics of the included publications, such as the location of the pooled procurement mechanism (country, region or organization), the operating level (sub-national, national, inter-country or global), the structural form (buyer's or third-party), the type of products that are being procured (disease specific, product specific, single source, multiple products), the study type (e.g., quantitative, qualitative, case study), the motivations for setting up the pooled procurement mechanism according to the authors (cost containment, increase availability, improve quality, increase process efficiency), the outcome measures (e.g., price, cost, availability), the factors that influenced the implementation and operation of the pooled procurement mechanism, and the main findings of each study. After extracting the data on characteristics, we used a thematic synthesis approach (Thomas & Harden, 2008). First, we coded the papers inductively. Then, the first

author and at least one of the co-authors were involved in identifying relevant descriptive themes of the included articles. Finally, analytical themes were identified and discussed between all co-authors during several group meetings. These analytical themes were separated for buyers, the pooled procurement organization and suppliers.

Results

Review process and outcomes

Our initial search yielded 1596 publications, of which 352 came from PubMed, 1133 from Scopus and 111 from Web of Science. After removal of duplications, we were left with 1053 publications. After scanning titles and abstracts, while applying our eligibility criteria, we were left with 114 publications. We selected 37 publications after reading the full text of the publications. In April 2021, we re-searched the three search engines for additional publications. This search yielded 2 more studies. Based on snowballing (i.e., scanning references of included articles) we added 5 more studies, bringing the total publications included in our literature review to 44. Figure 6 shows the flowchart of the selection process of the included publications in this literature review.

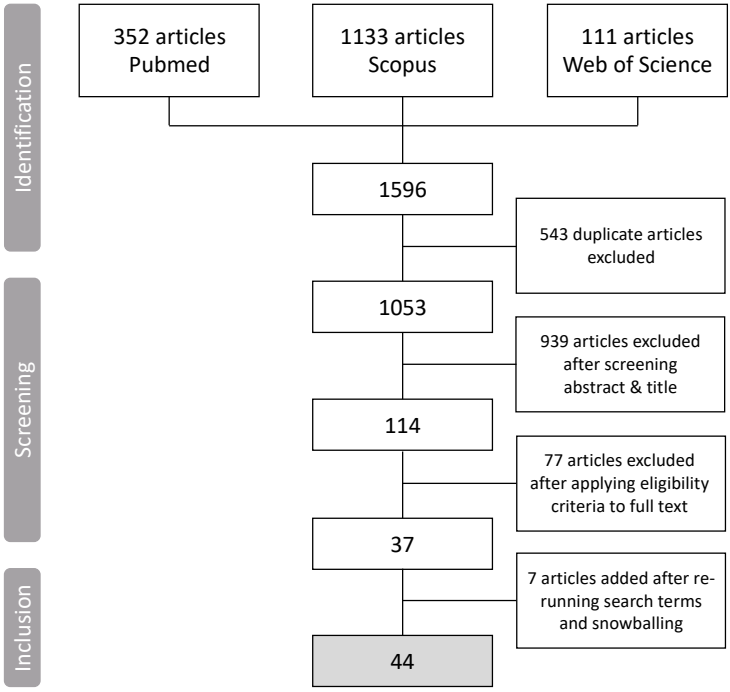

Figure 6. Flowchart of the selection process of the publications included in the literature review.

Characteristics of the pooled procurement mechanisms

We extracted three important general characteristics of the pooled procurement mechanisms described in the 44 included articles.[9] First, we identified the operating level of each pooled procurement mechanism (i.e., sub-national, national, inter-country and global). Figure 7 shows

[9] The characteristics of each pooled procurement mechanism included in our study can be found online in the article's supplementary material. See: https://doi.org/10.1186/s12992-022-00847-z

that the majority of the articles focused on pooled procurement mechanisms on sub-national level, followed by 11 at national level, 8 global level, and 6 inter-country pooled procurement mechanisms. 3 articles described or compared multiple pooled procurement mechanisms operating on both sub-national and national levels.

Second, we identified the type of product that was being procured by the pooled procurement mechanism described in the publication. These product types were categorized into disease specific (e.g., TB, HIV, Malaria), product specific (e.g., vaccines, orphan medicines, pediatrics), multiple products (e.g., essential medicines), single source (e.g., patented products), or as "not specified" if details on the product type were lacking. Figure 8 shows that the majority of the articles focused on pooled procurement mechanisms that procured multiple products, mainly essential medicines. This was followed by 11 articles on disease specific products, such as antiretrovirals (ARVs), cancer-medicine, hepatitis C medicine and antimalarials. 6 articles focused on product specific pooled procurement mechanisms, mainly vaccines.

Third, we identified the goals that each pooled procurement mechanism tried to achieve. These goals were based on the authors' description in each publication. We grouped these goals in four main categories: 1) to contain costs, 2) to improve quality, 3) to increase the efficiency of the procurement process and 4) to increase the availability of medicines or vaccines. The articles that did not mention any goal were grouped under "not specified". Also, some publications provided multiple goals. We added the articles containing multiple goals for pooled procurement to each goal category separately. Hence, the total number of articles does not add up to 44. Figure 9 shows that 28 articles mentioned cost containment as a goal for setting up the pooled procurement mechanism, followed by 8 articles that mentioned increasing availability of health products as the goal to achieve. 10 articles did not specify the goal for setting up the pooled procurement mechanism. In addition, we observed an increase in the number of publications on pooled procurement mechanisms in recent years. Figure 10 shows that 37 out of the 44 studies that met our eligibility criteria were published in the last ten years.

Furthermore, we have generated four world maps with varying pooled procurement operating levels to provide a global overview of the pooled procurement mechanisms described in the included studies. Each world map shows the countries that procure through a pooled procurement mechanism on a particular operating level. Figure 11a shows the countries mentioned in empirical studies that have a pooled procurement mechanism on sub-national level, Figure 11b shows the countries mentioned in empirical studies that have a pooled procurement mechanism on national level, Figure 11c shows the countries mentioned in empirical studies that have a pooled procurement mechanism on inter-country level, and Figure 11d shows the countries that procure through the global health organizations included in our review (i.e., Global Drug Facility, Global Fund, UNICEF Supply Division, UNRWA). This global overview shows that empirical studies of sub-national and national pooled procurement mechanisms have mainly focused on middle- and higher-income countries. There are very few empirical studies describing inter-country pooled procurement mechanisms, especially of failed attempts, in the English language peer-reviewed literature.

The remainder of this Results section is organized around the three categories of key actors that play a role in a pooled procurement mechanism: the buyers, the pooled procurement organization that carries out the actual procurement, and the suppliers. For each category of key actor, we identified elements essential for the successful implementation and functioning of pooled procurement mechanisms. While measures of success may vary, we classify these elements as essential because they appeared present in most or all well-functioning pooled procurement mechanisms, while where they were described as absent or incomplete, the mechanism often experienced difficulties or inefficiencies as a result. Our analysis concludes with an overview of pooled procurement's main outcomes that emerged from our analysis of the literature.

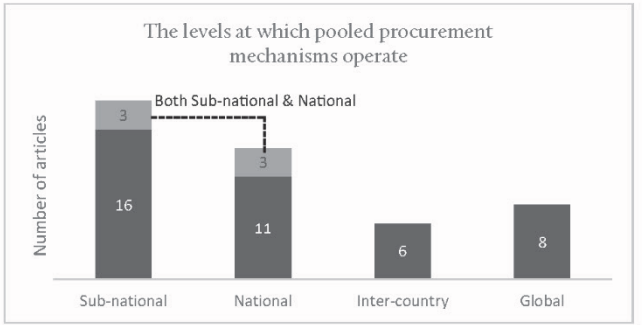

Figure 7. Number of articles per operational level.

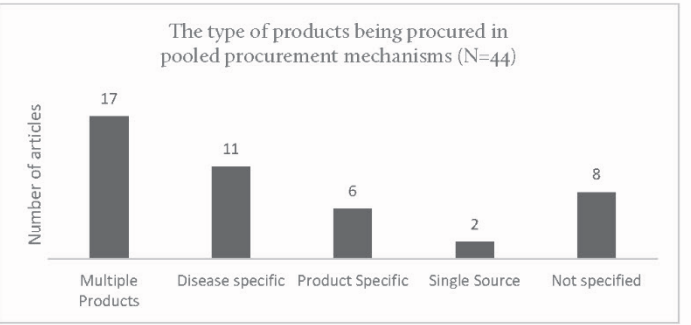

Figure 8. Number of articles per product type.

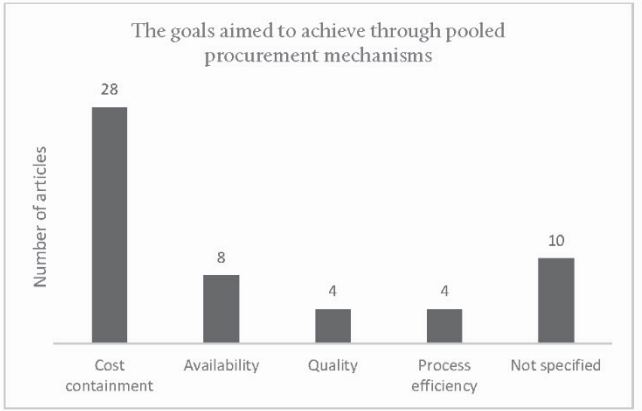

Figure 9. Number of articles containing any of the pooled procurement goal(s).

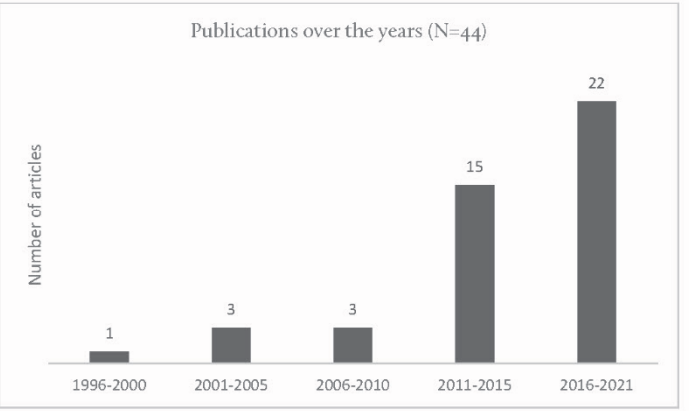

Figure 10. Number of articles published over the years.

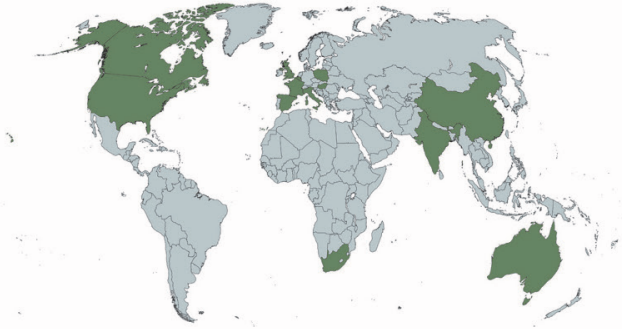

Figure 11a. Countries that have sub-national pooled procurement mechanisms included in our review.

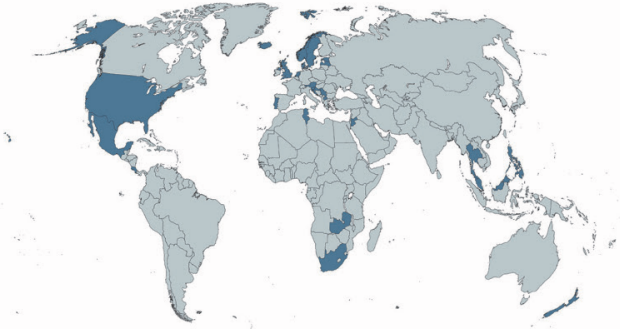

Figure 11b. Countries with national pooled procurement mechanisms included in our review.

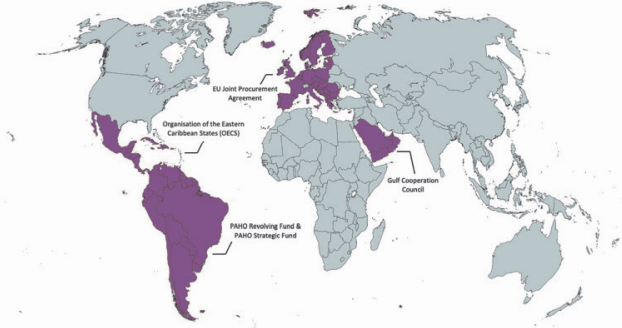

Figure 11c. Countries with inter-country pooled procurement mechanisms included in our review.

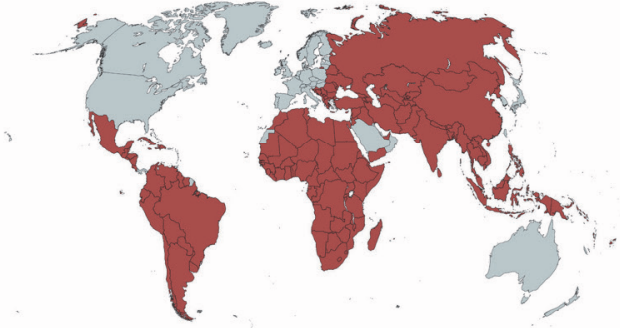

Figure 11d. Countries that procure through global health organization pooled procurement mechanisms included in our review.

Buyers

In the empirical studies, we found several elements that were essential at the level of the individual buyer, which ranged from a group of health facilities at the sub-national level to national level governments. The elements that emerged from the empirical studies included the buyer's degree of technical capacity, its level of financial capacity, and the presence of compatible laws and regulations.

Sufficient technical capacity of the individual buyer

A certain degree of technical capacity, which includes the presence of qualified human resources and the accuracy of demand forecasting, was required for all buyers to participate efficiently in a pooled procurement mechanism (Roy, 2013; Wafula, Marwa, et al., 2014). This was even the case for buyers for which the motivation to participate in a pooled procurement mechanism was a result of lacking technical capacity and inefficient procurement processes (Azzopardi-Muscat et al., 2017). In some cases, the lack of sufficient, dedicated and qualified procurement staff resulted in other staff having to take over the task of procurement on top of their existing responsibilities. For example, a case study focusing on the pooled procurement of Italian hospitals in Tuscany noted that mainly pharmacists were responsible for procurement related activities, compromising their clinical activities (Lega et al., 2013).

As mentioned above, another important aspect of technical capacity that was required at the individual buyer level to increase procurement efficiency was accurate demand forecasting. Demand forecasting is a crucial step to determine the appropriate quantity of each product at a given time to be procured. Underestimating demand can result in shortages, while overestimating can result in wastage. To procure the right quantity of a certain product at the right time, reliable demand data has to be provided by the buyer (Adesina et al., 2013; DeRoeck et

al., 2006; Osorio-De-Castro et al., 2009). However, even in the Organisation of Eastern Caribbean States' inter-country pooled procurement mechanism, accurate demand forecasting proved to be challenging at times (Huff-Rousselle & Burnett, 1996). The authors provided several reasons for the inaccurate forecasting, including inadequate stock management, formulary changes, marketing of new products by suppliers, partial shipments from previous orders and longer lead times. In another study, demand forecasts in three out of five Indian states included in the study, were based on overestimating last year's consumption data by 10-15% as a result of the lack of qualified staff. This lead to wastage of funding, resources and storage space (Singh et al., 2013). Some global health organizations, such as the Global Fund, have been trying to increase technical capacity by providing technical support and capacity building activities, including demand planning, quality testing, warehousing, logistics, monitoring and financial management (Kim & Skordis-Worrall, 2017; Kumaresan et al., 2004; Wafula, Marwa, et al., 2014). However, the empirical studies included did not report on the outcomes of this capacity building attempt in buyer countries.

Sufficient financial capacity of the individual buyer

Buyers also needed sufficient, timely and sustainable financial capacity to procure through the pooled procurement mechanism. For example, some of the public hospitals in Mexico that rely on centralized procurement of the Ministry of Health for cancer medicines experienced shortages due to insufficient funds at the hospital and ministerial level (Moye-Holz et al., 2020). Buyers lacking sufficient financial capacity were in some cases eligible for external funding from donor agencies, foreign ministries or other global (health) organization to procure their products through the mechanism (de Oliveira et al., 2011; Makinen et al., 2012). We identified a few examples of buyers, mainly participating in third-party global health organization pooled procurement

mechanisms, that rely on external funding to procure health products. For example, low income countries receiving GAVI-funding to procure their vaccines through UNICEF (Makinen et al., 2012), GAVI-eligible Latin American Countries to procure the Rotavirus vaccine through the PAHO RF (de Oliveira et al., 2011) and recipient countries that receive funding from the Global Fund to procure HIV, Malaria and TB medicines (Kim & Skordis-Worrall, 2017).

Compatible laws and regulations at the individual buyer

Buyers should also create a legal basis that allows for pooling between health facilities or countries. This means that national laws and regulations should be compatible with (international) pooled procurement and import of health commodities. Compatible laws and regulations were particularly relevant for inter-country or global pooled procurement mechanisms. For example, the adoption of the Decision on cross-border health threats (1082/2013/EU) by the European Parliament provided the required legal basis for the Joint Procurement Agreement to be negotiated (Azzopardi-Muscat et al., 2017). In the example of pooled procurement of ARVs in Latin America and the Caribbean, the participating countries paid higher prices than the negotiated reference price, which was partially due to incompatible legal frameworks to comply with the negotiated technical and administrative conditions (Osorio-De-Castro et al., 2009). One specific example of this are the national laws in Mexico. Chaumont et al. (2015) mentioned that national laws in Mexico limit the import of patented products to only the patent holder or an authorized licensee. This law prevents public institutions in Mexico to procure patented ARV medicines more cost-effectively through an international pooled procurement mechanism, such as the PAHO Strategic Fund. Other examples, both on sub-national and national level, underlined the importance of a legal basis for the functioning of pooled procurement mechanisms. In Italy, adaptations to national laws increased the legal mandate of

regional purchasing bodies such as signing framework agreements (Baldi & Vannoni, 2017), while the lack of a solid legal basis in China was seen as a potential reason for stakeholders to question the legality of pooled procurement in the long run (Chen et al., 2020).

Relative homogeneity at the inter-buyer level

When several buyers come together to procure through a buyer's pooled procurement mechanism (as opposed to a mechanism outsourced to a third party), the relative homogeneity of the buyers' characteristics at the inter-buyer level appeared to be important for the functioning of mechanism. These buyer characteristics included the joint need for specific products, the market size and demographics. The Eastern Caribbean Drug Service, now called the Organisation of the Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS), is an example of an inter-country pooled procurement mechanism where nine fairly similarly sized island nations pool together to increase their collective market size (Huff-Rousselle & Burnett, 1996). These nations shared similarities in financial capacity and epidemiological needs. They also benefit from a single central bank and currency, and have developed a joint Regional Formulary and Therapeutics Manual (Huff-Rousselle & Burnett, 1996).

The level of homogeneity of the buyer characteristics directly influences the ability to align motivations, goals and purpose of the pooled procurement mechanism among buyers (Meehan et al., 2017). The more divergent buyers' characteristics are, the more likely it is that the buyers' motivations to participate and goals will differ, or even conflict. In the case of a third-party organization pooled procurement mechanism that procures on behalf of its buyers, the motivations, goals, needs and purpose should be aligned between the individual buyer and the third-party organization (Vaillancourt, 2017). This became also apparent in another example of health centers in Quebec, Canada. In addition to diverging goals between buyers, the goals of some of the

participating health centers (i.e., buyers) were misaligned with the goals of the pooled procurement organization (i.e., purchasing group) (Nollet et al., 2017). According to some of the participating health centers, the third-party organization lacked flexibility to adapt to the needs of the health centers, restricting the scope of the products being procured.

Shared values for productive collaboration

Multiple articles underlined the importance of some essential general values that facilitate the process of productive collaboration and alignment. These values included sharing data and information in a transparent way (Adesina et al., 2013; Azzopardi-Muscat et al., 2017; Chaudhury et al., 2005; DeRoeck et al., 2006; Osorio-De-Castro et al., 2009; Perez et al., 2019; Vaillancourt, 2017), managing positive relationships (Meehan et al., 2017; Nollet et al., 2017; Vaillancourt, 2017), good communication and maintaining sufficient trust levels, both among buyers and between buyers and the pooled procurement organization (Chaudhury et al., 2005; Gómez-Dantés et al., 2012; Huff-Rousselle & Burnett, 1996; Meehan et al., 2017; Nollet et al., 2017; Perez et al., 2019). However, the empirical studies provided limited description of the specific activities required to achieve these values.

Pooled procurement organization

We identified several elements that the pooled procurement organization, which is an organization that is set up to carry out the actual procurement, had to meet to procure health products successfully. The elements that emerged from the empirical studies included the pooled procurement organization's level of financial capacity to both carry out procurement and cover organizational expenses, the organization's degree of technical capacity, and the organization's operational values and principles.

Sufficient financial capacity of the pooled procurement organization

Like buyers, the pooled procurement organization also needs sufficient, timely, and predictable budget. This budget is required to both procure health products, as well as to cover organization expenses (Singh et al., 2013). The empirical studies highlighted two main sources for the pooled procurement organization to secure sufficient, timely, and predictable budget to carry out pooled procurement: through buyers and through donor funding.

The OECS/PPS provides an illustrative example of buyer-financed budget. The island nations, which share a common currency, established a revolving fund at the inter-country level, managed by the Eastern Caribbean Central Bank. This financing structure allowed all participating countries to commit one third of their annual pharmaceutical budget to the mechanism, even before its establishment (Huff-Rousselle & Burnett, 1996). This was a clear demonstration of deep political commitment of the buyers. International global health organizations, such as the Global Fund and GDF, rely mainly on donor funding to aggregate sufficient, timely, and predictable budget to carry out pooled procurement (Kumaresan et al., 2004; Wafula et al., 2013).

Likewise, sufficient and timely budget is needed to cover organizational expenses. Azzopardi-Muscat et al. (2017) underlined that the lack of a dedicated central level financing to cover organizational expenses within the European Union Joint Procurement Agreement was a potential threat to the sustainability of the program. As shown in Table 3, we identified five different ways of covering organizational expenses: service fees paid by buyers; service fees paid by suppliers; membership fees paid by buyers; membership fees paid by suppliers; and external donor funding. For each way of financing, an example from the empirical studies is provided. Some mechanisms cover their organizational expenses through a combination of these payment forms.

Sources to cover organizational expenses	Explanation	Example
Service fees paid by buyers	*The service fee, often a fixed percentage added to each order, is paid by the buyer.*	The Organisation of the Eastern Caribbean States financed their organizational expenses through a 15% service fee on top of each order (Huff-Rousselle & Burnett, 1996).
Service fees paid by suppliers	*The service fee is paid by the supplier.*	The Gulf Cooperation Council (GCC) covered organizational expenses through country membership fees (see below) and supplier fees (e.g., sale of tender documents, supplier registration fees) (DeRoeck et al., 2006).
Membership fees paid by buyers	*A membership fee to participate in the mechanism is paid by the buyer.*	The PAHO Revolving Fund (RF) covered organizational expenses through PAHO's general budget paid by buyer countries (DeRoeck et al., 2006).
Membership fees paid by suppliers	*A membership fee to participate in the mechanism is paid by the supplier.*	Some Vaccine Purchasing Groups (VPGs) in the United States covered organizational expenses through membership fees, paid by the suppliers. VPGs reached agreements with vaccine suppliers, who in turn provided buyers with price discounts if buyers met the requirements of the supplier's loyalty program. Suppliers assessed buyer-loyalty by monitoring sales data (Cowan et al., 2016).

Donor funding	*The organizational expenses are covered by an external funder (i.e., donor).*	The Global Drug Facility covers their operational expenses mainly through external donor funding (Kumaresan et al., 2004). Donor funding is only sustainable if the procurement organization manages to limit their reliance on a single donor or manages to establish long-term partnerships with the donor.

Table 3. Different sources to cover organizational expenses of pooled procurement mechanisms.

Sufficient technical capacity of the pooled procurement organization

The functioning of pooled procurement mechanisms heavily relied on the technical capacity present at the level of the pooled procurement organization. To function successfully, the organization needed to have sufficient resources to carry out or outsource procurement tasks such as assessing product quality, aggregating demand data, tendering, and establishing an efficient payment mechanism. For example, the GDF has a dedicated secretariat with clear roles and responsibilities. For specialized tasks such as supply and quality-assurance, the GDF outsources its tasks to external agents on a contractual basis. According to Kumaresan et al. (2004), the GDF achieves higher operational efficiencies through outsourcing to external agents with expertise. In addition, Chaudhury et al. (2005) underlined that committed staff and sufficient technical capacity as a result of ongoing training programs were among the critical success factors for the functioning of Delhi's essential drug program, which includes its pooled procurement mechanism. The lack of sufficient technical capacity to assess the supplier's ability to fulfil contracts at the level of the organization led to

decreased availability of medicines in some local areas in China (Yang et al., 2017).

In addition to outsourcing, pooled procurement organizations have tried to increase qualified human resources in two ways: by pooling the available expertise and staff among its buyers to create expert networks (Azzopardi-Muscat et al., 2017; Gómez-Dantés et al., 2012); and by pooling resources to attract expert staff from outside the buyers pool (Baldi & Vannoni, 2017).

Independent operations of the pooled procurement organization

The concentration of authority in a single organization can be a double-edged sword. As the intermediator that carries out the actual procurement, the pooled procurement organization centralizes data, bargaining power, and procurement decisions. On the one hand, this allows for increased efficiency. On the other, it might make the organization vulnerable to influences of conflict of interest and even corruption if there are no checks and balances in place to guarantee independence and transparency of the organization and its staff. Several studies stressed that relative independence of the pooled procurement organization, which may limit the potential for conflicts of interest, is essential to function and achieve its intended outcomes. (Azzopardi-Muscat et al., 2017; Baldi & Vannoni, 2017; DeRoeck et al., 2006; Moye-Holz et al., 2020; Shi et al., 2018; Singh et al., 2013; Wafula, Marwa, et al., 2014). In many Chinese provinces, pooled procurement organizations have not been operating independently (Shi et al., 2018). These organizations were often affiliated with the health bureaus, responsible for public health in the county. Experts in the study (Shi et al., 2018) hypothesized that concentration of procurement power at the central level could facilitate bribing, since fewer people and organizations are involved in the process. Baldi and Vannoni (2017), however, demonstrated that areas in Italy with higher levels of corruption or lower levels of institutional quality benefited most from pooled procurement's

price reduction. The authors speculated that a central authority with high levels of institutional quality might be protected more effectively from influences of corruption and local favoritism of suppliers because larger tenders provide fewer opportunities for bribery.

The empirical studies also mentioned the importance of the organization's standardized and transparent procedures. Singh et al. (2013) underlined that transparency was needed at all levels of procurement. The procurement organizations in Tamil Nadu and Kerala established autonomous pooled procurement organizations. They also involved multiple stakeholders throughout their procurement, which contributed to open and transparent procurement processes. Separating the responsibilities of staff, such as awarding winners and paying suppliers, also reduced the vulnerability to conflict of interest. Shi et al. (2018) added that the procurement criteria set by pooled procurement organizations in China were often not scientifically based and difficult to quantify, leaving room for ambiguity and possible corruption. Wafula, Marwa et al. (2014) mentioned that the majority of countries receiving funding from the Global Fund opposed enforced procurement through the Global Fund's pooled procurement mechanism. Potential valid reasons for recipient countries to oppose enforced participation were the already existing sufficient technical capacity and experience at procurement agencies (Wafula, Marwa, et al., 2014), or the creation of over-dependence on external organizations, which might weaken health systems (Kim & Skordis-Worrall, 2017). Although not validated in the study (Wafula, Marwa, et al., 2014), another potential reason provided by the authors for opposing enforced participation might have been self-interest driven by procurement staff. Through enforced participation, procurement staff in recipient countries would lose their decision-making power, and possibly their channel to obtain illegitimate income.

Suppliers

Healthy supplier competition

In addition to buyers and the pooled procurement organization, suppliers are a fundamental category of actors that play a crucial role in the functioning of pooled procurement mechanisms. The articles pointed out a significant trade-off between short-term economic benefits and potential long-term availability issues.

On the one hand, the pooled procurement mechanism needs a healthy competition of suppliers in the market that are willing to participate in the tender. 17 of the 44 included studies have stressed the importance of supplier competition to sustain a pooled procurement mechanism. Sufficient supply-side competition has been linked with lower medicine and vaccine prices (Song et al., 2018; Wafula, Agweyu, et al., 2014; Wafula et al., 2013; Zhuang et al., 2019), whereas the price-reducing effect of pooled procurement mechanisms reduced in monopoly markets (i.e., single source products) (Dubois et al., 2021). Malaysia's policy to prefer local generic suppliers over international suppliers also reduced supply-side competition, which might reduce the pressure for local suppliers to lower prices (Hamzah et al., 2020).

On the other hand, a few studies (Chen et al., 2020; Meehan et al., 2017; Qendri et al., 2019; Song et al., 2018; Yang et al., 2017) have mentioned pooled procurement's potential influence on reducing competition on the supply-side. The reason given is that pooled procurement mechanisms aggregate demand, resulting in larger but less frequent tenders. The extensive pressure on prices might result in a race to the bottom for suppliers, driving out mainly small and medium suppliers. This might erode market competition, which eventually leads to shortages and an increase of medicine prices in the longer run. Although this explanation might be plausible, none of the included studies have demonstrated pooled procurement's supplier competition reducing effect in practice. This lack of empirical evidence was also mentioned by Toulemon (2018) and Burns and Lee (2008).

Incentives to supply

To increase supplier competition, the pooled procurement organization needs to offer suppliers sufficient incentives to participate in the mechanism. Several supplier incentives have been mentioned in the literature, such as creating a sufficient market size (Alabbadi, 2011; Azzopardi-Muscat et al., 2017; Cowan et al., 2016; DeRoeck et al., 2006; Huff-Rousselle & Burnett, 1996; Makinen et al., 2012; Nollet et al., 2017; Wafula et al., 2013). One way of increasing the market size for certain products is through unifying medicine formularies (Alabbadi, 2011; Huff-Rousselle & Burnett, 1996). Other supplier incentives included adopting an efficient and prompt payment mechanism (Azzopardi-Muscat et al., 2017; Chokshi et al., 2015; de Oliveira et al., 2011; DeRoeck et al., 2006; Huff-Rousselle & Burnett, 1996; Makinen et al., 2012; Singh et al., 2013), adopting standardized and transparent procurement procedures (Chaudhury et al., 2005; Chokshi et al., 2015; Huff-Rousselle & Burnett, 1996), issuing long-term framework agreements (Makinen et al., 2012; Qendri et al., 2019; Vaillancourt, 2017), aggregating accurate demand forecasts provided by the buyers (Adesina et al., 2013; DeRoeck et al., 2006; Makinen et al., 2012), protecting intellectual property rights (Adesina et al., 2013), and awarding multiple winners for tenders (DeRoeck et al., 2006; Huff-Rousselle & Burnett, 1996; Yang et al., 2017).

Outcomes of pooled procurement mechanisms

Figure 9 shows that there were four main goals for establishing a pooled procurement mechanism, as reported by the authors: to contain costs, to increase availability, to increase quality and to increase the efficiency of the procurement process. Similarly, the reported outcomes in the papers mainly focused on these four categories. However, the outcome reported in a paper did not necessarily match the main reason for establishing the mechanism. Hence, the number of papers provided in the following sections do not match the numbers in Figure 9.

Prices of medicines or vaccines

29 empirical studies reported on the effect of pooled procurement on prices or costs of medicines or vaccines. The majority of the papers observed a price reduction after introduction of pooled procurement (Alabbadi, 2011; Baldi & Vannoni, 2017; Burns & Lee, 2008; Chaudhury et al., 2005; Chen et al., 2020; Chokshi et al., 2015; DeRoeck et al., 2006; Huff-Rousselle & Burnett, 1996; Kumaresan et al., 2004; Lega et al., 2013; Moye-Holz et al., 2017; Qendri et al., 2019; Roy, 2013; Song et al., 2018; Tordoff et al., 2005; Toulemon, 2018; Wafula, Agweyu, et al., 2014; Wafula et al., 2013).

For example, Shi et al. (2018) mentioned that pooled procurement at the provincial level in China reduced medicine prices by around 30% in Beijing, 41% in Hebei and 46% in Shandong. Perez et al. (2019) even observed a 90% reduction of hepatitis C medicine prices in Colombia after procuring through the PAHO Strategic Fund, an inter-country pooled procurement mechanism. The authors attributed this price reduction to a combination of factors, including a comprehensive design and implementation strategy leading to the alignment of needs between various stakeholders, and the adoption of laws and regulations. Dubois et al. (2021) noted that the pooled procurement mechanisms included in their study led to a reduction of medicine prices by 15% on average. They hypothesized that price reduction might have been caused by the buyer's increased bargaining power in combination with higher purchase volume. However, where supply side was more concentrated (i.e., less supplier competition), the observed price reducing effect of pooled procurement became less.

Not all studies recorded sustainable price decreases as a result of implementing pooled procurement. Prices of patented ARVs in Mexico reduced with 38% after the first round of joint negotiations in 2008 (Adesina et al., 2013). However, the price reductions between 2008 and 2013 were minimal (Chaumont et al., 2015), and remained on average

five to six times higher for some ARVs compared to economically comparable countries (Adesina et al., 2013; Chaumont et al., 2015). Adesina et al. (2013) hypothesized that the initial price reduction of ARVs in Mexico might have been influenced by global trend of ARV price reductions during that time.

Zhuang et al. (2019) reported that prices of category 2 vaccines in China, which are non-mandatory vaccines that require payment from the patients, increased after introduction of pooled procurement in 2016. Possible reasons were related to quality, see section on quality below.

Kim and Skordis-Worrall (2017) found that the Voluntary Pooled Procurement mechanism of the Global Fund reduced the ex-works price of Efavirenz by 16.2%. However, they found no connection between transaction volume and price reduction or between market competition and price reduction. The price reduction was partially attributed to a general decreasing trend of ARV prices between 2005 and 2013. Similarly, Singh et al. (2013) found no connection between volume and price. The prices of some of the 32 selected medicine were higher in Tamil Nadu, which is expected to have significantly higher medicine consumption compared to Odisha, Punjab and Maharashtra.

He et al. (2018) observed no decrease in medicine prices or in total health expenditure after introduction of the Centralized Procurement of Medicine Policy in Sanming, China. Prior to implementation of this policy, Sanming adopted a Zero Mark-up Drug Policy, forcing hospitals to sell medicines at wholesale price. This policy led to significant reduction of medicine expenditure in the short term. This reduction diminished after the introduction of Centralized Procurement of Medicine Policy. Potential explanations given by the authors included the existence of a form of pooled procurement before the introduction of the Centralized Procurement of Medicine Policy, and the presence of kickbacks that incentivize physicians to overprescribe medicine.

Availability of medicines or vaccines

11 studies reported on pooled procurement's effect on availability of medicines or vaccines. Chaudhury et al. (2005) observed that availability of essential medicines increased in several tertiary hospitals in Delhi after implementing pooled procurement. Similarly, Wafula et al. (2013) mentioned increased availability of malaria commodities after implementation of the Global Fund's Voluntary Pooled Procurement.

Sruamsiri et al. (2015) noted significant increases of patients treated with cancer medicines in Thailand, which was used as a proxy for availability. However, the effect of pooled procurement on increased availability could not be determined, because during the same time the Thai government implemented additional pharmaceutical policies, such as issuance of compulsory licenses and price negotiations.

Chokshi et al. (2015) observed that Tamil Nadu managed to find suppliers for all medicines on their procurement list, while Bihar was only able to find suppliers for 56%, 59% and 38% of their medicines in 2006, 2007 and 2008, respectively. Although both states pooled their procurement of medicines, the authors explained that the difference was mainly caused by the financing and distribution mechanisms in Tamil Nadu, which were much more integrated with the procurement process compared to Bihar.

In contrast, Song et al. (2018) observed no increase in the overall availability of essential medicines in primary healthcare facilities after implementation of pooled procurement in two Chinese provinces, namely Shandong and Ningxia.

Procurement efficiency

17 studies reported on the effect of pooled procurement on the efficiency of procurement processes. A few studies pointed out that pooled procurement might be particularly beneficial for smaller buyers in the pool because they are expected to benefit most from increased market size, increased technical capacity, human resources and

financial capacity (Azzopardi-Muscat et al., 2017; DeRoeck et al., 2006; Makinen et al., 2012).

Budgett et al. (2017) noted increased standardization as a result of integrated procurement and information technology processes, both on national level in Costa Rica, as well as sub-national level in Victoria, Australia. Similar process efficiencies and standardizations were described in Italian hospitals in Tuscany (Lega et al., 2013), the OECS (Huff-Rousselle & Burnett, 1996), the GDF recipient countries (Kumaresan et al., 2004), the PAHO RF and in the GCC (DeRoeck et al., 2006).

Quality of products

There were only 3 studies reporting on the relationship between pooled procurement and the quality of medicine or vaccines.

The paper of Zhuang et al. (2019), referred to in the section on prices of medicines or vaccines, reported that the increase of prices of category 2 vaccine in China after the introduction of pooled procurement was potentially related to the increase of quality standards. These quality standards included the adoption of a standardized vaccine list with registered vaccines, the reduction of substandard or falsified vaccines and elimination of illegal or unregistered suppliers. The authors noted that other factors, such as purchase volume, inflation and the number of vaccine producers might also have affected the vaccine prices.

Two papers focused on the drug policy to increase access to essential medicines, adopted in 1994 by the state government of Delhi, India (Chaudhury et al., 2005; Roy, 2013). As part of this policy, Delhi implemented pooled procurement mechanism. To secure quality, a quality-assurance mechanisms, including prequalification of suppliers, Good Manufacturing Practice inspections, testing of procured batches in accredited laboratories, and sanctions for suppliers if medicines failed quality testing were integrated into the pooled procurement mechanism. As a result, the medicines that failed quality control decreased

from 1.45% in 2001 to 0.13% in 2009. This policy resulted in procurement of quality medicines for low costs in Delhi, India (Chaudhury et al., 2005; Roy, 2013).

Discussion

Pooled procurement of medicines and vaccines has been promoted and implemented to achieve a variety of goals, including lower prices, increased availability, higher quality and more efficient procurement processes. This review aimed to identify the elements that are essential in successfully implementing and operating pooled procurement mechanisms that meet some or all of these goals.

Essential elements for pooled procurement

In our analytical framework and analysis, we identified a great variety of pooled procurement mechanisms in terms of goals, structural form, operating level, type of products to procure, and outcomes. Although we identified essential elements for each key actor and various positive outcomes of pooled procurement mechanisms, the empirical papers tended to be narrowly focused in their analysis and insufficiently considered the interplay of these characteristics within the local contextual environment of each mechanism to identify general patterns. But in interpreting some of the results, we could infer that a combination of specific elements played an essential role in the implementation and functioning of specific pooled procurement mechanisms.

Our analysis shows that buyers require a certain level of technical capacity (e.g., to carry out accurate demand forecasting), financial capacity (e.g., to procure medicines or vaccines), compatible laws and regulations, and alignment of needs to participate in a pooled procurement mechanism. Similar elements have also been identified by non-academic reports and documents on pooled procurement of medicines and vaccines (Espín et al., 2016; World Health Organization, 2014). The

comparison between Mexico and Colombia provides an illustrative example. Two Latin American countries that have turned towards pooled procurement as a solution to reduce prices of patented medicines. Mexico set up a national joint negotiating mechanism to reduce ARV prices, while Colombia started procuring hepatitis C medicines through the PAHO Strategic Fund, an inter-country level mechanism. Although both countries observed price reductions, Mexico's price savings diminished after the initial negotiating round and ARV prices remained relatively high compared to other countries of similar economic status. Despite the medicines procured through the mechanisms targeted different diseases, the type of product (i.e., high-cost patented products) was similar in characteristics. We hypothesize that the presence of a specific combination of elements was at the basis of the difference in observed price outcomes.

Mexico's national law protected the patent holder and restricted the government to procure medicines through an inter-country pooled procurement mechanism, such as the PAHO Strategic Fund, for an even lower price (Chaumont et al., 2015), whereas Colombia's national law provided a legal basis for their participation in the PAHO Strategic Fund (Perez et al., 2019). In addition, the implementation of the mechanism in Colombia was a collaborative process between involved stakeholders resulting in alignment of incentives, and increased levels of transparency and ownership (Perez et al., 2019), while the mechanism in Mexico faced challenges of insufficient communication among committees and institutions (Gómez-Dantés et al., 2012) and lacked a clear description of the roles and responsibilities of the negotiating organization (Adesina et al., 2013).

Similarly, the pooled procurement organization or secretariat needs sufficient, timely and predictable budget to procure health commodities and cover organizational expenses. The procurement organization also needs sufficient technical capacity, both in terms of human

resources and expertise; to operate independently and transparently; and to provide suppliers with sufficient incentives to participate. However, pooled procurement's influence on supplier competition remains a debated issue. To sustain the pooled procurement mechanism, suppliers need to be incentivized to participate and the procurement organization needs to maintain the conditions for healthy supplier competition. In our analysis, we have described various supplier incentives that have been mentioned in the empirical studies. Pooled procurement organizations, however, need to strike a balance between pressing down on prices and sustaining a healthy supplier competition. Although the studies provided no empirical evidence, some articles mentioned that striking this balance might be challenging in practice because pooled procurement organizations are most effective in lowering prices when there are a maximum number of suppliers participating, while a minimum number of suppliers are awarded a contract. One way to tackle this potential imbalance is through awarding *multiple-winner* contracts instead of *winner takes all* contracts, which might increase supplier competition and secure supply sustainability in case of production disruptions (Barton & Berger, 2022a; Management Science for Health, 2012; Silverman et al., 2019).

Market shaping, which has received little attention in the included empirical academic literature, is another way for the pooled procurement organization to attract and incentivize suppliers. These market shaping efforts focus on providing a more comprehensive approach, including but not limited to pooled procurement, to create a sustainable market for specific product types (e.g., vaccines, diagnostics) or diseases (e.g., HIV, TB, malaria) with unmet needs because of market failures. These markets have previously been non-existent or economically unfeasible to produce for or supply to (Boston Consulting Group, 2019; Silverman et al., 2019; USAID Center for Accelerating Innovation and Impact, 2014). Various reports and documents have underlined market shaping efforts as essential for the successful implementation

and functioning of mainly third-party, global health organization pooled procurement mechanisms. Examples of market shaping efforts include stimulating research and product innovation, generation of evidence through piloting the introduction of new products, simplifying and standardizing complex treatment regimens into fixed-dose combinations, supplier relationship programs, and capacity building efforts such as guidance on product selection or quality assurance policies (Boston Consulting Group, 2019; Management Science for Health, 2012; Silverman et al., 2019; USAID Center for Accelerating Innovation and Impact, 2014).

Limited evidence on the implementation process

The studies provided little detail on how and under which specific circumstances pooled procurement mechanisms were realized. The implementation and operation of pooled procurement mechanisms is not a singular event, but a process that evolves over time. The studies included have provided little empirical evidence on these developments.

An important question that remains is: what specific work is required to align the motivations and goals of key actors to realize implementation of these mechanisms? Pooled procurement mechanisms do not emerge automatically. They are set up to provide solutions to certain problems that key actors might perceive. Converting these *individual problems* into a *shared pooled procurement solution* is a complex and multi-component process that requires active work and effort by the actors involved. Various pooled procurement initiatives have failed even before being realized, such as the Pacific Island Countries (Mendoza, 2010; World Health Organization Regional Office for the Western Pacific, 2009); have remained in the realization phase, such as the East African Community (Syam, 2014); or have failed after early operationalization, such as the Asthma Drug Facility (Bissell et al., 2016) or the African Association of Central Medical Stores for Essential Drugs (ACAME) (World Health Organization, 2014). We plan further

studies to examine the process of setting up pooled procurement mechanisms and to identify what is required to align motivations, goals and purpose between actors of the mechanisms.

Limitations

The articles and data included in this review carry a risk of bias. Similar to Seidman and Atun's (2017) observations, we noticed that the majority of the studies included provided examples of pooled procurement mechanisms that have been set up successfully. However, we are also aware of a number of pooled procurement initiatives which were not referred to in the peer reviewed articles yielded by our search. Several of these never reached the buying stage, while others collapsed after implementation. We conclude that mechanisms described in the papers in this review might be biased towards more successful outcomes of pooled procurement.

In addition, a potential selection bias might have occurred due to inclusion of only peer-reviewed empirical articles in English. Although we also searched for papers published in Dutch, no empirical publications meeting our eligibility criteria were found. Future investigations with different scopes may do well to include primary source material and gray literature, including program documentation, program evaluations, and press scans in different languages.

Another potential limitation is that we were unable to carry out a robust quality assessment of the articles included. Setting up universal quality appraisal criteria were both difficult and undesirable because of the wide scope of pooled procurement mechanisms included and their varying methods to assess and quantify their outcomes. Instead, we decided to include studies based on their relevance and their ability to meet our eligibility criteria. To minimize potential bias, we triangulated our findings between the articles. However, the importance of certain essential elements may have been over- or underemphasized, and we advise readers to interpret the findings of this review with this in mind.

Conclusion

Pooled procurement is a wide-ranging approach referring to different possible organizational structures, aiming to achieve a variety of goals, such as reducing prices, increasing availability or achieving more efficient procurement processes. While we have been able to identify certain common elements from empirical studies which increase likelihood of successful implementation and functioning of pooled procurement mechanisms, we believe that mechanisms must be matched to goals and content to maximize chances of success.

4

From promise to practice: A guide to developing pooled procurement mechanisms for medicines and vaccines

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Abstract

Introduction: Buyers of medicines and vaccines are increasingly interested in pooling their procurement to improve access to affordable and quality-assured health commodities. However, the academic literature has provided no detailed description of how pooled procurement mechanisms are set up and develop over time. These insights are valuable as it increases our understanding of implementing and operating pooled procurement mechanisms successfully. Therefore, the aim of this paper is twofold. First, to explore how such mechanisms evolve over time. Second, to clarify the work that is needed to set up and sustain a pooled procurement mechanism. These findings have been translated into our Pooled Procurement Guidance document.

Methods: This qualitative study draws upon theoretical insights from organizational life cycles, collaborative and network governance, semi-structured interviews with procurement experts and academic and grey literature documents on pooled procurement of medicines and vaccines.

Results: We identified four general developmental stages of pooled procurement mechanisms: promise, creation, early operational and mature. The promise stage is characterized by initiating engagement between participating actors, while they try to convert their perceived problem(s) or opportunities into a shared vision. The creation stage is where the participating actors formalize and design the mechanism through consensus-building, articulation of a shared plan, and mobilize resources to put the shared plan into action. The early operational stage is where the shared plan is being executed. The newly established or appointed procurement organization is required to learn fast from experience while showing flexibility to the changing needs of buyers

and suppliers. Once operations are routinized, the mechanism enters the mature stage. During this stage, the pooled procurement organization develops into a trusted player that provides sufficient incentives for all actors involved. Importantly, pooled procurement mechanisms can stagnate or turn inactive at any time during the developmental process when alignment between actors is threatened.

Conclusions: Pooled procurement mechanisms evolve over time. Setting up such mechanisms is a collaborative process that relies on intentional efforts by key actors involved. To increase the lifespan of pooled procurement mechanisms, key actors need to sustain a relative alignment of goals, needs, motivations and purpose of the mechanism throughout its entire life cycle.

Introduction

Pooled procurement, seen as a collaborative effort between buyers to consolidate their purchases, is implemented to achieve a variety of goals, including price reductions, improvement of procurement efficiency, incentivizing suppliers to secure supply and increase availability of products (Huff-Rousselle, 2012; Parmaksiz et al., 2022; Vogler et al., 2022). Although pooled procurement mechanisms have received increased attention as a potential solution to improve access to affordable and quality-assured medicines, setting up such mechanisms is not a straightforward process in practice. Some pooled procurement mechanisms never get beyond their promise after years of discussions. Other mechanisms have launched, but have failed to achieve their intended goals, such as lowering prices. There are also examples of mechanisms that have been scaled down or even ceased to exist after a short period of operation (Bissell et al., 2016; Parmaksiz et al., 2022; World Health Organization, 2014).

In a recent review of the academic literature on pooled procurement mechanisms for medicines and vaccines (Parmaksiz et al., 2022), several essential elements were identified that appeared to be critical for setting up and operating pooled procurement mechanisms. These included compatible laws and regulations, sufficient technical capacity for accurate demand forecasting and financial capacity for buyers. Similarly, the pooled procurement organization needed sufficient budget to procure health products and cover organizational expenses, and technical capacity to carry out procurement. Suppliers needed sufficient incentives to participate, such as accurate demand forecasts, framework agreements, and a timely payment mechanism. The systematic review (Parmaksiz et al., 2022) also described the complexity and diversity in the operational models of pooled procurement mechanisms. These mechanisms varied in their structural form (ranging from a third-party organization that procures on behalf of its

buyers to a more buyer's owned/inter-buyer mechanism that operates more collaboratively), operational level (i.e., sub-national, national, inter-country and global level), type of products to be pooled (e.g., single source, single disease, single product type, multi-products) and motivations and goals of the pooled procurement mechanism (e.g., price reduction, increase availability, procurement efficiency and share technical capacity).

However, there are limited studies that explore how pooled procurement mechanisms came into existence and how they developed over time. Nollet and Beaulieu (2003) explored the development of purchasing groups in the US healthcare sector, highlighting critical success factors and the need for adaptation to their changing environment. However, their study focused only on hospital collaborations and historical development of the entire "sector", rather than a single collaboration initiative. Another recent study by Vogler et al. (2022) on centralized national procurement in six European countries verified the lack of empirical insights into the development of pooled procurement mechanisms. Although the study provided rich descriptions of national level mechanisms, the authors emphasized the need for further study on pooled procurement mechanisms in inter-country settings. This paper aims to contribute to filling this gap.

To guide this empirical endeavor, we use theoretical insights from organizational life cycle literature, and collaborative and network governance, which we will expand upon in the following sections. These theoretical insights provide us with a more general understanding of the creation and development of networks, collaborations and organizations. This literature points us to the importance of looking at pooled procurement mechanisms not as a singular event, but as a process that evolves over time. Such an approach emphasizes the fact that these mechanisms require active effort by the actors involved to align the various motivations, goals and design of the mechanism. Insights

from this literature can therefore help us to better understand what work is required to make pooled procurement mechanisms a success.

To our knowledge, no attempt has been made to take such a process-approach to describe and explore the development of pooled procurement mechanisms over time. Such insights are important as they contribute to the understanding of how pooled procurement mechanisms are formed and sustained, while adapting to the evolving internal and external environment. Therefore, the aim of our is paper is twofold. First, to explore how pooled procurement mechanisms evolve over time. Second, to clarify what work and processes are needed within and between the various developmental stages of a pooled procurement mechanism. To reach this second aim, we translated the lessons learned into a Pooled Procurement Guidance document to help the development of pooled procurement mechanisms in practice. This study mainly focuses on buyer's owned inter-country and global level pooled procurement mechanisms. However, we believe that insights of this study also apply to local and national level pooled procurement mechanisms.

Theoretical background

To explore the development of and dynamics within pooled procurement mechanisms, we draw upon theoretical insights from literature on organizational life cycles and collaborative and network governance. The creation and functioning of collaboration initiatives is a widely discussed topic in the collaborative and network governance literature. In this paper, following Klijn and Koppenjan (2015), collaborations and networks are used interchangeably. Ansell and Gash (2018) pointed out that collaborations are characterized by extensive interaction between participating parties. These interactions foster joint action and mutual interdependence between parties, while keeping a certain degree of autonomy. Collaborative governance studies often

focus on the interaction processes and structures between the actors within those networks (Emerson et al., 2012).

Pooled procurement has recently been defined as *"a collaboration initiative that consists of two or more buyers, or a third-party organization that procures on behalf of its participating members*" (Parmaksiz et al., 2022, p. 2). In theory, such a collaboration is characterized by high levels of interdependence, management and collective action between various public agencies (e.g., regulatory bodies, procurement agencies), governments (e.g., Ministry of Health, Ministry of Finance) and private parties (e.g., suppliers, distributors). To gain insight into how these collaborations develop and the work required to manage and sustain these interactions between actors we focus on different developmental stages.

Developmental stages

Pooled procurement mechanisms are not static collaborations. They evolve during implementation and operation. Therefore, the elements and work required to form and sustain a mechanism depends on the stage of a mechanism. Using organizational life cycle theories allows us to better understand the processes that take place within and between each developmental stage of a pooled procurement mechanism. Since the 1960s, much has been written in the organizational life cycle literature on how organizations develop in largely predictable ways over time (D'Aunno & Zuckerman, 1987; Lippitt & Schmidt, 1967; Miller & Friesen, 1984; Minkman et al., 2009; Quinn & Cameron, 1983). Although these analyses focus on different aspects of the organizational life cycle and apply the theory to different contexts, they all have certain general elements of the developmental process in common: the emergence, the growth and the maturity of the collaboration. Kenis and Provan (2009) pointed out that the effort of newly emerging networks will mainly be directed towards "developing structures and processes". When these are established, networks should focus on gaining

legitimacy. Only after maturity has been reached, networks can be expected to operate efficiently and reach their predefined common goals.

Emergence

During the initial stages of emergence, participating actors need to be incentivized to engage with each other. Emerson et al. (2012) refer to this as consequential incentives. These incentives can be either internal, based on problems, needs or opportunities, or external, based on a crisis or a threat. Other drivers for participation include the presence of a complex problem that cannot be solved independently (Gray, 1985) and interdependency of resources between participating actors (Emerson et al., 2012; Klijn et al., 2010).

Although the boundaries can be fuzzy, Huxham and Vangen (2013) have identified various categories and levels of aims that participating actors might have when joining a collaboration. They note that an actor is often not a single person, but can consist of multiple individuals representing departments or organizations with varying opinions and interests. Therefore, aims can be on the individual level, on the organizational level or on the collaboration level. Aims can also be externally driven, that is by actors outside the collaboration initiative. Another important distinction they make relevant to our paper, is that aims can be explicit, unstated or hidden. Although these distinctions can help understand and categorize aims of actors, the authors underline that aims are fluid. Multiple aims can be present simultaneously, they can interact and can also change over time.

Once actors have been incentivized for initial participation, actors need to interact in more systematic and deliberate ways to explore possibilities of collaboration. Emerson et al. (2012) mentioned that these interactions, which they refer to as *principled engagement*, are characterized by four processes: discovery, definition, deliberation, and determination. The interaction starts with presenting "individual and shared interests, concerns and values" (*discovery*), followed by

articulating agreed purposes, concepts, expectations, and assessment criteria (*definition*). Within *deliberation*, involved actors negotiate and try to resolve clashing interests and reach relative alignment (Emerson et al., 2012). To reach relative alignment, participating actors often need to go through a process called *fruitful conflict*. This process is characterized by actors that try to "enhance or advance knowledge, understanding, meaning, or capacity between different or opposing perspectives and interests" (Ansell, 2011, p. 168). Finally, involved actors reach *determinations*, which include both substantive and procedural determinations (Emerson et al., 2012). This is the point where the collaboration has to be formalized through agreements on its operations and organizational design (Minkman et al., 2009).

During these various steps of interaction, actors need to develop professional and personal relationships. Emerson et al. (2012) refer to this as shared motivation, including mutual trust, mutual understanding, internal legitimacy and commitment. These relationship-building efforts can be influenced by various factors, such as actors' pre-existing and potentially differing (working) cultures, languages, procedures, customs, ideologies, history of collaboration, face-to-face dialogue, and continuity in representation (Ansell & Gash, 2008; Emerson et al., 2012; Huxham & Vangen, 2013; Klijn & Koppenjan, 2015).

Growth

The growth stage is characterized by expansion and development of the collaboration initiative. Once personal relationships have been established and relative alignment on aims, goals and purpose have been achieved, the collaboration has to further define its operations and structure. This includes formalizing procedural and institutional arrangements, such as establishing an organizational structure with clear roles and responsibilities, a clear mandate, standardized and transparent procedures, fair allocation of benefits and no conflict of interest (Ansell & Gash, 2008; Emerson et al., 2012; Wehrens et al., 2012). In

addition, the collaboration needs to attract a sufficient pool of resources to start and gradually expand the operations. These resources include funding, personnel, expertise and time (Emerson et al., 2012). After the start of operations, the collaboration initiative will accumulate practical and operational knowledge. If knowledge and experience acquired during early operations can be monitored, evaluated and reflected on systematically, the collaboration can apply its outcome to optimize and diversify operations and specialize organizational structure further (Minkman et al., 2009; Wehrens et al., 2012). This iterative process of learning from experience drives rapid expansion and growth of the collaboration initiative. An important motivator to sustain commitment during the growth stage is the participating actor's perceived benefit of the collaboration (Ansell & Gash, 2008; D'Aunno & Zuckerman, 1987). This also includes the actor's perceived benefits relative to the benefits of other participating actors. Schotanus et al. (2010) refer to this as *fair allocation of gains*. If members do not experience this fair allocation, they might withdraw from the collaboration (D'Aunno & Zuckerman, 1987).

Maturity

During the maturity stage, the growth of the collaboration stabilizes and operations are routinized at optimal efficiency levels (Miller & Friesen, 1984). The outcomes and impact it has generated during the previous stage drives the collaboration to adapt to the changing internal and external environment to become sustainable (Emerson et al., 2012). Potential new members might also seek to join the collaboration in the maturity stage. These new members might bring new interests and goals. The collaboration needs to strike a balance between providing sufficient flexibility towards evolving and diverging interests, while sustaining the predetermined goals and aims (Wehrens et al., 2012). D'Aunno and Zuckerman (1987) refer to this point as *critical crossroads*, while others refer to this as the *transformation stage* (Minkman

et al., 2009; Wehrens et al., 2012). If the collaboration does not react adequately to these changing dynamics and environment, the collaboration might evolve towards decline (Miller & Friesen, 1984), where the progress might stagnate or even result in the collapse of the collaboration. However, this decline is not always linear. It can occur at any stage of the development where alignment between members is threatened.

We use the stage-model to identify the processes of setting up pooled procurement mechanisms and explore the work that is required during the various developmental stages of pooled procurement mechanisms.

Methods

Study design

We conducted a multi-method qualitative study using a two-step study design. First, we developed Part 1 of the Pooled Procurement Guidance document by identifying essential elements for successfully implementing and operating a pooled procurement mechanism. A recent literature review of empirical papers on pooled procurement (Parmaksiz et al., 2022) served as the starting point for the development of our Guidance document. Based on the gaps that were identified in this review; we mobilized other sources of data to provide a more comprehensive overview of the elements that play a crucial role in pooled procurement mechanisms. We conducted a scan of academic and grey literature documents on pooled procurement. We scanned grey literature documents in various formats such as feasibility studies, policy papers, reports, academic theses, presentations, and newspaper articles. These documents were identified through various sources including suggestions of key procurement experts included in our study, scanning reference lists of both academic and grey literature

documents (i.e., snowballing), and targeted searches in online databases such as WHO's Institutional Repository for Information Sharing (IRIS), PubMed, Google Scholar, and various news outlets. We used the following search terms: pooled; bulk; joint; centralised and collaborative with procurement or purchasing in combination with medicine*; pharmaceutical*; drug*; vaccine*. We used Boolean operators to combine these search terms in the databases. Our search was not limited to a particular timespan to capture as many publications on pooled procurement mechanisms as possible. We ended our search in February 2023.

Second, to validate Part 1 of the Guidance document, we reached out to 27 purposefully selected procurement experts in several batches between November 2021 and May 2022 and asked them to comment on the Guidance. Their selection was based on their knowledge and expertise of the implementation and functioning of pooled procurement mechanisms. We identified these procurement experts from their publications and through our professional network on (pooled) procurement. We stopped our search for additional respondents after data saturation was reached. Of the 27 experts, 11 procurement experts returned their written feedback and suggestions.

We then invited these procurement experts to participate in a semi-structured interview to reflect on their feedback. During these interviews, we also asked respondents to further elaborate on *when* the processes, identified in Part 1 of the Guidance document, are essential. Our goal was to understand during which developmental stages these processes play a vital role. These insights were captured in Part 2 of the Guidance document. These semi-structured interviews were conducted virtually (e.g., Zoom, Microsoft Teams, and telephone) between December 2021 and May 2022, using an interview guide. We obtained oral and/or written informed consent for interviews and requested permission to audio-record them. Participants were anonymized using

identification numbers that were stored separately from the study data. Interviews were conducted both in English and Dutch and lasted between 30 and 60 minutes. The participants were based in different parts of the world. The majority was based in Europe, with 1 participant from South America, 1 participant from the Middle East and 2 participants based in North America. Furthermore, 2 participants held an academic position (professor or associate professor) focusing on public procurement; 1 participant was a department director at a national public health research institute; 1 participant worked as a director at a research center on public procurement; 2 participants were director at an international pooled procurement organization, and 5 participants were procurement specialists and consultants with extensive international experience in the field of procurement and supply chain of medicines and vaccines. The background of the participants is summarized in Table 4 below.

Category of participant	#
Procurement specialist/Consultant	5
Procurement agent	2
Academic	4

Table 4. Category and number of participants in the study, N=11.

Data analysis

The analysis of the expert opinions was an iterative process. For this, we used a constant comparative method approach (Boeije, 2002). As we collected our data in the form of written expert opinions, we compared and triangulated it with earlier collected data from the literature study, grey literature documents, theoretical insights, and previous interviews and expert opinion. This approach allowed us to verify our findings and take insights from previous data collection into account

during subsequent data collection. During the data collection, we held multiple sessions within the research team until consensus was reached on the adaptation of the Guidance document.

For the purpose of this paper we analyzed the semi-structured interview data using an abductive approach (Timmermans & Tavory, 2012). This approach, which is a recursive and reflexive process, allowed us to explore theoretical notions of organizational development and collaborations in the context of pooled procurement mechanisms, while providing leeway to identify potential gaps and new insights that are relevant and unique to the development of pooled procurement mechanisms of medicines and vaccines. As a first step, the first author (KP) read the transcripts to familiarize with the content and coded the interviews. After this, the first author and at least one of the co-authors were involved in identifying relevant descriptive themes from the interview transcripts. Finally, we identified relevant analytical themes for each developmental stage of the pooled procurement mechanism, and we discussed these between all co-authors during several group meetings. Examples of such themes were stakeholder engagement, consensus-building between buyers, securing sufficient and predictable budget and creating sufficient supplier incentives. NVivo (12.7.0) was used as the qualitative data analysis software.

Results

In this section, we present our Pooled Procurement Guidance.[10] The Guidance consists of two main parts. Part 1 of the Guidance identifies essential elements for each key actor in the pooled procurement mechanism (see Table 5). Part 2 of the Guidance explores the processes and

[10] The complete Pooled Procurement Guidance document with data sources can be found online in the article's supplementary material. See: https://doi.org/10.1186/s40545-023-00574-9

work that are required to set up and sustain a pooled procurement mechanism during its various developmental stages (see Table 6 and Figure 12). We present these different stages in the second part of our results section.

Part 1: Essential elements for pooled procurement

We developed Part 1 of the Pooled Procurement Guidance to provide a more comprehensive overview of the elements that play an essential role in the implementation and operation of pooled procurement mechanisms. We divided the actors into three groups of key actors: the buyers, the pooled procurement organization or secretariat, and the suppliers. We believe that these elements are often specific to a group of actors, but may differ slightly by type of procurement mechanism. For buyers, we differentiate between elements that are necessary for all buyers individually (even if procurement is outsourced to a third-party organization), and elements that are essential for buyers to share collectively, in a situation in which buyers participate directly in the management of the procurement mechanism, referred by us as a buyer's mechanism.

The Guidance document also provides information about why each element is considered essential. For example, each participating buyer needs to have access to funding with which to buy medicines from the pooled procurement organization, even if that funding ultimately comes from an external donor. Without the capacity to allocate or attract funding, the buyer cannot procure through the mechanism, which holds true for both buyer's mechanisms and third-party organization mechanisms. Meanwhile, all buyers collectively need to have a joint need for specific products to procure through the mechanism, including pack sizes, dosage forms and strengths. Without a joint need, pooling around specific types of products cannot take place, and therefore buyers will lose the financial benefits resulting from economies of scale. Finally, shared cultural factors and values (e.g., language,

traditions, etc.) among all buyers in a buyer's mechanism is more likely to enhance trust among buyers and increase understanding of each other's modus operandi and interactions.

However, the processes and types of work that are required to achieve some of these elements vary depending on the specific developmental stage of the pooled procurement mechanism. Therefore, we will continue zooming in on the processes and work, identified in Part 1 of the Guidance document, that are characteristic for each developmental stage.

Essential elements/ actor		Explanation
A.	**Buyers**	
All buyers need to have individually (both for buyers in inter-buyer PPM & third-party organization PPM):		
1.	Perceived problem for which pooled procurement may be a solution	*For a buyer to participate in a pooled procurement mechanism, the buyer needs to experience a problem for which pooled procurement might provide a solution, or see an opportunity that might potentially improve their current situation.*
2.	Motivations that outweigh the opportunity costs	*In addition to the problem, the buyer needs to perceive that the benefits of participation (e.g., price reduction, procurement efficiency, increased quality, sustainable supply) will outweigh the costs. Some factors that contribute to the buyer's motivation are the user-friendliness of the platform, degree of shared decision-making, flexibility in participation, and responsiveness of the pooled procurement organization.*
3.	Budget, either internal or external	*The buyer needs to have or be able to attract sufficient budget, either through internal budget or externally through donors*

4.	Sufficient technical capacity (e.g., demand forecasting)	*The buyer needs to have sufficient technical capacity to participate in a pooled procurement mechanism. For example, it needs the capacity to carry out accurate demand forecasting to procure the accurate number of products.*
5.	Compatible laws, regulations and policies that allow for (international) pooled procurement	*The buyer needs laws, regulations and policies in place that allow for procurement, import and regulatory harmonization (e.g., patent laws, import tariffs, willingness to accept joint product approval, etc.) in (international) pooled procurement mechanisms.*

If buyer's mechanism, all buyers combined, need to have:

1.	Demonstrated willingness to solve their problem collectively through pooled procurement **(shared vision)**	*The buyers need to demonstrate the willingness to solve their problem(s) collectively through a pooled procurement mechanism. This willingness includes political will, leadership, and ownership by relevant individuals or organizations.*
2.	Alignment on goals, purpose and operations of the pooled procurement mechanism **(shared plan)**	*The buyers need to align on goals, purpose and operations of the pooled procurement mechanism. This does not necessarily mean that all buyers need to have the same goals, purpose and operations for the mechanism. As long as they are not conflicting.*
3.	Joint need for specific products **(product alignment)**	*The buyers need to have a joint need for specific products. If there is no joint need, pooling around specific type of products cannot take place, and therefore buyers will lose the financial benefits resulting from economies of scale.*

4.	Sufficient market size to attract suppliers **(market size)**	*The buyers combined need to have a sufficient market size to attract suppliers for a favourable price.*
5.	Sufficient and stable financial capacity **(financial capacity)**	*The buyers combined need to have sufficient and stable financial capacity to procure through the pooled procurement mechanism.*
6.	Regulatory harmonization (e.g., shared quality standards, joint assessment, mutual recognition, etc.)	*Sellers are potentially attracted to pooled procurement systems because it increases their market size while reducing the need to re-register products in each country, an expensive and time-consuming proposition. If there is no shared system for approving products and allowing access to markets, then this advantage is lost in practice.*
7.	Trust (in other buyers and the pooled procurement organization)	*Buyers need to reach a certain level of trust in each other and the pooled procurement organization for them to share data and allocate budget. Trust levels can grow over time and can be reinforced by positive experiences with the pooled procurement mechanism.*
8.	Transparent data and information sharing	*To reduce information asymmetry, the buyers need to have a mechanism in place that allows for transparent data and information sharing on suppliers, prices and demand forecasts between each other. A lack of transparency will negatively affect trust between buyers, and will result in the pooled procurement mechanism not reaching its full potential.*
9.	No history of conflict or failed collaboration	*The level of trust between buyers might be negatively affected if the buyers share a history of conflict or a history of failed collaboration.*

10.	Homogeneity of buyer's characteristics related to their needs	*Buyers need to share similar characteristics (e.g., market size, demographics, financial capacity, bureaucratic structures, etc.) related to their collective needs (e.g., type of products, motivations, goals, etc.). If there is no homogeneity between buyers related to their needs, there is a greater possibility of conflicting interests within the pooled procurement mechanism, which might negatively affect the sustainability of the mechanism.*

If buyer's mechanism, all buyers combined, nice to have:

1.	Shared cultural factors and values (e.g., language, traditions, etc.)	*Buyers sharing similar cultural factors and values (e.g., language, traditions, etc.) are more likely to trust and understand each other and their way of working/interacting, which will benefit the pooled procurement mechanism.*
2.	Existing political or structural mechanisms	*Buyers having pre-existing political or structural mechanisms in place are more likely to trust and understand each other and their way of working/interacting. These pre-existing political or structural mechanisms do not have to be limited to the area of medicine procurement. A greater level of interdependence between buyers to solve their problem(s) in other areas will stimulate buyers' collaboration and adherence to the mechanism.*

B. Pooled procurement organization

1.	Organizational and good governance structure with clear roles and responsibilities	*The pooled procurement organization needs an organizational and good governance structure with clear roles and responsibilities that buyers and suppliers trust to do business with*

2.	Clear mandate	*The pooled procurement organization needs a clear mandate that is provided by the buyers on whose behalf they procure*
3.	Standardized and transparent procedures	*The pooled procurement organization needs standardized and transparent procurement procedures to increase trust and user-friendliness*
4.	Sufficient, predictable and timely budget, either internal (through service fees) or external (through donors) to carry out pooled procurement	*The pooled procurement organization needs sufficient, predictable and timely budget to procure medicine, to attract suppliers, and to respond to unforeseen circumstances with sufficient financial buffers.*
5.	Sufficient, predictable and timely budget, either internal (through service fees) or external (through donors), to cover organizational expenses	*The pooled procurement organization needs sufficient, predictable and timely budget to cover their organizational expenses, including salaries, insurances and rental leases.*
6.	Predictable, timely and efficient payment mechanism	*Sellers will be more attracted to the pooled procurement mechanism if the pooled procurement organization has a predictable, timely and efficient payment mechanism, including single source payment, single currency, acceptable payment period, upfront payment.*

7.	Human resources (sufficient in numbers and expertise)	*The pooled procurement organization needs sufficient and expert human resources. This also means that the pooled procurement organization needs sufficient budget to provide competitive salaries to attract skilful staff.*
8.	Sufficient technical capacity (e.g., procurement, quality assessment, forecasting, etc.)	*The pooled procurement organization needs sufficient technical capacity to carry out tenders, to assess quality of products, to aggregate demand data, to provide capacity building for buyers, etc.*
9.	Positive reputation	*The pooled procurement organization needs to develop a positive reputation, which is based on trust from other actors in the pooled procurement mechanism. Positive reputation is necessary to attract and be entrusted with funding from buyers and funders. This positive reputation is reinforced by providing a rounded procurement service to its buyers and suppliers, including capacity building, risk sharing, market shaping, responsiveness, accountability and transparency.*
10.	No conflict of interest	*The staff at the pooled procurement organization should have no conflict of interest. The organization should operate independently, maximizing the benefits for all its buyers.*
11.	"User-friendliness" (both towards buyers and sellers)	*The pooled procurement organization should provide services to buyers and suppliers in a user-friendly manner with a reliable management information system. The benefits of procuring and supplying through the pooled procurement organization should outweigh the costs, both in terms of finances and effort.*

	C. **Suppliers**	
1.	In the case of generic medicines, sufficient number of qualified suppliers	*In the case of generic medicines, an effective pooled procurement mechanism needs a sufficient number of qualified suppliers in the market. If there is no sufficient number of qualified suppliers, there will be no healthy competition among suppliers, threatening the security of supply. A potential way of overcoming the lack of a sufficient number of qualified suppliers is for the pooled procurement organization to incentive suppliers for production and supply.*
2.	Sufficient production incentives	*Incentives for suppliers to produce products for the pooled procurement organization include a consolidated and sufficient market size; warehouse(s) providing buffer stock; take-off agreements; long-term framework agreements; multiple-buyer tenders*
3.	Sufficient supply incentives	*Incentives for suppliers to supply/sell products to the pooled procurement organization include predictable timely and efficient payment mechanism; regulatory harmonization; user-friendliness; positive reputation*
4.	Sufficient number of distributors with favourable delivery terms	*An effective pooled procurement mechanism needs a sufficient number of distributors/logistics companies that are willing to deliver the product(s) for favourable delivery terms (including lead time, costs, incoterms)*

Table 5. Part 1 of the Pooled Procurement Guidance: essential elements of pooled procurement.

Part 2: Development of a pooled procurement mechanism

Drawing upon the theoretical insights on organizational life cycles and a review of the empirical literature on pooled procurement mechanisms (Parmaksiz et al., 2022), we have identified four ideal developmental stages: the promise stage, the creation stage, the early operational stage and the mature stage. The remainder of the results chapter is organized around these stages. Within each developmental stage, we highlight the essential elements that need to be present during each stage and the work that is required to reach the next stage. A schematic representation of these developmental stages and the work that is required to evolve between stages is provided in Figure 12.

Promise stage

The first stage, which we refer to as the "promise stage", is where each buyer (e.g., pharmacy, hospital, relevant authority in a district or country, etc.) decides that it is in their interest to participate in the development of a concrete plan for establishing a pooled procurement mechanism. A buyer, however, is often not a single person, but consists of multiple individuals, departments or organizations with varying opinions and interests. Therefore, achieving internal agreement within each buyer organization to participate should therefore not be neglected.

The goal in the promise stage is to create engagement between buyers in the pooled procurement mechanism by converting their perceived problem(s) or opportunities into a shared vision. To reach a shared vision, potential buyers need to engage with each other first. Motivations for buyers to engage might differ. Some buyers might perceive a problem for which pooled procurement provides a solution, while other buyers might see an opportunity that potentially improves their current situation. The recognition of a problem or opportunity might be initiated internally (i.e., from within the buyer), or externally

(e.g., other buyers, global development organizations or intergovernmental organizations). Some buyers, however, might not necessarily experience an explicit problem or see a promising solution, but simply want to take part in the conversation or try something potentially new.

Box 1. The role of individual actors in stakeholder engagement.

The Pan American Health Organization (PAHO) Revolving Fund (RF) is an example of a pooled procurement mechanism that has been initiated by an intergovernmental organization. PAHO, which is the regional office of the World Health Organization (WHO) in the Americas, adopted a resolution (CD25.R27) in 1977 to establish a revolving fund with the goal to improve immunization programs in the Americas by increasing access to affordable and quality-assured vaccines (DeRoeck et al., 2006; Pan American Health Organization, 1977). The implementation of the PAHO RF in 1979 is often credited to the leadership and vision of a Brazilian epidemiologist, who was a strong advocate of reducing reliance on donor funding for vaccine procurement, adopting national immunization programs and one of the driving forces in the eradication of polio in the Americas (Andrus, 2017; Andrus et al., 2017; Arie, 2014). This shows us that setting up such mechanisms also relies on the commitment and ownership of individuals in bringing together actors.

In addition to commitment and ownership, engaging actors in the promise stage is a long-term process that requires careful planning. Engagement can take place in various ways. Through informal relationships between buyers (e.g., healthcare organizations or pharmacies that procure certain health products jointly), through pre-existing political and structural relations or mechanisms (e.g., European Union countries procuring COVID-19 vaccines centrally), or initiated by a third-party.

Box 2. Example of stakeholder engagement in faith-based organizations in Cameroon.

The implementation pooled procurement example of faith-based organizations (FBOs) in Cameroon was a result of regular engagement between stakeholders. This process consisted of the following steps: mapping of potential stakeholders; informing stakeholders about pooled procurement; identifying common goals, interests and barriers; adopting a shared vision and potential plan; and agreeing on a decision-making process. The Ecumenical Pharmaceutical Network, which is a non-profit Christian umbrella organization of faith-based healthcare organizations and professionals globally, played an active role in engaging potential actors. They intentionally organized meetings inviting all FBOs in Cameroon to discuss the possibility of setting up a pooled procurement mechanism (Ghoneim et al., 2016).

To reach a shared vision on pooled procurement during initial engagement, we identified several preconditions that have to be met: buyers' motivation to participate should be compatible in terms of their relation to the proposed solution (i.e., the operational model of the pooled procurement mechanism), the potential benefits of buyers to participate in a pooled procurement mechanisms (e.g., price reduction, procurement efficiency, increased quality, sustainable supply, fair allocation of savings) should outweigh its costs (e.g., reduced autonomy, less flexibility), and buyers need to demonstrate willingness and ownership to collectively overcome their (potentially differing) problems.

Box 3. Example of reaching a shared vision in the Organization of the Eastern Caribbean States.

The Organization of the Eastern Caribbean States Pharmaceutical Procurement Service (OECS/PPS) demonstrates how relatively similar sized islands managed to reach a shared vision during

initial engagement (Parmaksiz et al., 2022). Motivated by their shared problems of small market size, limited availability of essential medicines, fairly remote geographic location and limited financial and technical capacity, the OECS nations and the United States Agency for International Development (USAID) initiated discussions on pooled procurement of essential medicines (Huff-Rousselle, 2012; Huff-Rousselle & Burnett, 1996). Pre-existing political and economic structures in the region, such as the OECS Secretariat and the Eastern Caribbean Central Bank, facilitated communication and high-level political commitment. As a result, participating OECS nations pledged a third of their pharmaceutical budget to the mechanism, even before the OECS/PPS was fully operational (Burnett, 2003; Huff-Rousselle & Burnett, 1996). These existing preconditions together with deep political commitment acted as a catalyst for OECS nations to agree on a shared vision: a buyer's-owned mechanism that procures essential medicines for the public sector with the aim to achieve cost savings and higher procurement efficiency.

We can conclude from the above that the promise stage is essential for stakeholder engagement and reaching a shared vision between buyers. Once potential buyers have reached a shared vision, formed an initial working group to advance discussions and decided to develop a concrete plan for setting up a pooled procurement mechanism, the second stage of the development process begins.

Creation stage

The second stage, which we refer to as the "creation stage", is the stage prior to the operations of the pooled procurement mechanism. The goal in this creation stage is to formalize the pooled procurement mechanism through articulation of the shared vision into a shared plan and to put the shared plan into action.

Often, developing a shared plan starts with a situational analysis of the buyers to determine the status quo, current needs and goals of the buyers (Ghoneim et al., 2016; SADC Secretariat, 2012b). This is often carried out by an independent person or organization that is not related to the buyers. Based on this feasibility study, buyers need to go through a deliberation process during which buyers negotiate and try to resolve clashing interests. One respondent mentioned that this alignment process is often a negotiation process that benefits some actors more than others:

> *Often everybody benefits through pooled procurement, but generally some more than others. The question is, how big of a problem is that.* [Academic]

In practice, the buyers need to transcend their individual goals and interests and reach an overarching consensus on the goals, purpose and operations of the pooled procurement mechanism (Barton & Berger, 2022b). This process is often led by an independent facilitator that is trusted by all involved parties (Ghoneim et al., 2016). During this process of consensus-building, several factors should be taken into account. Part 1 of our Guidance document shows that buyers should agree on factors such as determining the roles and responsibilities of actors, agreeing on financing of the mechanism, adopt laws, regulations and policies that allow for (international) pooled procurement, establish regulatory and policy harmonization between buyers and alignment on type of products to procure. A recently published WHO report mentioned that in the European context, the alignment of procurement timelines between buyers was another operational challenge that is often overlooked (World Health Organization Regional Office for Europe, 2020). One respondent provided an example of buyers having different purposes for participating in a pooled procurement mechanism:

> *Sometimes procurement takes place, and every now and then a few [hospitals] from the network participate. But a lot of people use it actually as a type of information exchange, and not necessarily for actual procurement. I notice this even in the Netherlands between homogeneous hospitals, who are part of different sorts of networks, but not procuring at all, while it is called a procurement collaboration.* [Academic]

These individual goals and motivations are influenced by the characteristics of each buyer, including market size, demographics, financial capacity, and bureaucratic structures. Relative homogeneity of characteristics between buyers related to their needs is an important facilitator for productive alignment. Diverging buyers' characteristics are more likely to lead to diverging or even conflicting goals and motivations (Parmaksiz et al., 2022).

Box 4. Example of diverging buyer characteristics in the Southern African Development Community.

The implementation of the Southern African Development Community (SADC) Pooled Procurement Services (SPPS), which dates back to the late 1990s, provides an illustrative example of diverging buyers' characteristics (McDonnell et al., 2021). Based on a situational analysis in the region (SADC Secretariat, 2012b), the 16 member states vary greatly on geographic, demographic, economic, pharmaceutical policy and procurement characteristics. From relatively remote island nations like Seychelles and Comoros, to landlocked countries such as Botswana and Zimbabwe, to large and populated countries such as DR Congo and South Africa. Similar disparities exist in characteristics such as economy in terms of GDP, health and pharmaceutical expenditure, burden of disease, availability of essential medicines, procurement and information systems, and medicine regulation. These wide variations among member states are highly likely to affect the

incentives and motivations of each member state to participate in SPPS. Although the SADC Health Ministers approved the SADC Strategy back in 2012 ('t Hoen et al., 2018), suggesting a stepwise approach starting with information and work sharing, the challenges in operationalizing SPPS highlight the complexity of aligning diverging characteristics, goals and motivations.

Factors that could facilitate the alignment of goals and motivations in more homogenous buyer's mechanisms include open communication and continuity in representation, transparent data and information sharing on factors such as suppliers, prices and demand planning, shared cultural factors and values, and trust between buyers, including no history of failed collaborations. One respondent mentioned that trust consists of various dimensions:

> *There are different types of trust: competence, honesty, and benevolence. If the buyers don't trust each other, a third-party can play an important role in data gathering.* [Academic]

Another respondent underlined that trust does not always have to be present between all layers of an organization or individuals to engage:

> *If it is like a top-management decision that we should collaborate, and the trust exists between the top-management, it doesn't necessarily have to translate to the trust and relationship between the operational levels. (...) I have a feeling that if the benefit or the problem is big enough, or if there is a strategic decision, they have to do it.* [Academic]

After alignment on goals, motivations and operations has been created, the pooled procurement organization or secretariat, which

carries out the actual procurement, needs to be appointed or established. The structure of the pooled procurement organization depends on the structural form of the mechanism. This structural form ranges from a third-party organization procuring on behalf of its buyers, to a more buyer's owned mechanism that operates more collaboratively (Parmaksiz et al., 2022). Examples of existing pooled procurement mechanisms show that third-party organization pooled procurement mechanisms are often led by an organization that operates independently from its buyers. Examples of such organization include the Global Drug Facility (GDF), PEPFAR and hospital group purchasing organizations in the United States.

There are also buyer's owned mechanisms, which are more collaborative in nature. These are generally governed by three main types of pooled procurement organizations:

1. **Lead buying organizations**, in which the responsibility of operations is outsourced to one buyer in the collaboration (Schotanus & Telgen, 2007). One example is Tanzania's Medical Stores Department in the newly established SADC pooled procurement mechanism (The Citizen, 2021).
2. **Shared-responsibility organizations**, in which buyers share a fairly equal distribution of tasks. Examples include the Gulf Health Council for the Gulf Joint Procurement mechanism and the secretariat of the Organisation of Eastern Caribbean States (OECS).
3. A more hybrid governance approach, which can be classified as "**rotating secretariat**", is an organization form in which the responsibility of the operations rotates between buyers in predetermined time intervals. The Baltic Procurement Initiative is an example of this (World Health Organization Regional Office for Europe, 2020).

The Pacific Island Countries provide an illustrative example of a failed pooled procurement mechanism where buyers could not agree on some of the abovementioned preconditions. Discussions on pooled procurement came to a halt in the creation stage due to the lack of a combination of factors such as no harmonized rules and regulations, a failure to finance and establish a dedicated procurement secretariat, cultural differences and a lack of trust between countries (Macé, 2022; World Health Organization, 2014).

To realize any of the buyer-owned mechanisms, buyers need to mobilize resources to put the shared plan into action. These resources consist of securing sufficient, timely and predictable budget both for procurement and to cover organizational expenses, hiring staff that is sufficient in numbers and expertise, and providing physical and technological infrastructure to facilitate operations and communication.

The findings show us that the creation stage is crucial for consensus-building and reaching relative alignment between buyers on goals, purpose, products and operations of the pooled procurement mechanism. In addition, buyers need to develop a shared plan, in which buyers formalize the roles and responsibilities of actors and the pooled procurement secretariat. Once the buyers have put their shared plan into action by setting up or appointing a pooled procurement organization with sufficient resources, staff and expertise, the third stage of the development process begins.

Early operational stage

The third stage, which we refer to as the "early operational stage", is where the pooled procurement organization has been launched and starts procuring their first products. The goal in this stage is to execute the shared plan into shared practice. After establishing or appointing the pooled procurement organization or secretariat in the creation stage, several organizational elements should be taken into consideration to facilitate the

efficient functioning of the organization. These include the presence of an organizational and good governance structure with clear roles and responsibilities, a clear mandate, standardized and transparent procedures, and no conflict of interest. One procurement expert added that buyers need sufficient representation in the pooled procurement organization to guide and oversee its operations. Another respondent pointed out that these elements are not necessarily essential, but act as facilitators:

> *Is it really essential? Or is it something that they firefight as they come across it? I don't know. (...) In the limited cases I have seen, I don't always see this. I see it being considered as something very important. After they go into it, they say: "oh, we should've thought about this from the beginning. We should have had this clear mandate. We should have had clear procedures."* [Academic]

The sustainability of the mechanism will greatly depend on the adaptability and flexibility of the pooled procurement organization to overcome operational problems during this stage. These problems might include attracting and hiring dedicated and qualified staff, collect timely payments from buyers, adherence of the buyers to procure through the mechanism, achieving favorable contract conditions from suppliers, and carrying out accurate demand forecasting based on reliable data. Several respondents underlined the issue of inaccurate demand forecasting as one of the biggest challenges:

> *The other challenge is also the data. Because you need to have near accurate forecasts. To be able to tell the manufacturers: "look, in the next year or two, this is what we are looking at." But you don't have the data to inform a very good quantification. So that is the very huge challenge that we noticed most countries are facing.* [Procurement expert]

Another respondent provided a specific example of inaccurate demand forecasting in an inter-country pooled procurement mechanism:

> *There is a gap between primary initial quantity and the final quantity procured after the announcement of the final award. And sometimes they [i.e., countries] submit 1 million tablets for an item to receive the price. And after the award, they buy about 5 million. This inaccuracy in planning is a big challenge in procurement.* [Procurement agent]

A feasibility study on the SADC pooled procurement mechanism provides us insights into other challenges that pooled procurement mechanisms might face in the early operational phase. These challenges include a lack of regulatory harmonization, limited political commitment, different product needs and procurement goals generated by divergent characteristics (e.g., geography, demography, economy, pharmaceutical policy, procurement processes, etc.), a lack of an efficient payment mechanism that allows for upfront payments, and laws and regulations that limit international pooled procurement (SADC Secretariat, 2012a; World Health Organization, 2014).

During the early operational stage, suppliers also need to be invited and incentivized to participate in the mechanism. If suppliers do not experience sufficient incentives to participate, procurements can fail. This can be caused by a lack of supplier interest or by non-compliance to the terms and conditions set by the pooled procurement organization (Vogler et al., 2022). This can have far-reaching consequences, particularly in the early operational phase, where buyer-supplier relationships have not been well-developed yet and alternative procurement channels are limited. One respondent mentioned that incentivizing suppliers often starts with knowing your suppliers:

> *You need to have a sufficient number of suppliers, but also to know your suppliers. So, for me it makes sense to have some prequalification of the suppliers, which in some countries is really just a formality. They just give you the name and the number of the company and I think that doesn't work. I would also be in favor if suppliers, who used to fail or to commit that they are, for instance, then blocked for some time, or at least blacklisted.* [Academic]

Our findings show that the sustainability of the pooled procurement mechanism relies on the flexibility and adaptability of the pooled procurement organization to overcome initial problems during the early operational stage. Once the pooled procurement organization has overcome these operational problems, their work has been routinized, the suppliers are willing to participate and the buyers have reconfirmed that the value of pooled procurement outweighs its costs, the mechanism enters the fourth stage.

Mature stage

The fourth stage, which we refer to as the "mature stage", is where the pooled procurement organization has become an experienced and reputable actor that is recognized by other actors in and closely related to the pooled procurement mechanism. The goal in this mature stage is to develop the mechanism into a sustainable practice. Reinforced by a positive track record and reputation, the pooled procurement organization can also start providing incentives to suppliers for products that are demanded by its buyer, but were not financially attractive or feasible before to produce or supply (i.e., market shaping). This is often seen around disease- or product-specific third-party pooled procurement mechanisms that focus on a limited set of products. One such example is UNICEF's

vaccine procurement mechanism. The vaccine market is generally characterized by high supplier concentration because of high costs and complexity of manufacturing (USAID Center for Accelerating Innovation and Impact, 2014). Therefore, when UNICEF faced shortages of supply and suppliers of certain vaccines, it shifted its vaccine procurement strategy. As a reaction to these shortages and associated price volatilities, UNICEF's focus changed from "high-volume-low-price" to a more "healthy market" oriented approach (Bare, 2015). They achieved this healthy market principle, in which supply and demand are more balanced, mainly through a combination of accurate demand forecasting, long-term agreements, and multiple-winner awards. These market-shaping efforts were confirmed by one of the respondents:

> *After they got into the situation where the market got too concentrated and they actually lost supply and technical capacity of vaccines because some of the players were not interested in the vaccines, they used part of their demand to shape the market like what the WHO does, for example. To share technical capability with the countries. And they also [promised] these future contracts by saying: "We will give you the technical capability, the knowledge, we will even send someone from the WHO or from UNICEF to sit down with you about the production. And if you manage to get the right quality and the capacity, then we will buy from you.* [Academic]

Another important incentive to maintain the commitment of both buyers and suppliers is the user-friendliness and the positive reputation of the pooled procurement organization. This positive reputation is reinforced by providing a rounded procurement service adding financial and operational value, including capacity building, risk sharing, flexibility, responsiveness, e-procurement, and transparency.

Box 5. Example of user-friendly and rounded procurement services by PAHO Revolving Fund (RF).

Many of these rounded procurement services have been underlying the success of the PAHO RF. In addition to pooling demand, central contracting and dedicated staff, the PAHO Secretariat also provides technical, financial and organizational incentives to both buyers and suppliers. It supports buyers in areas such as accurate demand planning, harmonizing legislation, advocating for national budget lines, implementation of national immunization programs, financial flexibility by allowing buyers to pay after the receipt of goods, and prequalification of suppliers (DeRoeck et al., 2006; Nemzoff et al., 2019; Pan American Health Organization, 2015; Porrás, 2019; World Health Organization, 2014).

At the same time, the PAHO Secretariat incentivizes suppliers by providing access to a consolidated and sustainable market, financial security through a predictable, timely and efficient payment mechanism and long-term framework agreements, reduced transaction costs and operational efficiency through standardization of products and processes (Porrás, 2019; USAID Center for Accelerating Innovation and Impact, 2014).

We can conclude that the pooled procurement organization develops into the mature stage once operations are routinized and the procurement organization has become a trusted and reputable actor that provides long-term incentives for both buyers and suppliers in the mechanism.

Developmental stages of a pooled procurement mechanism

Based on our analysis of the theoretical literature, grey literature documents, and insights provided by our respondents, we have identified four general stages of a pooled procurement mechanism: the promise

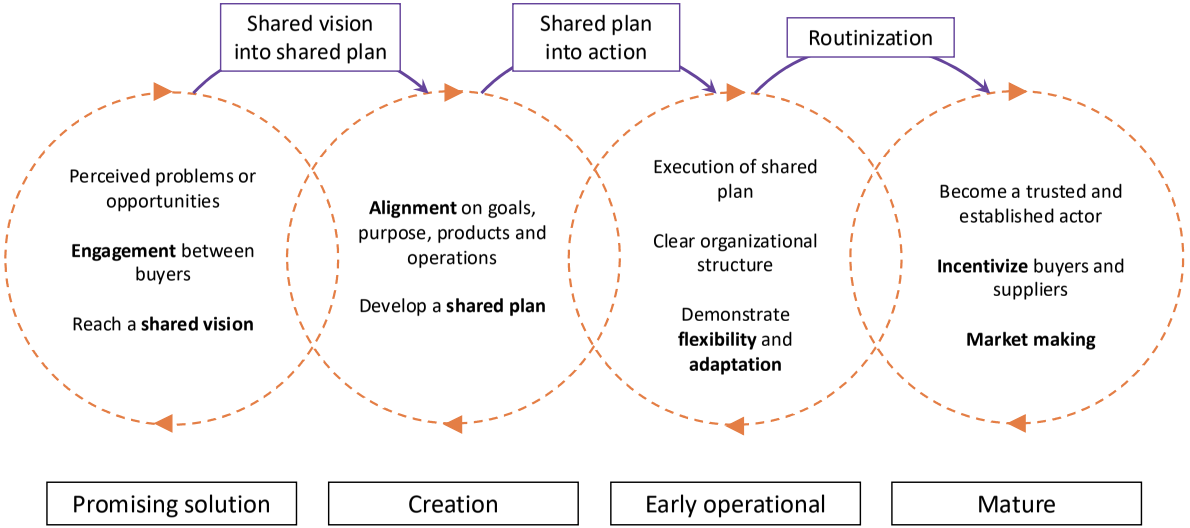
stage, the creation stage, the early operational stage, and the mature stage. These stages are presented in Table 6 with their corresponding main goal to be achieved during each stage.

Developmental stage	Main goal
Stage 1: Promise stage	To create engagement between participating actors and to convert the perceived problem(s) or opportunities into a shared vision.
Stage 2: Creation stage	To formalize the pooled procurement mechanism through articulation of the shared vision into a shared plan and put the shared plan into action.
Stage 3: Early operational stage	To execute the shared plan into shared practice.
Stage 4: Mature stage	To develop the mechanism into a sustainable practice.

Table 6. Developmental stages of a pooled procurement mechanism.

In addition, we have developed a schematic representation of these developmental stages in Figure 12. This representation includes the building blocks that need to be present within each stage, and the work that is required to reach the next stage. The development of the stages is presented as cyclical to depict the non-linearity of the work that is required to reach from one stage to the other.

Figure 12. Schematic representation of the developmental stages of pooled procurement mechanisms.



Fragility of alignment

Even though the stages in Figure 12 are presented cyclical, our analysis might give the impression that the development of a pooled procurement mechanism progresses somewhat linearly. However, when alignment between actors is threatened, pooled procurement mechanisms can also struggle to sustain or develop further, which happens more often than not. This is when the mechanism turns inactive, falls back to earlier stages, transforms into a new model or stops existing. Like the development process, this process of decline is often not linear and it does not chronologically follow certain stages. Therefore, it should not be seen as a separate stage. It can happen at and between any stage of its lifecycle, where alignment between members is threatened. Many mechanisms have been dreamed of but never born, while others experience excessively long creation periods and then cease to exist perinatally.

ACAME (African Association of Central Medical Stores for Essential Drugs) is an example of an inter-country pooled procurement mechanism that was discontinued after its initial pilot. After the devaluation of the CFA franc in the early 90s, several central medical stores of francophone countries in the Western African region established ACAME in 1996 with the goal to improve access to affordable and quality-assured medicines and to increase information sharing among participating members (World Health Organization AFRO, 1999; Jaguga, 2018; World Health Organization, 2014). In 1998, Guinea, Mali and Niger participated in a pilot to jointly procure five antimicrobials. Although this pilot resulted in financial savings for each country between 7% and 27%, the project was discontinued due to a lack of political commitment (World Health Organization, 2014). Challenges reported during its operational period included political instability in the region, a lack of procedural transparency, delayed deliveries, challenges with product registration and no unified payment mechanism (Abdallah, 2005; Jaguga, 2018). Since then, ACAME has continued as an

information-sharing platform on areas such as pharmaceutical pricing, availability, quality, technical specifications, and promotion of regulatory harmonization between participating countries (Iyengar et al., 2016; World Health Organization, 2014).

The Gulf Cooperation Council's (GCC) pooled procurement mechanism is another example that shows that alignment between buyers is a dynamic process, which has to be sustained during the entire lifecycle of the mechanism. The Gulf Joint Procurement program, which is carried out by the Gulf Health Council (GHC), was established in 1978 as one of the first inter-country collaboration initiatives on pooled procurement. It was set up with the goal to consolidate relations and strengthen integration between member states, and promote health for all its citizens in the six Member States (DeRoeck et al., 2006; Nemzoff et al., 2019). Although the GCC countries managed to create relative alignment on the goals, purpose and operations of the mechanism initially, the current transition in some of the GCC countries towards national procurement threatens the sustainability of the mechanism. One procurement agent explained that Saudi Arabia, accounting for over 70% of the market size in the GCC, recently started procuring their medicines through the national centralized procurement agency (i.e., NUPCO) to reduce duplication of work, increase autonomy and spending efficiency. As a result, the total volume and value of health products procured through the GCC Joint Procurement Program has reduced significantly:

> *Previously, we procured around 2.8 billion dollars for all GCC countries. Currently around 1.5 or 1.7 billion dollars.* [Procurement agent]

These examples underline that pooled procurement mechanisms that are unsuccessful in sustaining alignment or reacting adequately to the changing internal and external environment are vulnerable to

stagnation, fall back to earlier stages, develop into something new, or might even cease to exist.

Discussion

The aim of this study was to analyze the development of pooled procurement mechanisms over time and to provide a clear understanding of the work and processes required for their success. Our analysis shows that setting up a pooled procurement mechanism often includes long-term processes that generally evolve along the lines of four developmental stages: the promise stage, the creation stage, the early operational stage and the mature stage. Although strongly interconnected, we have subdivided the emergence phase, identified in our theoretical background, into a "promise stage" and a "creation stage". We believe that this distinction allowed for a more comprehensive examination of the processes that are required to evolve from a shared vision (i.e., promise stage) into a shared plan (i.e., creation stage). During this development, involved key actors have to gradually shift their focus from an individual to a collective perspective. This means that after initial engagement between key actors and internal deliberation on potential benefits and costs, buyers need to transcend their individual goals and interest to reach alignment on collective goals.

Applying collaborative governance and life cycle theories to the context of pooled procurement mechanisms has provided us insight into the general development of a pooled procurement mechanism. Various examples of inter-country pooled procurement mechanisms show that initiating, building consensus, and maintaining pooled procurement mechanisms is a complex and laborious process, that should not be underestimated. In addition, our findings underline that alignment between key actors is fragile. Alignment is a reflexive and recursive process that should be sustained during the entire life cycle of a mechanism. Even after the mechanism has reached the mature stage.

In this paper, we have mainly explored the development of buyer's owned or inter-buyer pooled procurement mechanisms. Pooled procurement mechanisms of third-party organizations, however, appear to develop differently. Although third-party organizations were not the main focus of this study, we believe that further research to increase our understanding of the development of such organizations will provide significant scientific and practical value for the implementation and operation of pooled procurement mechanisms. In contrast to inter-buyer mechanisms, third-party pooled procurement mechanisms tend to be centered around specific diseases (e.g., HIV, TB, Malaria) or products (e.g., vaccines); operate and serve buyers on a global level; have limited involvement of buyers in its operations, governance and decision-making processes; require less harmonization and consensus-building during implementation; are potentially setup with public-private partnerships; and lack a guaranteed market to sell their products, since buyers are generally not the initiators of such mechanisms (Barton & Berger, 2022a; Huff-Rousselle, 2012; Kuwawenaruwa et al., 2020; Parmaksiz et al., 2022). Understanding these differences in characteristics are relevant since inter-buyer pooled procurement mechanisms have often been promoted based on the successes of these global health organizations in terms of consolidating demand and reducing prices (Parmaksiz et al., 2022). However, there have been no detailed studies to date identifying and setting out these differences in characteristics between these varying structural forms. Therefore, we plan further studies to explore the characteristics and development of third-party organization pooled procurement mechanisms, and compare these findings with inter-buyer pooled procurement mechanisms.

The purpose of the Pooled Procurement Guidance document

Earlier academic studies (Huff-Rousselle, 2012; Parmaksiz et al., 2022) have attempted to describe what factors play a role in the functioning of pooled procurement mechanisms. Although these studies identified

factors that are relevant for the functioning of particular pooled procurement mechanisms, they have not attempted to combine these factors into a general framework. We believe that policy-makers and procurement experts can benefit from a more comprehensive overview of how pooled procurement mechanisms develop over time and the elements that play an essential role in setting up and functioning of such mechanisms.

Our Guidance highlights that setting up a pooled procurement mechanism is a complex process that requires consideration of multiple components by each key actor involved (e.g., buyers, procurement organizations, and suppliers). However, it is important to keep in mind that this Guidance document is not meant to be treated as a finished product that universally applies to all pooled procurement mechanisms in its current form. As our analysis shows, creating a successful pooled procurement mechanism requires conscious effort and collaboration from all key actors involved. Our guidance document should be used as a compass with essential elements to consider, rather than a strict roadmap with a checklist to follow.

We believe that practical application and adaptation to real-life scenarios will greatly enhance the usefulness of this Guidance document in improving existing or developing new pooled procurement mechanisms. Some elements might be more relevant to consider in specific contexts, compared to others. For example, a lack of regulatory harmonization between buyers might be a dealbreaker for procurement on inter-country level, but might be less relevant to consider when pooling takes place between hospitals within the same country. Another point for consideration is that the Guidance document specifies what elements are relevant for which key actor, but not during which developmental stage. Some elements, such as trust among buyers, might be essential to sustain during all stages, while other elements, such as a clear mandate for the organization, might be relevant from the early operational stage onwards. Future applications and in-depth case

studies using this Guidance document are needed to further clarify our understanding of when, how and why certain elements are essential under which specific circumstances.

Limitations

Our study has some potential limitations. The number of key procurement experts included in our study as respondents might carry a risk of bias. However, triangulation of our data sources (e.g., theoretical insights from organizational life cycles, collaborative and network governance, systematic review of academic literature (Parmaksiz et al., 2022), grey literature documents, and semi-structured interviews), and triangulation of our analysis by working within a research team, increases our confidence in the validity and reliability of our study findings. Furthermore, both parts of our Pooled Procurement Guidance document might benefit from practical application. This can be in the form of in-depth or comparative case studies of existing and/or failed pooled procurement mechanisms.

Conclusion

This article provides a comprehensive overview of the process of setting up a successful pooled procurement mechanism for medicines and vaccines. It shows that pooled procurement mechanisms are long-term collaborative processes that develop over time. Understanding the developmental path of pooled procurement mechanisms is crucial to increase the chances of successful implementation and functioning. Our Pooled Procurement Guidance document contributes to this understanding in three ways: it provides a comprehensive overview of essential elements for each key actor in the mechanism to consider; it explores and describes the four general developmental stages of pooled procurement mechanisms; and it clarifies the work that is required to form and sustain such mechanisms. We believe that alignment

between key actors on goals, needs, motivations and purpose of the pooled procurement mechanism is a dynamic and reflexive process. For pooled procurement mechanisms to survive, this relative alignment has to be sustained during the entire lifecycle of the mechanism and requires continuous work and reflection. The elements identified in the different stages in this paper can help to direct this work.

5

Does structural form matter? A comparative analysis of pooled procurement mechanisms for health commodities

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Abstract

Introduction: Pooled procurement can be seen as a collaboration initiative of buyers. Such mechanisms have received increased attention during the COVID-19 pandemic to improve access to affordable and quality-assured health commodities. The structural form of pooled procurement mechanisms ranges from a third-party organization that procures on behalf of its buyers to a buyer's owned mechanism in which buyers operate more collaboratively. However, little is known about how these types of pooled procurement mechanisms differ in terms of characteristics, implementation and developmental process. To fill this gap, we compared four pooled procurement mechanisms. Two buyer's owned mechanisms: the Organisation of the Eastern Caribbean States (OECS) and the Pacific Island Countries (PIC). And two third-party mechanisms: the Global Drug Facility (GDF) and the Asthma Drug Facility (ADF).

Methods: For this qualitative study, we used a multiple case-study design. The cases were purposefully selected, based on a most-similar case study design. We used the Pooled Procurement Guidance to collect data on individual cases and compared our findings between the case studies. For our analysis, we drew upon peer-reviewed academic articles, grey literature documents and 9 semi-structured interviews with procurement experts.

Results: Buyers within a buyer's owned mechanisms differ in procurement systems, financing structures, product needs and regulatory and legal frameworks. Therefore, buyers within such mechanisms require relative alignment on motivations, goals and operations of the mechanism. Our study showed that buyers' relative homogeneity of characteristics and their perceived urgency of the problems was particularly relevant for achieving that alignment.

Third-party organization mechanisms require less alignment and consensus-building between buyers. To participate, buyers need to align with the operations of the third-party organization, instead of other buyers. Elements that were essential for the successful implementation and operation of such mechanisms included the procurement secretariat's ability to create local and global awareness around the problem, to induce political will to act upon the problem, to mobilize sufficient funding and to attract qualified staff.

Conclusion: To successfully sustain pooled procurement mechanisms over time, key actors should drive the mechanism through continuous and reflexive work on stakeholder engagement, mobilization of funding and alignment of interests and needs.

Introduction

The COVID-19 pandemic exposed the fragility of global supply chains of medicine and medical products. Scarcity of raw materials, lockdowns, export bans and shortages of finished products such as vaccines and personal protective equipment caused a ripple effect of supply chain disruptions, which ultimately led to shortages, price increases, quality issues and waste of resources (Covax, 2022; Interpol, 2020; Kuchler, 2020a, 2020b; Suneja, 2020). To minimize the effect of these supply-side issues, pooled procurement mechanisms — collaboration initiatives of at least two buyers or a third-party organization that procures on behalf of its participating members (Parmaksiz et al., 2022) — regained global attention. As a result, buyer-countries bundled their financial and technical resources to increase their market size and financial capacity. Examples of such mechanisms during the COVID-19 pandemic include the European Union (EU) Joint Procurement Agreement (JPA) (Vogler et al., 2021), the African Union's (AU) Africa Medical Supplies Platform (AMSP) (Wadvalla, 2020), and the Covax initiative's pooled procurement of COVID-19 vaccines (de Bengy Puyvallée & Storeng, 2022). Aided by the nature of the crisis, buyers managed to set up these pooled procurement mechanisms in an exceptionally short time frame.

Pooled procurement during the COVID-19 pandemic was helped by the shared sense of urgency as well as the need for a single health product. Such conditions are often lacking during non-pandemic times, delaying or even preventing such mechanisms to come to fruition. Pooled procurement mechanisms are often seen as a uniform approach to increase access to affordable and quality-assured health commodities. However, a recent review (Parmaksiz et al., 2022) showed that pooled procurement mechanisms are complex, multi-component and context specific mechanisms that vary in structural form (from buyer's owned/inter-buyer to third-party), operational level (i.e., sub-national, national, inter-country and global), and

product types (e.g., patented products, disease-specific products, vaccines or a wide range of essential medicines). Pooled procurement mechanisms also evolve over time. Parmaksiz, Bal, et al. (2023) identified four general developmental stages: the promise stage, the creation stage, the early operational stage and the mature stage. With each stage, the main goal evolves from reaching a shared vision, to developing a shared plan, to establishing a shared practice and finally reaching a sustainable practice. To evolve from one stage to another, continuous effort is required from participating actors to maintain alignment on the various motivations, goals and operations.

Certain types of pooled procurement mechanisms seem to be more complex to set up and sustain compared to others. For example, several successful examples of disease- or product-specific, third-party pooled procurement mechanisms, in which the procurement organization procures on behalf of its buyers, exist. These include the Global Fund (GF) and the Global Alliance for Vaccines and Immunizations (GAVI). Inter-country, buyer's owned mechanisms that aim to procure a wide range of essential medicines, however, are more complex to set up because countries with often diverging procurement and financing structures, product needs and legal frameworks are more likely to complicate the process of aligning interests, needs and operations (Parmaksiz et al., 2022; Parmaksiz, Bal, et al., 2023).

Following Parmaksiz, Bal, et al. (2023), we noticed a lack of academic publications that explore and compare the creation and operational processes within and between different structural forms. Although pooled procurement mechanisms are being promoted as a solution to reduce prices, increase availability, and achieve more efficient procurement processes, there is still limited knowledge on how they function and what makes them successful or not. This paper contributes to filling that gap by increasing our understanding of creating and maintaining pooled procurement mechanisms of health commodities through comparing successful and failed examples of both inter-buyer and third-party pooled procurement mechanisms by answering the following research questions:

1. What elements help to understand successful implementation and operation of both inter-buyer and third-party pooled procurement mechanisms?
2. How do inter-buyer and third-party pooled procurement mechanisms differ in terms of characteristics and developmental process?

To answer these questions, we conducted a comparative case study of four cases. These cases include two buyer's owned mechanisms, of which one is still active, the Organisation of the Eastern Caribbean States (OECS), and one inactive, the Pacific Island Countries (PIC). And two third-party pooled procurement mechanisms, of which one is still active, the Global Drug Facility (GDF), and one inactive, the Asthma Drug Facility (ADF).

In the following methodology section, we expand on the multiple case-study design that we have used. Then, we present our results, in which we compare the four pooled procurement mechanisms and explore which critical factors played a role in their success or failure. Finally, we summarize our main findings and provide a reflection in the discussion section.

Methods

Study design

We used a multiple case-study design. This study design allowed for in-depth analysis of individual cases, while providing an opportunity to compare the effects of contextual factors on the implementation and operations of purposefully selected pooled procurement mechanisms (Halperin et al., 2020; Yin, 2014).

The cases were purposefully selected, based on a most-similar case study design. In this approach, cases for comparison are selected based on many similar characteristics they share. The relevant characteristics for our study include geography, economic level, population size, type

of products they aim to procure and structural form of the pooled procurement mechanism. The most-similar case study design allows researchers to focus on factors that differ between cases that might explain the contrast in their outcome variable, which in this case was the status of the pooled procurement mechanism: active or inactive (Halperin et al., 2020; Della Porta, 2008). Another important selection criterion was the availability of sufficient data in the public domain such as websites, meeting reports, feasibility studies, presentations and peer-reviewed academic papers.

Case selection

For our study, we compared four pooled procurement mechanisms. Table 7 provides general characteristics of the pooled procurement mechanisms that have been included in our analysis. We selected and paired two buyer's-owned inter-country pooled procurement mechanisms (The Organisation of the Eastern Caribbean States and the Pacific Island Countries). Comparing these cases was interesting because both pooled procurement mechanisms consist of island nations that share many similarities in terms of population and market size, geographical remoteness, type of products to be pooled and financial capacity, but experienced different life cycles.

We also selected and paired two third-party global health organization pooled procurement mechanisms (the Global Drug Facility and the Asthma Drug Facility). Our main reason to compare these third-party mechanisms was because the ADF was set up based on the initial success of the GDF, but again, with a different outcome.

The included mechanisms operate or have stopped operating during different developmental stages (cf. Parmaksiz, Bal, et al., 2023). The PIC and ADF have stopped existing in the creation and early operational stage, respectively. The two mechanisms included in our study that are currently still active (i.e., OECS and GDF) both operate in the mature stage.

	OECS	PIC	GDF	ADF
Status	Active	Inactive	Active	Inactive
Developmental stage	Mature	Creation	Mature	Early operational
Geographical level	Inter-country	Inter-country	Global	Global
Type of products	Essential medicines [multi-product]	(Essential medicines) [multi-product]	TB products [disease specific]	Asthma products [disease specific]
Level of collaboration	Central contracting	(Group contracting)	Central contracting	Central contracting
Structural form	Buyer's	(Buyer's)	Third-party	Third-party

Table 7. General characteristics of the pooled procurement mechanisms included in this study. The characteristics in brackets represent intentions during initial discussions because the PIC pooled procurement mechanism never came to fruition.

Data collection

To assist our data collection and analysis, we used the Pooled Procurement Guidance developed by Parmaksiz, Bal, et al. (2023). This Guidance document consists of two parts. Part 1 identifies essential elements of pooled procurement mechanisms organized around buyers, pooled procurement secretariat and suppliers. Part 2 provides an overview of the general development of pooled procurement mechanisms over time. The Pooled Procurement Guidance has been developed based on theoretical insights from organizational life cycle literature and collaborative and network governance, semi-structured interviews with procurement experts, and academic and grey literature documents on pooled procurement of medicines and vaccines (Parmaksiz, Bal, et al., 2023).

First, we collected data on the historical development and the implementation of each pooled procurement mechanism. For the purpose of our study, we mainly focused on the elements identified under Part 1 of the Guidance. For the inter-buyer mechanisms (i.e., OECS and PIC), we looked at all identified elements in this part of the Guidance. For the third-party pooled procurement mechanisms (i.e., GDF and ADF), we tried to collect data on all but elements A6-A17. These elements are mainly relevant to share among buyers in an inter-buyer mechanism, and therefore do not apply to buyers in a third-party, global health organization mechanism.

Data was collected from various sources to triangulate our findings, including grey literature documents, academic literature and 9 semi-structured interviews. We scanned grey literature documents in the public domain about these mechanisms such as annual reports, feasibility studies, evaluation and review reports, news articles and presentations. Databases used to collect these data included official websites and data repositories of the included pooled procurement mechanism, Google Scholar, PubMed, WHO's Institutional Repository for Information Sharing (IRIS) and news outlets. In addition, we used

snowballing by scanning references of both academic and grey literature documents to search for relevant sources. Search terms we used included variations of: pooled, joint, group, centralized, bulk, procurement, and purchasing in combination with medicines and pharmaceuticals. We used Boolean operators to combine these search terms in the databases. Data collection took place between February 2021 and March 2023.

The semi-structured interviews, which were carried out as part of an earlier comparative case study (Monsuur, 2020) between April and May 2020, were held with purposefully selected respondents with expertise on the implementation and operations of the Global Drug Facility (GDF) and Asthma Drug Facility (ADF). During this study (Monsuur, 2020), 9 respondents were asked to provide insight on the emergence, development and operations of these mechanisms. 1 procurement specialist/consultant, 1 academic and 7 respondents who worked as a procurement agent were interviewed. The interviews were held online and conducted in English, lasting between 60 and 120 minutes. Written informed consent was obtained for interviews and permission was requested for audio recording. The respondents were pseudonymized using identification numbers and these numbers were stored separately from the transcripts. Unfortunately, we did not manage to carry out additional interviews for the other case studies included (i.e., OECS and PIC) because we did not get a reply from potential key respondents to participate in semi-structured interviews and we experienced difficulty in reaching out to the respondents that were involved during the time of preliminary discussions, especially for the Pacific Island Countries. However, the volume of data and triangulation of data sources increases our confidence in the validity and reliability of our study data.

Data analysis

We analyzed the data using mainly a deductive approach, which allowed for testing the earlier developed Pooled Procurement Guidance

in practice and explaining why certain elements were more relevant for the emergence, development and the success or failure of the included pooled procurement mechanisms. We used a thematic synthesis approach for the cross-case comparison. This approach allowed us to identify most important themes emerging from the collected data (Cruzes et al., 2015).

The structure of Part 1 of the Pooled Procurement Guidance served as the foundation for our data collection and analysis. The elements identified in Part 1 of the Pooled Procurement Guidance were selected as descriptive themes. The collected data in the form of grey literature documents, academic publications and semi-structured interviews on the historical development and the relevant elements identified in the Pooled Procurement Guidance were analyzed, summarized and consolidated in a Guidance table.

After the in-depth individual case studies, we compared our findings within each pair of pooled procurement mechanism (i.e., ADF vs. GDF and OECS vs. PIC). This allowed us to explore why certain elements appeared to be more essential in the emergence, development and operations of certain pooled procurement mechanisms compared to others. After that, we also compared between the case study pairs (i.e., ADF/GDF vs. OECS/PIC), to explore if there were any elements that were particularly essential for a certain structural form of pooled procurement mechanism (buyer's owned vs third-party). We then held multiple sessions within the research team until consensus was reached on the relevant analytic themes. The analytic themes that emerged from the thematic analysis included: 1) the problem, the politics and the motivations to participate; 2) Securing sufficient, predictable and timely budget; 3) Continuous alignment of goals, purpose and operations; 4) Clear organizational structure of the secretariat; and 5) Incentives for suppliers. NVivo (12.7.0) was used as the qualitative data analysis software.

Results

Our analysis is based on case studies of four pooled procurement mechanisms: The Organisation of the Eastern Caribbean States (OECS), the Pacific Island Countries (PIC), the Global Drug Facility (GDF) and the Asthma Drug Facility (ADF).[11]

In the following sections, we have highlighted important findings that emerged from our comparative case-study analysis, explaining the success or failure of the included pooled procurement mechanisms. We explore how the key components of a pooled procurement mechanism, which include the way the buyers, the budget, the pooled procurement organization and suppliers are organized, incentivized and interact with each other. In this section, we do not expand on all essential elements identified in the Pooled Procurement Guidance (Parmaksiz, Bal, et al., 2023) for each case study. Instead, we highlight the essential elements that were critical for the success or failure of these mechanisms. A comprehensive overview of the presence, partial presence or absence of the essential elements for each case study can be found in Table 8.

The problem, the politics and motivations to participate

Before establishing any pooled procurement mechanism, it is imperative that potential buyers, such as high burden countries, and other key actors in the global health arena, such as global health organizations and donors, experience the problems for which pooled procurement may be a solution. If and how these key actors experience the problems that need to be solved, depends on multiple factors.

[11] The in-depth case studies for the selected pooled procurement mechanisms with further information on general characteristics, historical background and essential elements can be found online in the article's supplementary material. See: https://doi.org/10.1186/s12992-023-00974-1

In the case of Tuberculosis (TB), the combination of three main factors created the preconditions to raise global attention: the nature of the disease, the high disease burden, and the possibility to cure TB with the right treatment. TB is an airborne communicable disease caused by the *Mycobacterium tuberculosis*. The bacteria are transmittable from human-to-human and can lead to death if left untreated (World Health Organization, 1999; World Health Organization, 2020a). TB has a high global disease burden. The World Health Organization (WHO) estimates that a quarter of the world population has a TB infection, with 30 high burden TB countries, mainly low- and middle-income countries, accounting for 90% of the TB cases (World Health Organization, 2020a). Currently, TB is estimated to cause 1.6 million deaths per year (World Health Organization, 2022). The development of an effective multi-component treatment strategy, called DOTS (Directly observed treatment, short-course), was an important breakthrough for curing people with TB (World Health Organization, 1999). However, many high burden TB countries experienced challenges in implementing the DOTS strategy. These challenges included lack of financial resources to procure TB medicines, lack of access to high quality TB medicines, inefficient procurement systems, lack of national TB programs, a small market size for TB medicines and diagnostics, and limited human resources to accurately diagnose and treat TB (Kumaresan et al., 2004; Matiru & Ryan, 2007; Waning, 2019).

In 1993, TB climbed its way up on the global health agenda after the WHO declared TB a global health emergency, acknowledging that the spread of TB could only be contained if a universal approach would be taken (World Health Organization, 1993). This global attention brought many key actors together, including global health organizations, high burden TB countries, donors and NGOs. One important initiative that emerged from this multi-actor engagement in the battle against TB was the Stop TB Partnership (Kumaresan et al., 2004; The World Bank, 2009). This partnership led to the establishment of the

Global Drug Facility (GDF). The GDF was set up to solve the problems of lacking high quality and affordable TB medicines, which was seen as an important barrier in the rapid expansion of the DOTS strategy (Kumaresan et al., 2004; World Health Organization, 1998; World Health Organization, 2001).

Increased global awareness, the availability of external funding, which we will discuss in the next section, and the multi-stakeholder approach put TB also on the national agenda of potential buyers. These buyers realized that pooled procurement, as organized by the GDF, could provide a solution to the problems they experienced in the fight against TB.

In the case of the Asthma Drug Facility (ADF), these preconditions for global awareness and multi-actor engagement were lacking to a large extent. An estimated 262 million people worldwide are affected by asthma causing approximately 461,000 deaths annually (Vos et al., 2020). In contrast to TB, however, asthma is a non-communicable disease caused by a chronic inflammation of the airways with no cure. Asthma treatment is mainly focused on symptom relief (The Global Asthma Network, 2018). The lack of perceived urgency to treat asthma in the global health arena and in potential buyer countries, mainly low- and middle-income countries, have been attributed to multiple factors. In many of the potential buyer countries these include insufficient health services around chronic diseases, poor access to accurate diagnostics, inaccurate demand forecasting of asthma treatments, a lack of context-specific national programs, guidelines and training on asthma, and inadequate knowledge among clinicians and the general public on the diagnosis, disease, treatment and management of asthma (Beran et al., 2015; Bissell et al., 2016; Chiang et al., 2022; International Union against Tuberculosis and Lung Disease, 2011; Monsuur, 2020; Perrin, 2013; The Global Asthma Network, 2018; The Union, 2012). One of our respondents confirmed that low- and middle-income countries did not perceive asthma as an urgent problem:

> *Countries did not see what problems Asthma Drug Facility was able to solve for them, because they did not see any problem: for them asthma was not an issue.* [Procurement agent]

As a result, the ADF experienced difficulties with creating sufficient global awareness on the problems around treating asthma, constructing a global health infrastructure to congregate key actors, attracting external funding, and convincing potential buyers to focus on detecting and treating asthma. The ADF tried to provide a solution with high quality and affordable medicines to problems that were not equally perceived as urgent by other key actors.

Motivations to participate

However, even if a pooled procurement mechanism manages to provide a solution to urgent problems, the perceived urgency of the problem in itself is not sufficient for buyers to participate in a pooled procurement mechanism. The motivations to participate in such a mechanism need to outweigh the costs of participation. For example, some Pacific Island Countries (PIC), who procure their medicine from other countries in the Pacific region with whom they have had a strong historical relationship, such as Australia and New Zealand, showed little motivation to participate in an inter-country pooled procurement mechanism (Macé et al., 2011; World Health Organization Regional Office for the Western Pacific, 2007a, 2007b). In addition, some PIC were concerned that the additional distribution costs of a potential inter-country pooled procurement mechanism, and the high costs of integrating administrative, political and bureaucratic structures would outweigh the financial benefits that the inter-country pooled procurement mechanism would generate (Mendoza, 2010; The World Bank, 2016).

The GDF, on the other hand, does not merely operate as an intermediate organization that consolidates demand and carries out pooled procurement. It also provides a rounded procurement service to incentivize buyers to participate in the mechanism. For example, the GDF provided grants to eligible buyer countries at initiation (Kumaresan et al., 2004). Currently, a Flexible Procurement Fund (FPF) provides financial flexibility to buyers that have difficulty to adhere to GDF's prepayment conditions (Stop TB Partnership, 2019). The GDF also supports buyer countries with capacity building and technical assistance in several areas, including demand planning and stock monitoring (Boston Consulting Group, 2019; Matiru & Ryan, 2007; Stop TB Partnership, 2014). The GDF and the Stop TB Partnership, under which the GDF is housed, both operate under the United Nations umbrella. This institutional backing legitimized GDF's operations and provided the GDF high-level access to high burden TB countries. Reciprocally, the GDF involves representatives of high burden TB countries in its governance mechanism as board members of the Stop TB Partnership (Stop TB Partnership, n.d.-b; The World Bank, 2009). This governance structure increased the buyer's trust in the GDF. GDF's user-friendly services with high client satisfaction ratings (Waning, 2019), combined with a positive track record of increasing access to quality-assured and affordable TB medicines have reinforced the GDF's positive reputation to attract and incentivize potential buyers to procure through its pooled procurement organization.

The findings show us that in order to establish pooled procurement mechanisms successfully, it is essential for buyers and other key actors in the global health arena to experience an urgent problem for which pooled procurement may provide a solution. This perceived problem should generate sufficient political will from buyers. In addition, the buyers' motivations to participate in the mechanism

should outweigh their costs of participation. Finally, the proposed solution (i.e., the operational model of the pooled procurement mechanism) should be compatible with the experienced problems.

Securing sufficient, predictable and timely budget

The presence of sufficient, predictable and timely budget, either internal or external (i.e., through donors) is needed to both procure medicines and to cover organizational expenses. Securing this budget depends heavily on the key actors' perception of the problem, their motivations to participate and their political willingness and power to act on the problem, as discussed in the previous section. In addition, this budget is required at all levels (i.e., the buyer level, the inter-country level, and the pooled procurement organization level), which we will further specify in the following section.

Allocating internal budget at the buyer's level relies on the potential buyer's perceived urgency of the problems that the pooled procurement mechanism aims to solve. Often, the limited internal budget that is available in low- and middle-income countries, especially for non-communicable diseases, has to compete with other more urgently perceived (communicable) diseases, as seen in the examples of the ADF. Attracting external funding relies mainly on the perceived urgency of the problems by donor countries or organization, as seen in the example of the GDF. The nature of TB, which spreads from human-to-human through air poses a potential health threat for higher income countries. This threat, in combination with the high disease burden and the fact that TB is curable with the right treatment, allowed the "TB-sector" to attract a significant amount of external funding from donor organizations and development aid from high-income country foreign ministries.

In buyer's mechanisms, a collective sufficient and stable budget at the inter-country level is required. The importance of this collective

budget became evident in the PIC example, where a lack of agreement and coordination of PIC's budget was influenced by a lack of agreement on which currency to use and the absence of an appropriate and trusted financial organization in the region that could coordinate the financial process (Arifaj-Blumi, 2007; Mendoza, 2010).

In contrast, the member countries of the Organisation of the Eastern Caribbean States (OECS) share a common currency and succeeded in establishing a revolving fund at the inter-country level, managed by the Eastern Caribbean Central Bank (ECCB). These preconditions created a trusted and user-friendly mechanism to transfer money resulting in OECS members to deposit one-third of their annual internal pharmaceutical budget to individual country drug accounts at the ECCB (Burnett, 2003). This was a clear demonstration of political will from OECS members at initiation of the mechanism.

The pooled procurement organization or secretariat that carries out the procurement also requires sufficient, predictable and timely budget to both procure medicines and to cover organizational expenses. These organizational expenses might include salaries of staff, office rent, maintaining IT systems, daily management tasks and organizing meetings. While inter-country pooled procurement mechanism like OECS and PIC relied mainly on the buyer's internal budget, disease-specific third-party pooled procurement organizations were more likely to target external funding to procure medicines. Some were successful like the GDF, and some unsuccessful like the ADF, for the reasons explained above.

Similarly, organizational expenses have been covered with internal budgets, mainly through service fees, or external, through donor funding. The OECS inter-country pooled procurement mechanism was set up in 1986 with initial support from USAID, which provided technical assistance and covered its operating costs for the first

couple of years (Huff-Rousselle, 2012; World Health Organization, 2014). After the initial funding, the organization became self-sustaining in 1989 through relying on service fees, which was incrementally reduced from 15% in 1986 to its current level of 9% since 2016 (OECS/PPS, 2016; World Health Organization, 2014). Similarly, the ADF aimed to sustain its secretariat by adding a mark-up to every order (Macé et al., 2011). But due to a lack of incoming orders, the International Union Against Tuberculosis and Lung Disease (The Union), under which ADF was housed, had to bear the costs of ADF's operations. This financial burden eventually resulted in The Union terminating ADF's operations in 2013, before the ADF could reach its aim of financial sustainability (Monsuur, 2020). The GDF, on the other hand, relies mostly on external funding from USAID, secured through congressional budget, to cover organizational expenses of its secretariat (Babaley, 2020; US Department of State, Foreign Operations, and Related Programs, n.d.).

We can conclude from the above that sufficient, predictable and timely budget is needed at all levels of the pooled procurement mechanism, both to procure health products and to cover organizational expenses. Securing sufficient budget is highly connected to the key actors' perceptions of the problem, their motivations to participate and their political willingness and power to put the problem on the national and global agenda.

Continuous alignment of goals, purpose and operations

In a buyer's owned pooled procurement mechanism, in which the buyers manage the operations of the mechanism more collaboratively compared to a third-party organization pooled procurement mechanism, the buyers need to continuously align on goals, purpose and operations of the mechanism. Alignment does not necessarily mean that all buyers need to have the same goals, purpose and

operations for the mechanism. But alignment can still be achieved as long as the goals, purpose and operations of different buyers are not conflicting.

In the case of the OECS, all buyer countries experienced similar problems, such as a small market size, limited availability of health products, relatively high costs of procurement of health products, and a limited efficiency of procurement and supply management (Huff-Rousselle & Burnett, 1996; Management Science for Health, 2012; Organisation of Eastern Caribbean States, 1990). These shared problems resulted in converging needs for OECS members, facilitating the alignment on goals, purpose and operations of the pooled procurement mechanism. For example, the similarity of characteristics between OECS members in population size, demographics and financial capacity results in a common need to increase their market size and a joint need for specific products. Agreeing on these products is a deliberate process that requires continuous work and alignment. The products are listed in the *Regional Formulary and Therapeutic Manual* and are reviewed annually by the Technical Advisory Committee (Huff-Rousselle & Burnett, 1996). In addition, OECS member's geographical location as remote island nations and their small population size generates the common need to reduce (distribution) costs and increase availability of health products. The relatively high homogeneity of OECS member characteristics related to their needs allowed the OECS to set up a central contracting mechanism, the most integrated form of pooled procurement.

Similar to OECS, the Pacific Island Countries (PIC) consist of a broad range of remote and dispersed island nations in the Pacific Ocean. Unlike OECS, the characteristics of PIC are more heterogeneous related to their needs. This heterogeneity is particularly apparent when comparing the PIC's population size, demographics, financial

capacity, currency, and health outcomes. which might translate in different needs for health products, increasing the difficulty of product alignment (The Pacific Community, 2020a, 2020b; UNICEF Pacific Office, 2017). The PIC's divergence in buyer's characteristics related to their needs, has contributed to misaligned goals, purpose and motivations among PIC. The motivations for smaller island states (SIS) were mainly to increase access to affordable medicines by increasing their market size, whereas Fiji's driving force to participate was mainly to become the leading country of the inter-country pooled procurement mechanism, expressing concerns about their sovereignty if they were not provided with this leading role (Mendoza, 2010). However, other PIC, such as the Solomon Islands have resisted the idea of Fiji taking a leading role in the inter-country pooled procurement mechanism, partially because of past experiences of failed collaborations, e.g., the attempt in 1971 to set up a joint airline, called Air Pacific which fell apart because many PIC, particularly the Solomon Islands, believed that the airline was mainly benefitting Fiji (Dornan & Newton Cain, 2014). Although there have been successful examples of collaboration initiatives in the Pacific region, such as the Forum Fisheries Agency and the South Pacific Tourism Organisation (Dornan & Newton Cain, 2014), the negative experiences have made PIC reluctant to rely too much on others within the inter-country pooled procurement mechanism. Inevitably, these failed collaborations have impacted the level of trust between Pacific Island Countries. Also, the great diversity in culture, tradition and languages between the PIC might have had an impact on these trust levels (Macé, 2022; West, n.d.). The fragility of the trust level between PIC were underlined recently, when five PIC of the Micronesian subgroup quit the Pacific Islands Forum over a dispute on selecting the Forum's new Director-General (Carreon & Doherty, 2021). As seen in the examples above, the history of collaboration among buyers, and the presence of pre-existing organizational and political structures

can influence the alignment of buyers and creation of pooled procurement mechanisms. These collaboration efforts can reinforce trust among the buyers, as seen in the OECS example, or reduce trust, as seen in the PIC example.

Our findings show that relative and continuous alignment on products, goals, purpose and operations between buyers is essential. This alignment is heavily influenced by the homogeneity of buyers' characteristics, their experienced levels of trust and their experiences in collaboration. This is especially important for a buyer's mechanism, because buyers often participate directly in the management and operations of the pooled procurement mechanism.

Clear organizational structure of the secretariat

Our analysis showed that the pooled procurement mechanisms that were still operational relied on the presence of a dedicated secretariat with clear roles and responsibilities. For example, the OECS Pharmaceutical Procurement Service (PPS) is run by a permanent secretariat with dedicated staff. All buyer countries are represented through the policy board of the PPS. Procurement is carried out by various committees with clear task divisions and integrated safeguards to limit the possibility of conflicts of interest (Burnett, 2003; Huff-Rousselle, 2012; Huff-Rousselle & Burnett, 1996).

Similarly, the GDF is run by a dedicated secretariat with sufficient human resource capacity. The GDF secretariat consist of around 40 staff members, of which around 30 are based at the headquarters in Geneva, Switzerland; and the remaining staff operating externally in different regions, mainly in high burden TB countries. The staff of the GDF are highly trained and highly specialized, focusing on many areas, including TB advocacy, market shaping, sourcing, stakeholder alignment and coordination, demand forecasting and quantification,

technical assistance and capacity building, tendering, contract management with suppliers, oversight of quality assurance, warehousing, distribution, and data management (Stop TB Partnership, n.d.-a). GDF's organizational structure with a dedicated secretariat, sufficient in numbers and expertise, allows the GDF to provide a rounded procurement service. In addition, the GDF involves representatives of high burden TB countries, global health organizations, international donors and technical agencies in its governance mechanism as members of the Stop TB Partnership Coordinating Board. This structure, where a wide variety of stakeholders take part in GDF's operations, contributes to legitimizing GDF's operations in the buyer countries, and provides an arena that facilitates continuous alignment of goals and incentives (Stop TB Partnership, 2023; The World Bank, 2009).

In contrast, the Asthma Drug Facility (ADF), another disease-specific third-party organization pooled procurement mechanism, lacked a clear organizational structure and dedicated staff to carry out the pooled procurement of asthma treatment. The ADF was housed under The Union and was run by a small in-house team. However, according to our respondents, ADF's in-house team had to carry out procurement and related tasks on top of their already existing duties and responsibilities for The Union, impeding their output.

Incentives for suppliers

Besides buyers, the pooled procurement organization, and a sufficient and predictable source of funding, suppliers are essential for the functioning of the pooled procurement mechanism. The suppliers (i.e., manufacturers, wholesalers and distributors) produce and supply health products to buyers via the pooled procurement organization or secretariat. For suppliers to participate in the mechanism, buyers and the pooled procurement organization need to sufficiently incentivize suppliers. Parmaksiz, Bal, et al. (2023) have made a distinction between

production and supply incentives. Production incentives incentivize suppliers to specifically produce products for the buyers in the particular pooled procurement mechanism, whereas supply incentives incentivize suppliers to supply products that are already being produced by the supplier for other markets, to the buyers in the pooled procurement mechanism.

The OECS pooled procurement mechanism was set up to procure relatively high demand essential medicines (Burnett, 2003; Huff-Rousselle & Burnett, 1996). Since these products were already being produced in high volumes by suppliers, providing sufficient production incentives was less relevant for OECS members. Instead, OECS members had to provide sufficient supply incentives for suppliers to supply these essential medicines to the Eastern Caribbean Island nations. These supply incentives included a centralized payment mechanism, standardized and transparent procurement processes, enforced participation of OECS members creating a public sector monopsony, a consolidated market, a generally positive reputation, and long-term framework agreements (Burnett, 2003; Huff-Rousselle, 2012; Huff-Rousselle & Burnett, 1996; Nemzoff et al., 2019).

Although both the OECS and the Pacific Island Countries (PIC) consist of island nations, there are important difference between the two regions. The PIC are more geographically remote and dispersed, increasing delivery times and distribution costs (Mendoza, 2010; World Health Organization Regional Office for the Western Pacific, 2007b). Also, the prices of medicine in the Pacific Islands region were already relatively low. For example, Vanuatu and Solomon Islands already achieved lowered medicine prices compared to the OECS pooled procurement mechanism (Arifaj-Blumi, 2007). Further, the PIC have a limited financial capacity and lack a unified payment mechanism (Arifaj-Blumi, 2007; Mendoza, 2010). In addition, there is no centralized authority or secretariat that facilitates the procurement and/or

distribution of health products in the region (Arifaj-Blumi, 2007). Even if the PIC pooled procurement mechanism had managed to evolve from its creation stage into an early operational stage, the PIC would have had to overcome these barriers to provide sufficient supply incentives to potential suppliers.

Providing sufficient production incentives and shaping the market was more relevant for GDF's pooled procurement mechanism. Prior to GDF, there was a lack of quality generic TB medicines (Kumaresan et al., 2004; Matiru & Ryan, 2007). The GDF has taken multiple market shaping approaches and provided several production incentives to suppliers for the production of quality TB medicines. As part of its market shaping efforts, the GDF accelerated the simplification and standardization of complex TB treatment regimens by consolidating demand in buyer countries around affordable fixed-dose combination (FDC) treatments and incentivizing its production (Blomberg & Fourie, 2003). Similarly, the GDF has played a critical role in driving research and development, procurement and adoption of pediatric TB medicines (Scott et al., 2015; Waning, 2019). The GDF also provided many production incentives to suppliers. For example, the TB medicines market, which was too small and unpredictable, made it risky and expensive for suppliers to carry stock. The GDF tackled this by establishing a Strategic Rotating Stockpile (SRS). The SRS created a buffer stock and levelled off the erratic demand of buyers, resulting in sharing the risk of stock carrying with suppliers and reduced delivery lead times of TB medicines (Stop TB Partnership, 2018). The GDF also provided suppliers long-term framework agreements giving suppliers a certain degree of security to produce, as long as they adhered to the agreed conditions and quality standards (IDA Foundation, 2020). Also, the quality of mainly domestically produced TB medicines was improved in close collaboration with the WHO Prequalification Programme. The GDF achieved annual fee

exemption of TB medicines with relatively low profit margins from the WHO Prequalification program, lowering the barrier for manufacturers to obtain prequalification for their products and making the production of prequalified TB products economically feasible (Stop TB Partnership, 2018). This fee-exemption and GDF's quality-assurance policy requirements forced suppliers to adhere to either WHO-prequalification or Stringent Regulatory Authority standards if suppliers wanted to get access to a consolidated TB medicines market provided by the GDF (Hauk et al., 2020). In addition to production incentives, the GDF also provides suppliers with several supply incentives, such as the adoption of a predictable, timely and single currency payment mechanism to facilitate prompt payment of suppliers and the packaging of TB medicines in four languages by the GDF to reduce the supplier's burden of repackaging and translating (Boston Consulting Group, 2019; Global Drug Facility, 2007).

The ADF, on the other hand, struggled with shaping the market for asthma treatments and providing sufficient production incentives to suppliers. The ADF tried to expand the market for asthma inhalers in lower- and middle-income countries and incentivize suppliers to produce and supply quality and affordable asthma medicines to these markets. However, in part due to the complexity of the technology of asthma inhalers, there were insufficient incentives for new generics manufacturers to produce asthma inhalers resulting in a relatively low competition in the market (Beran et al., 2015; The Global Asthma Network, 2014; Virchow et al., 2015). Although production incentives were limited, ADF's promise of consolidating previously non-existing markets in lower- and middle-income countries did provide sufficient supply incentives for some manufacturers that were already producing single ingredient pressurized metered dose inhalers. Several of these manufacturers, both originator and generics, entered ADF's qualification process (The Global Asthma Network, 2014). According to our

respondents, generics manufacturers participated in ADF's qualification process because they perceived the ADF as an opportunity to enter new markets that were traditionally dominated by originator companies, whereas the originator manufacturer considered the ADF's mechanism as a form of tiered pricing policy to reach low- and middle-income markets in addition to their already secured high-income markets.

ADF's initial efforts resulted in significant price reduction of asthma medicines and inhalers, reaching more than 50% reduction of annual costs per patient with severe asthma in some countries (Babar et al., 2013; Macé et al., 2011; Ramakant, 2013). However, despite ADF's initial successes in reducing prices and incentivizing manufacturers to supply asthma products, these incentives were not sufficient. The ADF did not reach a sufficient market size to manage a sustainable pooled procurement mechanism, because asthma was not perceived as an urgent problem that needed to be solved by potential buyer countries, resulting in a lack of demand. In addition, potential buyer countries lacked the financial capacity to procure asthma medicines through ADF, while the ADF failed to attract sufficient donor funding due to the nature of the disease.

Our results show us that in order to operate a sustainable pooled procurement mechanism, suppliers need to be incentivized to participate in the pooled procurement mechanism, both in terms of production and supply.

Essential elements/actor	**OECS**	**PIC**	**GDF**	**ADF**
Status	*Active*	*Inactive*	*Active*	*Inactive*
A. Buyers				
All buyers need to have individually:				
1. Perceived problem for which pooled procurement may be a solution (problem)	✓	✓	✓	✗
2. Motivations that outweigh the opportunity costs	✓	✗	✓	✗
3. Budget, either internal or external (through donors)	✓	✓	✓	✗
4. Sufficient technical capacity (e.g., demand forecasting)	✓	✗	✗	✗
5. Compatible laws, regulations and policies that allow for (international) pooled procurement	✗	✗	✓	✓
If buyer's mechanism, all buyers combined, need to have:				
6. Demonstrated willingness to solve their problem collectively through pooled procurement (shared vision)	✓	✗	–	–
7. Alignment on goals, purpose and operations of the pooled procurement mechanism (shared plan)	✓	✗	–	–

8.	Joint need for specific products (product alignment)	✓	✓	–	–
9.	Sufficient market	✓	✗	–	–
10.	Sufficient and stable financial capacity (financial capacity)	✓	✗	–	–
11.	Regulatory harmonization (e.g., shared quality standards, joint assessment, mutual recognition, etc.)	✓	✗	–	–
12.	Trust (in other buyers and the pooled procurement organization)	✓	✓	–	–
13.	Transparent data and information sharing	✓	✓	–	–
14.	No history of conflict or failed collaboration	✓	✗	–	–
15.	Homogeneity of buyer's characteristics related to their needs	✓	✗	–	–
16.	Shared cultural factors and values (e.g., language, traditions, etc.)	✓	✗	–	–
17.	Existing political or structural mechanisms	✓	✓	–	–

	B. Pooled procurement organization				
1.	Organizational and good governance structure with clear roles and responsibilities	✓	–	✓	✓
2.	Clear mandate	✓	–	✓	✗
3.	Standardized and transparent procedures	✓	–	✓	✓
4.	Sufficient, predictable and timely budget, either internal or external (through donors) to carry out pooled procurement	✓	–	✓	✗
5.	Sufficient, predictable and timely budget, either internal (through service fees) or external (through donors), to cover organizational expenses	✓	–	✓	✗
6.	Predictable, timely and efficient payment mechanism	✓	–	✓	✗
7.	Human resources (sufficient in numbers and expertise)	✓	–	✓	✗
8.	Sufficient technical capacity (e.g., procurement, quality assessment, forecasting, etc.)	✓	–	✓	✓
9.	Positive reputation	✓	–	✓	✓

10.	No conflict of interest	✓	–	✓	?
11.	"User-friendliness" (both towards buyers and sellers)	?	–	✓	✓
	C. Suppliers				
1.	Sufficient number of qualified suppliers	✓	✗	✓	✓
2.	Sufficient production incentives	–	–	✓	✗
3.	Sufficient supply incentives	✓	✗	✓	✓
4.	Sufficient number of distributors with favorable delivery terms	✓	✗	✓	?

Abbreviations: OECS (Organisation of the Eastern Caribbean States); PIC (Pacific Island Countries); GDF (Global Drug Facility); ADF (Asthma Drug Facility).

✓: Present, ✓: Partially Present, ✗: Absent, ?: No information, – Not relevant

Table 8. Comparative overview of the presence, partial presence and absence of the essential elements within the case studies.

Discussion

In this article, we compared the implementation and operation of two types of pooled procurement mechanisms: inter-buyer and third-party organization mechanisms. These insights are valuable as inter-buyer mechanisms are often set-up inspired by success stories of third-party pooled procurement mechanisms, but with limited success to date due to the additional complexity that is involved in setting up such inter-buyer mechanisms. In this section, we reflect on why some pooled procurement mechanisms were successful while others were not, with specific attention to how inter-buyer mechanisms differ from third-party organization mechanisms in their characteristics and developmental process.

As we have argued, potential buyers and other key actors in the global health arena should experience or face a problem for which pooled procurement may be a solution. In the absence of such an explicit problem, the mechanism might struggle to get off the ground or endure. As was seen in the example of the ADF, their efforts to create national and global awareness and engage stakeholders was a short-lived success. Putting a problem successfully on the national and/or global agenda is highly political and directly linked with the ability to mobilize sufficient funding. Asthma, which is a non-communicable disease without cure, suffered from low detection rates in potential buyer-countries because of a lack of accurate diagnostics. The ADF struggled to create local political awareness and convince potential buyers to allocate sustainable national budget to asthma treatment. The ADF also failed to attract international donor funding to procure medicines and cover organizational expenses. We argue that this might have been influenced by the complexity of treatment options and lower prioritization of non-communicable diseases over communicable diseases by global health donors (Jailobaeva et al., 2021). The

GDF, on the other hand, had a better recipe for success. High burden of disease in potential buyer-countries combined with accurate diagnostics, effective treatment regimen and potential threat to global health security provided favorable breeding grounds for multi-actor engagement, political determination to act upon the problem, mobilization of funding and attracting sufficient and qualified staff.

This research also shows us that establishing an inter-buyer mechanism, such as the OECS and PIC, is often more complex than third-party organization mechanisms because each participating buyer-country has its own procurement systems, financing structures, product needs and regulatory and legal frameworks that need relative alignment among buyers. Buyers' relative homogeneity of characteristics and their perceived urgency of the problems was particularly important as it facilitated alignment on motivations, goals and operations of the mechanism between buyers. Success depends on alignment, but not perfect agreement. Buyers can have differences in operations and motivations to participate, as long as these do not clash with the goals and operations of the designated pooled procurement secretariat. The example of the PIC shows that this alignment process can be influenced by various factors. The diverging characteristics of buyers (e.g., population size, demographics, financial capacity) in combination with a history of failed collaboration examples (e.g., Air Pacific) and a fear of loss of sovereignty have reduced trust levels among potential buyers. In turn, the lack of political determination and the non-existence of an entity that takes responsibility to drive the mechanism forward (Macé, 2022), has resulted in the collapse of the negotiations on inter-country pooled procurement between the Pacific Island Countries. In addition, the motivations to participate in a mechanism should outweigh the costs of participation. Participation should generate a net benefit.

Creating a window of opportunity to align interests, however, is not a singular event. The incentives of buyers might change, based on changes in the political, economic, health and demographic

environment. In addition, the pharmaceutical market or the international context the mechanism operates in, might change. Preserving alignment is a continuous and reflexive process that requires broad involvement, work and support by the buyers in the mechanism (Parmaksiz, Bal, et al., 2023). To facilitate this consensus-building, specific infrastructure such as forums, committees and advisory boards, as seen in the examples of the OECS and GDF, need to be in place.

In contrast to inter-buyer mechanisms, however, third-party organization mechanisms require less involvement of buyers in their operations and therefore less consensus-building among buyers. On the one hand, the governance structure of these mechanisms is often less complex, because each buyer should align with the operations of the pooled procurement secretariat (e.g., ADF, GDF), but not necessarily with other buyers. While on the other hand, setting up such mechanisms requires additional work and effort for third-party organization mechanisms because they are often not initiated by buyer-countries themselves. As we have seen, the ADF was launched by The Union, while the Global Drug Facility was set up with great efforts of the WHO. Because buyers are not directly involved in the creation of third-party pooled procurement mechanisms, the procurement secretariat lacks a guaranteed market to sell their products in the early operational stage. The procurement secretariat's ability to create a consolidated market by raising local awareness and convince potential buyers to procure through their secretariat is critical for their survival.

In our analysis, we did not address each essential element identified in the Pooled Procurement Guidance, as shown in Table 8, separately. To facilitate our comparative analysis, we focused on elements that played a critical role in the success or failure of one or more mechanisms instead. As a result, some elements might have been under- or overemphasized in explaining the process of setting up and operating each case study individually. We advise readers to interpret our findings with this in mind.

Recommendations for applying the Pooled Procurement Guidance

This research shows us that some of the elements identified in the Pooled Procurement Guidance (Parmaksiz, Bal, et al., 2023) are more political (e.g., urgency of the perceived problem, motivations to participate, creating continuous alignment, incentivizing suppliers), while others are more organizational (e.g., sufficient and predictable budget, sufficient staff and expertise, clear organizational structure). However, these are both strongly related and intertwined in the sense that the political elements influence the organizational elements, and vice versa. Without an urgent problem, there will be no sufficient budget to procure health products and cover organizational expenses, and without a sufficient budget, there will be no suppliers to supply or produce the products.

Further, applying the Pooled Procurement Guidance is a valuable exercise that can be done during each developmental stage of the pooled procurement mechanism. For those involved in and responsible for setting up pooled procurement mechanisms such as policy-makers and consultants, the Pooled Procurement Guidance can provide a structure to align interest and goals. For researchers, the Guidance provides a framework to decompose the complexity around pooled procurement mechanisms. It facilitates identification of elements that contribute to the success or failure of such mechanisms during implementation and operation. Although this exercise provides a comprehensive overview of the elements that might influence the mechanism's implementation and operations, it remains a snapshot of that particular moment in time of when the exercise was carried out. Therefore, we encourage researchers, policy-makers and others to update the document with regular intervals and reflect on the outcomes as the mechanisms evolves over time. We also believe that this Guidance might further benefit from a more detailed, micro-level application on how a

single pooled procurement mechanism develops over time. Therefore, we plan further studies to explore how a single pooled procurement mechanism develops over time in order to increase our understanding of why and how specific elements are essential during which developmental stage.

Limitations

Our study might carry a risk of bias. We conducted additional semi-structured interviews with respondents involved in two out of four selected case studies (i.e., GDF and ADF). This might have resulted in less detailed descriptions and personal experiences on the OECS and PIC case studies. One of our criteria to purposefully select these case studies, other than their similarity in characteristics, was the availability of sufficient data in the public domain. We attempted to overcome this limitation through data triangulation by using a variety of sources including peer-reviewed academic literature and grey literature documents such as official reports, feasibility studies, newspaper articles and presentations.

Conclusion

This comparative case study draws lessons from four purposefully selected pooled procurement mechanisms. We have highlighted why some elements were essential for the implementation and operations of certain pooled procurement mechanisms, while other elements were not. Our findings show that to establish a pooled procurement mechanism, buyers and other key actors should experience an urgent problem for which pooled procurement may provide a solution. This problem should generate sufficient political will from buyers, while the motivations to participate in the mechanism should outweigh their costs of participation. In order to sustain the pooled procurement mechanism successfully, key actors should drive the mechanism

through continuous and reflexive work on stakeholder engagement, mobilization of funding and relative alignment on products, goals, purpose and operations, which is influenced by the homogeneity of buyers' characteristics, their experienced levels of trust and their previous experiences in collaboration.

6

Towards regional access to medicines: The development of the East African Community pooled procurement mechanism

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Abstract

Introduction: The East African Community (EAC) has been facing challenges in ensuring access to affordable and quality-assured medicines. To address these problems, the EAC Partner States have been working on implementing an inter-country pooled procurement mechanism since 2005. However, with limited progress to date. The aims of this study were to explore how the EAC pooled procurement mechanism has been developing over time, and to clarify the work and efforts made during this development process to draw lessons for enhancing such collaborative efforts.

Methods: For this study, we carried out a multi-method qualitative case study. We used the Pooled Procurement Guidance to collect and structure our data drawn from academic papers, grey literature documents, observations and field notes. For the analysis, we used an inductive thematic analysis approach.

Results: Over the past two decades of the EAC's pooled procurement journey, we have identified two developmental stages so far: the promise stage and the creation stage. The promise stage was characterized by initial engagement and alignment efforts between Partner States. However, the lack of dedicated funding and ownership to drive the project forward led to stagnation of the process for some years.

Following the establishment of a dedicated organization, the pooled procurement mechanism entered the creation stage. This stage has been characterized by continuous alignment work consisting of project management, efforts to build inter-personal relationships, and facilitation of negotiations to harmonize goals, needs and operations. This process has been aided by broad and recurring involvement of regional experts.

Conclusion: To successfully implement a pooled procurement mechanism, we suggest EAC Partner States to continue their alignment efforts, sustain political will and allocate sustainable funding using a phased implementation approach towards pooled procurement.

Introduction

Medicines are fundamental for managing disease burden. Many low- and middle-income countries, however, face challenges in ensuring access to affordable and quality-assured medicines (Bigdeli et al., 2013; Cameron et al., 2011; Ozawa et al., 2019). Similar challenges have been experienced in the East African Community (EAC); an intergovernmental organization established to promote economic, political, social and cultural integration. The EAC currently consists of eight countries, referred to as Partner States: The Republic of Burundi, the Democratic Republic of the Congo, the Republic of Kenya, the Republic of Rwanda, the Republic of South Sudan, the Republic of Uganda, the United Republic of Tanzania and the Federal Republic of Somalia. Most of these Partner States have been facing problems to ensure access to quality and affordable medicines. Several factors underly this problem, such as a relatively small market size leading to high prices, inadequate supplier incentives causing shortages of certain essential medicines, insufficient technical capacity or staff resulting in the entry of uncertain or poor quality medicines into the market, limited local production capacity, and inefficiencies in procurement and supply chain processes (EAC RCE-VIHSCM et al., 2023; East African Community, 2018a; Yenet et al., 2023).

In response to these problems, the EAC Partner States started discussions on pooled procurement in 2005 during the 1st EAC Sectoral Council of the Ministers of Health meeting (East African Community, 2005). Pooled procurement can be defined as "*a collaboration initiative that consists of two or more buyers, or a third-party organization that procures on behalf of its participating members*" (Parmaksiz et al., 2022, p. 2). Setting up such mechanisms is not a standardized process. They differ in structural form (ranging from inter-buyer to third-party), operational level (i.e., local to global), product types (e.g., patented products, disease-

specific products, vaccines or a basket of essential medicines), and need to be embedded within the local contextual environment (Parmaksiz et al., 2022). They also differ in levels of collaboration and integration, ranging from *informed buying* (information sharing on prices, product quality and suppliers), *coordinated informed buying* (conducting joint market research), *group contracting* (engaging in joint negotiation) to *central contracting* (through a dedicated procurement agent acting on behalf of the buyers) (Management Science for Health, 2012; World Health Organization, 2020b). Additionally, they have a tendency to evolve over time following a path of developmental stages (Parmaksiz, Bal, et al., 2023; Schotanus et al., 2011).

A recent study (Parmaksiz, Bal, et al., 2023) developed a *Pooled Procurement Guidance*, which we will use as an analytical tool to structure and analyze our data. The guidance was developed to assist policymakers and procurement experts in the implementation and operation of such mechanisms. It was constructed by integrating empirical (i.e., academic and grey literature studies), practical (i.e., expert opinion) and theoretical (i.e., collaborative governance and organizational life cycle literature) insights. It describes how pooled procurement mechanisms tend to develop over time, and which elements are essential in setting up and sustaining such mechanism. A follow-up study (Parmaksiz, van de Bovenkamp, et al., 2023) applied this Pooled Procurement Guidance to both inter-buyer and third-party pooled procurement mechanisms. One of its main conclusions was that establishing inter-country, buyer's owned pooled procurement mechanisms in practice seems more complex compared to third-party, disease-specific pooled procurement organizations (e.g., Global Fund, Global Drug Facility). This is predominantly a result of diverging procurement, supply chain and financing processes among buyers, along with differing product needs and incompatible legislative frameworks. These heterogeneities add further layers of complexity to the alignment of

interests and operations between buyers within inter-buyer mechanisms (Parmaksiz, van de Bovenkamp, et al., 2023).

The EAC pooled procurement mechanism provides another good example of complex, inter-buyer alignment processes. This is best illustrated with the fact that discussions on implementing pooled procurement have been ongoing for nearly two decades. Yet, little is known about how the EAC pooled procurement mechanism has evolved over time. What work and efforts have been made to align interests and develop the mechanism? What challenges and complexities have been encountered? And which lessons have been learned? This paper aims to provide answers to these questions. We believe this longitudinal and in-depth approach is valuable as it increases our understanding of how inter-country, buyer's owned pooled procurement mechanisms develop in practice. These insights also provide important lessons for other, inter-country pooled procurement mechanisms facing similar challenges.

Methods

Research context

Cooperation between East African countries such as Kenya, Uganda and Tanzania dates back to the early 1900s. In 1917, Kenya and Uganda formed a Customs Union, which Tanganyika (now the United Republic of Tanzania) joined in 1927. Between 1948-1961 these three countries formed the East African High Commission, which was renamed after independence of the countries into East African Common Services Organisation between 1961-1967, and later into the East African Community (EAC). This first iteration of the EAC collapsed after political disagreement between Partner States, and was eventually dissolved in 1977 (Cooksey, 2016; East African Community, n.d.-a). It was

not until 1999 that these three countries formalized their international cooperation with a treaty (East African Community, 2002) by reviving the EAC. Kenya, Uganda and Tanzania became the three founding Partner States of the EAC, who were joined by Rwanda and Burundi in 2007, South Sudan in 2016, and the Democratic Republic of Congo in 2022 (East African Community, n.d.-c). The Federal Republic of Somalia, the latest Partner State, joined in 2023 (East African Community, 2023d). The Democratic Republic of the Congo and the Federal Republic of Somalia, having both recently joined the EAC, have not been actively involved in the development of the pooled procurement mechanism so far. Therefore, their participation and efforts have not been incorporated into this paper. The EAC is one of the eight Regional Economic Communities (RECs) recognized by the African Union, has a combined population of over 330 million people and its EAC Partner States share a common history, culture and language (Kamwanja et al., 2010). Coordinated by the EAC Secretariat, the EAC is governed by different bodies such as the Summit, the Council of Ministers, East African Legislative Assembly and East African Court of Justice (East African Community, n.d.-b).

Study design

We carried out a multi-method qualitative case study. The study consisted of two phases that took place simultaneously, which allowed us to triangulate our data. This study design enabled us to examine how the EAC pooled procurement mechanism has evolved over time, clarify the work and contributions made by different actors, and identify the current challenges, needs, practices and processes (e.g., procurement, financing, regulation) within the EAC Partner States.

The first phase aimed to capture data on how the implementation of EAC pooled procurement mechanism has been developing over time. First, we began by searching academic literature related to the pooled procurement in the EAC in February 2020 in databases such as

PubMed and Google Scholar with the following search terms: pooled; joint; bulk combined with procurement or purchasing. These search terms were combined with EAC and East African Community. We used Boolean operators to combine these search terms, and did not limit our search to a timespan to capture as many publications as possible. We found no papers published in academic journals focusing on this subject. Next, we expanded our scope to grey literature documents, including policy papers, feasibility studies, academic theses and newspaper articles. We used the same search terms and looked in databases including Google Scholar, WHO's Institutional Repository for Information Sharing and the EAC Information Resource Centre. We also scanned reference lists for further publications (i.e., snowballing). Over the years, we continuously updated our search using the same search terms. Additionally, we sought recommendations from key actors in the field for further relevant publications. This process continued until our final search was conducted in April 2024. This search yielded 8 key documents. In addition, we included 23 meeting reports of the EAC Sectoral Council of Ministers of Health between July 2005 (1st ordinary meeting) and February 2023 (23rd ordinary meeting), and 9 EAC regional stakeholder meeting reports between 2008 and 2023.

The second phase aimed to identify the work and efforts made, and by which actors, during this implementation process. We drew upon unstructured observations of which extensive field notes were made during four regional stakeholder meetings that we were present at between March 2020 and August 2023, with a total duration of approximately 100 hours (see Table 9). Our observations were focused on capturing the interaction between stakeholders. Particularly examining how they aligned their respective challenges and needs and negotiated towards a unified pooled procurement mechanism. We wrote down our observations and thick descriptions as fieldnotes, and compiled them into trip reports after each day or after the meeting had been concluded (Emerson et al., 2011; Wolfinger, 2002). In addition, we

conducted informal interviews with stakeholders during these regional stakeholder meetings to verify our observations and gather additional background information.

Meeting	Date	Place
Regional Stakeholders' Meeting to Build Consensus on the Pooled Procurement Model for the EAC Partner States	4-6 March, 2020	Nairobi, Kenya
Regional Meeting to Develop a Detailed Model and Operational Plan for Pooled Procurement	21-25 June, 2021	Nairobi, Kenya
Regional Meeting to Validate the EAC Pooled Procurement Market Survey Report and Model	13-15 March, 2023	Entebbe, Uganda
Meeting of Heads/CEOs of the National (Central) Medical Stores	7-8 August, 2023	Kigali, Rwanda

Table 9. Overview of stakeholder meetings during which observations took place.

Data were gathered by researchers and supply chain and procurement experts who have been actively involved at various stages during the development process of the EAC pooled procurement mechanism in activities such as organizing and facilitating stakeholder meetings, commissioning reports, next to collecting data. In addition to facilitating data access and collection, our active involvement also allowed us to verify and triangulate our findings among researchers who were engaged in the process. This variation in time of participation is also reflected in the detail presented in our analysis. While some of our data comes from informal interviews with experts involved during the early stages of the EAC pooled procurement mechanism, most of the data on that period is based on document analysis and literature review. As a result, our main focus during this stage was on reconstructing the

developmental process. After 2016, when personal involvement of our research team increased, data sources were expanded with personal observations, experiences and data collected for the purpose of the *East African Community Pooled Procurement of Medicines and Health Commodities Market Survey Report* (EAC RCE-VIHSCM et al., 2023), carried out between November 2022 and February 2023. This resulted in richer analysis of the development of the mechanism and the type of work that took place.

Data analysis

We used the *Pooled Procurement Guidance* document (Parmaksiz, Bal, et al., 2023) as introduced earlier to structure our analysis through inductive thematic analysis. The Pooled Procurement Guidance consists of two parts. Part 1 identifies essential elements to consider for developing a pooled procurement mechanism, while Part 2 focuses on the development of such mechanisms over time.

In Part 1, essential elements are organized around key actors (i.e., buyers, pooled procurement organization and suppliers) in the mechanism. These elements can be seen as preconditions or objectives to achieve during the implementation and operation process. They include – but are not restricted to – the presence of compatible laws and regulations, sufficient budget to procure health products and cover organizational expenses, sufficient technical capacity for accurate demand forecasting, regulatory harmonization, trust, transparent information sharing, and sufficient incentives for suppliers to participate in the mechanism.

In Part 2, four general developmental stages have been identified: the promise stage, the creation stage, the early operational stage and the mature stage. This classification enabled us to delineate the developmental stages that the EAC pooled procurement mechanism has gone through so far: the promise stage and the creation stage. We then carried out a more systematic analysis of all EAC Sectoral Council of Ministers of

Health meeting reports and EAC regional stakeholder meeting reports to identify key events and trace its chronological development over time, using NVivo (12.7.0) as the qualitative data analysis software.

Next, we carried out a thematic synthesis analysis to explore which factors influenced those key events within each developmental stage. The essential elements in Part 1 of the *Pooled Procurement Guidance* document were used as an analytical tool to structure and analyze the most important themes emerging from our collected data (i.e., literature review, document analysis, observations, informal interviews).[12]

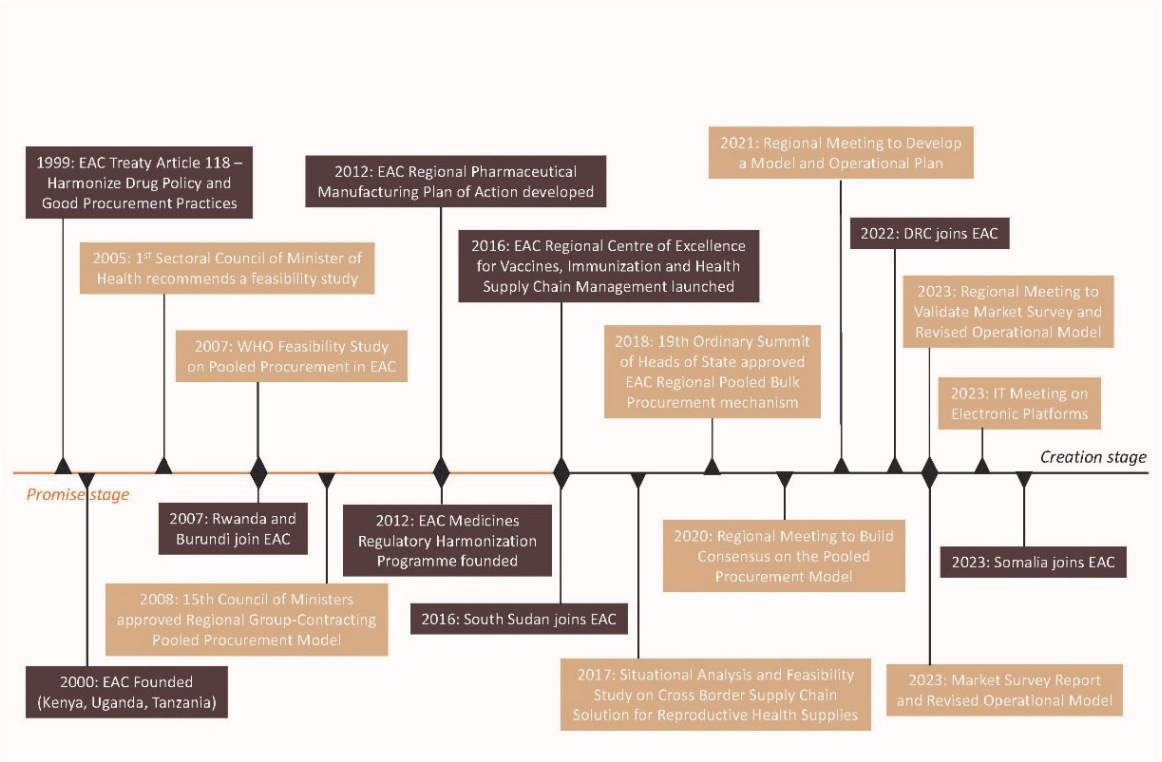
We then discussed our findings within the research team during multiple sessions until we reached consensus on the analytic themes. After refining our descriptive themes, we arrived at the following set of analytical themes that together provide insights into the historical development process of the EAC pooled procurement mechanism: (1) initial stakeholder engagement; (2) seeking alignment; (3) presence/absence of process ownership and accountability; (4) broad involvement and continuity in representation; (5) project management; and (6) reflexive process and ongoing negotiations.

Results

In this section, we present our findings on the developmental process of the East African Community (EAC) pooled procurement mechanisms. Based on the classification of Parmaksiz, van de Bovenkamp, et al. (2023), we have organized this section around two developmental stages: the promise stage (1999–2015) and the creation stage (2016–present).

[12] A comprehensive review of the EAC pooled procurement mechanism with further information on general characteristics, historical background and essential elements using the Pooled Procurement Guidance can be found online in the article's supplementary material. See: https://doi.org/10.1080/20523211.2024.2390653

Figure 13. Timeline of key developmental events of the EAC pooled procurement mechanism. Green blocks refer to general developments in the EAC; orange blocks refer to developments related to the EAC pooled procurement mechanism.



Promise stage

The promise stage is characterized by creating engagement between potential buyers, while they try to convert their perceived problem(s) or opportunities into a shared vision (Parmaksiz, Bal, et al., 2023). In this section, we will focus on three themes that emerged from our data analysis of our literature review and informal interviews: (1) initial stakeholder engagement, (2) seeking alignment, and (3) designating ownership.

Initial stakeholder engagement

The foundations for the discussions around pooled procurement in the EAC region were laid with the re-establishment of the EAC. Article 118 of the Treaty for the Establishment of the EAC (East African Community, 2002) focuses on increased cooperation in terms of developing "a common drug policy which would include establishing quality control capacities and good procurement practices" (Article 118c) and "harmonise drug registration procedures so as to achieve good control of pharmaceutical standards without impeding or obstructing the movement of pharmaceutical products within the Community" (Article 118d).

It took, however, a few more years before pooled procurement came on the EAC agenda. In 2005, during the 1st Ordinary Meeting of the Sectoral Council of the Ministers of Health (East African Community, 2005, p. 9), the health ministers recommended to carry out a situational analysis on "medicines policy, legal and regulatory framework, procurement, distribution and management within the EAC Partner States to facilitate the process of harmonisation within the EAC." The ministers pointed out that within this study, special attention should be paid to learn from experiences of already existing inter-country pooled procurement mechanisms, and the possibilities and challenges to set up an inter-country pooled procurement mechanism for selected

essential medicines, including HIV/AIDS, malaria and tuberculosis medicines (East African Community, 2005). Discussions continued in November 2006, when regional stakeholders came together in Zanzibar during a meeting on pooled procurement of ARVs and Essential Medicines in the EAC. During this meeting, stakeholders re-iterated their interest to implement an inter-country pooled procurement mechanism. During a regional expert meeting in Arusha, Tanzania in April 2007, the experts proposed to analyze the feasibility of *group contracting* and *central contracting* as options for pooled procurement in the EAC (East African Community, 2007; World Health Organization et al., 2007).

Seeking alignment

After these initial engagement efforts between regional stakeholders, EAC Partner States took their first steps in aligning interests. They started with a situational analysis and needs assessment of the countries with the intention to converge them into common goals and purposes for the pooled procurement mechanism.

In 2007, a comprehensive assessment looked at political and organizational commitment, procurement legislations and policies, medicines regulatory procedures, medicine supply chain systems, financial resources & systems, and pricing policies. Based on their findings, the consultants suggested that group contracting would be more feasible for the EAC than central contracting (World Health Organization et al., 2007). During the 2nd Ordinary Meeting of the Sectoral Council of Ministers of Health in 2007 in Arusha, Tanzania, the health ministers considered and approved the final report and recommendations of the situational analysis (East African Community, 2007). Six months later, during the 15th Ordinary Meeting of the Council of Ministers in March 2008 (East African Community, 2008; Syam, 2014), the central decision-making and governing organ of the EAC consisting of Ministers or Cabinet Secretaries from the Partner States responsible for regional

co-operation, approved the group contracting as the pooled procurement model for the region.

In September 2008, the 3rd Ordinary Meeting of the Sectoral Council of Ministers of Health (East African Community, 2008) held in Entebbe, Uganda, directed the EAC Secretariat to develop a draft strategic plan of action and multi-year budget for the implementation of such a mechanism. In addition, the health ministers appointed a wide variety of stakeholders from the Partner States to the *Regional Essential Medicines Pooled Bulk Procurement Expert Task Force*, and urged Partner States to establish a national task force in each country to facilitate coordination between the national and the EAC level.

In September 2009, stakeholders convened during a regional meeting on *Regional Harmonisation of Policies, Legal and Regulatory Framework for EAC Partners States National Medicines Regulatory Authorities (NMRAs) and National Medicines Procurement Agencies (NMPAs)* (East African Community, 2009). During plenary discussions, the stakeholders agreed to tackle potential issues of resistance to change among NMPAs, to develop a regional Essential Medicine List, to prioritize activities to ensure progress, and to update the members of the Expert Task Force.

Up to this point, the Partner States had been showing clear and sustained high-level political commitment to explore the feasibility of pooled procurement for health products in the region. This commitment was visible on multiple actor levels, including Ministers of Health, EAC council of Ministers and regional experts from Partner States.

Designating ownership

However, limited progress was made in the following years. During the 5th Ordinary Meeting of the Sectoral Council of Ministers of Health in 2011 (East African Community, 2011a), the health ministers reiterated

their directive to the EAC Secretariat to finalize the development of a business plan and prepare the Terms of Reference for the National Task Forces in the EAC Partner States. The topic of pooled procurement was not discussed during three consecutive Ordinary Meeting of the Sectoral Council of Ministers of Health (East African Community, 2011b, 2012a, 2012b).

One of the major issues at that time was the lack of dedicated funding from EAC Partner States. Although the Health Department of the EAC Secretariat kept oversight and organized meetings on pooled procurement, they were responsible for a wide variety of tasks on numerous health related topics. Therefore, the project lacked a designated driving force and a system in which organizations could be held accountable for delays in the process. To stimulate progress and increase ownership of various priority areas in the region, the EAC Secretariat proposed assigning specific Partner States to host certain projects. During the 9th Ordinary Meeting of the Sectoral Council of Ministers of Health in April 2014 (East African Community, 2014), the EAC Sectoral Council of Ministers of Health directed the EAC Secretariat to set up *Regional Centres of Excellence* (RCoEs, now RCE) for "skills and tertiary education in higher medical and health sciences education program" across the region, both in terms of research and healthcare delivery. Each RCE would be hosted by one of the EAC Partner States. The Republic of Rwanda was assigned to host the *EAC Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management* (EAC RCE-VIHSCM) among others.

One of the EAC RCE-VIHSCM's core responsibilities would be to preserve the progress of the pooled procurement initiative (East African Community, 2014). This development also marks the end of the promise stage, in which buyers were mainly concerned with converting their individually perceived problem(s) or opportunities into a shared vision through stakeholder engagement, regular meetings, situational analyses and feasibility studies (Parmaksiz, Bal, et al., 2023).

Creation stage

The creation stage is characterized by the joint efforts of stakeholders to build consensus around goals and needs, develop a shared operational plan and mobilize sufficient resources (Parmaksiz, Bal, et al., 2023). In this section, we will focus on four themes that emerged from our data analysis of our literature review, observations and field notes: (1) process ownership and accountability, (2) broad involvement and continuity in representation, (3) project management, and (4) reflexive process and ongoing negotiations.

Process ownership and accountability

The mechanism's transition from the promise stage to the creation stage was propelled by the establishment of the EAC Regional Centre of Excellence for Vaccines, Immunization, and Health Supply Chain Management (EAC RCE-VIHSCM). In March 2016, the EAC RCE-VIHSCM, hosted by the University of Rwanda was launched with financial support from Germany's Federal Ministry for Economic Cooperation and Development (BMZ) through the German Development Bank (KfW), which has since been its biggest funder. One of the projects that EAC RCE-VIHSCM was mandated to facilitate, together with the EAC Secretariat, was establishing the inter-country pooled procurement of health commodities (EAC RCE-VIHSCM, 2019; East African Community, 2019b). The EAC RCE-VIHSCM's embedding and close collaboration with the EAC Secretariat legitimized their operations and expedited the trust-building process among key stakeholders from various Partner States.

After setting up their organizational structure and hiring skilled staff to run the center, the EAC RCE-VIHSCM started the pooled procurement project with conducting a feasibility study and situational analysis on cross-border supply chain solutions for reproductive health in 2017 (IMS Health, 2017). The study's inception report was approved in

May 2017 (East African Community, 2017), and the final report was validated in October 2017 after consultations with five out of six Partner States due to national elections in Kenya. The 16th EAC Sectoral Council of Ministers of Health in 2018 (East African Community, 2018b) acknowledged the progress made, but was dissatisfied with the study's conduct, directed finalizing the in-country validation process and resubmitting the feasibility study. The country visit to Kenya took place in December 2018, a couple days before the next regional stakeholders meeting. At this regional stakeholder meeting in 2018 in Naivasha, Kenya (East African Community, 2018c), stakeholders recommended to set up an adequately staffed pooled procurement secretariat, secure sufficient financial resources, and develop harmonized procurement policies. They also agreed to integrate lessons from the feasibility study on reproductive health into the ongoing essential health commodities project to avoid duplication (East African Community, 2018c).

In the following year in 2019, the Sectoral Council of Ministers of Health took note of the recommendations and directed the EAC Secretariat and the EAC RCE-VIHSCM to conduct a regional meeting to build consensus on the inter-country pooled procurement model before the 19th Ordinary Sectoral Council meeting to be held later that year (East African Community, 2019a). This deadline could not be met, and it was not until 2020 that this meeting was held in Nairobi, Kenya.

The findings show us that the presence of a dedicated organization or secretariat that is equipped with ample resources and mandate was crucial for the development of this mechanism. The establishment of the EAC RCE-VIHSCM gave new impetus to the alignment process, which can be observed by the increased frequency of regional stakeholder meetings between Partner States in the following years. The EAC RCE-VIHSCM's institutional backing by and strong collaboration with the EAC Secretariat further legitimized their operations. In addition, our findings showed that discussions between Partner States

during those frequent meetings focused on laying the groundwork for shaping the initial structure of the mechanism.

Broad involvement and continuity in representation

In March 2020, the EAC Secretariat in collaboration with the EAC RCE-VIHSCM organized the *Regional Stakeholders Meeting to Build Consensus on the Pooled Procurement Model for the EAC Partner States* (East African Community, 2020). A wide variety of stakeholders from all participating EAC Partner States were present. In addition, representatives from global health agencies such as WHO, WHO-Afro and USAID were present to share their experiences with inter-country pooled procurement mechanisms. The meeting was facilitated by an external consultant, who presented best practices from existing pooled procurement mechanisms and a brief situational analysis of the Partner States. After plenary sessions, the representatives from the EAC Partner States were divided into working groups to discuss and provide input on topics such as country preparedness towards inter-country pooled procurement, availability of resources for information sharing and work sharing. Additional working groups sessions were held on budgeting and funding, current laws and regulations, developing a roadmap and structural arrangements for inter-country pooled procurement mechanism. These working group sessions were followed by plenary discussions with all representatives. Discussions evolved around the proposed governance structure of the mechanism. Some international global health organizations suggested a more efficient and leaner structure that operates more independently from national structures. Although the representatives agreed with the suggestions of a lean structure, they emphasized the hierarchical nature of operations within the EAC. The pooled procurement governance structure had to be integrated into the overall EAC governance structure, since working groups and committees are guided by higher-level council decisions and directives.

Another example in which the hierarchical nature of operations in the EAC became apparent was during discussions on the pace of implementation:

> *It was the third and final day of consecutive meetings. The stakeholders, visibly tired from the discussions of the previous days, had to address one final pressing issue on the implementation approach before the meeting report could be drafted.*
>
> *The consultant proposed to conduct a phased implementation approach to pooled procurement, starting with information sharing. While two Partner States initially agreed with the suggested approach of the consultant, two other Partner States disagreed by putting forward the Sectoral Council of Ministers of Health's directive to implement a group contracting model. Therefore, the focus of this meeting should not be on information sharing but on group contracting. These Partner States were mostly concerned about further possible delays of the implementation process. With the guidance of the consultant, the Partner States eventually reached consensus on a phased approach. The Partner States recognized that these two phases of pooled procurement are not mutually exclusive. In fact, information sharing is an important precondition to reach group contracting.* [Fieldnotes Nairobi meeting March 2020]

The meeting concluded with recommendations to leverage existing expert knowledge on procurement within the region and put in place a mechanism to share this expertise among Partner States.

After the 2020 Nairobi meeting, the EAC Secretariat and the EAC RCE-VIHSCM organized another regional stakeholder meeting in June 2021 with the goal to *Develop a Detailed Model and Operational*

Plan for Pooled Procurement in Nairobi, Kenya (East African Community, 2021c). Continuity in representation turned out to be an important facilitator in the trust-building process among stakeholders. The facilitator, many of the country delegates and supporting staff had been involved in previous meetings on pooled procurement in the region. This expedited the familiarization process between stakeholder, resulting in open and transparent discussions during plenary discussions. During this meeting stakeholders held discussions on the goals and needs of the pooled procurement mechanism. The vision, mission, guiding pillars and strategic objectives were all formulated, reviewed and agreed upon in a plenary session. The needs for the products to be procured were not agreed upon during this meeting. Although the Partner States reached consensus on including essential medicines and not focus on products that are procured from or by global health partners in the early stages of the mechanism, the specific types of products were yet to be determined. Since priorities for health products might differ for each Partner State, the Partner States agreed to submit their top categories of health commodities at a later stage.

When stakeholders are unable to align interests, we observed that sometimes, an external actor might be needed to bring stakeholders together when discussing sensitive topics, as seen in the following example on the governance structure:

> *The contrast with previous year's regional stakeholder meeting could not have been bigger: this time with masked participants, socially distanced chairs, and even dedicated hotel staff tasked with sanitizing microphones.*
>
> *After lively discussions on the potential governance structure previous year, we (i.e., the facilitators) left the topic of the governance structure for last because we did not want it to negatively influence discussions on other subjects. Initially, agreeing on a governance structure proved*

challenging. Partly because of the plenary setup of the session, which made developing a focused structure difficult, and partly because each Partner State wanted to remain in control over their procurement processes. This meant that the Partner States expected to be part of the decision-making process in the pooled procurement mechanism.

After plenary discussions reached an impasse, one of the stakeholders proposed to ask the facilitator to draft a governance structure based on lessons from other inter-country pooled procurement mechanisms. The stakeholders agreed and the meeting was adjourned for an hour. As the facilitator of this meeting, KP initially felt a bit at unease with this new dual role as consultant and researcher. He had to step in last-minute because last year's facilitator could not attend this meeting due to COVID-19 restrictions and his replacement got rejected a visa before boarding. Nevertheless, he agreed with the task, found a quiet spot, came up with a draft governance structure based on existing inter-country pooled procurement mechanisms while taking the recommendations of the 2020 Nairobi meeting into account, discussed them with his colleague consultants and presented it after the plenary session resumed. After minor changes, the stakeholders agreed on the governance structure proposed by the facilitator and discussions continued onto the next subject.
[Fieldnotes Nairobi meeting June 2021]

The next subject to be discussed was on increasing ownership of the project at the national level. The stakeholders recommended to nominate a focal person from each Partner State who would be responsible for communication, monitoring progress and data collection within each country. Also, the focal person would collaborate closely with the EAC Secretariat, EAC RCE-VIHSCM and the consultants to drive the

implementation process forward. This was another example of ownership and responsibility of the project, but on the Partner State (i.e., national) level.

After the plenary sessions, technical experts were divided into three groups to discuss conditions for successful information sharing, the information to be shared, and the sharing platform. Although this exercise identified important factors, experts agreed that a more in-depth market survey was needed. In the final plenary discussion, Partner States agreed the survey should assess each Partner State's procurement processes, financial mechanisms, legislation, technical capacity, market size, and local production capacity for a phased approach towards group contracting. The goal was to complete the market survey and present it for approval during the 21st Ordinary Meeting of the Sectoral Council of Ministers of Health later that year.

These examples show that continuity in representation facilitates trust-building and strengthening of personal relationships between stakeholders. In turn, these relationships promote open and transparent communication during regional meetings. In addition, calling in externals is a deliberate and effective strategy deployed to navigate impasses around sensitive topics. The combination of these factors turned out to be an essential precondition for aligning interests, goals and purposes.

Managing the project

Managing the project in practice, however, does not always go according to plan. Preparations for the market survey analysis started in July 2021 with the development of the Terms of Reference by the EAC Secretariat in collaboration with the EAC RCE-VIHSCM and experts from the EAC Partner States for the assignment. After initial agreement with two consultants, and a supporting role for KP (i.e., the first author), the consultants and the EAC RCE-VIHSCM agreed that

conducting a comprehensive analysis could not be completed before the next Sectoral Council of Ministers of Health meeting planned in December later that year. Therefore, they decided to carry out the market analysis over a longer period of time. In October 2021, a new consultant was hired because the previous consultants were not available anymore. After initial meetings on the setup of the market survey analysis between the EAC RCE-VIHSCM, the consultant and the focal persons in early 2022, there were delays in obtaining official requests for collecting data from some of the Partner States for the analysis.

In September 2022, the task resumed again with the consultant and KP conducting a background study, developing data collection tools and an inception report with input from EAC RCE-VIHSCM and the focal persons. These were approved during an online meeting with regional stakeholders in December 2022. Around the same time, data collection through questionnaires and semi-structured interviews started. The focal persons were instrumental during this process. They were responsible for distributing the questionnaires to local experts and collecting data within the Partner States, and providing additional input during the analysis of the data. This was an iterative and reflexive process. After three rounds of meetings with each focal person and three group meetings, the consultant and KP finalized the draft of the market survey report.

This example shows us that initial plans often deviate from practice. Many factors, both related or external to the specific project, can contribute to this. For instance, a staff member might be replaced or an emergency situation such as a pandemic or a critical shortage of medicines might occur that demands time and resources, resulting in delays of the ongoing project. A clear ownership of the project in combination with sufficient resources is therefore required. Not only to keep momentum going, but also to overcome such obstacles.

Reflexive process and ongoing negotiations

The output of the market survey analysis was presented during a regional stakeholder validation meeting in Entebbe, Uganda in March 2023 (East African Community, 2023b). Continuity in representation was also visible during this meeting. Most of the country delegates in Entebbe were also present during the 2020 and 2021 regional stakeholder meetings in Nairobi. One of the things that became obvious during these meetings was the continuous and reflexive nature of the alignment process between stakeholders. Although some of the goals and needs were already discussed during previous meetings, organizing these stakeholder meetings allowed Partner States to revise and renegotiate previous decisions. One example was the selection of products to be procured. During both Nairobi meetings in 2020 and 2021, the stakeholders agreed to start information sharing on essential medicines, which are often required in high volumes, are needed by all Partner States, and have already obtained market access in each Partner State. However, during the Entebbe meeting, some Partner States highlighted the need to include regionally produced pharmaceuticals to incentivize local manufacturing, while other Partner States emphasized the need to include "hard to source" products in the joint products list. Based on these suggestions, this meeting recommended that the EAC Secretariat should send out a letter to each Partner State requesting a list of hard to source products to be included in the initial list of products for information sharing. Currently, the EAC Secretariat is in the process of collecting these hard to source product lists.

Another point of discussion during stakeholder mapping was that buy-in was required from various stakeholders such as Central Medical Stores to avoid friction and slow implementation. Therefore, the meeting recommended to present the EAC pooled procurement framework and revised Operationalization Model to the heads of National/Central Medical Stores and relevant experts, including Chief Pharmacists and Ministry of Health officials.

Following the Entebbe Meeting in March 2023, the EAC Secretariat in collaboration with the EAC RCE-VIHSCM started the implementation of the meeting recommendations. In May 2023, a meeting was organized to develop the technical specifications for the digital platform that will facilitate information sharing, and eventually pooled procurement (East African Community, 2023c). During this meeting, stakeholders discussed various desired modules for information sharing and agreed on the frequency and initial set of activities/information to be shared among the Partner States. These include stock status, availability and registration status of selected health commodities. In addition, Partner States agreed to share information on local and foreign manufacturers.

In August 2023, the EAC Secretariat in collaboration with the EAC RCE-VIHSCM organized a regional stakeholder meeting in Kigali, Rwanda with the CEOs of the National/Central Medical Stores from each Partner State, as suggested by the regional stakeholders in the Entebbe meeting five months earlier (East African Community, 2023a). During this meeting, key findings of the market survey report, the proposed governance structures during information sharing (Phase 1) and group contracting (Phase 2) and the information to be shared were presented by the EAC RCE-VIHSCM. The aim was to inform the Central Medical Stores, receive their input, and obtain their buy-in and approval as key stakeholders in the pooled procurement mechanism.

The reflexive and continuous nature of the negotiations were also seen at this meeting, where discussions on the initial list of health products for information sharing continued:

> *Around 40 participants were present during the 2-day regional stakeholder meeting, including CEOs of the National/Central Medical Stores, chief pharmacists and Ministry of Health officials. The participants had been listening to three back-to-back presentations on the progress*

made so far on pooled procurement in the region. After the final presentation, the floor opened for a plenary discussion. One of the stakeholders took the opportunity and proposed to go for lunch first but to no avail. He got opposed by his colleagues. One of them replied: we should continue and forge the iron while it is still hot.

The stakeholders proceeded to discuss the initial list of health products for information sharing at launch. A representative from one of the Partner States commented that the list should reflect the products that they, as a country, have difficulties procuring. A representative from another Partner State agreed and added that the list should also include more products on non-communicable diseases. A third representative disagreed and commented that the list should not be overcomplicated at this stage. In his opinion, the Partner States should continue with the current list as is by starting small and revising the list along the way. The organizer and facilitator of the meeting reassured the Partner States that this current list should be seen as a "living list" that will be adapted by stakeholders from each country during future expert working groups, according to the needs of the Partner States. In the end, the meeting participants found a middle ground by accepting the initial tracer list of products, supplemented with a brief list of hard-to-source products. [Fieldnotes Kigali meeting August 2023]

This excerpt provides an illustrative example of the complexity of alignment in practice. During this process, Partner States engage in negotiations that delve into their actual perceived problems. The complexity increases due to the diversity in characteristics among Partner States, leading to differences in their specific product needs. This negotiation is further shaped by the EAC's general decision-making

process. Unlike a majority-vote structure, decisions in the EAC are forged through consensus, granting each Partner State a theoretical veto power. However, the EAC's strong hierarchical governance and accountability structure, which regional stakeholders are aware of, balances this dynamic. When higher-level officials have already decided on the way forward – in this case, implementing a pooled procurement mechanism – the efforts of regional stakeholders are primarily directed towards finding common ground and reaching agreements to realize that goal. Sometimes in the form of unanimity and, on other occasions, in the form of finding a middle ground, as demonstrated in the example above.

The stakeholders concluded the meeting with their approval to start information sharing (Phase 1), once the information sharing platform had been developed and/or adapted. Finally, the meeting recommended the EAC Secretariat and the EAC RCE-VIHSCM to convene additional Expert Working Group meetings on legal, finance and procurement matters to develop appropriate implementation documents and guidelines as also proposed during the validation meeting in Entebbe.

At the time of writing, these additional working groups are being planned and conducted. The alignment process between Partner States is still in progress and it remains unknown when the EAC pooled procurement mechanism becomes operational, starting with information sharing.

Discussion

Attempts to implement the EAC pooled procurement mechanism have been ongoing for nearly two decades. Despite intensified efforts in the past couple of years, the mechanism has not reached fruition yet. In this article, we set out to explore how the EAC pooled procurement

has been developing over time and what work and efforts have been made to align inter-country interests. In-depth case studies of such collaboration initiatives are often lacking in academic literature. We believe that insights from this long-term study are relevant as they help to delineate complexities involved in setting up such collaboration initiatives in practice. In addition, the application of the Pooled Procurement Guidance as an analytic tool increases our understanding of why, how and when certain elements are essential during the developmental process.

So, why did the EAC pooled procurement mechanism originally stagnate? Our findings showed that a lack of dedicated funding, sufficient resources and ownership played an outsized role in the promise stage of the EAC pooled procurement mechanism. Following the initial multi-level engagement efforts between Partner States in the mid-2000s, the EAC Partner States started their pooled procurement journey with an attempt to align interests. After conducting a comprehensive needs assessment, the Partner States agreed on group contracting as the pooled procurement model for the region as early as 2008. In the years that followed, however, progress came to a halt due to a lack of dedicated funding and the absence of a designated secretariat to spearhead inter-country alignment and implementation processes going forward. Although progress was not always linear during this promise stage, incremental developments allowed the project to regularly recur on the EAC agenda.

After nearly a decade of dormancy, what prompted the EAC Partner States to pursue another attempt following the initial stagnation? Primarily, the establishment of a dedicated secretariat (EAC RCE-VI-HSCM), whose main project was to take ownership and responsibility over the development of the pooled procurement mechanism through *alignment work* consisting of converging needs, managing the process and building inter-personal relationships. Since then, Partner States have been involved in an intricate dance of negotiations and

harmonization efforts led by the EAC Secretariat and the EAC RCE-VIHSCM. As our excerpts illustrate, this has been a continuous and reflexive process of negotiations and re-negotiations on challenges, needs and design during market survey analyses, feasibility studies and consecutive regional stakeholder meetings. In addition, our findings show that external experts (i.e., stakeholders from outside the EAC Partner States) play an important role in making sensitive issues manageable and debatable.

Going forward, however, we argue that continuous alignment efforts will be needed as this construct does not inherently sustain itself. Alignment remains fragile particularly due to the voluntary nature of participation and the availability of alternative venues (i.e., outside the pooled procurement mechanism) for participating countries to achieve their aims. In addition, sustained political will and long-term dedication of funding of Partner States will be required. This commitment will depend on the Partner States' perception of equal representation, active involvement and fair allocation of benefits within the mechanism. In addition, strengthening inter-personal relationships among Partner States, as well as with the (yet to be established) procurement secretariat, will be essential for its success. Factors that can influence this relationship include continuous and broad involvement, mutual trust, absence of conflict of interest, history of collaboration, credibility and development of a positive reputation and track record (Parmaksiz, Bal, et al., 2023; Parmaksiz, van de Bovenkamp, et al., 2023). To reinforce these interpersonal dynamics, secure sustained funding, and acquire political buy-in, we suggest Partner States to continue the phased approach towards group contracting by starting with information sharing. This gradual and iterative process will facilitate learning from experience, while interim benefits, such as costs savings and increased availability, can further encourage commitment from Partner States.

Similar to the pooled procurement mechanism, the EAC has also been evolving. In the last two years, the Democratic Republic of the Congo and the Federal Republic of Somalia have both joined the EAC, but have not yet been actively participating in the development of the mechanism. Incorporating their needs into the pooled procurement mechanism can be viewed as both an opportunity and a challenge. While expansion increases the pool of regional experts, market size – and with that presumably buying power – and regional manufacturing capacity, it also requires more intensive alignment efforts and integration of in-country processes such as procurement and supply chain systems, financial operations and legal frameworks. Similarly, it is essential to consider and align the interests and needs of Partner States that are concurrently involved in other inter-country pooled procurement initiatives. The extent to which this alignment succeeds will be an important determinant for the mechanism's sustainability.

Strengths and limitations

Our (partial) involvement in the development of the EAC pooled procurement processes poses some risk of bias. To minimize this risk, we verified and triangulated our data in two ways. First, we used various data sources such as grey literature documents (e.g., policy papers, feasibility studies, newspaper articles), document analysis of regional stakeholder and ministerial meetings, observations and informal interviews with experts involved in earlier stages of the mechanism. Second, the involvement of experts from diverse backgrounds and countries has enabled us to verify and frequently reflect on our data and assumptions within our research team.

On the flip side, our close proximity to and involvement in these processes has provided a unique insight into the development of complex inter-country pooled procurement mechanisms. It has allowed us to observe, document and reflect on the continuous work and efforts of participating actors – including ourselves – over a longer period of time

in terms of *alignment work*, consisting of facilitating negotiations, process management and inter-personal relationship building. We believe these detailed insights provide valuable academic and practical lessons for researchers, policy-makers, and other stakeholders by shedding light on the (frequently overlooked or undocumented) complexities involved in setting up such (inter-country) pooled procurement mechanisms.

Conclusion

Our study provides insights in the longitudinal development of the EAC pooled procurement mechanism. It shows that setting up collaboration initiatives such as inter-country pooled procurement mechanisms require: (1) continuous consensus-building and alignment work to harmonize goals, needs and operations; (2) a driving force to lead this alignment work by taking ownership over the process and be receptive to the needs of stakeholders; and (3) fostering inter-personal relationship and trust among participants.

Moving forward, we believe that continuous alignment efforts, long-term political determination and sustained funding will be necessary to successfully achieve the gradual implementation of the EAC pooled procurement mechanism. To support this process, we recommend Partner States to regularly revisit the essential elements in the Pooled Procurement Guidance and reflect on their adoption and relevance as their needs and the mechanism evolves over time.

7

On the emergence, development and sustainability of collaborative approaches

The Dallas Buyers Club, which set the scene for this dissertation, can be seen as one of the earliest versions of a (third-party) pooled procurement mechanism. The approach of Ron Woodroof – the drug-addicted Texan cowboy that tries to increase access to medicines to his fellow HIV-patients during the early years of the AIDS pandemic in the US – provides us valuable lessons. In order to achieve his goal, he recognized the need to consolidate resources and work collaboratively on finding solutions to improve access to medicines in resource-limited settings: he witnessed – and personally experienced – the large-scale suffering of HIV-patients (*perceived urgency of the problem*), aggregated the demand of HIV-patients (*market consolidation*), bought medicines in bulk (*lower transaction costs*), provided medicines for a monthly fee (*sustainable financing mechanism*), and hired assistants with specific roles to run the business (*clear organizational structure*).

It lacked, however, a few important ingredients to make it a sustainable operation, not the least of which was the incompatibility of his operations with the legal and regulatory framework in the US. The medicines he was procuring from Mexico, were not FDA-approved and therefore illegal. Because of its brief operational lifespan, the buyers club was also unable to shape the antiretrovirals (ARVs) market and secure a sustainable supplier base. It could not offer suppliers with sufficient production and supply incentives to bring down their outrageous (read: immoral) prices for ARVs, which were still under patent protection at that time.

Nevertheless, the movie does provide us a poignant example of the power and potential of collaborative approaches in addressing the issue of constrained access to medicines by, in this example, shedding light on the acute unmet need of HIV patients in and around Dallas.

In the introduction of this thesis, I have described why access to medicines remains an enduring problem with complex roots. One of the issues is that the problem of access spans across multiple inter-

dependent domains. Additionally, a myriad of actors including patients, regulators, politicians, industry and health professionals are involved. Each with different needs, interests and responsibilities, at times diverging or even conflicting. These tensions often stem from various opposing values and dynamics, such as national-level enforcement mandate vs. global-level trade incentives, health vs. profit maximization, or short-term (re)election ambition vs. long-term sustainability of the healthcare system. Therefore, tackling access to medicines remains somewhat enigmatic.

I further discussed the consequences of constrained access to medicines and summarized some of the efforts that have been made in the past decades to tackle this problem. Although extensive work has been done by the global health community including advocacy, development of standardized lists, guidelines and tools, as well as the establishment of organizational structures, the issue is far from solved. Nearly two billion people worldwide continue to have constrained access to essential medicines (World Health Organization, 2017c).

Therefore, my aim was to make a contribution to understanding how to increase access to affordable and quality-assured medicines by focusing on two collaborative approaches that have been promoted and implemented to achieve that goal: pooled procurement and pharmaceutical track and trace. I have combined a systematic literature review, document analyses, semi-structured interviews, comparative case studies and theoretical insights from collaborative governance and organizational life cycle literatures to explore the creation, the multi-actor interactions and the general development of collaboration initiatives over time.

Before I continue to answer my research questions, I will reiterate them to save you from excessive page-flipping. The research questions that guided my empirical work were as follows:

1. What are the preconditions for the emergence of collaboration initiatives?
2. How do collaboration initiatives develop over time?
3. What work is needed to implement and sustain collaboration initiatives?

In the previous chapters, I explored the implementation process of the pharmaceutical track and trace system in Turkey (Chapter 2), conducted a systematic review of the academic literature on the implementation and functioning of pooled procurement mechanisms for medicines and vaccines (Chapter 3), developed a *Pooled Procurement Guidance* that provides a structured overview of how pooled procurement elements evolve over time and what elements are essential during that process (Chapter 4), compared successful and failed examples of pooled procurement mechanisms that differ in structural form (i.e., inter-buyer vs. third-party mechanisms) (Chapter 5), and finally delved into the developmental process and multi-actor engagement of the East African Community (EAC) pooled procurement mechanism over a longer period of time (Chapter 6).

In the remainder of this final chapter, I bring together insights from these chapters, focusing on four things. First, I provide answers to my research questions and highlight some of my key empirical findings. Second, I discuss the practical and theoretical implications of my findings, followed by some methodological reflections. Third, I suggest a future research agenda based on my findings. And fourth, I conclude this chapter with my final thoughts.

Emergence of collaboration initiatives

The first research question explored how collaboration initiatives regarding access to medicine emerge. It sought to investigate what

preconditions drove their implementation and adoption process by identifying systemic factors and essential elements that must be taken into account to successfully realize these collaboration initiatives within their specific local contexts.

Before collaboration initiatives are initiated, one or multiple so-called *drivers for collaboration* are required. A driver can be seen as a force or an impulse that causes a certain situation to change or develop. Such drivers often originate when actors identify problems and/or opportunities with their current situation. These can either arise internally, in the form of problems or opportunities perceived by involved actors, or externally by events such as the COVID-19 crisis or a global donor urging actors to increase their collaborative efforts.

To set change in motion, these drivers need to be strong enough to alter the status-quo. Prior to change, "the current situation" often remains in a state of equilibrium. It is held together by a variety of things such as laws, regulations, norms, values and actors that are generally resistant to change. A strong impetus is needed to disrupt this balance and rearrange the order before it eventually oscillates into a new state of equilibrium over time. A clear example of this can be seen in Turkey, where the presence of a specific set of political and economic drivers urged the central government to implement a track and trace system. At that time, the newly elected government sought to build political legitimacy among its citizens by expanding universal health coverage delivered through a single-payer state institution. When reimbursement fraud jeopardized the sustainability of this coverage, resulting in billions of dollars of public funds flowing down the drain, it created political and economic drivers that were so strong for the national government to address the issue by implementing an ambitious technological solution within an exceptionally tight timeframe.

In addition to the force of the drivers, the *enforcer* also requires a certain degree of power and fortitude to set change in motion. In Turkey, this power emerged from a politically determined central government

that was backed by a big market size (i.e., large population) and a public single-payer system in combination with high insurance coverage rates. This created a central power to impose a new system on pharmaceutical stakeholders. In other settings where such elements are missing, suppliers and distributors that do not want to incur the costs of system changes, might pull out and leave for more profitable markets. An illustrative example of such dynamics, in a different context, has recently appeared in the Netherlands, where policies to make medicines more affordable have inadvertently contributed to shortages of essential medicines. In the last year, a record-high five million Dutch patients faced challenges obtaining their prescribed medicines at pharmacies. This shortage arose from an overly successful preferential price policy[13] that drove prices so low that, when for example production errors occurred at the manufacturing site, the Netherlands found themselves relegated to the bottom of the industry's priority list due to insufficient market size and profit margins (van der Geest, 2024a; NOS, 2024). It is important to note that the ability to enforce change is not limited to only strong and powerful central governments. A single actor might feel a strong drive to solve a problem or seize an opportunity and initiate a change. To achieve more higher-level and systemic change, however, a broader coalition of interdependent actors need to be engaged and involved in the process of change.

This brings me to my second point; relative alignment is needed between participating actors on goals and operations of the collaboration initiative. This starts with engagement between actors. This engagement needs to be set up, either by the participating actors themselves or facilitated by an external organization that is perceived as trustworthy, neutral, potent and competent. This engagement process can be

[13] The preferential price policy in the Netherlands allows health insurers to designate one preferred generic version of a medicine. Only the selected product, typically the cheapest, is eligible for reimbursement during a restricted time period of usually between 6 to 12 months (Vogler et al., 2017).

influenced by inter-relational drivers such as prehistory of collaboration or conflict between actors, and the existing imbalances in power, resources, and knowledge between actors (Ansell & Gash, 2008). While imbalances are inevitable, and to some extent even desirable and enriching (da Rosa et al., 2023), successfully setting up collaboration initiatives requires each participating member to possess at least an adequate level of resources (e.g., budget, staff, expertise, technical capacity, time) to participate in the collaboration. Additionally, compatible laws and regulations must be in place in the country or countries that the collaboration spans across (Vogler et al., 2021). The failed attempt of the Pacific Island Countries (PIC) pooled procurement mechanism provides an illustrative example (Chapter 5). Their prior experiences of unsuccessful collaboration initiatives (e.g., Air Pacific) and their diverging goals emanating from asymmetries in power, resources and knowledge led to unsuccessful alignment of goals of the pooled procurement mechanism.

My third, and final point is that there needs to be relative alignment between the shared goals of the participants and the structure and purpose of the collaboration. Collaborative organizations are diverse and complex in nature. In addition to relative alignment amongst participating members, as emphasized in my previous point, there needs to be relative alignment between the shared goals of the participants and the structure and purpose of the collaboration. In other words, its characteristics need to be compatible with the shared goals it aims to achieve. The varying characteristics of collaboration initiatives identified in this dissertation include, but are not limited to the **structural form** (ranging from a third-party organization to an inter-buyer mechanism), the **operational level** (i.e., sub-national, national, inter-country and global level), the **goals** (e.g., reduce costs, increase efficiency, increase quality, increase availability), and the **means** of the collaboration initiative (e.g., buying products, sharing technical capacity, implementing a technological system). These characteristics have been

identified in the context of pooled procurement mechanisms (Chapter 3), but they are likely to apply to other collaboration initiatives as well. To help delineate this complexity in the context of pooled procurement mechanisms, I have developed a *Pooled Procurement Guidance*. It is a practical tool that facilitates the identification and formulation of goals, needs, characteristics (e.g., legal landscape, size, organizational structure) and resources (e.g., finances, human resources, expertise, technology) of the participating members (Chapter 4).

In conclusion, three preconditions need to be met for the emergence of collaboration initiatives: strong drivers, relative alignment between participating members, and compatibility between the collaboration's characteristics and the shared goals it aims to achieve. Collaboration initiatives might struggle to come off the ground when these preconditions are not met, or when other delaying or obstructing factors are in place – such as incompatible laws and regulations, insufficient resources, or participation costs not limited to financial aspects – that outweigh the benefits the collaboration might offer.

Developing collaboration initiatives

The second research question focused on the temporal dimension of collaboration initiatives. It explored how such mechanisms change over time, identifying general developmental stages and delineating the essential processes that take place within each developmental stage. In formulating the developmental stages in Chapter 4, I particularly drew upon insights from theoretical literature on organizational life cycle (D'Aunno & Zuckerman, 1987; Miller & Friesen, 1984) and collaborative governance (Ansell & Gash, 2008; Bryson et al., 2006; Emerson et al., 2012). I applied these theoretical insights to the context of one of the collaboration initiatives (i.e., pooled procurement mechanisms). However, as I will show in the following sections, the general

trend of development applies to a wider array of collaboration initiatives, including pharmaceutical track and trace systems.

Based on my findings, I identified four general stages that successful collaborative approaches typically go through: the promise stage, the creation stage, the early operational stage and the mature stage. Although the boundaries of each stage are somewhat arbitrary, each stage focuses on various aspects of the developmental process. The main goal in the **promise stage** is to create inter-actor engagement and agree on a shared vision. During the **creation stage**, actors focus on putting the shared vision into a shared plan by reaching alignment on goals, purpose and operations of the collaboration initiative. Once the shared plan is developed, it should be put into practice during the **early operational stage**. Important to highlight during this stage is that many unforeseen (practical) challenges will be faced that require flexibility and adaptation to solve. After these challenges have been surmounted, the initiative enters the **mature stage**, evolving into sustainable practice with routinized processes. Also, the initiative becomes a trusted and established actor of its own, extending its value beyond its initial target audience to external actors.

Collaboration initiatives do not develop through these stages linearly, however. To understand how collaboration initiatives develop in practice, I will elaborate on lessons drawn from three empirical cases studied in Chapters 2, 5 and 6.

As described in Chapter 2, following the launch of the pharmaceutical track and trace system in Turkey, the system crashed, and fell back into the creation stage where it had to be redeveloped from scratch before entering the early operational stage again. A few elements are important to note in this case. The central government's political determination led both to its downfall and salvation. Because of the perceived urgency of the problem (i.e., reimbursement fraud), the government forced stakeholders to implement the system as soon as possible.

This resulted in the software crashing shortly after becoming operational. That same political determination, however, convinced that failure was not an option, resulted in the redesign of the software system within a very short timeframe. While the outcome was non-negotiable, as the system *had* to be implemented, the roadmap to achieving that end goal was far from predefined. Since Turkey was the first country in the world to implement a full pharmaceutical track and trace system on a national scale, no blueprints existed on how to implement such a system. Although the Ministry of Health (MoH) developed guidelines and standards in the early operational stage, some of these quickly proved to be incompatible with industry practices. Consequently, the government granted industry stakeholder sufficient flexibility and leeway to tailor the system according to their needs, while facilitating a shared learning environment to make the system work within the Turkish pharmaceutical context. Once industry stakeholders overcame these challenges, and software glitches were resolved, the system evolved into the mature stage. At this stage, the system itself matured to cater additional unintended benefits including recall optimization for faulty products, provision of up-to-date medicine information to citizens through a mobile application, and the facilitation of inventory control and stock-outs monitoring for both the MoH and pharmacists.

In Chapter 6, another non-linear trend could be noticed during the development of the East African Community (EAC) pooled procurement mechanism. After entering the creation stage, the mechanism stagnated for years due to lack of funding, political determination and dedicated ownership of the project. It was only revived after the *Regional Center of Excellence for Vaccines, Immunization and Health Supply Chain Management* (EAC RCE-VIHSCM) was launched and was entrusted with responsibility for overseeing its implementation process. Unlike the previous example in Turkey, this collaboration initiative is not

propelled by a single, strong centralized power (i.e., government). Instead, it comprises of a coalition of six countries, referred to as Partner States, each possessing equal decision-making power. This resulted in a longer preparation phase during the second attempt of the creation stage. It involved a systematic analysis of challenges, needs and current practices in the EAC Partner States in the form of feasibility studies and market surveys. In addition, a broader involvement of Partner States during this renewed creation stage coupled with the active leadership of a dedicated driver (i.e., EAC RCE-VIHSCM) has reignited political will to push this pooled procurement mechanism forward.

Similar to the development of collaboration initiatives, their decline does not follow a linear pathway either. When alignment between actors is threatened or the operations of the initiative enter a state of prolonged stagnation, collaboration initiatives can turn inactive, revert to earlier stages, transform into something new or stop existing all together.

The decline of the Asthma Drug Facility (ADF) pooled procurement mechanism in Chapter 5 is one example of a collaboration initiative that did not manage to overcome its challenges, turning inactive and eventually ceasing to exist after the early operational stage. The ADF, created to solve the neglected global problem of asthma, struggled to create local political awareness. Asthma, a non-communicable disease without cure, proved challenging to detect in target countries because of a lack of accurate diagnostics, leading to the problem being perceived as less urgent. Compounded by the inability of the ADF to organize sufficient multi-actor engagement due to the non-communicable nature of the disease also translated into a lack of appeal for external donor funding. Despite initial successes in incentivizing suppliers and reducing prices of asthma medicines and inhalers, these achievements could not be sustained due to insufficient scaling of market size, a consequence of the perceived lack of urgency in potential buyer

countries. Since its financing model relied on sales through mark-ups, the operations of the ADF came to a halt when new orders dried up.

In conclusion, collaboration initiatives generally follow a non-linear development across four stages. Each stage requires different goals, focuses and types of work from participating key actors to evolve from one stage to another. It is important to note that decline can set in at any time, when alignment between key actors is threatened.

Sustaining collaboration initiatives

The third research question delved deeper into the work and effort required to create, implement, embed and sustain collaboration initiatives over a longer period of time. It also paid attention to inter-personal dynamics and the often overlooked, mundane work that goes into engaging, motivating and aligning actors to drive initiatives forward.

In the context of pooled procurement mechanisms, I have distinguished three key actors involved in the mechanism: buyers, the pooled procurement organization and suppliers. Each of these actors have different needs, roles and responsibilities, and therefore, perform different types of work. In my answer to the first research question, I have already touched upon the complexity and diversity of pooled procurement mechanisms. For this question particularly, it is important to highlight the disparity in work required for two distinct structural forms: inter-buyer and third-party pooled procurement mechanism.

Inter-buyer mechanisms, as the name already suggests, are mechanisms that are set up in a collaborative effort between buyers. Its governance structure is often more democratic and egalitarian compared to third-party organizations. Third-party organization mechanisms, on the other hand, consist of an external procurement organization that procures *on behalf of* its buyers. These two structural forms,

however, are not binary categories; they represent the front- and tail-end of a spectrum that encompasses a myriad of hybrid forms, including *piggy-backing* (i.e., buyers benefiting from contractual terms of one of the buyers) and *lead buying* (i.e., one buyer acting as a procurement agent for other buyers) (Kenis & Provan, 2009; Schotanus, 2007).

In Chapter 5, I showed that buyers in a mechanism with characteristics closer to inter-buyer require a high degree of relative alignment. This stems from the fact that each buyer, especially in inter-country collaborations, possesses different characteristics related to their needs. To further specify, each buyer has different procurement systems, financing structures, product needs and regulatory and legal frameworks. When buyer characteristics show greater homogeneity, like in the example of the Organisation of the Eastern Caribbean (OECS) island nations, achieving this relative alignment is more feasible. After all, buyers that share similar characteristics face similar challenges, and therefore, generally require similar solutions to solve those challenges. In other instances where buyers' characteristics are more divergent and gaps are harder to bridge, alignment is more likely to fail, such as in the example of the Pacific Island Countries (PIC).

This alignment, however, is not a set-and-forget, self-sustaining construct. It is a continuous and reflexive process that needs to be forged and nurtured by credible actors that are trusted by all parties involved. As seen in the example of the East African Community (EAC) pooled procurement mechanism, a dedicated organization (EAC RCE-VIHSCM) with a formal leadership role was created with the goal to drive this project (and others) forward. In Chapter 6, I showed that *alignment work* consists of mainly two types of work: on the one hand, more subject-related substantive tasks, and on the other hand, more process-related, managerial tasks. The former comprises of work that identifies individual goals and needs, defines shared visions and protocols, facilitates discussion and formalizes operations, following the concept of *principled engagement* as prescribed Emerson and

Nabatchi (2015). In this example, often in the form of carrying out market surveys or feasibility studies and facilitating plenary discussions during regional stakeholder meetings. The latter, however, focuses on more mundane, but often omitted day-to-day tasks of managing the process, also referred to as micro-governance (Wegner & Verschoore, 2022). This includes writing emails, organizing (face-to-face) meetings, finding competent consultants, attracting and managing funding but also fostering and strengthening inter-personal relations by trust-building and motivating actors to maintain committed to the process. Both types of work are essential, as they enable actors to engage, build inter-personal relationships, resolve differences and transcend individual needs to reach overarching, collective goals.

Moving closer towards the third-party organization end of the spectrum, the need for alignment and consensus-building between buyers fades. For third-party organizations mechanisms to come off the ground, buyers need to align their needs, goals and operations with the procurement organization, instead of other buyers. In addition, third-party organizations are often set up around tackling specific diseases (e.g., HIV, TB or Malaria) or health products (e.g., vaccines or orphan drugs), narrowing down discussions and consensus-building efforts on product needs. Although third-party organizations might seem more straightforward and hassle-free to set up compared to inter-buyer mechanisms in this regard, it comes with other complexities. First, third-party organizations lack a guaranteed market to sell their products because buyers are generally not involved in setting them up. Therefore, third-party organizations require a more active recruitment of funds, markets and other resources. Second, third-party organizations rely more heavily on creating local (i.e., in potential buyer countries) and global (e.g., global health organizations, international donors) awareness around the problem that they are trying to solve. On top of that, the procurement organization needs to induce political will and determination to act upon the problem

which needs to translate into (potential) buyers allocating budget and human resources to solve their problems through the proposed solution of the procurement organization.

Once the pooled procurement mechanism has been established and becomes operational, works of the procurement organization in both inter-buyer as well as third-party mechanisms becomes more convergent. In both mechanisms, the procurement organization will be responsible for procurement related tasks such as aggregating demand data, carrying out tenders, assessing product quality and providing capacity building for buyers. In addition, the procurement organization has to dedicate efforts towards responsive communication, timely problem-solving, and building a positive reputation based on a track record of competence and trust. As opposed to third-party mechanisms however, the procurement organization in inter-buyer mechanisms will also remain responsible for continuous (re-)alignment efforts of buyers at regular intervals. If goals and needs of individual buyers change, the longevity of the mechanism can be jeopardized, potentially leading to stagnation or decline like in the case of the Gulf Cooperation Council (GCC) Joint Procurement Program, as detailed in Chapter 4.

Similar to third-party pooled procurement mechanism dynamics, the governance structure of pharmaceutical track and trace systems resemble a more centralized model with the government positioned at the core of the interconnected actors (e.g., industry stakeholders, distributors, pharmacists, health professionals or software engineers). The central actor, in this case the government, is primarily tasked with offering guidance, developing a legal framework, fostering stakeholder engagement, driving implementation through political power while allowing sufficient flexibility to stakeholders in the practical execution of the system.

The other stakeholders have largely been responsible for translating policy into practice through *articulation work* (Star & Strauss, 1999).

This type of work is characterized by adapting and embedding the policy into the local contextual environment of daily practice. This also involves anticipating and dealing with contingencies that arise. Many practical and software-related adaptations had to be made in the case of Turkey as described in Chapter 2. For instance, manufacturers had to adapt conveyor belts and production lines, sales notifications had to be revised by incorporating minimum-order-quantities and changes had to be made to logistics units. In circumstances where no predefined roadmap and standards exist, successful implementation and adoption in practice relies on sufficient leeway and flexibility. In other circumstances, more rigid guidelines and standards might be required, especially if strong drivers or political power is lacking, as discussed in my response to the first research question.

To sum up, collaboration initiatives encompass a wide spectrum of structural forms. In the context of pooled procurement, these structural forms range from inter-buyer to third-party mechanisms. Especially for the inter-buyer end of the spectrum, the relative homogeneity of buyer characteristics (related to their needs) is an important determinant for successful alignment. Achieving and sustaining this relative alignment demands active work and efforts by participating actors, often led by a dedicated actor that is entrusted with this role. This *alignment work*, consisting of both substantive tasks and managerial tasks, is a continuous and reflexive process that is required during the entire life cycle of the collaboration initiative. For collaboration initiatives with a structural form closer to third-party organizations, buyers need to align their needs, goals and operations with the procurement organization. Third-party mechanisms also require more effort to create awareness and attract buyers, funds and other resources. As the collaboration progresses, *articulation work* becomes essential for embedding policies and operations into the participants' local contextual environment of daily practice.

Implications of research

This dissertation has several practical and theoretical implications. I will discuss them in turn.

Practical implications

The findings of this dissertation have various practical implications for policy-makers, practitioners and scholars involved in the implementation and operation of both pharmaceutical track and trace systems and pooled procurement mechanisms. My thesis has also multiple implications for the ongoing global efforts to increase access to medicines.

Implications for implementing pharmaceutical track and trace systems

Contrary to popular belief, pharmaceutical track and trace systems – like many technological solutions – are not a silver bullet to solve the problems that underly constrained access to medicines. Track and trace systems do not have a direct effect on lowering prices or increasing the quality of (substandard) medicines.[14] They are mainly effective in increasing the transparency of (otherwise opaque) regulated supply chains, but only under specific circumstances and highly dependent on the presence of a specific set of preconditions. In Turkey, this was a combination of four factors: strong political will (induced by reimbursement fraud), political power (derived from a single-payer institution creating a substantial pharmaceutical market), adherence to the system by linking the reward (i.e., money) to the intended functioning

[14] In fact, track and trace systems might even increase prices in the short term because of the upfront investments industry has to make. In the longer term, however, prices might drop because of optimized supply chain management through more efficient inventory management, optimized recall processes of substandard products (mitigating the negative health impact as well as reputation damage), and barring falsifiers to enter their products into the (legitimate) supply chain protecting their income and value.

of the system, and sufficient flexibility and leeway to adapt the system according to the local practice of stakeholders. To function, such systems must be embedded into a well-defined legal framework and supported by adequate regulatory capacity, including laboratories, staff and financial resources.

In countries that lack these preconditions, the results of this thesis would suggest policy-makers to start with performing a systemic analysis of market, political, economic, technical, and legal factors prior to implementing any pharmaceutical track and trace system. This provides an overview of the current situation, and identifies the aims and needs of government and industry partners. This can serve as a starting point for further alignment between key stakeholders. For track and trace to work successfully, strong industry incentives and participation are essential. This is not guaranteed, since there is often a mismatch between national-level political interests (of governments) and global-level economic incentives (of suppliers). If incentives are inadequate and governments lack political power (either due to small market size or limited financial capacity), the additional requirements of adopting track and trace systems might drive suppliers to withdraw their products from the market in search of more profitable markets. To paraphrase one of my respondents: developing the software [that runs the track and trace system] was not the biggest challenge, but overcoming the hurdle of aligning personal and institutional interests was far greater than any technological challenge.

Implications for implementing pooled procurement mechanisms

As I have shown by now, pooled procurement mechanisms are complex, multi-component, diverse and context-specific. To set up a successful pooled procurement mechanism, its characteristics need to be compatible with the specific problems it aims to solve because each problem requires a different approach, operational focus and levels of integration and collaboration. A commonly used categorization

distinguishes between four progressive levels of collaboration in pooled procurement mechanisms ranging from *informed buying* (information sharing on prices, product quality and suppliers), *coordinated informed buying* (conducting joint market research), *group contracting* (engaging in joint negotiation) to *central contracting* (through a dedicated procurement agent acting on behalf of the buyers)[15] (Management Science for Health, 2012; World Health Organization, 2020b).

In the following section, I will first reflect on the implications of my findings with regards to the five core challenges identified by the *Lancet Commission on Essential Medicines Policies* (Wirtz et al., 2017), as outlined in the Introduction chapter. Then, I will reflect on the tool that I have develop to identify problems and facilitate the alignment of aims and goals between buyers.

Buyers seeking to tackle their lack of **inadequate and sustainable financing** to buy essential medicines through pooled procurement mechanisms might find themselves disappointed. Insufficient financial capacity is not a condition that pooled procurement can intrinsically solve. Instead, money is a prerequisite that members *need* to participate. Sufficient funding is a *condicio sine qua non* for setting up and sustaining collaborations. What collaboration initiatives can do, however, is aid the attraction of external funding (e.g., USAID funding operational costs of OECS), or help identify and prioritize areas for allocation of funding.

If a buyer's primary motivation to participate is to **reduce prices** of medicines, pooled procurement might be of better use. Although evidence on this subject remains inconsistent as shown in Chapter 3 (Chaumont et al., 2015; Kim & Skordis-Worrall, 2017; Waning et al.,

[15] The first two levels (informed buying and coordinated informed buying) are regarded as modes of *information sharing* – a necessary precondition for procurement – while the latter two levels (group contracting and central contracting) are perceived as modes of actual *(pooled) procurement*.

2009), various research articles indicate that pooling demand and consolidating the buyer-side of the market might have a positive impact on increasing buying power and lowering prices (DeRoeck et al., 2006; Dubois et al., 2021; Perez et al., 2019; Roy, 2013). Although there is a paucity of evidence, pooling *distribution* might also have a positive impact on reducing prices. Especially for landlocked countries that gain access to seaports through pooling with other countries.

If, for example, a buyer's main motivation is to **increase the quality** of their medicines, a lesser degree of procurement integration – such as *informed buying* or *coordinated informed buying* – might suffice, as achieving this objective typically requires sharing regulatory guidelines and standards, laboratories, human resources and practices, rather than actually procuring medicines collectively. In fact, establishing regulatory harmonization between buyers is an essential precondition that needs to be in place before more advanced forms of inter-country pooled procurement mechanisms, such as *group contracting* or *central contracting*, can be achieved. Without the collective approval of medicine regulators, medicines slated for joint procurement will not be able to gain market access within the buyer countries. The East African Community Medicines Regulatory Harmonization Programme (EAC-MRH), the European Medicines Agency (EMA) and the Gulf Committee for Drug Registration (GCC-DR) are all examples of inter-country regulatory harmonization programs aiming to increase medicine quality through assessing and approving market access collectively.

If a buyer seeks to minimize the **inappropriate use of medicines**, an issue that often leads to wasting money and reducing the efficacy of medicines, pooled procurement might be indirectly beneficial. The sharing of information and expertise might lead to increased technical capacity and more accurate demand planning. As a result, the likelihood of shortages decreases, minimizing the necessity for patients to switch to therapeutically alternative medicines, which has been linked with reduced adherence and inappropriate use, stemming from

misperception about the generic substitution (Håkonsen et al., 2009).

Finally, if a buyer's main motivation is to tackle the **mismatch between development of new medicines and burden of disease in LMICs**, pooled procurement can play an essential role in offering production incentives to manufacturers. By consolidating the market, manufacturers might be incentivized to invest in tackling diseases and produce medicines that were previously not financially feasible. The creation of the Global Drug Facility (GDF), as discussed in Chapter 5, provides an illustrative example. Through its rounded procurement services and market shaping efforts, it offered manufacturers with ample incentives to scale-up the production of high-quality generic TB medicines. To be more specific, the GDF consolidated demand around fixed-dose combination (FDC) treatments incentivizing its production, it levelled off the erratic demand of buyers by creating a Strategic Rotating Stockpile and it adopted long-term framework agreements that provided suppliers with a level of security to produce medicines, as long as they met the specified conditions and quality standards.

However, these challenges rarely exist in isolation. Buyers often have multiple motivations to participate and goals to achieve at the same time. This can become a barrier, especially if buyers are striving to achieve conflicting goals. For example, when buyers seek to enhance the quality of medicines while simultaneously reducing prices, a relationship that some evidence shows is inversely correlated because quality literally comes at a cost (Pisani et al., 2019). To maximize the probability of success for such mechanisms in achieving their predetermined goals, it is essential for policy-makers and practitioners to start with identifying their problems and aligning their aims within and among buyers prior to setting up a pooled procurement mechanism. Within this dissertation, I have developed a *Pooled Procurement Guidance*. It consists of two parts: **Part 1** identifies essential elements for setting up and operating pooled procurement mechanisms and

Part 2 provides a general overview of how such mechanisms develop over time. I have developed this Pooled Procurement Guidance as a practical tool for those involved in pooled procurement mechanisms (e.g., policy-makers, consultants, researchers) to facilitate the identification of aims, needs, motivations, resources, technical capacity and legal landscape of buyers.

In the previous sections, I have emphasized that alignment is fragile, and alignment work is a continuous and reflexive process that is required during the entire life cycle of a pooled procurement mechanism. This guidance can serve as a starting point, or as input for routine reflexive exercises aimed at maintaining alignment on aims, needs and operations among buyers. If buyers have limited incentives to participate because they can achieve their goals independently or through alternative venues (Ansell & Gash, 2008), this alignment work becomes particularly relevant. In such circumstances, however, it might also be helpful to question the purpose of the particular pooled procurement mechanism more fundamentally as such mechanisms are a means to an end (i.e., to collectively solve problems that you are not able to solve individually), not a goal in itself. The Pooled Procurement Guidance offers various elements to consider and collectively harmonize on. Chapter 5 showed that some of these elements are more *political* in nature (e.g., urgency of the perceived problem, motivations to participate, creating continuous alignment, incentivizing suppliers), while others are more *organizationally* relevant (e.g., sufficient and predictable budget, sufficient staff and expertise, clear organizational structure). Both are important and essential for creating and sustaining a mechanism.

Furthermore, the Pooled Procurement Guidance also offers a shared vocabulary that can facilitate in identifying and harmonizing the goals and purposes of the mechanism among buyers. At times, key actors use terminologies interchangeably when they (in fact) mean different

things – such as demand forecasting vs. demand quantification or purchasing vs. procurement. On other occasions, involved actors use broad concepts without sufficient specificity. For example, *budget* (e.g., budget to buy medicines? To cover organizational expenses?), or *incentives* (e.g., supply incentives? production incentives? buyer incentives?). Often, this adds unnecessary complexity and the potential for misunderstanding into an already intricate process. On a subject (i.e., pooled procurement) where more than 170 variations and synonyms exists to indicate a (more or less) similar approach (Schotanus, 2007), a standardized terminology and shared vocabulary promotes clarity, minimizes the risk of misunderstandings, aids in organizing thoughts, and provides consistency in communication. As the case study of the EAC pooled procurement mechanism (Chapter 6) highlights, the Pooled Procurement Guidance contributes to achieving a common understanding among participants. It does this by providing detailed descriptions of each concept and by emphasizing specific aspects of certain concepts. The guidance serves as an analytic tool that aids discussions around the interpretation of these concepts and facilitates alignment around its practical application in the specific local context.

Implications for ongoing global efforts

My findings also have implications for the ongoing global efforts to increase access to medicines. Following the post-colonial era, a gradual transition has been taking place in *Global Health* shifting focus from protecting the health of colonizers – mostly from infectious diseases – through *tropical medicines* towards empowering LMICs to lead health programs (Abimbola, 2018). In recent decades, this shift has been evident in a growing number of countries that have been transitioning from donor funding to securing and dedicating their own financial resources and national health budgets. The rise of inter-country pooled procurement mechanism, increasingly promoted in global health arenas, can be seen in light of these developments. However, with limited

success to date due to its complexity described in Chapters 3, 4, 5 and 6. Lessons from this thesis along with the *Pooled Procurement Guidance* can aid transitioning countries in their effort to shape the global agenda towards *their* problems, needs and proposed solutions. The tool facilitates further clarification, articulation and harmonization of local priorities. In doing so, it is crucial for transitioning countries to focus on continuous and reflexive (re-)alignment to reinforce the urgency of addressing their disease burdens.

For third-party, global health organization pooled procurement mechanisms such as the Global Fund, Global Drug Facility and Asthma Drug Facility, the interests and needs of the *Global North* remain visible. Attraction of (external) funding and creating global awareness around a disease relies mainly on the perceived urgency of the problem by donor countries or organizations, as shown in Chapter 5 of this dissertation. Most third-party, global health pooled procurement mechanisms that have been successful to date reflect this underlying premise. In general, they focus on diseases that are often communicable in nature, posing a potential threat to high-income, donor countries. The success of attracting sufficient funding and setting up such mechanisms, therefore, hinges on the presence of such an urgent (global) threat and the availability (or attainability) of an effective cure. Additionally, the impact of wider political and economic factors should not be underestimated. One can imagine, for example, that addressing (chronic) respiratory diseases in LMICs by increasing awareness around environmental policies might not be high on the priority list of the *Global North* as it may conflict with their economic interests of maintaining production costs low for the goods they import. I thus suggest global donors, policy-makers and other stakeholders in the international community to be more aware and reflexive regarding these, often implicit, contradicting interests. Embracing a more sensitive, receptive and demand-driven approach towards global health would unquestionably contribute to meeting local needs and maximizing health benefits.

Theoretical implications

In this dissertation, I drew upon theoretical insights from collaborative governance and organizational life cycle to explore the creation, the functioning and the temporal development of collaboration initiatives. I applied these lenses to the field of access to medicines, the implications of which I discussed in the previous section. The opposite, however, also holds true. The application of these theories to collaborations in the field of access to medicines also yields valuable lessons for theory and scholars involved in the debates surrounding them.

Collaborative governance studies predominantly focus on the interaction processes and structures between interdependent actors within collaborations that are formed with the goal to attain public goods or services (Emerson et al., 2012; Smith, 2020). What is often underemphasized or omitted from these studies, however, is how such collaborations develop over time (temporal change). Various eminent studies acknowledge the dynamic nature of collaborative processes, which evolve through cyclical or iterative interactions rather than linear sequences (Ansell & Gash, 2008; Emerson et al., 2012). As (unintended) intermediate outcomes arise and both the member composition and the system context changes over time, the aims and needs of participating members also evolves in response to these developments (Huxham & Vangen, 2013).

This dissertation, however, emphasized that in addition to changing dynamics and aims within a collaboration, the collaboration itself also changes over time. Even in cases where the system context and member composition remain unaltered over an extended period of time, the collaboration iteratively transitions through various developmental stages. Engaging (potential) members and developing a shared vision, defining shared goals and converting the shared vision into a shared plan, putting the shared plan into practice and overcoming operational

challenges, and routinizing operations and allocating benefits fairly all require different focus, involvement, work and effort from participating members. In addition, a *collaborative* governance approach might not always be desired or conducive for progress, as seen in the example of the Turkish pharmaceutical track and trace system. If the central government allowed more voices to participate in the early stages of the implementation process instead of showing strong political determination, industry partners – burdened with bearing the upfront costs – might have been more effective in resisting and prolonging the implementation process. In later stages, however, the collaborative aspect was crucial for its success. If the central government continued to impose guidelines and regulations on industry partners without their input, the policy would not have survived in practice. These insights are valuable as they highlight that not only the collaborative dynamics within the collaboration change over time, but also the collaboration itself and its evolving requirements change.

Another theoretical implication of this dissertation is the expansion of collaborative governance in the context of inter-country (i.e., cross-border) collaborations. Successfully setting up and sustaining collaborations is inherently challenging and time-consuming because it intends to converge different aims, needs and operations of actors and organizations. Inter-country collaborations, however, add additional layers of complexity. Actors or organizations within inter-country collaborations must integrate often divergent legal frameworks, political and economic climates, histories, cultures, languages and traditions (Bianchi et al., 2021; da Rosa et al., 2023). This thesis shows the need for continuous and intentional alignment work. Unlike previous recent studies that highlight the importance of *alignment* during the early stages of cross-border collaborations (da Rosa et al., 2023), I argue that alignment work is needed during all stages of a collaboration initiative's life cycle due to its fragility. Without periodic efforts to actively

align goals, aims and needs among collaborative actors, they might diverge, leading to the decline of the collaboration as discussed in previous examples of the GCC or ADF. Despite the group size being an important indicator for its success (Schotanus et al., 2010) – after all, the greater the multitude of voice, the harder to reach consensus – our study showed that not necessarily the quantity, but the group members' homogeneity of characteristics (related to their needs) was an important determinant for its success. Although these factors – size and characteristics – are often interdependent, our empirical findings suggest that it seems more likely to sustainably unite a large group of participants with similar characteristics (e.g., OECS) compared to a small group of participants with diverging characteristics (e.g., GCC).

A final theoretical implication has to do with the process of *decline*, which has been receiving limited attention in academic literature. Despite various eminent studies drew attention to the significance of organizational decline in the public sector, this process has remained relatively underdeveloped in empirical studies. One of the more obvious reasons for this is that organizations in decline are typically more occupied with surviving rather than welcoming researchers to promote organizational learning (Levine, 1978; Peretz, 2021; Ribeiro Serra et al., 2013; Weitzel & Jonsson, 1989; Whetten, 1980). In the context of collaboration initiatives, decline has received even less (academic) attention compared to organizational decline. Decline is often seen as inevitable part of the organizational life cycle (Levine, 1978; Mintzberg, 1984), and it can have various consequences such as stagnation, reduction, transformation or collapse.

Unlike Miller and Friesen (1984), I argue that decline is not a stage in the same chronology as a collaboration's promise, creation, early operation and mature stages. Decline is a process that lies dormant in the background. It surfaces when any of the other stages become unstable or absent. Levine (1978) makes a distinction between internal and

external causes for organizational decline. Decline can set in from a failure to adapt to external, environmental changes (Weitzel & Jonsson, 1989). My empirical findings show that the risk of decline is especially imminent when internal alignment is fragile. This is often the case in collaborations that are formed on a voluntary basis, where members lack mutual interdependence and participating members have alternative venues available to achieve their aims. Continuous alignment of goals, needs and operations is essential to maintain resilient against decline. This is a reflexive process in which both individual members and the collaboration as a collective need to engage in regularly. Once decline sets in, it often becomes much harder to reverse the process. To reverse downwards spiraling, targeted strategies – referred to as *turnaround work* – have been suggested. While most articles studying turnaround work have mainly been focusing on improving operational efficiency from an economic perspective (e.g., cutting costs, revise product portfolio, reduce staff turnover rate) to reverse decline (Ribeiro Serra et al., 2013; Weitzel & Jonsson, 1989), I argue that collectively redefining purpose and enhancing inter-personal dynamics (e.g., trust, mutual understanding, shared commitment) might be equally relevant strategies to reverse decline in the context of collaboration initiatives.

Methodological reflections

Before I set out my methodological reflections, I first would like to take you back to early 2019, the beginning of my PhD trajectory. After finishing my study on the pharmaceutical track and trace system in Turkey, I – together with my supervisors at that time – realized that it was crucial to *procure* the right products to secure affordable, quality-assured medicines to enter the supply chain. As a result, we decided to focus on procurement, and in particular on pooled procurement as it was becoming increasingly popular in global health arenas, but with limited operational success.

I then set out to identify potential case studies of pooled procurement mechanism to learn how and why some pooled procurement mechanisms did seem to work successfully, and others had been struggling to get off the ground after years of deliberation. I identified multiple pooled procurement mechanisms varying in structural form and developmental stage – the East African Community (EAC), the Southern African Development Community (SADC), the Organisation of the Eastern Caribbean States (OECS), Gulf Cooperation Council (GCC), the Global Fund (GF), Asthma Drug Facility (ADF), and the Global Drug Facility (GDF). After a year of: 1) engaging with local universities and attending conferences to establish partnerships aimed at gaining access to key actors and data, and promoting local input to embed our research project and enhance the likelihood of our findings being adopted; 2) forming international research teams; 3) writing individual research proposals; and 4) applying for local ethics clearances, the global COVID-19 pandemic hit and we were all compelled to work from home and redefine our purpose and ways of working. Obviously, this ubiquitous push on the big red reset button also affected the organizations and universities with whom I was about to enter partnerships to carry out the in-depth case studies. As a result, my research plans were put on hold, as was all (social) life in the rest of world, which forced me to take a step back, and shift my focus on reviewing and drawing lessons from what we already knew on pooled procurement mechanism based on (academic) literature. This approach turned out to be very helpful to compile existing knowledge and identify the remaining research gaps.

Fortunately for me though, once initial COVID-19 restrictions were lifted in 2021, I still got to reap the benefits of my initial relationship-building efforts at the beginning of my trajectory. One of them was with the East African Community (EAC) pooled procurement mechanism, as described in Chapter 6, that I would like to reflect on in particular. This long-lasting relationship and involvement came with

many benefits, and some methodological challenges. On the one hand, it provided me a unique opportunity to witness and contribute to the continuous consensus-building and alignment work in practice during various regional stakeholder meetings for an extended period of time. A jackpot that most (PhD) researchers can only dream of. It also granted me widespread access to valuable data sources in the form of questionnaires, interviews and observations, which I got to be part of during their development, execution and analysis.

On the other hand, this case study placed me in the dual role as researcher and consultant as a result of a combination of circumstances: I had to replace a consultant who was unable to attend a regional stakeholders' meeting due to COVID-19 restrictions, while his replacement got rejected a visa before boarding. Personally, I saw this as a great opportunity to learn and put the knowledge I accumulated thus far into practice. Later, this involvement continued with my participation in the execution of a market survey analysis, in which I supported the consultant by compiling academic literature, analyzing the data that we collected during this assignment, writing up the findings in study reports and disseminating outcomes during regional stakeholder meetings. Despite my role being mainly facilitative and directed at fostering alignment and consensus-building among local experts and stakeholders, it meant that I actively took part in the process, instead of merely observing from the sidelines.

So, what does this mean for interpreting my findings? And would I have done something differently if I had the opportunity to do it again with hindsight knowledge? To start with the latter, probably not so much. I believe it is somewhat naïve to think that one – as a foreign PhD student from the Global North – will be granted (unrestricted) access to the core of the action if one's goal is to merely observe a process from the side-lines in situations where there is, initially, a lack of mutual benefit, no prior relationships or interdependencies. To gain access, it is therefore imperative to build relationships and trust by

adding value to the process you want to observe. To answer the first question, however, my proximity to and involvement in the process might have led to potential bias in terms of less sensitivity to assumptions and unexpected findings. To ensure a reflexive attitude and minimize the impact of bias I used three strategies. First, all forms of data collection, analysis and interpretation of the findings were carried out within two (separate) research teams. The internal research team consisted of two local researchers and six focal persons – one expert from each EAC Partner State – while my other, external team consisted of researchers and supervisors that were not personally involved in the case study. This set-up allowed me to continuously verify and triangulate the findings among researchers who were both involved in and distant to the process that was being observed. Second, I triangulated my findings with a variety of data sources such as extensive document analysis (of regional stakeholder meeting reports), academic papers and theses, grey literature documents (e.g., policy papers, feasibility studies, newspaper articles), (quantitative) procurement data, observations, (semi-structured) interviews and questionnaires. Third, I kept detailed field notes and memos while observing and participating in regional stakeholder meetings during my field trips. These strategies allowed me and my supervisory team to regularly reflect on my findings and (underlying) assumptions.

Suggestions for future research

After answering my research questions and reflecting on the various implications of my findings, many unexplored territories and opportunities to expand this field of research remain. Here, I will provide various suggestions for future research.

In the previous section, I started out with presenting a summary of my (research) journey throughout my PhD trajectory. Although my final research design has offered numerous opportunities and valuable

lessons, as discussed previously, I sometimes still wonder about the projects that I initially set out to do, but did not manage to bring to fruition within this timeframe. I believe conducting in-depth empirical case studies of collaboration initiatives in different parts of the world, similar to those proposed, would be highly valuable. These insights could help further validate, falsify and contextualize my findings by applying the lessons I have learned, and translated into a comprehensive Pooled Procurement Guidance. I believe that the general developmental process, alignment work and inter-personal dynamics within collaborations as specified in this guidance document is also well-suited to test in different fields and practices of collaboration initiatives. I particularly suggest focusing on examples of collaboration initiatives that have failed or are in decline because quite often the unsuccessful examples, which are generally overlooked or omitted from (academic) research – partly due to publication bias[16] – offer as much, if not more, valuable lessons in terms of identifying underlying root causes compared to the successful ones.

Another area that remains underdeveloped in this thesis is the perspective of (pharmaceutical) industry stakeholders in collaboration initiatives. In general, public opinion tends to hold an antagonistic view towards the pharmaceutical industry largely fueled by scandals, overcharging for medicines and non-transparent practices concerning data and costs (Gallup Inc, 2019; Singh et al., 2023). Sometimes, this distrustful attitude and moral outrage is (more than) justifiable, as seen in the instances of immoral pricing of ARVs as portrayed in *The Dallas Buyers Club* or other examples of exorbitant prices that frequently find their way into newspapers (Dye & Crow, 2018; Robbins, 2023; de Visser, 2021). In fact, one of the main reasons that collaboration initiatives are formed is to consolidate power against industry stakeholders.

[16] Publication bias refers to the failure to publish the results of a study on the basis of the direction or strength of the study findings (Dickersin & Min, 1993).

However, in the context of collaboration initiatives that aim to improve access to affordable and quality-assured medicines, one cannot exist without the other, and vice versa. Therefore, to ensure the success and sustainability of collaboration initiatives, I recommend expanding research towards studies that take the needs, operations and incentives of industry stakeholders into account when developing and implementing such initiatives.

Finally, the empirical studies in this thesis have mainly focused on the procurement and supply chain management of medicines in the public sector. In many resource-limited countries where public procurement and supply chain management falls short, however, the gap is filled or complemented by private sector parties (Domfeh, 2021; Kuwawenaruwa et al., 2020). As opposed to the public sector, (for-profit) private sector parties generally operate within a less regulated environment, while being primarily driven by economic incentives. This results in different dynamics such as a greater influence of market forces and less attention towards attaining public good and transparency (Management Science for Health, 2012; Manyathi et al., 2021). Therefore, my final suggestion would be to broaden the scope of future research to encompass the incentives and practices of private sector actors, while also focusing on interactions within public-private partnerships in procurement and supply chain management. I believe that combining insights from both public and private sectors can provide valuable lessons for improving access to affordable and quality-assured medicines.

Concluding remarks

This brings me to my final words. In this thesis, I have tried to shed a light on the complexities involved in ensuring access to affordable and quality-assured medicines. In my effort to address these complexities,

I have carried out multiple empirical studies focusing on two collaborative approaches that have been promoted and adopted to achieve this goal: pharmaceutical track & trace systems and pooled procurement mechanisms. Although both of these approaches contribute to solving a piece of the puzzle, access to essential medicines remains an enduring challenge. For those left unfulfilled and seeking a quick fix, I hate to disappoint but cure-alls do not exist. As this thesis shows, underlying root causes are intertwined and solving them requires a collaborative effort spanning multiple domains, including political, economic, regulatory and industrial actors. Moving forward, sustained commitment and continuous alignment work remains essential towards achieving access to affordable and high-quality medicines for all.

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Summary

While medicines have been playing a vital role in preventing illness, curing disease and protecting health, ensuring access to affordable and quality-assured medicines continues to be a global problem. The World Health Organization (WHO) estimates that nearly two billion people worldwide struggle to access essential medicines–those critical for addressing priority health needs of the population. Many factors contribute to this problem, including global economic structures that reward monopolistic behavior and drive-up medicine prices, countries and health care organizations that lack sustainable funding to buy medicines in the right quantities at the right time, and limited regulatory capacity such as laboratories, trained staff and financial resources to assess the quality of medicines. If not addressed, this lack of access to medicines will continue to have serious consequences on public health and place even greater financial strain on both countries and individuals. This thesis explores how two collaborative initiatives – pharmaceutical track & trace systems and pooled procurement mechanisms – can increase access to affordable and quality-assured medicines, and examines how to make such systems work in practice. I do this by addressing the following central research questions:

1. What are the preconditions for the emergence of collaboration initiatives?
2. How do collaboration initiatives develop over time?
3. What work is needed to implement and sustain collaboration initiatives?

To get medicines from manufacturers to patients, they must pass through a complex and opaque supply chain. A myriad of stakeholders – such as patients, regulators, custom offices, politicians, suppliers, pharmaceutical industry, and health professionals – are involved, each with unique needs, interests, and responsibilities that frequently diverge or even conflict. In addition, the issues constraining access to

medicines extend across multiple interdependent domains (e.g., political, economic, industrial, health, regulatory, legal). This complexity often leads to inefficiencies and creates opportunities for corruption, fraud, or theft. Regulating medicine quality, therefore, becomes like searching for a needle in a haystack, as regulators typically oversee products within their national borders, while pharmaceutical manufacturers, distributors, and wholesalers operate on a global scale, often involving many profit-seeking middlemen.

Since the root causes of these challenges are intertwined, solving them requires a collaborative effort involving multiple stakeholders across multiple domains. One collaborative approach to reduce the complexity of the pharmaceutical supply chain is through a pharmaceutical track and trace system; a digital tool that allows for monitoring the journey of medicines as they move through the supply chain. The effect of such systems on guaranteeing affordable and quality-assured medicines to enter the supply chain, however, are limited. To overcome this, buyers should focus on procuring the right products, in the right quantities, at the right time. Pooled procurement – where two or more buyers, or a separate organization acting on behalf of the buyers, collaborate to procure products or services together – is currently promoted in resource-limited settings with constrained technical capacity. Though promising, little is known about how these collaboration initiatives work in practice, and what is needed to make such systems work within their context.

To guide my empirical endeavors, I draw upon theoretical insights from collaborative governance and organizational life cycle literatures. While collaborative governance studies offer helpful insights into exploring what (pre)conditions need to be in place, how multiple actors engage within the collaborative process, and how to adapt the collaboration to the specific context, organizational life cycle literature enables the examination of how collaborations develop and/or decline

over time. Bringing together these theoretical literatures allows a closer look into the work and efforts required to align goals, motivations, and needs between actors to set up, implement and sustain collaborative initiatives.

My empirical journey begins with an exploration of the emergence and functioning of Turkey's pharmaceutical track and trace system. I focus on the underlying political and economic factors that enabled Turkey to become the first country in the world to implement a full pharmaceutical track and trace system. From there, I take a step back in the process to explore what is required for affordable and quality-assured medicines to enter pharmaceutical supply chains in the first place, shifting my focus to pooled procurement. I draw on insights from academic literature and identify essential elements for pooled procurement mechanisms to succeed. Building on these insights, I apply the lessons learned to pooled procurement mechanisms of two global health organizations and two inter-governmental bodies in the Western Pacific and Eastern Caribbean islands. My empirical journey ends with an in-depth examination of the development process of the inter-country pooled procurement mechanism in East Africa.

Throughout this empirical journey, I employ various methodological approaches by combining several data collection methods, including (semi-structured) interviews, (systematic) literature reviews, theoretical insights, document analysis, and observations. To enable this empirical research, I also developed an analytic tool – the Pooled Procurement Guidance – designed to collect, structure and analyze data on pooled procurement mechanisms.

Chapter 2 focuses on the implementation and functioning of the pharmaceutical track & trace system in Turkey. It zooms in on the concept of the pharmaceutical supply chain, and the complexities involved in regulating them. It shows that the implementation of new

technologies is generally driven by political and economic factors, and that technology alone is not sufficient to make such systems work in practice. I argue that a combination of four factors was crucial for Turkey's success: 1) strong political determination to solve a problem (i.e., to eliminate reimbursement fraud), 2) political power (derived from a single-payer institution creating a substantial pharmaceutical market), 3) adherence to the system by linking the reward (i.e., money) to the intended functioning of the system, and 4) sufficient flexibility and leeway to adapt the system according to the local context and practices of stakeholders that use the system. The study also points out that pharmaceutical track and trace systems do not have an inherent quality mechanism built in. To guarantee product quality, such systems must be embedded into a well-defined legal framework and supported by adequate regulatory capacity, including laboratories, staff and financial resources. Without it, pharmaceutical track and trace becomes merely an efficient system for delivering poor-quality medicines to patients.

Chapter 3 introduces the concept of pooled procurement and presents the findings of a systematic review of the academic literature on the implementation and functioning of pooled procurement mechanisms for medicines and vaccines. It focuses on processes, as well as summarizing lessons on outcomes of pooled procurement mechanisms. It identifies several elements that are essential for pooled procurement mechanisms to function linked to three key actors involved in pooled procurement mechanisms: buyers, the pooled procurement organization, and suppliers. The review shows that pooled procurement mechanisms are very diverse. They differ in characteristics and organizational structures and are set up to achieve a variety of goals. While certain essential elements are more likely to increase successful implementation and functioning of pooled procurement mechanisms, the organizational structure must be aligned with the goals of the

mechanism and adapted to its local environment. This process, which I refer to as *alignment work*, facilitates multi-actor engagement, strengthens inter-personal relationships, resolves differences, and transcends individual needs to achieve shared goals.

Chapter 4 builds on the findings and gaps identified during the previous chapter. It delves deeper into the idea that setting up pooled procurement mechanisms is not a singular event, but a process that evolves over time. These mechanisms require active effort by the actors involved to align the various motivations, goals and design of the mechanism which changes according to the different development stages. Generally, pooled procurement mechanisms evolve along the lines of four developmental stages: the promise stage, the creation stage, the early operational stage and the mature stage. With each stage, the main goal evolves from 1) reaching a shared vision, to 2) developing a shared plan, to 3) establishing a shared practice and finally 4) reaching a sustainable practice. When alignment between actors is threatened, however, pooled procurement mechanisms can also struggle and turn inactive. Like the developmental process, this process of decline is often not linear and can occur at any point in or between stages of its lifecycle.

To assist policy-makers and procurement experts in the implementation and operation of pooled procurement mechanisms, these findings were translated into a comprehensive *Pooled Procurement Guidance*[17]. This guidance document provides a structured overview of the elements and processes that are essential to set up and sustain pooled procurement mechanisms, while it also describes how such mechanisms evolve over time and the work that is involved in these processes.

[17] The *Pooled Procurement Guidance* document with data sources can be found online in the supplementary material. See: https://doi.org/10.1186/s40545-023-00574-9

Chapter 5 applies the Pooled Procurement Guidance in a comparative analysis of four pooled procurement mechanisms that differ in structural form. It focuses on purposefully selected cases of successful and failed examples of inter-buyer (i.e., the Organisation of the Eastern Caribbean States & the Pacific Island Countries) and third-party mechanisms (i.e., the Global Drug Facility & the Asthma Drug Facility). This comparative study shows that inter-buyer mechanisms generally require more *alignment work* during the initial stages of its development as buyers – usually countries, districts or hospitals – often differ in procurement systems, financing structures, product needs and regulatory and legal frameworks. Such mechanisms are more likely to succeed if buyers share similar characteristics and feel a similar sense of urgency about the problem(s) that the pooled procurement mechanism tries to solve.

Third-party, global health organization mechanisms, on the other hand, require less alignment and consensus-building between buyers. To participate, buyers need to align with the operations of the third-party organization, instead of other buyers. The study also draws attention to certain elements that are essential for the successful implementation and operation of such mechanisms. It shows that both local and global awareness around the problem is highly political and closely tied to the ability to induce political will to act upon the problem, as well as the ability to mobilize sufficient funding. For example, mechanisms set up to address communicable diseases with accurate diagnostics, effective treatment regimens and potential threat to global health security are more likely to succeed compared to mechanisms that lack these preconditions.

Chapter 6 presents findings from a longitudinal single case study. It takes the reader to East African as it zooms in on the ongoing developmental process of the East African Community (EAC) pooled procurement mechanism over the past twenty years. It uses the Pooled

Procurement Guidance to structure the analysis. The study builds on the notion that such mechanisms develop incrementally and non-linearly over time, and offers detailed insights into the individual country needs, the alignment work, continuous negotiations, and the efforts required to advance the mechanism.

Despite initial interest to set up a pooled procurement mechanism, the process stagnated due to a lack of dedicated funding, insufficient resources and ownership to advance inter-country alignment, preventing it to evolve from the promise stage to the creation stage. However, countries showed renewed interest nearly a decade later, following the establishment of a new secretariat responsible for developing the mechanism. In the years since, EAC Partner States have engaged in an ongoing and reflexive alignment process of negotiating and re-negotiating their interests, challenges, needs, and the mechanism's design.

Alignment, however, remains fragile due to the often voluntary nature of participation and the inclusion of new buyers in inter-country mechanisms. Therefore, the study argues that continuous alignment efforts, long-term political commitment and sustained funding are essential for the successful gradual implementation of inter-country pooled procurement mechanism.

Chapter 7, the concluding chapter, brings together insights from my empirical chapters and provides answers to the research questions. Collaborative initiatives require three preconditions to emerge: 1) strong *drivers*, 2) relative *alignment* among participants, and 3) *compatibility* between the collaboration's characteristics and its shared goals. Once these preconditions are met success is not guaranteed, however, as collaborations evolve through various developmental stages over time in a non-linear fashion. If alignment between key actors is threatened at any point, *decline* of the collaboration can set in. To prevent decline, sustaining collaborations requires intentional work. Although the focus of work varies slightly between structural

forms such as inter-buyer and third-party mechanisms, it must be continuous and reflexive. I differentiate between *alignment work*, as described above, and *articulation work* – which involves adapting and embedding the policy into the local context of daily practice.

The chapter continues with exploring the practical and theoretical implications of my key findings for policy-makers, practitioners, and scholars. I begin by discussing the practical implications for implementing pharmaceutical track and trace systems. I argue that these systems must be backed by specific political and economic factors, embedded in well-defined legal frameworks, and supported by adequate regulatory capacity. Next, I reflect on how my research on pooled procurement relates to the five core challenges identified by the Lancet Commission on Essential Medicines Policies. While pooled procurement can effectively address some of these challenges, it cannot tackle them all at once. To increase the chances of success, policy-makers and practitioners should first identify their problems and align their goals before setting up a procurement mechanism. I also provide reflections on how buyers can use the Pooled Procurement Guidance to achieve this. Finally, I reflect on how global donors, policy-makers, and international stakeholders can support local needs and help transitioning countries to maximize health benefits.

Theoretically, I argue that 1) collaborations evolve non-linearly over time, along with changing dynamics and goals, 2) ongoing alignment work is essential throughout the entire lifecycle, and 3) when alignment is disrupted, the risk of decline is always present.

Next, I offer methodological reflections on my dual role as researcher and consultant, explaining how I mitigated potential bias by discussing findings within multiple separate research teams (investigator triangulation), using various data sources (data triangulation), and keeping detailed field notes to reflect on my assumptions. I conclude this chapter

with suggestions for a future research agenda that further explores the incentives and practices of the pharmaceutical industry and other private sector actors.

Samenvatting

Hoewel medicijnen essentieel zijn voor het voorkomen en behandelen van ziekten en het beschermen van de volksgezondheid, blijft de toegang tot betaalbare en goede kwaliteit medicijnen een mondiaal probleem. De Wereldgezondheidsorganisatie (WHO) schat dat bijna twee miljard mensen wereldwijd moeite hebben om toegang te krijgen tot essentiële medicijnen. Dat zijn medicijnen die in de belangrijkste gezondheidsbehoeften van een bevolking voorzien. Diverse factoren spelen hierbij een rol, waaronder wereldwijde economische structuren die monopolistisch gedrag belonen en medicijnprijzen opdrijven. Daarnaast ontbreekt het veel landen en zorginstellingen aan houdbare financiering om op het juiste moment de juiste hoeveelheden medicijnen aan te schaffen. Ook mist vaak de capaciteit om de kwaliteit van medicijnen te reguleren en waarborgen door middel van laboratoria, getraind personeel en financiële middelen. Als dit probleem niet wordt aangepakt, zal het blijvende negatieve gevolgen hebben voor de volksgezondheid en leiden tot toenemende financiële lasten voor zowel overheden, als individuen.

Dit proefschrift onderzoekt hoe twee samenwerkingsinitiatieven – farmaceutische track & trace systemen en gezamenlijke inkoopmechanismen (*pooled procurement*) – de toegang tot betaalbare en kwalitatief goede medicijnen kunnen verbeteren. Ik doe dit door de volgende centrale onderzoeksvragen te beantwoorden:

1. Wat zijn de voorwaarden voor het ontstaan van samenwerkingsinitiatieven?
2. Hoe ontwikkelen samenwerkingsinitiatieven zich in de loop der tijd?
3. Welk werk is nodig om samenwerkingsinitiatieven te implementeren en in stand te houden?

Om medicijnen van fabrikant naar patiënt te krijgen, passeren ze een complexe en vaak ondoorzichtige toeleveringsketen. Talloze

belanghebbenden actoren zijn hierbij betrokken, zoals patiënten, toezichthouders, douanekantoren, politici, leveranciers, de farmaceutische industrie en zorgprofessionals, die allemaal unieke behoeften, belangen en verantwoordelijkheden hebben die vaak uiteenlopen of zelfs conflicteren. Bovendien strekken de problemen die de toegang tot medicijnen beperken in de toeleveringsketen zich uit over meerdere domeinen (bijv. politiek, economisch, industrieel, zorg, juridisch) die onderling afhankelijk zijn. Deze complexiteit kan leiden tot inefficiënties en creëert mogelijkheden voor corruptie, fraude of diefstal. Daarnaast is het opsporen van slechte kwaliteit medicijnen als het zoeken naar een speld in een hooiberg. Dit komt met name omdat toezichthouders vaak binnen nationale grenzen opereren, terwijl farmaceutische bedrijven, distributeurs en groothandelaren wereldwijd actief zijn. Vaak met tal van tussenpersonen van wie het primaire doel winstmaximalisatie is.

Omdat de onderliggende oorzaken van deze uitdagingen met elkaar verweven zijn, vereist het oplossen ervan een gezamenlijke inspanning van meerdere belanghebbenden uit verschillende domeinen. Een voorbeeld van zo'n gezamenlijke aanpak om de complexiteit van de farmaceutische toeleveringsketen te verminderen, is via een **farmaceutisch track & trace systeem**. Dit digitale hulpmiddel maakt het mogelijk medicijnen te volgen tijdens hun reis door de toeleveringsketen. Hoewel het systeem helpt bij het inzichtelijker en transparanter maken van de toeleveringsketen, lost het niet de uitdagingen van betaalbaarheid en kwaliteit op. Om dit te verbeteren, moeten kopers zich richten op het aanschaffen van de juiste medicijnen, in de juiste hoeveelheden, op het juiste moment. **Pooled procurement**, waarbij twee of meer kopers, of een externe organisatie die namens de kopers optreedt, samenwerken om producten of diensten aan te schaffen, wordt momenteel gezien als een veelbelovende strategie voor kopers met beperkte middelen en technische capaciteit. Hoewel deze aanpak potentie heeft, is er nog

weinig bekend over hoe deze initiatieven in de praktijk werken en wat er nodig is om ze succesvol te implementeren.

Mijn onderzoek combineert theoretische inzichten uit *collaborative governance* en *organizational life cycle* literatuur om te begrijpen hoe samenwerkingsinitiatieven ontstaan en zich ontwikkelen. Collaborative governance biedt inzicht in welke (voor)waarden nodig zijn om samenwerking te laten ontstaan en hoe actoren dat proces vormgeven. Organizational life cycle literatuur helpt te begrijpen hoe samenwerkingen in de loop van de tijd ontwikkelen en/of in verval raken. Het combineren van deze theoretische kaders biedt mij de mogelijkheid om onderzoek te doen naar het werk dat nodig is om samenwerkingsinitiatieven op te zetten, te onderhouden en af te stemmen op de doelen en behoeften van de betrokken actoren.

Om dit empirische werk te ondersteunen, heb ik verschillende methodologische benaderingen gebruikt, waaronder (semi-gestructureerde) interviews, (systematische) literatuuronderzoeken, documentenanalyses en observaties. Daarnaast heb ik een analytisch hulpmiddel – de *Pooled Procurement Guidance* – ontwikkeld om gegevens over pooled procurement mechanismen te verzamelen, structureren en te analyseren.

Hoofdstuk 2 richt zich op de implementatie en werking van het farmaceutische track & trace systeem in Turkije, dat als eerste land ter wereld een volledig farmaceutisch track & trace systeem wist te realiseren. Het zoomt in op het concept van de farmaceutische toeleveringsketen en de complexiteit die gepaard gaat met het reguleren ervan. Het laat zien dat politieke en economische factoren een cruciale rol spelen bij de implementatie van nieuwe technologieën, en dat alléén technologie niet voldoende is om dergelijke systemen in de praktijk te laten werken. Uit het onderzoek komt naar voren dat een combinatie van vier factoren cruciaal was voor de succesvolle

implementatie van het system in Turkije: 1) een sterke politieke vastberadenheid om het probleem rondom fraude met vergoedingen van medicijnen uit te bannen; 2) een grote markt, gedomineerd door één publieke zorginkoper, wat, in dit geval de staat de politieke macht gaf om een nieuw systeem op te leggen; 3) naleving van het systeem door de "beloning" (d.w.z. geld) te koppelen aan de beoogde werking van het systeem; en 4) voldoende flexibiliteit en speelruimte om het systeem aan te passen aan de lokale context en praktijken van belanghebbenden die het systeem gebruiken. De studie laat daarnaast zien dat farmaceutische track & trace systemen geen inherent kwaliteitsmechanisme ingebouwd hebben. Om de productkwaliteit te garanderen, moeten dergelijke systemen worden ingebed in goed gedefinieerde wettelijk kaders en worden ondersteund door voldoende reguleringscapaciteit, onder andere door middel van laboratoria, gekwalificeerd personeel en financiële middelen. Zonder dit wordt farmaceutische track & trace slechts een efficiënt systeem voor het leveren van medicijnen van (mogelijk) slechte kwaliteit aan patiënten.

Hoofdstuk 3 neemt een stap terug in het proces om te onderzoeken wat er nodig is om betaalbare en goede kwaliteit medicijnen in de toeleveringsketen te krijgen. Het introduceert het concept van pooled procurement en presenteert de bevindingen van een systematisch literatuuronderzoek over de implementatie en werking van dit concept met betrekking tot medicijnen en vaccins. De studie richt zich met name op processen en vat de belangrijkste lessen samen met betrekking tot de uitkomsten van pooled procurement mechanismen. Het identificeert de essentiële elementen voor het succesvol opzetten en functioneren van pooled procurement mechanismen. Deze elementen zijn gegroepeerd rond de drie belangrijkste actoren die betrokken zijn bij dergelijke mechanismen: de kopers, de uitvoerende organisatie (het secretariaat) en de leveranciers. De review toont aan dat pooled procurement mechanismen zeer divers zijn, met verschillen in kenmerken

en organisatiestructuren, en vaak opgezet om uiteenlopende doelen te bereiken. Hoewel bepaalde essentiële elementen de kans op succesvolle implementatie en werking van deze mechanismen vergroten, moet de organisatiestructuur worden afgestemd op de specifieke doelstellingen en aangepast aan de lokale context waarin het geïmplementeerd wordt. Dit proces, dat ik *alignment work* noem, is gericht op het bevorderen van de betrokkenheid van actoren, het versterken van interpersoonlijke relaties, het helpen om conflicten op te lossen en het overstijgen van individuele belangen om gezamenlijke doelen te realiseren.

Hoofdstuk 4 bouwt voort op de bevindingen en kennishiaten uit het voorgaande hoofdstuk. Het benadrukt dat het opzetten van pooled procurement mechanismen geen eenmalige gebeurtenis is, maar een geleidelijk proces dat zich in de loop van de tijd ontwikkelt. Deze mechanismen vereisen voortdurende inspanningen van alle betrokken actoren om hun verschillende motivaties en doelen af te stemmen met de karakteristieken van het mechanisme. Bovendien kunnen zowel de motivaties en doelen van de actoren als de karakteristieken van het mechanisme veranderen naargelang de ontwikkelingsstadia. Pooled procurement mechanismen doorlopen doorgaans vier stadia: belofte, creatie, vroeg operationeel en volwassenheid. In elk stadium verschuift het centrale doel van 1) het bereiken van overeenstemming over een gezamenlijke visie, naar 2) het ontwikkelen van een gemeenschappelijk plan, naar 3) het implementeren van gedeelde praktijken, en uiteindelijk naar 4) het bereiken van een langdurig stabiele praktijk. Wanneer de afstemming tussen actoren echter onder druk komt te staan, kunnen deze mechanismen stagneren of zelfs inactief worden. Net als de ontwikkeling is ook dit proces van achteruitgang vaak niet-lineair en kan het op elk moment in de levenscyclus plaatsvinden.

Om beleidsmakers en inkoopexperts te ondersteunen bij het opzetten en onderhouden van pooled procurement mechanismen, heb ik

deze inzichten vertaald naar een uitgebreide Pooled Procurement Guidance[18]. Dit document biedt een gestructureerd overzicht van de essentiële elementen en processen voor het succesvol implementeren en beheren van deze mechanismen, en legt uit hoe ze zich in de loop van de tijd ontwikkelen en welke inspanningen daarbij nodig zijn.

In **Hoofdstuk 5** wordt deze Pooled Procurement Guidance toegepast in een vergelijkende analyse van vier voorbeelden van zowel succesvolle als gefaalde pooled procurement mechanismen met verschillende structurele vormen. De analyse richt zich op *inter-buyer* mechanismen – opgezet tussen kopers, zoals de eilandengroep van de Organisatie van Oost-Caribische Staten en de eilanden in de Stille Oceaan – en *third-party* mechanismen – waarbij een externe organisatie namens de kopers optreedt, zoals de Global Drug Facility en de Asthma Drug Facility. Deze vergelijkende studie toont aan dat inter-buyer mechanismen vooral in de beginfase meer afstemmingswerk vereisen, omdat kopers – meestal landen, districten of ziekenhuizen – vaak verschillen in inkoopsystemen, wetten en regelgeving, financieringsstructuren, en productbehoeften. Dergelijke mechanismen zijn succesvoller wanneer de kopers vergelijkbare kenmerken delen en een gezamenlijk gevoel van urgentie hebben over de problemen die het mechanisme probeert op te lossen.

Third-party mechanismen, vaak beheert door internationale gezondheidsorganisaties, vereisen daarentegen minder afstemming tussen de kopers onderling. Deelnemende kopers moeten vooral afstemmen met de werkwijze van de externe partij. De studie benadrukt ook de politieke dimensie van deze mechanismen: wereldwijd bewustzijn van een probleem, de wil om het aan te pakken en het vermogen om voldoende financiering te mobiliseren zijn cruciale factoren voor succes. Mechanismen die zijn opgezet voor de bestrijding van

[18] Het *Pooled Procurement Guidance* document, samen met de verwijzingen, is online beschikbaar in de *supplementary material* van het artikel. Zie: https://doi.org/10.1186/s40545-023-00574-9

overdraagbare ziekten met duidelijke diagnostiek en behandelingsmethoden, en die een potentiële dreiging vormen voor de mondiale gezondheid, blijken daarbij meer kans te hebben op succes in vergelijking met mechanismen zonder deze voorwaarden.

Hoofdstuk 6 presenteert de bevindingen van een langdurige case study van het pooled procurement mechanisme in de East African Community (EAC), met als doel om inzicht te geven in het ontwikkelingsproces van de afgelopen twintig jaar. De studie bouwt voort op het idee dat dergelijke mechanismen zich incrementeel en niet-lineair ontwikkelen in de loop van de tijd, en biedt gedetailleerde inzichten in de behoeften van individuele landen, het alignment work, en de voortdurende onderhandelingen en inspanningen die nodig zijn om het mechanisme vooruit te helpen.

Ook in deze studie was de Pooled Procurement Guidance een relevant analytisch hulpmiddel. De studie laat zien hoe ondanks aanvankelijke interesse, het mechanisme jarenlang stagneerde in de beloftefase door met name een gebrek aan financiering, toewijding en afstemming tussen de landen. Bijna tien jaar laten werd de ontwikkeling nieuw leven ingeblazen door de oprichting van een centrum verantwoordelijk voor het implementeren van pooled procurement. In de daaropvolgende jaren onderhandelden en heronderhandelden de deelnemende partner staten voortdurend over hun belangen, behoeften en de structuur van het mechanisme.

De onderlinge afstemming blijft echter fragiel vanwege het vaak vrijwillige karakter van deelname en de toetreding van nieuwe landen, en daarmee mogelijk nieuwe belangen, in de EAC. Daarom betoogt deze studie dat continue afstemming, langdurige politieke toewijding en aanhoudende financiering essentieel zijn voor de succesvolle en geleidelijke implementatie van een pooled procurement mechanisme.

Hoofdstuk 7, het afsluitende hoofdstuk, vat de belangrijkste inzichten uit de empirische hoofdstukken samen en beantwoordt de centrale onderzoeksvragen. Het stelt dat drie voorwaarden noodzakelijk zijn voor het ontstaan van succesvolle samenwerkingen: 1) sterke drijfveren, 2) relatieve afstemming tussen de deelnemers, en 3) overeenstemming tussen de structuur en eigenschappen van het samenwerkingsverband én de gedeelde doelen. Zelfs als aan deze voorwaarden is voldaan, is succes niet gegarandeerd, omdat samenwerkingen zich in de loop van de tijd op een niet-lineaire manier door verschillende fasen ontwikkelen. Als de afstemming tussen actoren verstoord raakt, dreigt achteruitgang, tenzij er bewuste inspanningen worden geleverd om de samenwerking in stand te houden. Hoewel dit proces varieert voor verschillende structurele vormen zoals inter-buyer en third-party mechanismen, is het belangrijk dat deze inspanningen voortdurend en wederkerig zijn. Ik maak daarbij onderscheid tussen *alignment work*, zoals hierboven beschreven, en *articulation work*, dat gaat over de aanpassing en inbedding van beleid in de lokale context.

Het hoofdstuk gaat verder met een uiteenzetting van de praktische en theoretische implicaties van deze bevindingen voor beleidsmakers, praktijkdeskundigen en wetenschappers. Voor de implementatie en werking van farmaceutische track & trace systemen is politieke en economische ondersteuning essentieel, evenals goed gedefinieerd wettelijk kaders en voldoende regulerende capaciteit. Hoewel pooled procurement een rol kan spelen in de aanpak van uitdagingen rondom de toegang tot betaalbare en kwalitatief goede medicijnen, is het geen wondermiddel om alle problemen tegelijk op te lossen. Om de kans op succes te vergroten is het van belang dat beleidsmakers en professionals hun doelen goed afstemmen voordat ze een mechanisme opzetten. Daarnaast reflecteer ik ook op hoe betrokken partijen de Pooled Procurement Guidance kunnen gebruiken om deze afstemming te bereiken. Tot slot bespreek ik hoe mondiale donoren, beleidsmakers en

internationale stakeholders lokale behoeften kunnen ondersteunen en landen in transitie kunnen helpen om gezondheid te maximaliseren.

Op basis van mijn onderzoek draag ik ook op drie punten bij aan theorievorming over collaborative governance en organizational life cycle literatuur, namelijk dat 1) samenwerkingen zich niet-lineair ontwikkelen, 2) voortdurende afstemmingsinspanningen essentieel zijn gedurende de gehele levenscyclus, en dat 3) het risico op achteruitgang altijd aanwezig blijft als afstemming ontbreekt.

Vervolgens bied ik methodologische reflecties op mijn dubbele rol als onderzoeker en consultant. Ik leg uit hoe ik mogelijke *bias* heb verminderd door mijn bevindingen te bespreken binnen meerdere afzonderlijke onderzoeksgroepen (onderzoekerstriangulatie), door verschillende gegevensbronnen te gebruiken (datatriangulatie) en door gedetailleerde veldnotities te maken om te reflecteren op mijn aannames. Ik sluit dit hoofdstuk af met suggesties voor een toekomstige onderzoeksagenda die de prikkels en praktijken van de farmaceutische industrie en andere actoren uit de private sector verder bestudeert.

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Hester, zonder jou was dit boek er misschien niet gekomen. Hoewel je later bij dit promotietraject aanschoof, en dit onderwerp buiten jouw vakgebied viel, ben ik ontzettend dankbaar dat je daartoe bereid was. Ik heb zeer fijn met je samengewerkt, en dat merkte ik ook aan hoe soepel en vlot de laatste loodjes gingen. In een wereld waarin onderzoeken nooit écht af zijn en er altijd ruimte is voor meer feedback, gaf jij me het vertrouwen om er een punt achter zetten. Ook heb ik ervaren hoeveel de ogenschijnlijk kleine dingen kunnen betekenen. Zoals het sturen van een kort berichtje om in te checken als je een poos niets van me had gehoord of de momenten dat je de tijd nam om écht naar mij te luisteren.

Daarnaast is het doen van een PhD vaak een rollercoaster waarin je het ene moment het mooiste beroep ter wereld denkt te hebben, en op het andere moment de dag vervloekt dat je eraan begon. Het hebben van lotgenoten heeft het proces een stuk draaglijker gemaakt. Daarom wil ik hier mijn collega's bij HCG en ESHPM bedanken.

Oemar, rasoptimist, er zijn er maar weinig die kunnen tippen aan jouw passie (of moet ik zeggen obsessie?) voor de zorg. Fijn om met elkaar op te trekken in verschillende "netwerken". *Keep trusting the process*! Jolien, ik ben blij dat ik jou ook buiten het PhD-leven beter heb leren kennen. Jouw eindeloze energie om naast je werk nog deel te nemen aan allerlei sociale activiteiten en sport zijn jaloersmakend. Hopelijk blijf ik, met de rest van ons groepje, daar nog lang onderdeel van! Amalia, we had the same experiences going through this journey and I'm happy I was not alone in it. Thank you for all the Indonesian treats and I'm looking forward to reading your final thesis. Hang in there! Robert, het was fijn om onze PhD struggles, Afrika-ervaringen en passie voor sneakers met elkaar te delen! Gijs, ik ben blij dat ik niet de enige gek binnen HCG was die de wekker zette om tien mannen achter een stuiterende bal aan te zien rennen. Sabrina, jij was altijd in voor gezelligheid, een drankje of een goed gesprek. Embus, always smiling. I admire your positivity and the way you've managed to settle in this cold country, far away from your family. Vincent, als oud scriptie-student wil ik jou ook zeker bedanken voor je inzet en je bijdrage aan het onderzoek in Hoofdstuk 5 van dit boekje.

Daarnaast wil ik nog een groep mede-phd'ers bedanken voor hun gezelligheid en inspiratie: Hugo, Jonathan, Margot, Renee, Iris V, Leonoor, Chiara, Teyler, Nienke, Mirjam, Jacqueline, Nada, Gigi, Estella, Karin, Laura, Syb, Roman, Milan, Thomas en de rest! Ook heb ik veel gelachen met en geleerd van mijn andere collega's bij HCG, waaronder Iris W met haar onvermoeibare drive, Martijn met zijn avontuurlijke karakter, Bert met zijn gevoel voor humor, Susan met haar talent om de boel bij elkaar te houden, en al die andere knappe koppen binnen onze vakgroep!

My journey into this research topic began with my "falsified medicines family" – or, as Elizabeth elegantly dubbed us, "The Mudlarks". The name, inspired by the term for those who scavenged the banks of the

River Thames for treasures at low tide, couldn't have been more fitting. We were a diverse group who, had we lived a few hundred years earlier, might have been raiding each other's villages. Instead, we dug deep, working tirelessly across multiple time zones, searching for answers in places where others wouldn't bother looking.

Our initial core team included Elizabeth, Maarten, Adina, Jingying, and Amalia, with support from an advisory group of brilliant minds whom I still look up to. Some memories continue to live rent-free in my head, like the time we spent more energy preparing and color-coding hats for a silly roleplay game than for our actual presentations at the MQPH conference in Oxford. Or the moments of developing new frameworks to understand market risks for poor-quality medicines, which at times felt more like scrapbooking than scientific exercises. But also taking our afternoon walks at cemeteries, moments of existential questioning as you were busy reciting Homer in a candlelit living room, and witnessing some of you on a seesaw in the heart of London in the middle of the night. It was great fun during those initial years.

I also would like to express my gratitude to the U.S. Pharmacopeia (USP) Quality Institute (QI) for giving me the opportunity to become a research fellow in *Quality of Medical Products*, a path that ultimately led to this PhD. I'd like to thank Erin, Kavitha, Philip, June, Amy and my USP supervisors Farouk and Katherine for their support and guidance throughout this journey. I would also like to thank my fellow USP QI fellows: Tatenda, Yelena, Ashley, Carley, Gayathri and Matthew. Although we didn't have the chance to meet in person, I learned a lot listening to your presentations and enjoyed our 'virtual coffee hours,' where we shared our research struggles and supported each other during Covid-19.

Türkiye'deki araştırmam sırasında bana çok yardımcı olan, ilgilenen ve geniş networkünü kullanmama olanak sağlayan Ilkay ablama, aynı

şekilde ilgilenen Sezer abime çok teşekkür ederim. Bunun dışında, içtenlikle sorularımı cevaplayan bilirkişilere ve katılımcılara, ayrıca orada tanışıp, Hollanda'da sık sık görüşme fırsatım olan Kağan'a teşekkürlerimi sunuyorum.

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Throughout my research, I crossed paths with many experts and academics in the field, and I consider myself fortunate for the opportunities to learn from them. Rob, na ons korte interview nodigde je me uit om naar Nairobi te komen en het werk in de praktijk te observeren en ondersteunen. Ik heb veel van je geleerd en bewonder hoe je erin slaagde een zaal vol kritische en sceptische mensen op één lijn te krijgen. Deze ervaring heeft uiteindelijk geleid tot een mooi hoofdstuk in dit boekje, en daar ben ik je erg dankbaar voor. Hoewel je nu van je welverdiende pensioen geniet, ben ik blij dat je betrokken blijft bij ons komende project, zodat ik nog steeds van je waardevolle ervaring kan blijven leren. Per, despite the uncertainty about whether our project would ever take off, I'm so glad it finally did. I want to thank you for your positive energy, can-do attitude, and the ease with which you

offer compliments. I've truly enjoyed our collaboration and our time in Entebbe, and I'm excited that we'll continue working together on a new project.

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Curriculum Vitæ

PhD Portfolio

Name: Koray Parmaksiz

Department: Erasmus School of Health Policy & Management

PhD period: 2019 – 2024

Promotors: Prof.dr. Roland Bal & Prof.dr. Hester van de Bovenkamp

Co-promotor: dr. Maarten Kok

Peer-reviewed academic publications

Pisani, E., Nistor, A.L., Hasnida, A., **Parmaksiz, K.**, Xu, J., & Kok, M. O. (2019). Identifying market risk for substandard and falsified medicines: an analytic framework based on qualitative research in China, Indonesia, Turkey and Romania. *Wellcome Open Research, 4,* 70. https://doi.org/10.12688/wellcomeopenres.15236.1

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Parmaksiz, K., Pisani, E., & Kok, M. O. (2020). What makes a national pharmaceutical track and trace system succeed? Lessons from Turkey. *Global Health: Science and Practice*, *8*(3), 431–441. https://doi.org/10.9745/GHSP-D-20-00084

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Other publications

Parmaksiz, K., Bal, R., van de Bovenkamp H., & Kok, M. O. (2023). Pooled Procurement Guidance [Supplementary material]. *Journal of Pharmaceutical Policy and Practice, 16*, 73. https://doi.org/10.1186/s40545-023-00574-9

EAC RCE-VIHSCM, EAC Secretariat, **Parmaksiz, K.**, & Kronslev, P. (2023). *East African Community pooled procurement of medicines and health commodities market survey report*.

EAC RCE-VIHSCM, EAC Secretariat, **Parmaksiz, K.**, & Kronslev, P. (2023). *East African Community pooled procurement of medicines and health commodities operational model*.

Courses

2019	Basic didactics	Risbo
2020	Responsible research data management	EGSH
2021	Microlab supervise	Risbo
2021	Dilemma game	ESHPM
2021	Pharmaceutical supply management for developing countries	Udemy
2021	Pharmaceutical policy analysis	UU
2021	Basic security and safety course for field research in complex, remote and hazardous places	EGSH
2022	Didactics of delivery of education	Risbo
2022	Maximise your visibility as a researcher	EGSH
2022	Bounce back: handling the mental and emotional challenges of doing a PhD	EGSH
2022	Procurement of medicines and medical supplies	i+solutions
2022	Network and collaborative governance: Theories, methods and practices	NIG
2022	Shut up and write	EGSH
2022	Communicating your research: lessons from Bitescience	EGSH
2022	Qualitative coding and analysis of textual data with Atlas.ti	EGSH

Contributions to conferences, seminars and webinars

2018 *Main drivers of success of the pharmaceutical track and trace system in Turkey* at the Medicine Quality & Public Health (MQPH) conference at Keble College, University of Oxford

2019 *The 3rd MSD – Manufacturers/suppliers annual general meeting and 2nd Saving Lives Sustainably: 2019 Global Forum in Africa* in Dar es Salaam, Tanzania

2019 *The pharmaceutical policy* meeting in Riyadh, Saudi Arabia

2019 *Medicine quality* meeting at Wolfson College, University of Oxford

2020 *The East African Community (EAC) regional stakeholders' meeting to build consensus on the pooled procurement model for the EAC Partner States* in Nairobi, Kenya

2020 *Pooled procurement of medicines* at USP Quality Institute Research Rounds webinar

2021 Update on *pooled procurement of medicines* at USP Quality Institute Research Rounds webinar

2021 Update on *pooled procurement of medicines* at USP Compendial Science and Policy webinar

2021 *The East African Community (EAC) regional meeting to develop a detailed model and operational plan for pooled procurement* in Nairobi, Kenya

2021 *Pooled procurement of medicines in context* at the HERA EGA in Schelle, Belgium

2022 *The journey to collaborative procurement in the CAREC region* webinar organized by the Asian Development Bank

2022 *Developing inter-country pooled procurement mechanisms* at NIG Conference in Gent, Belgium

2023 *The East African Community (EAC) regional meeting to validate the EAC pooled procurement market survey report and model* in Entebbe, Uganda

2023 *Medicine quality* meeting at the University of Oxford
2023 *The East African Community (EAC) regional meeting of heads/CEOs of the national (central) medical stores* in Kigali, Rwanda

Teaching activities

BSc Health Sciences

2019 – 2020 Tutor in course 'De Nederlandse Gezondheidszorg'
2020 – 2021 Tutor in course 'De Nederlandse Gezondheidszorg'
2023 BSc Thesis supervision

MSc Health Economics Policy and Law

2021 – 2022 Tutor in course 'Comparative Health Policy'
2022 – 2023 Tutor in course 'Comparative Health Policy'
2022 MSc Thesis supervision

Guest Lectures

2022 Online Lecture on the *Pharmaceutical track and trace system in Turkey* at National Yang Ming Chiao Tung University, Taiwan
2023 Lecture on *Quality of healthcare technologies and medicines* at Erasmus University Rotterdam
2024 Online Lecture on the *Pharmaceutical track and trace system in Turkey* at National Yang Ming Chiao Tung University, Taiwan

Ancillary activities

2019–2021 Research fellow in *Quality of Medical Products* at U.S. Pharmacopeia Quality Institute
2021–2023 Advisor to the East African Community Regional Centre of Excellence for Vaccines, Immunization and Health Supply Chain Management

About the author

Koray Parmaksiz was born in Amersfoort, the Netherlands on the 3rd of August 1993. Prior to his PhD, he completed his BSc degree in Health and Life Science at VU University before pursuing a master's degree in in Health Care Management from Erasmus University Rotterdam and graduating cum laude from VU University with a second master's degree in Health Sciences, specializing in International Public Health. For his second master's thesis, he studied the implementation and functioning of Turkey's pharmaceutical track and trace system, as part of a larger four-country project identifying market risks factors related to substandard and falsified medicines.

After completing his academic studies, he became a research fellow in *Quality of Medical Products* at U.S. Pharmacopeia Quality Institute (USP QI). During his fellowship, he laid the groundwork for his research on pooled procurement of medicines and vaccines. Around this time, he also began his PhD research at the Department of Healthcare Governance (HCG) at the Erasmus School of Health Policy & Management (ESHPM), focusing on exploring how collaboration initiatives to increase access to affordable, quality-assured medicines emerge, develop and sustain. His broader research interests include medicine quality, global health policy, health system strengthening and health care governance.

Throughout his PhD, Koray has taught various bachelor's and master's courses and supervised thesis students. He also applied his academic expertise in various advisory roles. He contributed to the development of the East African Community pooled procurement mechanism and served as a member of a technical working group on pooled procurement mechanisms for diabetes-related products at the University of Geneva. Currently, Koray is involved in several international projects related to pooled procurement in Africa and other parts of the world, where he examines the feasibility and practical implementation of such procurement mechanisms.

In his free time, Koray enjoys supporting Galatasaray & Ajax, squeezing in more sports broadcasts than a weekend has hours, indulging in popcorn at the movies, and exploring new countries, cultures, and cuisines.

Medicines play a vital role in preventing illness, curing disease, and protecting public health. However, ensuring access to affordable, quality-assured medicines remains a global challenge.

Medicines Buyers Clubs delves into two collaborative initiatives that are currently being adopted to improve access to affordable, quality-assured medicines: pooled procurement mechanisms and pharmaceutical track & trace systems. One focuses on bringing such medicines into the supply chain, while the other ensures their safe delivery to patients.

It explores the preconditions necessary for setting up such collaborations and provides insights into how they evolve over time, from the initial promise and creation stages to early operations and maturation. It also explores the work and efforts needed to align goals and sustain collaboration among various actors.

Spanning all continents, this book offers rich insights, real-world examples, and practical tools for policymakers, practitioners, scholars, and anyone interested in collaborative approaches to improving access to affordable medicines that work.