

Review

Vaccine procurement in the Middle East and North Africa region: Challenges and ways of improving program efficiency and fiscal space



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ABSTRACT

Improving vaccine procurement performance has been a priority concern of national health authorities in the Middle East and North Africa (MENA) region for years particularly in terms of its role in accessing new vaccines and assuring a steady supply of quality vaccines at affordable prices. This article reviews the vaccine procurement mechanisms in the MENA region; analyzes the factors and drivers affecting demand for and supply of vaccines; discusses the main challenges; and suggests measures which can increase efficiency gains and generate the budgetary room to introduce life-saving vaccines. Based on in-depth analysis of available data and interviews with key informants at the regional and country level, this paper explains why most of the current strategies do not sufficiently recognize the specific characteristics of vaccine markets and best practices in procurement given these markets. The paper suggests potential efficiency gains for governments and global partners from pooling demand and moving from transaction-based purchasing to strategic purchasing in order to strengthen immunization services and introduce more life-saving vaccines.

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1. Introduction

Strengthening the efficiency of vaccine procurement mechanisms and regulations has been a priority issue in the Middle East and North Africa (MENA) region for years. The region comprises 20 countries with six high-income countries (HICs) of the Gulf Cooperation Council (GCC) which typically face no major constraints when financing new vaccines or their immunization programs. The three long-standing Gavi-eligible countries in the region and most recently the Syrian Arab Republic (henceforth, Syria) benefit from external assistance and access to the lowest priced vaccines. However, the remaining 10 non-Gavi countries face difficulties from the realities of the global vaccine market, highly constrained funding, limited negotiation capacity and inadequate country-level procurement mechanisms.

Vaccines are a large share of the full costs of immunization services, second only to labor as documented in the recent studies of low and lower-middle income countries [1]. Therefore, measures to reduce vaccine procurement costs may generate significant efficiency gains that can be reallocated to strengthen the immunization system and to introduce new vaccines. This is particularly true for non-Gavi MICs lagging behind the other countries in the region in terms of new vaccine introduction and regular supply of quality vaccines at favorable prices [2].

Several strategies have been proposed to improve access to affordable vaccines, including local production of vaccines in partnership with large pharmaceutical companies or the establishment of a regional procurement system such as the Pan American Health Organization (PAHO) Revolving Fund [3]. These strategies have been tested or partially implemented in the MENA region with limited success to date. We contend that these strategies neither sufficiently recognize the specificities of the vaccines and the markets, nor the characteristics of procurement mechanisms in place in the MICs.

The purpose of this article is to describe the vaccine procurement mechanisms in the MENA region; analyze the factors and drivers affecting demand for and supply of vaccines; discuss the main challenges; and suggest measures to increase system performance by reducing supply risks and ensuring affordable prices for quality vaccines.

2. Methods

We reviewed the 20 countries included in the UNICEF MENA region. This list included six GCC countries, 12 middle-income countries (MICs) and two low-income countries (LICs). We regrouped them in three categories: the six GCC countries – Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, United Arab Emirates (UAE); the three long-standing Gavi-eligible countries – Djibouti, the Sudan (henceforth, Sudan) and Yemen, and in 2019 Syria became Gavi-eligible with the recent re-categorization of its National Income per capita (it had received targeted support from Gavi on an exceptional basis in 2017 and 2018); and the 10 non-Gavi countries – Algeria, Egypt, the Islamic Republic of Iran (henceforth, Iran), Iraq, Jordan, Lebanon, Libya, Morocco, State of Palestine (henceforth, Palestine) and Tunisia.

For each group, we compiled data on procurement mechanisms used; volume and value of procurement for 2016 and 2017;

procurement shares by source (multinational or developing country manufacturers); share of UNICEF Supply Division (SD) in vaccine procurement in the region; and vaccine prices paid and year of new vaccine introductions, focusing on pneumococcal conjugate vaccines (PCV) and rotavirus vaccines (RV). We used data from UNICEF SD and data shared by the 14 countries out of 20 reporting prices through the World Health Organization (WHO)-UNICEF Joint Reporting Form (JRF).

A literature review was conducted using the following search terms: “vaccine”, “procurement”, “supply”, “middle-income countries”, “Middle East and North Africa”, and “developing countries.” First, the authors searched for published articles. Second, grey literature on the subject was collected from experts and immunization managers and staff working in vaccine procurement and immunization policy.

We conducted face-to-face interviews with experts and government officials during the UNICEF MENA Regional Office Consultative Review held in November 2017 in Amman, Jordan to understand the existing purchasing mechanisms and practices; current issues in access to quality and affordable vaccines; strengths and weaknesses of country and UNICEF procurement mechanisms; and reported barriers to new vaccine introductions in the public sector.

Most of the data are self-reported by countries in their annual JRF submissions. We compared the reported prices of RV, PCV, and pentavalent (DTwP-HepB-Hib) vaccines among the MENA countries, as well as to the UNICEF SD and PAHO Revolving Fund prices. Country names are not indicated but income level is mentioned as well as whether the country is using the UNICEF SD procurement services.

3. Results

Vaccine procurement is a complex process at the intersection of public health, public finance, commodity security, governance and supply. Vaccine procurement in countries is determined by several local and external programmatic, market, financing and regulatory factors. Multiple actors intervene at various levels making vaccine procurement highly sensitive to policy and political considerations. In this section we describe vaccine procurement performance by looking at the procurement mechanisms, demand, supply and prices.

3.1. Procurement mechanisms

In terms of vaccine procurement modalities, the MENA region is very diverse as shown in Fig. 1. The 20 MENA countries can usefully be divided into three groups according to how procurement is handled:

- **GCC countries:** These countries either purchase directly or through the mechanism of GCC group purchases especially for vaccines included in the national vaccination programs. Based on a group contracting model, the GCC purchasing program centralizes the tender and bid process for its countries. The countries then contract with and pay suppliers on their own. Unlike the PAHO Revolving Fund [4], the GCC program handles only the tendering, bidding, selection and adjudication parts of

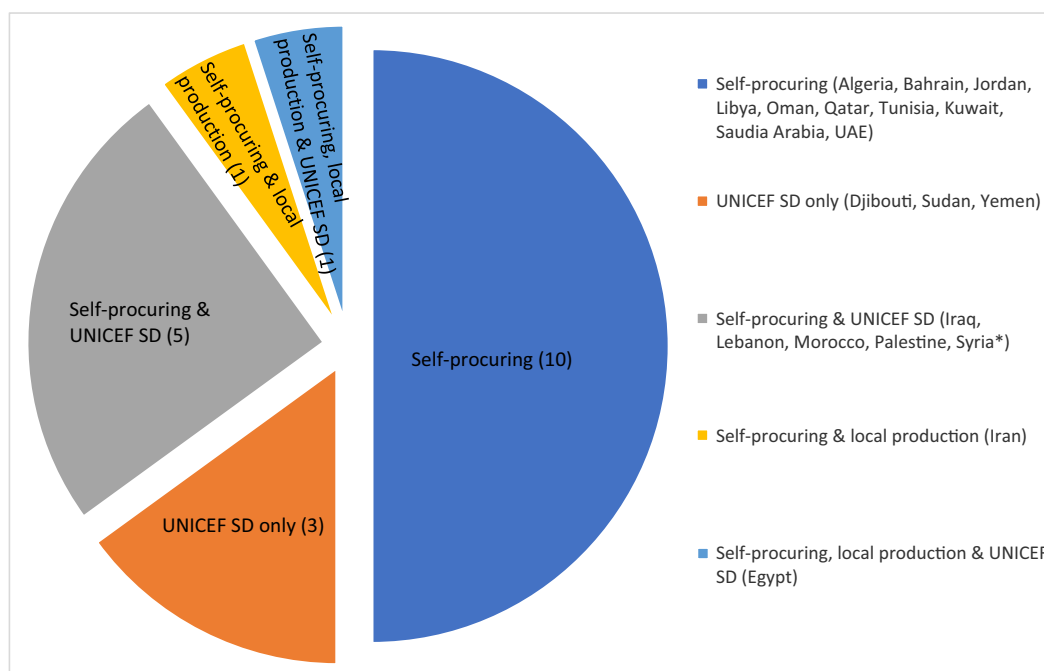


Fig. 1. Vaccine procurement modalities in use in MENA countries, 2017. Source: WHO-UNICEF Joint Reporting Form, 2017. *Syria has started procuring almost all its vaccines through UNICEF SD.

the procurement process. When producers contract with countries, they are obliged to offer the same prices across all six countries. The system makes it possible to benefit from the advantages of group purchasing, particularly for small countries, while leaving the responsibility to each country to finance its supply and to commit partially or totally to fulfill its national program vaccine requirements through this mechanism. The competitiveness of the prices obtained by the GCC purchasing program is limited by the size of the market and the expressed preferences for new products and for vaccines manufactured in industrialized countries [5].

- **Countries that receive Gavi support and source through UNICEF Supply Division procurement services:** As long-standing GAVI-eligible countries, Djibouti, Sudan and Yemen, and most recently Syria receive funding from Gavi for new and underused vaccines, and benefit from WHO pre-qualified products. Their Gavi-financed vaccines as well as traditional vaccines are procured through UNICEF SD at favorable prices. In some cases, traditional vaccines are funded, all or in part, with external assistance. UNICEF SD provides end-to-end tendering and order management services, issues requests for proposals, and communicates instructions and criteria for selection [6]. It pools vaccine demand, signals pricing and volume targets, evaluates manufacturer bids, and follows up with manufacturers regarding shipment, logistics and payment. This support is efficient from a market perspective, as it pools demand, decreases transaction costs, and reduces needed points of contact between buyers and sellers. With this considerable external technical and financial support, these countries have been able to introduce new vaccines and to pursue the Global Vaccine Action Plan targets and Sustainable Development Goals. However, governance challenges, instability and conflict in these countries have slowed progress and achievement of target objectives. The benefits of this procurement approach are large, but there might be drawbacks over the long term as countries risk losing the opportunity to build capacity, autonomy to make decisions and ownership.

- **Non-Gavi countries (Algeria, Egypt, Iran, Iraq, Jordan, Lebanon, Libya, Morocco, Palestine and Tunisia) that mostly conduct self-procurement on the world market:** A few of these countries use UNICEF SD to procure some of their vaccines (Egypt, Morocco, Palestine, Lebanon, Iraq). Iran, and to a lesser extent Egypt and Tunisia, have very modest local production for a few traditional vaccines. In some countries, central medical stores import vaccines in addition to other medical supplies. In others, Pasteur Institutes used to be or still are in charge of supplying vaccines. Public and private entities are also involved which makes the procurement system complicated, costly and not always very transparent. In many countries, the public and private local entities are charging local governments high fees and margins, as vaccine imports generate income to cover their own recurring costs. This may have a perverse effect on vaccine procurement performance. In many countries, public procurement procedures designed for other commodities and pharmaceutical products are applied to biological products without consideration of the special characteristics of vaccine products and markets. This is explained further in the following section. Most of these countries face challenges in meeting their vaccine needs, accessing a steady supply of products at affordable prices, and introducing the new vaccines recommended by WHO and National Immunization Technical Advisory Groups (NITAGs).

In total, vaccine procurement in MENA appears fragmented and complicated. There is variability in the national immunization schedules, vaccine presentations and procured vaccines across the countries. This makes the possibility of regional pooled procurement more difficult. Compared with other regions [7], regulation of vaccines and biological products in MENA is poorly harmonized as almost every country has specific requirements and procedures, despite some recent progress with WHO support on vaccines regulation through the National Regulatory Authorities (NRAs). For example, information exchange on Adverse Events Following Immunization, vaccine efficacy, and supplier performance is very

limited among countries. There is almost no mutual recognition of product registration among countries in the region, except within the GCC. Each country attempts to develop its own quality control laboratory infrastructure instead of sharing information, lessons learned and resources with neighboring countries.

3.2. Demand trends and drivers

Since 2000, vaccine demand has grown rapidly in the region due to factors such as population growth (the total birth cohort in the region is currently over 10 million infants), national income and health spending increase, unmet needs and international and national recommendations and policies. There is also an increasing number of new, safe and effective vaccines, such as human papillomavirus (HPV), RV and PCV.

Most vaccines consumed in MICs are supplied and funded through large-scale governmental programs. However, there is also private demand for vaccines [8]. This includes people immunized at for-profit private clinics or offices (e.g. travel vaccines) and employers who provide influenza vaccines to their employees [9]. The wealthier segment of the population in MICs is increasingly able to afford more expensive vaccines or presentations than those included in the public programs, resulting in growing private demand for vaccines.

There are marked differences in the uptake of WHO-recommended vaccines in the region [3]. WHO recommendations currently include 12 antigens in the routine schedule for children, adolescents and adults to be considered by countries depending on their local context. Table 1 details the introduction year of PCV, RV, HPV and inactivated polio vaccine (IPV). All GCC countries introduced PCV and RV between 2005 and 2009. IPV-containing vaccine was introduced first in Jordan in 2005 and since has been adopted in other countries. HPV was introduced nationwide only in Libya in 2013 and on a small scale in UAE.

Among the MICs, Morocco was the earliest adopter of PCV and RV vaccines, with both introductions in 2010. Libya and the three long-standing Gavi-eligible countries have followed. The remaining MICs have not introduced one or both vaccines and Egypt, Syria

and Tunisia have not adopted either yet as of April 2019¹. Despite being identified as an immunization priority, and often supported by a NITAG recommendation, these vaccines have not been introduced since budgetary allocation has not been granted to finance their costs.

3.3. Supply sources and drivers

The MENA region is almost fully reliant on imports of vaccines from the global market. Until 2000, most countries were supplied by multinational manufacturers. Since 2000, three changes have occurred. First, local public-sector production has almost disappeared except for Iran. Second, the number of multinational manufacturers globally has declined with mergers and acquisitions within the vaccine and pharmaceutical industry. Third, an increasing number of manufacturers from developing countries are now offering WHO pre-qualified vaccines and play a critical role in global supply. Fig. 2 shows the share of multinational versus emerging manufacturers in the total government purchases of vaccines in 2016 and 2017 (in volume and value in the MENA region).

At the global level, UNICEF, WHO, Gavi, and the Bill and Melinda Gates Foundation play a strategic role in vaccine market shaping. WHO's prequalification process sets standards and assesses safety and quality of vaccines. This process has facilitated the opening of global United Nations markets to emerging manufacturers. The above partners are working in close collaboration to increase, pool where possible, and secure demand from low-income and lower middle-income countries (LMICs) to facilitate access to new vaccines at affordable prices. Efforts are also underway with vaccine manufacturers in developing countries to increase production capacity of the most needed vaccines [10].

These changes have started to have a positive impact on vaccine supply in a few MENA countries. Multinational suppliers now dominate the market for only a few vaccines such as hexavalent vaccine, PCV, and HPV. Emerging manufacturers supply most of the other vaccines, adopting a low price/high volume approach [11]. A few GCC countries, which had previously purchased almost entirely from multinational manufacturers, are now starting to procure some vaccines from emerging manufacturers (Fig. 3).

UNICEF supplies vaccines to Gavi-eligible countries and increasingly to non-Gavi MICs such as Iraq and Morocco. By value, procurement of vaccines through UNICEF SD makes up about 24% in volume and 10% of total public procurement of vaccines in the MENA region in 2016–2017².

Polio-containing vaccines dominate purchases (by volume) that UNICEF procures for the region. PCV, measles-mumps-rubella (MMR) and pentavalent vaccines lead purchases by value. Sudan, Egypt, Yemen and Jordan are the main clients both in terms of volume and value. For Jordan, part of procurement undertaken by UNICEF SD is not for the national immunization program as such, but for refugees in Jordan and in other neighboring countries. Procurement for the region through UNICEF SD has been relatively stable in the recent years but declined in 2016 and 2017 (Fig. 4).

Is there a “healthy vaccines market” in the MENA region? [12,13] Countries can purchase vaccines from multinational pharmaceutical companies, as well as from emerging manufacturers. However, countries do not necessarily have wide variety of choices or benefit from a competitive market particularly if they are self-procuring. Vaccine supply is constrained. For example, in 2016, for 58% of the procured vaccines, there were only two suppliers per vaccine available to the countries. Due to limited availability

Table 1
Introduction of PCV, RV, HPV and IPV.

Vaccines	Introduced in the following countries (year of introduction)	Not introduced
PCV	Algeria (2016), Bahrain (2008), Djibouti (2012), Iraq (2017), Kuwait (2007), Lebanon (2015), Libya (2013), Morocco (2010), Oman (2008), Qatar (2005), Saudi Arabia (2009), Sudan (2013), UAE (2007), Yemen (2011)	Egypt, Iran, Jordan, Syria, Tunisia
RV	Bahrain (2008), Djibouti (2014), Iraq (2012), Kuwait Jordan (2015), Libya (2013), Morocco (2010), Qatar (2009), Saudi Arabia (2013), Sudan (2011), UAE (2014), Yemen (2014)	Algeria, Egypt, Iran, Kuwait, Lebanon, Oman, Syria, Tunisia
HPV	Libya (2013)	All the countries except Libya
IPV	Algeria (2016), Bahrain (2008), Djibouti (2016), Egypt (2018), Iraq (2016), Iran (2015), Jordan (2005), Kuwait (2010), Lebanon (2012), Libya (2014), Morocco (2015), Oman (2010), Qatar (2010), Saudi Arabia (2008), Sudan (2015), Syria (2008), Tunisia (2014), UAE (2010), Yemen (2015)	Not applicable

Source: WHO, http://www.who.int/immunization/monitoring_surveillance/data/en/
Data on Palestine are not available.

¹ The authors were recently informed that Tunisia and Jordan intend to introduce PCV in coming months.

² Data from 16 countries, (no data for Libya, Saudi Arabia, Sudan and UAE), source: WHO-UNICEF Joint Reporting Form, 2017.

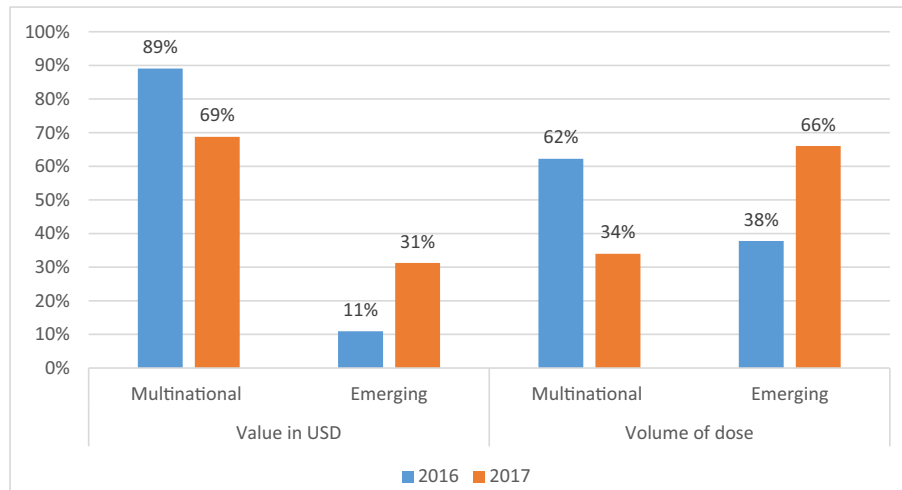


Fig. 2. Multinational and emerging manufacturers in MENA as a share of total government purchases and total doses, 2016 and 2017. Source: WHO-UNICEF Joint Reporting Form, 2017.

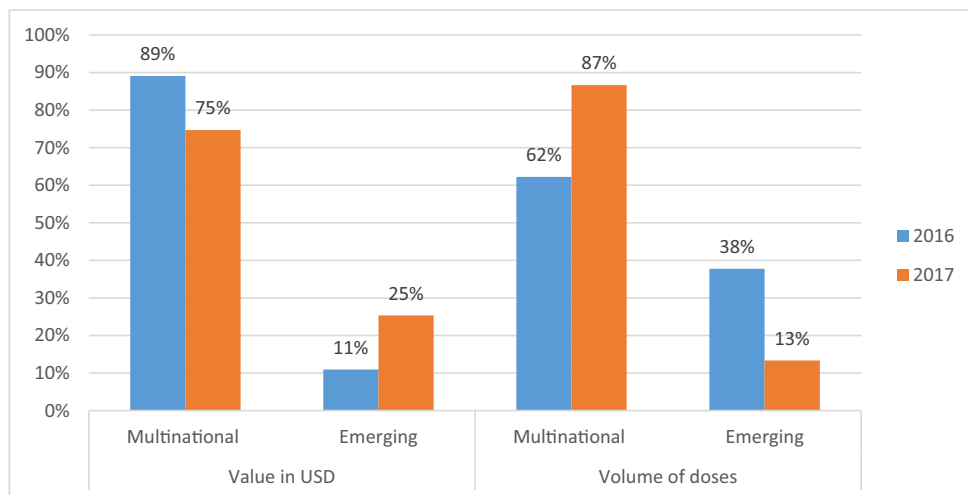


Fig. 3. Vaccine supply to GCC countries, as share per value and volume for multinational and emerging manufacturers, 2016 and 2017. Source: WHO-UNICEF Joint Reporting Form, 2017.

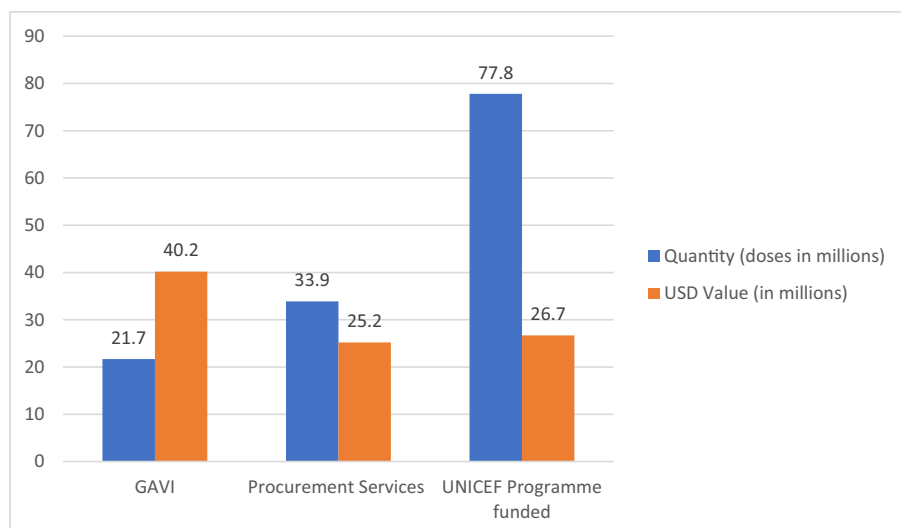


Fig. 4. UNICEF vaccine procurement in MENA by funding sources, value and doses, 2017. Source: UNICEF Supply Division.

for some vaccines, manufacturers are not always interested in supplying vaccines to small markets at competitive prices. Of course, these issues are not unique to the MENA region and apply to other relatively small non-Gavi eligible MICs.

We were limited by data availability in reviewing other important factors that may discourage or limit the competition at the country level, such as regulatory (registration fees and local agent requirements) and programmatic requirements (product formulation and presentation), and contractual terms.

3.4. Price drivers and differences among countries

Table 2 contains the 2017 reported prices for RV, PCV and pentavalent vaccines. The main purpose is to show price variation across countries and a few factors potentially influencing prices. We indicate if the vaccine were supplied through UNICEF SD. The table includes published prices from the PAHO Revolving Fund and UNICEF SD as reference points. Where countries reported procurement through UNICEF SD and provided a “price” paid, this price often differed from prices reported by UNICEF SD due to additional costs of delivery and insurance.

HICs generally pay the highest prices as expected. HICs tend to use acellular pertussis (aP)-containing vaccines and primarily single-dose presentations where available. Gavi-eligible countries access the lowest prices available in the region. These countries benefit from UNICEF SD’s capacity to secure quality vaccines at affordable prices. On the other hand, non-Gavi MICs report price variation with several MICs appearing to pay relatively higher prices for new vaccines, even compared to other countries of similar income per capita. This is particularly the case for self-procuring countries.

Factors that contribute to the price variation are not easy to determine with the limited data available [14]. Income level is one dominant factor particularly for new vaccines. Other factors include vaccine presentation, volume purchased, length and type of contract, payment modalities, product maturity, market dynamics and vaccine industry strategies [15,16].

A major factor for price reduction is competition and the role of partners in vaccine market shaping. For example, in 2000, pentavalent vaccine was supplied to UNICEF by one producer at a price of US\$ 3.60 per dose. By providing demand forecasts, secure financing, and multi-year contracts, and encouraging the introduction of a ten-dose vial, the number of manufacturers grew, and the price

Table 2
Reported price per dose of selected vaccines in 14 MENA countries, USD, 2017.

Countries by income level	Pentavalent Single dose presentation	Pentavalent 10 Dose presentation	RV Liquid Single dose presentation	PCV 13 Single dose presentation
HIC 1	4.93		13.03	26.34
HIC 2			11.00	26.25
HIC 3	3.40			26.25
HIC 4	4.95		11.00	26.25
LMIC 1			4.00	
LMIC 2	2.51			
LMIC 3		0.75		
LMIC 4		0.85	4.00	
LMIC 5		0.75	3.57	
LMIC 6	2.60		2.46	3.50
LMIC 7		0.68		
UMIC 1	1.10			3.30
UMIC 2*	2.79	2.25		
UMIC 3				15.77
UNICEF Price 1**	1.40	0.85	3.20	3.30
UNICEF Price 2**	0.80	0.68	1.88	
PAHO WAP***	1.06		6.60*	14.50

Notes:

* 2016 prices.

** UNICEF price 1 (from manufacturer 1), UNICEF price 1 (from manufacturer 2).

***WAP: weighted average price.

In yellow: Vaccines procured through UNICEF Supply Division.

Source: WHO-UNICEF Joint Reporting Form, 2017

has fallen. The lowest price for pentavalent per dose offered through UNICEF SD is now US\$ 0.65 per dose in 2018 (10-dose), and there are five suppliers providing vaccines through UNICEF SD [17]. More importantly for the MENA region, market shaping has benefited non-Gavi countries as this price is now available to any country procuring pentavalent vaccine through the UNICEF SD (regardless of Gavi-eligibility).

The majority of MICs that use UNICEF SD benefit from lower prices than self-procuring countries. This scenario is due to a combination of factors such as high volume, multi-year contracting, secured funding, on-time payments in hard currency and reduction of transaction costs. But this is not always the case as a few upper middle-income countries (UMICs) using UNICEF SD are not getting the lower price. Several LMICs are not using UNICEF either because of regulation and financial impediments, or for the time being UNICEF is unable to procure their vaccines of choice (e.g. Hexavalent). Vaccine formulation and presentation sizes tend to differentiate prices of products between income groups, with higher prices being paid for products and presentation sizes preferred in HICs (e.g. acellular pertussis, single dose vial).

4. Discussion

For MENA countries, procuring quality vaccines and related products at affordable prices has been a considerable challenge due to local and external factors. But opportunities have also arisen both at country and global levels.

4.1. Emerging suppliers

Several multinational public and private companies left the vaccine market in the 1980s and 1990s due to increasingly stringent and costly regulation requirements and low profitability of the vaccine business [18]. Since then, vaccine technology and market have evolved spectacularly with the arrival and use of new vaccines [19, 20]. Merger and acquisition activity provided further evidence for the new status of the vaccine business within the pharmaceutical industry. In 2008, five suppliers (GSK, Sanofi-Aventis, Merck, Wyeth and Novartis) controlled 85% of the vaccine market by value. In 2018, four producers (Sanofi, GSK, Pfizer and Merck) dominate the global market with parallel quasi-monopolies for several newer vaccines (RV, PCV and HPV).

However, a small group of vaccine suppliers located mainly in India, China, Brazil and Indonesia are progressively playing an important role in global vaccine supply, both for traditional vaccines and for newer vaccines [21]. They are benefiting from several factors, such as a growing demand in low and middle-income countries; increased procurement by UNICEF and PAHO; Gavi financial support to eligible countries; and the WHO pre-qualification process. Emerging suppliers are also taking up market segments with the departure of multinational companies, such as the production of basic vaccines at a very large scale or the development of meningitis A and other vaccines of regional importance (Japanese encephalitis, typhoid, cholera) [22]. The upshot is that emerging manufacturers are playing an increasing role in MENA (Fig. 2) when their products are sold both through UNICEF SD or directly to the countries.

4.2. Procurement through UNICEF SD

Although the use of UNICEF SD procurement services by MICs is growing, it has been limited due to a few UNICEF SD requirements that conflict with country public procurement rules, such as a direct memorandum of understanding with UNICEF without a competitive bidding process, payment in hard currency and pay-

ment before receiving vaccines [23]. Several countries mention the issue of liability and quality assurance by the contractual party, i.e. with UNICEF SD directly. At the same time, a few countries have adjusted their local procurement rules in view of the many benefits of UNICEF procurement, while others are trying to find common ground with UNICEF SD and to negotiate clauses and provisions compatible with country public procurement rules.

4.3. Asymmetry of information

Lack of information on vaccine market dynamics and prices has been raised in country interviews as one of the main obstacles to evidence-based decision making on whether and when to adopt new vaccines. This issue is being partly addressed by several initiatives to promote information sharing on vaccine prices, such as UNICEF and PAHO's publication of prices awarded in their vaccine tenders, WHO's Market Initiative for Access to Vaccines (MI4A), which is building on the WHO Vaccine Product, Price and Procurement (V3P) project, and Médecins Sans Frontières' advocacy and analysis on vaccine prices. Significant progress has been made recently as shown by the number of countries sharing information on vaccine prices, which is then reported back anonymously through the WHO-V3P/MI4A platform [22]. The challenge is more at the country level to interpret and properly use the available data, and with partners providing customized support and building country capacities.

4.4. Fragmented demand and pooled procurement

Alongside these challenges at the global level on vaccine procurement, some additional challenges arise from regional and local factors. One of the characteristics of vaccine demand in MENA is its fragmented nature. There is minimal visibility or predictability of vaccine demand at the regional or subregional levels except for the GCC countries where a certain consolidation of the demand is conducted.

In 2010, member states of the WHO Eastern Mediterranean Regional Office (EMRO)³ expressed their strong interest in establishing a regional vaccine procurement system and requested EMRO to initiate and coordinate their efforts.

Despite a valiant effort, this initiative did not get effectively launched due to several factors. First, on the programmatic side, it was difficult to agree on a common set of vaccines and presentations. Second, there were marked differences among countries in their regulatory and financial arrangements. Third, there was lack of strong support from global partners and a reluctance of many manufacturers to participate. Finally, it did not help that the region faced a deteriorating context stemming from conflict and political unrest. However, there are great lessons learned from this initiative, including a better understanding and lens into the regional power and political dynamics, which can be applied to existing mechanism and/or future efforts.

4.5. Regulatory processes and coordination

Vaccines with limited suppliers generally have higher prices and/or production constraints. In several MENA countries, competition is further restricted by strict government policies around registration and tendering and by inadequate procurement rules and procedures.

In a number of countries, barriers to product registration, such as high fees and lengthy timelines for registration, and requests

³ The WHO Eastern Mediterranean Region includes 22 countries and territory and has its regional office in Cairo, Egypt. UNICEF MENA region comprises 20 countries and state and is based in Amman, Jordan.

for additional vaccine testing and control, as well as clinical trials, even for WHO pre-qualified products, can discourage manufacturers from market participation. Procurement rules further add a layer of restrictions and disincentivize manufacturers, particularly emerging suppliers, from responding to tenders. Examples of requirements include that: a product is used in the routine program of the country of origin of production; suppliers import and deliver the product up to the district level; payments being made in the local currency; and all documentation is done in the local or official language of the purchasing country.

In addition, there is insufficient coordination between vaccine procurement staff and entities dealing with regulation, budget and program stakeholders. Communication is often inconsistent, roles and responsibilities among concerned entities are not always clear, and standard operating procedures are not effectively used by all concerned parties.

To overcome some of these issues, since 2015 UNICEF SD “convenes buyers of vaccines from MICs to exchange and learn from each other on how to develop adapted procurement practices that ensure supply to meet national demand for vaccines” [24]. Moreover, UNICEF has adopted a MICs strategy and has been working with MICs in the region for many years to facilitate vaccine introduction by accessing affordable supply of new vaccines through a variety of procurement modalities (single-country tenders in the short term and pooled procurement tenders in medium term) [25]. UNICEF has also conducted a multi-year MICs New Vaccine Tender, but with limited success to date.

4.6. Suggested way forward

Any strategy and activity that increased the efficiency of vaccine procurement and significantly reduced vaccine prices would create opportunities for savings that could free up funding to support the introduction of new vaccines and to strengthen routine immunization, among other priorities. The following recommendations may be considered in the MENA region:

Recommendation 1: Create a strategic country vision and plan

Ensuring regular quality vaccine supply at affordable prices requires governments to decide in advance and on a multi-year basis which vaccines they want to adopt, the required volumes, and the choice of procurement mechanisms (through UNICEF SD, self-procurement or both). This mid-term vision and plan cannot be achieved without a solid understanding of vaccine market dynamics, government commitment, strong data on disease burden, clear priority setting mechanisms, a functional NITAG, and a multi-year budget.

Recommendation 2: Consider procurement as a strategic function, break up the silos and enhance coordination

Procurement is often seen as a support function rather than a strategic and integral part of successful national immunization programs. In many self-procuring MICs, procurement is done in relative silos by entities dealing with pharmaceutical products and medical devices.

In Algeria, Egypt and Tunisia, procurement entities charge ministries of health high margins on vaccine prices which generates revenue for their operational costs. This creates a disincentive to secure lower prices. The characteristics of the vaccine market and products are often ignored or misunderstood which can lead to costly mistakes and missed opportunities when, for example, competition is restricted by rigid public procurement rules around registration and tendering. Vaccine procurement involves a wide range of actors and requires strong coordination and alignment,

as well as specialized capacities and skills in data analysis, forecasting, budgeting, market intelligence, tendering, contract negotiation, financial management, communication and performance evaluation.

Recommendation 3: Develop functioning regulatory and advisory bodies

NRAs and NITAGs exist in most MENA countries; however, they are not all functional and strong enough to determine in a transparent, evidence-based process which vaccines a country should introduce and when, the schedule and presentation, how to regulate the procurement and administration processes, as well as monitor and evaluate results and outcomes from the programmatic and financing perspectives [26]. Economic evaluation tools and multi-disciplinary approaches including health technology assessment can be used to make strong and convincing analyses available to decision makers. NITAGs can review the current schedule and vaccine presentations as changes may lead to substantial savings that can be used to introduce new vaccines.

Recommendation 4: Understand vaccine market dynamics to make sound choices

A general understanding of global vaccine market dynamics can help country procurement entities anticipate supply gaps and shortages, minimize risks and take advantage of opportunities for cost savings and access to quality vaccines at affordable prices. As each vaccine market is unique and sometimes unstable, developing a functional understanding of market dynamics, the level and nature of competition, and available and pipeline products across each vaccine in the national immunization schedule can help governments better navigate and negotiate with suppliers and yield cost savings. Many sources of information have been developed and are publicly available, but their use remains low.

Recommendation 5: Explore vaccine prices beyond price per dose

Procurement activities to reduce prices are capturing the attention of policy makers, payors and program managers due to their potential for quick efficiency gains. MICs can certainly benefit from vaccine price transparency as it can help countries answer several important questions on affordability, efficiency and sustainability. However, countries should understand that there are a number of factors that can influence vaccine prices, including but not limited to product characteristics and presentation [27]. The V3P and MI4A platform at WHO are providing practical and tools.

Recommendation 6: Pool demand and purchase strategically

In times of financial constraints and challenging vaccine markets, pooling demand helps counter fragmentation and small orders, and seeks economies of scale – thereby enhancing their attractiveness and negotiation capacities which are crucial elements for long term security of vaccine supply. Pooling demand can be a key enabler to accessing quality vaccines at affordable prices and can be done, first, at country level by developing sound product selection and forecasting of needs with a secure medium-term budget. [28] With that in place, countries can agree with suppliers on multi-year contracts.

This option maybe not be sufficient for MICs with small birth cohorts or/and limited financial capacity as they are not attractive for manufacturers. Therefore, joining regional, intercountry or international pooled procurement mechanisms is a more efficient approach. While pooled procurement has very stringent conditions to succeed (vaccine selection, sound planning and forecasting,

secured funding and timely payment) and requires strict discipline and explicit long-term commitments, some countries have succeeded in using UNICEF SD's procurement services successfully.

Moving from transaction-based purchasing to strategic supply management is central to increasing value for money and improving immunization performance and sustainability. This approach can be achieved by promoting evidence-based choice of products and interventions; sound forecasting of demand and credible budget preparation and execution; regular consultations with other countries and with suppliers; transparent tendering and contracting tools and processes; centralizing purchasing mechanisms; and collection and analysis of market information.

5. Conclusion

Non-Gavi MICs in MENA are spending more money on vaccines and related technologies and services but are still lagging behind many countries on new vaccine introductions. Despite the current political landscape, MENA MICs can create immunization budgetary room through structural reforms and performance improvement measures. Vaccine procurement is one of the areas with high potential quick wins and significant efficiency gains. Potential cost savings can be used to finance new vaccine introductions and to strengthen immunization system functions such as service delivery, surveillance, supply chain and regulation. Several measures can be considered by countries to move from passive to strategic purchasing by pooling demand, increasing capacities, exploring market opportunities and implementing innovative contractual arrangements with suppliers. Governments may have to make difficult political decisions which should be strongly backed by partners at regional and global level. This support should be customized and aimed at promoting an enabling environment in favor of innovative contractual arrangements, fair competition and pricing, information transparency and sharing of best practices.

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Conflict of interest

None declared

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