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# The impact of vaccine procurement methods on public health in selected European countries

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## ABSTRACT

**Introduction:** Across Europe, immunization programs have brought immense benefits to the prevention of infectious diseases. The vaccines used are procured through a variety of models such as tenders and Pricing & Reimbursement. However, to date, the impact of the procurement method on the performance and sustainability of vaccination programs and on public health has received little attention.

**Areas covered:** Drawing on a review of the academic and policy literature, complemented by an interview program with stakeholders involved in the procurement of vaccines, the authors have documented the relationship between procurement method dynamics and the level of protection against vaccine-preventable diseases in Germany, Italy, Spain and Romania for, measles-containing vaccines, hexavalent and influenza vaccines.

**Expert opinion:** Price-based tenders can contribute to vaccine supply issues, discourage the provision of value-added services supporting vaccination coverage and disincentivise future R&D. Although it is observed that price-based tenders can intensify competition in the short term, there can be unintended consequences such as damage to long-term competition. As European countries are committed to strengthen their immunization programs, they should consider the implications of current vaccine procurement models on the vaccine ecosystem and on public health.

## ARTICLE HISTORY

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## KEYWORDS

Europe; public health; procurement; tendering; vaccination coverage; vaccine purchasing

## 1. Introduction

### 1.1. Background

Vaccines have been demonstrated to be one of the most effective interventions in the prevention of infectious disease and, from a public health perspective, the success of large-scale immunization programs is unequivocal [1]. Immunization programs save the lives of over 2.5 million children each year, are responsible for the eradication of smallpox and major progress made toward the eradication of polio, and have eliminated measles, diphtheria, and rubella from large parts of the globe [2,3]. There are significant challenges in many developing countries, where vaccination coverage has now reached a plateau and coverage rates are well below the target levels [4]. In this paper, we consider the situation in developed countries where the vaccine coverage rates are often higher but for some diseases have been falling in recent years.

In Europe, vaccination programs have achieved some of the highest uptakes in the world with 9 in 10 children receiving basic vaccination resulting in healthier and more productive lives while dramatically reducing child mortality [5]. In adults, vaccination remains the most effective means of protecting against infectious diseases such as influenza and, therefore, acts to negate the economic costs associated with reduced workforce productivity and increased healthcare burden.

Further, the value of vaccines in adults and the elderly will become increasingly important in light of an aging population and a rise in chronic diseases [6]. The economic benefit of vaccines is not however limited solely to safeguarding public health, as Europe is the world leader in both vaccine development and production. According to Vaccines Europe, the region receives 71% of global vaccine R&D investment, is the producer of 80% of the world's vaccine doses and is home to 45% of all vaccine producers [7]. As such, vaccination is also a key asset for European innovation and economic growth.

Despite these well-established benefits, vaccination rates in Europe have seen a recent decline: routine immunization coverage of the first dose of a measles-containing vaccine has declined in 12 EU Member States since 2010 [8]. This has been accompanied by an inevitable resurgence in infectious diseases [9]. Measles alone saw a fourfold increase in 2017, due to the drop in vaccination coverage and herd immunity, inflicting serious damage to Europe's ambition of eliminating measles and rubella, and resulting in 35 preventable deaths that year [10]. In addition, due to the complex and lengthy manufacturing process, compounded by suboptimal supply-demand forecasting, some European countries have experienced shortfalls in vaccine supplies and have been forced to ration immunization [11]. Such cases give a clear mandate to policymakers to ensure long-term access to vaccinations. Vaccine procurement methods are a key item of vaccination policies, and as such should contribute to the

**Article highlights**

- Vaccination rates in Europe have seen a recent decline accompanied by an inevitable increase in infectious diseases. Vaccine procurement methods are a key item of vaccination policies, and as such should contribute to the overall sustainability of vaccination programs to meet public health objectives.
- Procurement methods can be categorized into a spectrum from focusing primarily on price – which we refer to as price-based – to those that include a more holistic approach based on the value which we refer to as value-based.
- While price-based tenders can reduce the price of vaccines, they do not lead to sustainability in vaccines supply. Although there are many factors that affect the sustainability of supply (manufacturing capacity, payer budgets, transport logistics, etc.), the way vaccines are purchased has been found to exacerbate supply issues.
- Price-based tenders reduce choice and provision of value-added services, which are important for VCR and safeguarding public health. Value-added services such as awareness activities for physicians and patients can be particularly important in informing public debate especially given the rise in anti-vaccination campaigns.
- Although price-based tenders can bring short-term financial savings from reduced vaccine prices, the unintended impact on the sustainability of the vaccine ecosystem requires careful consideration. A more flexible procurement system of multiple winners, shorter tender durations, and appropriate delivery timelines that take into account the complexity of vaccine manufacturing could help encourage suppliers to remain in the market reducing the risk of supply issues.

overall sustainability of vaccination programs to meet public health objectives.

This study focuses on the situation in Europe specifically and covers three types of vaccines: measles-containing vaccine, seasonal influenza, and hexavalent vaccines.

For over 50 years, the measles vaccine has been in use in Europe and is recommended by the WHO and National Health Authorities for the immunization of all susceptible children and adults. Measles-containing vaccines include measles monovalent vaccines; measles and rubella vaccines; and measles, mumps, and rubella (MMR) vaccines. All countries in the EU have introduced MMR immunization in the second year of their child immunization schedules, which is in line with WHO recommendations [12,13]. At present in Europe there are three types of MMR vaccines available; Proquad® (with marketing authorization at 2006), MMR Vaxpro® (2006) and Priorix® (2012). Successful elimination of measles – as planned by the WHO for the end of 2020 – requires a stable vaccination rate of at least 95% [14]. While European coverage of measles-containing vaccine has been maintained above 90% for the last 15 years, a recent decrease in coverage rates has meant large numbers of cases and outbreaks continue to occur [15]. The latest WHO-UNICEF estimates of national immunization coverage of measles-containing vaccine show that only four EU/EEA countries (Hungary, Portugal, Slovakia, and Sweden) reported at least 95% vaccination coverage for both doses in 2017 [16].

Seasonal influenza is an acute respiratory infection caused by influenza viruses which circulate in all parts of the world. Yearly influenza epidemics can seriously affect all populations, but the highest risk of complications occurs among pregnant women, young children, the elderly, and individuals with specific chronic medical conditions. As a result, the WHO European Region and the European Council recommend annual vaccination for these groups in addition to health-

care workers, due to their high exposure to the virus with a 75% vaccination coverage target for the elderly population [17]. The composition of the seasonal influenza vaccine is updated annually to adapt to the circulating strains, as such, vaccination against influenza is recommended yearly. Recommendations for the vaccine composition for the northern hemisphere are published by WHO in February every year and it takes approximately 6–8 months to produce influenza vaccines [18]. Trivalent influenza vaccines have been used for years to protect against three different influenza strains (two A strains and one B strain); however, quadrivalent vaccines (two A strains and two B strains) are increasingly being made available in European countries. In total, seven influenza vaccine manufacturers produce and deliver a range of trivalent and quadrivalent seasonal influenza vaccines in Europe [19].

In October 2000, the hexavalent combination vaccine for diphtheria, tetanus, acellular pertussis, Haemophilus influenzae type B, poliovirus, and hepatitis B (DTaP-Hib-IPV-HepB) was first licensed and introduced in Europe. Since then, the hexavalent vaccine has been included in immunization schedules for infants in most European countries [20]. The European Vaccine Action Plan 2015–2020 has a target for 48 out of the 53 countries to have more than 95% coverage with three doses of diphtheria, pertussis, and tetanus (DTP) containing vaccine, and the remaining to have 90% [21]. There are currently three hexavalent vaccines approved for use in Europe; Infanrix Hexa® (2000), Hexyon® (2013) and Vaxelis® (2016).

Given the importance of vaccines to public health, the impact of how vaccines are purchased should be an area of considerable policy attention. This study seeks to understand the different types of procurement methods used for vaccines and their relationship between vaccine market dynamics, specifically: vaccine coverage; supply sustainability; competition/vaccine choice; value-added services; and incentives to invest in Research and Development (R&D).

## 1.2. Methods

Information on the four case study countries selected for their varying approaches to vaccine procurement (Germany, Italy, Romania, and Spain) was collected through a literature review and a series of interviews.

A literature review was undertaken during the period of May to September 2017 and updated in September 2019, which included government publications; academic literature; online newspaper articles and publications from non-governmental organizations. The academic literature included peer-reviewed articles available in academic and open-source databases (including PubMed, Springer, EconLit, and Google Scholar) published over the last 10 years. Government websites, databases, and key media sources were searched using a variety of keywords, including 'procurement method,' 'vaccine purchasing,' 'vaccine tendering' and 'impact on [market dynamic].' Literature was reviewed in the local languages, but English language versions of official documents generally were available. In total, the literature review identified 283 publications. Relevant publications were selected that identified a relationship between purchasing method, market dynamics, and public health in our four reference countries. In order to identify this link, we used a set of indicators to assess the

impact across market dynamics as set out in Table 1. This selection process provided 38 relevant publications that were included in this review. Results from these publications are organized according to the market dynamic impacted.

To complement the literature review, an interview program was conducted to validate findings, address gaps in the literature and review ongoing trends and evidence between procurement methods, vaccine market dynamics, and public health. A total of 11 interviews were conducted across Italy, Romania, and Spain between May to August 2018. In each market, stakeholders contacted included payers, government officials responsible for vaccine policy, health professional associations, leading academics, and public health specialists. The stakeholders were selected based on their involvement in vaccine procurement within that country or region and their understanding of vaccination from a public health perspective. The number of interviews per country and the organizations stakeholders represented is listed in Table 2. Interviews were conducted over the telephone and each country interview followed a structured discussion guide that focused on understanding the procurement landscape for vaccines in that country; views on how the purchasing method used impacts each of the vaccine market dynamics and ongoing trends in vaccine procurement.

## 2. Types of procurement methods for vaccines in Europe

Findings from the literature review and interviews illustrate that payers use a multitude of methods to purchase vaccines. At European level, there are legal structures in place as guiding principles for procurement (focusing on transparency,

equal treatment, and nondiscrimination), and countries across Europe have applied this framework to medicinal products in different ways [22–25]. Beyond European legal definitions, the academic and policy literature on the use of different procurement methods and its application to vaccines uses a range of different terminologies for different types of processes. These focus on differentiating between types of procurement method and there are a range of different terms including ‘tendering,’ ‘competitive bidding,’ and ‘auctions’ [23–25].

Drawing from the European legal framework for procurement and the types of procurement for vaccines identified in the wider academic and policy literature, five vaccine procurement methods can be categorized into a spectrum from focusing primarily on price – which we refer to as price-based – to those that include a more holistic approach based on value which we refer to as value-based as outlined in Figure 1. This provides a stylized mapping of different purchasing methods used across countries; however,, in reality, the procurement mechanisms differ from country to country:

- In Germany, the method of purchasing has changed over the last decade. Prior to 2010 vaccines, the price of vaccines was determined through a price and reimbursement process and vaccines were purchased by providers. Tenders for influenza vaccines began in 2011 and required bidding suppliers to fulfill basic pre-qualifications. Their use was considered a ‘tool to limit the prices of vaccines’ [26]. In practice, they were only used to purchase flu vaccines. These tenders originally had a single winner model but in 2014, tenders were required to have two winners. But not long after in 2017, following a political debate, an AMVSG law was passed outlawing the use of tenders [27]. Now flu, together with all other vaccines go through the standard pricing and reimbursement system.
- In Italy, once the vaccine schedules are set, each region decides on its own immunization scheme and organizes their own tenders through their Regional Health Authorities, in line with the European procurement directive [28]. All regions use a similar tender process but there are some differences: lot structure; success criteria; number of winners per tender and length of contract.
- In Romania, the procurement of vaccines, like the setting of the vaccination schedule, is conducted at a national level through tenders managed by a department in the Ministry of Public Health [29]. Decisions are made based only on price and a pre-qualification of the bidder’s financial standing [30]. Up until the recent changes due to the inter-ministerial vaccine taskforce, vaccine tenders were conducted annually [29]. However, now all vaccine procurement agreements are between 2- to 4-year contracts [31].
- In Spain, there are two mechanisms through which autonomous communities (ACs) can choose their preferred vaccine supplier, both of which have potential for differentiation through factors beyond price. At national level, under the Centralized Procedure, vaccines must comply with certain specifications to be eligible to take part (e.g. safety and quality). There is a maximum

**Table 1.** Summary of relevant indicators assessing market impact.

Market dynamic	Indicators to assess impact
Vaccine coverage	<ul style="list-style-type: none"> <li>• Vaccination Coverage Rate (VCR) in the recommended population</li> </ul>
Supply sustainability	<ul style="list-style-type: none"> <li>• Cases of supply shortages</li> <li>• Cases of disease outbreaks</li> </ul>
Competition/vaccine choice	<ul style="list-style-type: none"> <li>• Introduction of new vaccines</li> </ul>
Encouraging value-added services	<ul style="list-style-type: none"> <li>• Consideration of vaccine awareness activities by manufacturers</li> </ul>
Incentives to invest in R&D	<ul style="list-style-type: none"> <li>• Stakeholder perceptions on investment and vaccine R&amp;D across markets</li> </ul>

**Table 2.** Stakeholders’ interviews across countries.

Italy	Romania	Spain
Local Health Authority Bari	Romanian Association for Pediatric Education in Family Healthcare	Public Health Specialist Canary Islands
Public Health Specialist Calabria	National Institute of Public Health	Regional Ministry of Health for the Autonomous Community of Madrid
Vaccine buyer Lazio	Vaccination Group within the Romanian National Society of Family Doctors MoPH Ministry of Public Health	Regional Ministry of Health for the Valencian community

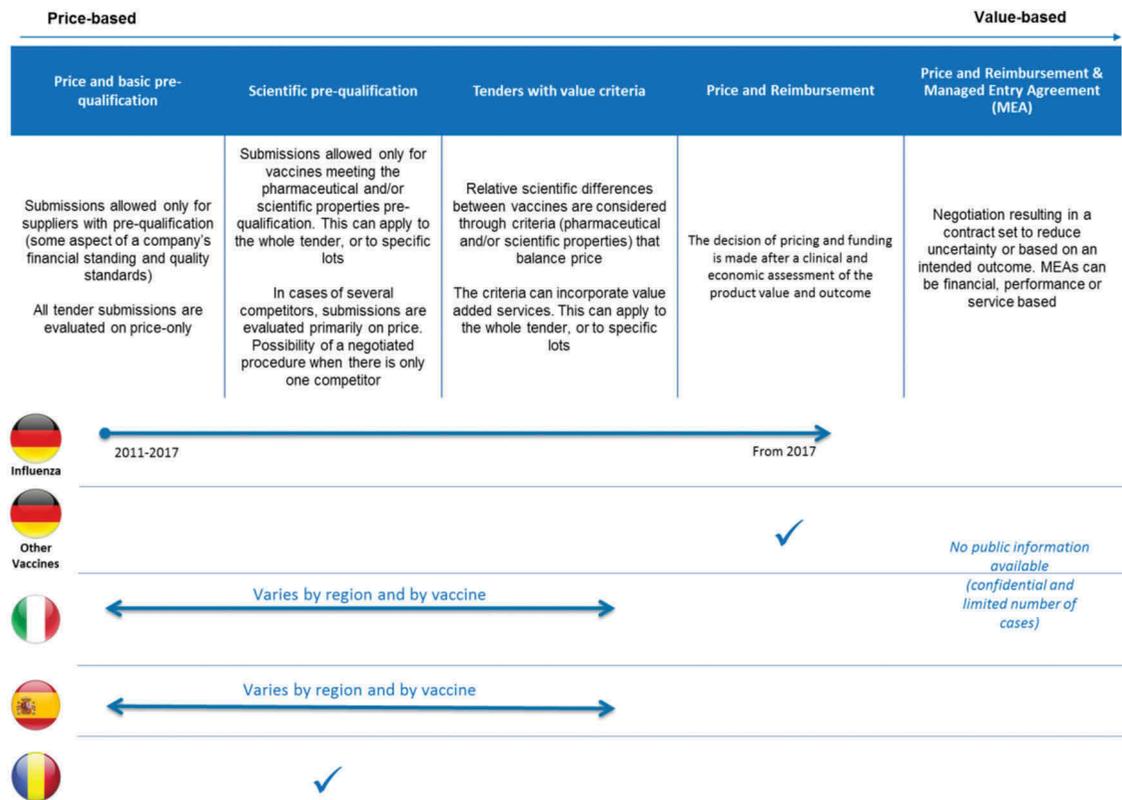


Figure 1. Types of procurement methods for vaccines.

price established for every vaccine, and usually bidders offer this price to ensure they are selected [32]. At regional level, ACs can also procure vaccines independently from the centralized process. In this decentralized system, ACs set their own tender frameworks, resulting in a range of combinations of success criteria, including factors beyond price [33].

### 3. The relationship between procurement method, market dynamics, and public health

There is data to indicate that the use of price-based tenders, particularly 'winner takes all' tenders, has resulted in a reduction in prices, at least in the short term. In Spain, national price and basic pre-qualification tenders (through the national framework agreement) were introduced in 2011 and of the regions we interviewed, Madrid and the Valencian community (until 2017) procured vaccines in this way. Since 2014, influenza vaccine prices have dropped by 27.5% [34]. The government has attributed the reduction in price, in part, to the aggregation of purchases [35]. Similarly, in Germany, influenza vaccines were tendered and prices fell between 2010 and 2017 (Figure 2). The average influenza vaccine price across three vaccines that had been consistently available in the market since 2011 was €140.27 (10 × 0.5 mL vial doses) for the 2011/12 season when tenders were first introduced. Prices subsequently dropped. The average price drop was 30% from the 2011/12 to 2012/13 flu season, and subsequently 56% by the following year [36,37]. In contrast, hexavalent and MMR vaccines were not purchased with price-based tenders and their prices remained constant over this time.

Yet this review shows that price reductions can have negative consequences across market dynamics.

#### 3.1. Relationship between price and vaccination coverage

Firstly, there is an association between worsening vaccination coverage and the reduction in price observed in our case study countries. As vaccination coverage rates (VCR) are influenced by multiple factors (particularly the public perception of vaccination value stemming from psychological and social reasons [38]), it is difficult to draw a direct correlation with price; thus, this association does not necessarily imply causation. However, vaccine case studies across countries do show that lowering prices are not able to increase vaccination coverage. In Spain, the national procedure to facilitate a homogenous low price for all regions was contemporaneous with the fall in VCR for influenza, with no evidence to suggest that the low prices have helped the VCR recover (Figure 3) [39]. Similarly in the Puglia region of Italy, where price is the only criteria considered in tender lots, over time as prices have reduced, VCR has also declined (Figure 4) [40]. An interviewed public health decision-maker from Azienda Sanitaria Locale della provincial di Bari agreed that lower prices have not been able to maintain or increase VCR.

In Romania, low influenza vaccine prices and a low VCR are observed. Based on insights from interviews, the low VCR across the country is primarily due to insufficient political endorsement. However, low vaccine prices do not itself help increase VCR and the focus only on price means other stakeholders – such as vaccine manufacturers – are not incentivized

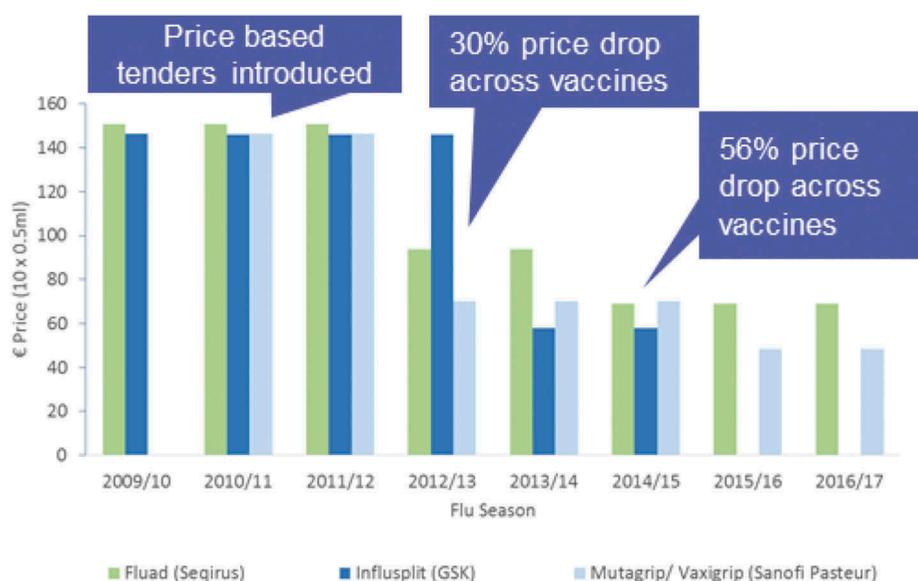


Figure 2. Germany – Influenza vaccine prices 2009–2017 (10x0.5ml).

Source: Lauer-Taxe

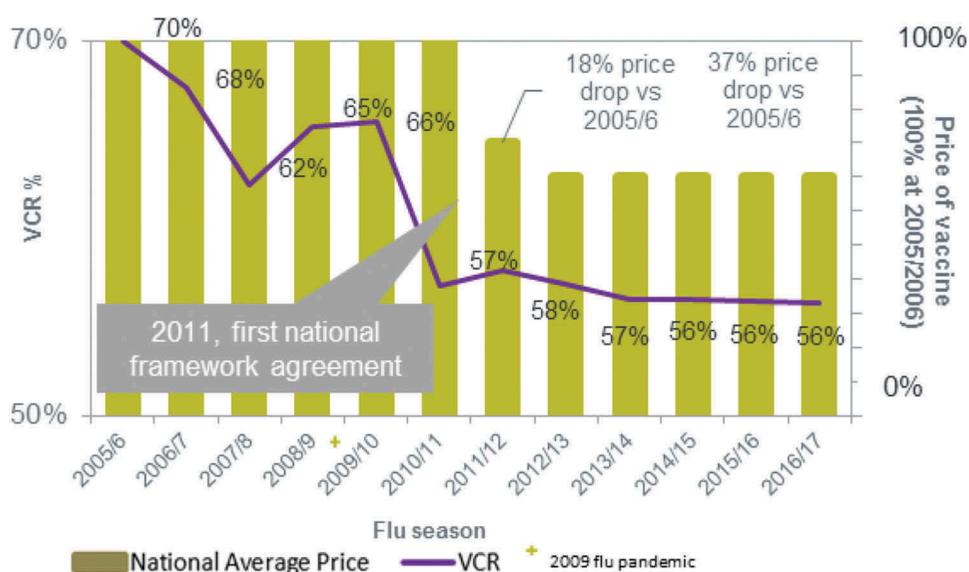


Figure 3. Influenza vaccine price and vaccine coverage rate in Spain (2005–2017).

Source: Ministry of Health, Social Services, and Equality.

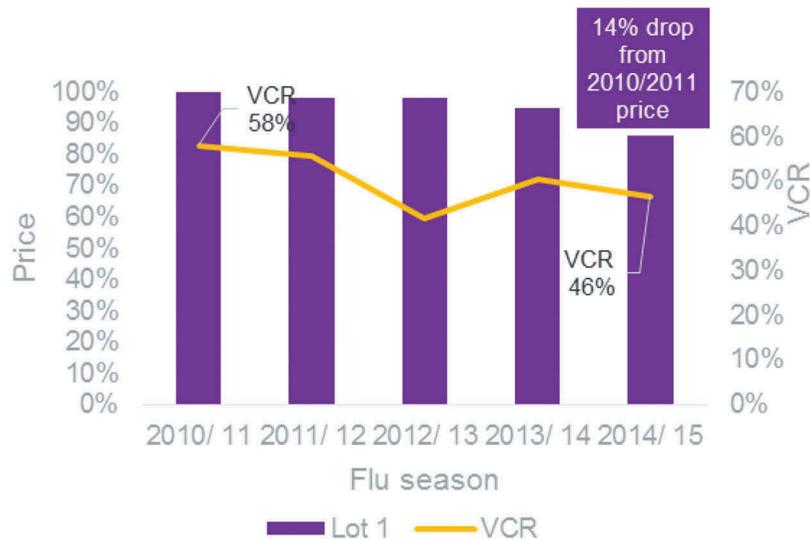
to undertake activities that could improve coverage (such as value-added services, which is discussed later).

### 3.2. Relationship between price and supply sustainability

While price-based tenders can reduce the price of vaccines, they do not necessarily encourage sustainability in supply and the vaccines market in the long term. Since Spain has implemented price-based tenders for vaccines, it has experienced problems in attracting bids, particularly for diphtheria, MMR, tetanus, pertussis, pneumococcus, typhoid fever, rabies, and yellow fever vaccines due to the lower market attractiveness to companies [41]. In response, the government increased the

MMR price in 2014 as an incentive to suppliers to continue supplying the Spanish market [42]. When suppliers find the market less attractive and exit, not only does the potential for supply interruptions increase but also the potential for an increase in vaccine prices as competition is reduced [43].

Moreover, due to the complex and lengthy production process for vaccines, particularly for combination vaccines, it seems that tenders with single winners could contribute to the exacerbation of these supply issues. For example, in 2008 the Ministry of Public Health in Romania purchased a volume of influenza vaccines that was grossly inadequate for the population [44]. Due to the rules and tender process for vaccine procurement, the only solution was to re-run the tender process. This resulted in a period of time where the market had an insufficient quantity of influenza



**Figure 4.** Comparison of influenza vaccine coverage rate and changes in price of tender issued per lot in the Liguria region 2010–2015.

Note: Change in price represents percentage change from baseline level in 2010/11.

Source: Liguria regional health ministry.

vaccines [45]. In Germany, several federal states awarded a sole supplier the responsibility of supplying influenza vaccines for the year 2012, but this supplier was unable to deliver the contracted one million doses due to identified impurities [46]. The tender framework at the time only solicited one supplier and no other influenza suppliers had produced or stocked excess doses. This presented a challenging situation in which the states could not purchase from another producer and had to solicit vaccines from other federal states [47]. Indeed, the WHO has acknowledged that tendering and procurement practices should be critically reviewed to identify where they could lead to possible causes of shortages [48].

The implications of production lead times in combination with inaccurate planning of local supply needs might mean that a population misses the immunization window [49]. When there is only one winner and the winner cannot fulfill its contract (as was the case when manufacturers failed to supply Germany), other manufacturers cannot automatically increase production or reallocate vaccine doses, even in systems with a 'back-up' supplier (e.g. Italy, where back-up suppliers have little incentive to create capacity). The result of this is that manufacturers are not encouraged to enter or maintain their presence on the market. In Spain during the 2012/2013 flu shortage, back-up winners were not able to immediately provide the shortfall in influenza vaccine due to the late demand visibility and the necessary production time for influenza vaccines [50].

In the long term, delays and disruptions to supplies can put countries at an additional risk of outbreaks. All four case study countries have VCR lower than the EU recommended VCR of 95% for measles, and it is reasonable to conclude that MMR supply shortages have the potential to increase the possibility of measles outbreaks.

### 3.3. Relationship between price and competition/vaccine choice

Price-based tenders can contribute to a reduction in choice of vaccines available for patients and physicians. 'Winner takes

all' price only tenders such as those in Romania severely restrict the number of influenza vaccine suppliers on the market for the duration of the tender contract, thereby reducing the available choice of vaccines [51]. Similarly, the quadrivalent flu vaccine that offers a broader protection was not introduced in routine vaccination in Germany despite being available since 2015, as price-only tenders did not account for its added value over the trivalent vaccine [52].

In Italy, the choice of vaccines is typically limited to one winner in a region. However, there are again differences across regions, and the lot structure has an impact on whether there are multiple winners. In the case of influenza and hexavalent vaccines where there are multiple tender lots, there could be a greater choice of innovation in some regions, including the three regions interviewed [53].

### 3.4. Relationship between price and encouraging value-added services

Interviews suggest that lower prices, or market exclusion, resulting from price-based tenders can lead to a reduction in the provision of value-added services which are important for VCR and public health. As VCR is very much linked to the public perception of vaccination value, value-added services such as awareness activities for physicians and patients can be particularly important in informing public debate especially given the rise in anti-vaccination campaigns. In 2019, four European countries (Albania, Czech Republic, Greece, and the United Kingdom) lost their measles-free status, and outbreaks of the disease have been blamed on the growth of the anti-vaccination movement [54]. Right-wing populist parties in Italy have promoted a bill removing mandatory vaccination for children, have also been influential in pulling the public away from scientific orthodoxy. In the Tuscany region in Italy, the recent measles outbreaks have been triggered by low VCR that stems from the media focus on anti-vaccination [55]. To counter this some Italian regions have been undertaking efforts to educate the public and promote the

value of vaccines. While some public health decision-makers in Italy agreed that these efforts were worthwhile and easily afforded by local government, other local regions (Calabria and Lazio) found these efforts are costly and therefore, challenging for regions to sustain in their current economic state [53].

### 3.5. Relationship between price and incentives to invest in R&D

Taking into account investment decisions are made after consideration of multiple factors and vaccine development requires manufacturing capacity building, it is difficult to substantiate an association between vaccine procurement method and vaccine R&D investment. However, it is suggested that lower prices, and therefore lower profitability for R&D-based producers, have contributed to market consolidation and a decrease of companies over time [56]. For example, it has been noted that ‘vaccines is a capital-intensive industry with high barriers to entry, as margins are not as high as in other fields (for example, oncology) and it takes years and a EUR 500 million investment to build a plant’ [57]. Various stakeholders agree that the negative impact of price-based tenders was a significant concern:

- In Germany, politicians stated that they were concerned about the ‘impact of price-based tenders on the incentive to invest’ and cited this realization as ‘one of the justifications to legislate against the use of tender for vaccines’ [58].
- In Italy, interviewees from both Puglia and Calabria recognized that ‘the current system dampens the incentive to innovate and continue with R&D for vaccines.’ However, it was also recognized that the ability to isolate the impact from other market factors was ‘challenging’ [59]. An expert from Azienda Sanitaria Locale della provincial di Bari emphasized the current procurement criteria used for pharmaceuticals may be too complicated for vaccines and that this could be simplified to encourage suppliers to stay in the market.

## 4. Sustainable approaches to vaccine procurement

Although price-based tenders can bring short-term financial savings from reduced vaccine prices, the unintended impact on the sustainability of the vaccine ecosystem requires careful consideration. For example, GAVI, which purchases vaccines for many low and middle-income countries, has recognized the negative externalities stemming from market-shaping activities and has sought to monitor and revise its procurement strategy [60]. Also, countries like the United States have changed their vaccine tender frameworks to facilitate long-term competition in the vaccine market by moving away from price-based tenders [61].

In Romania, a recent shortage of MMR vaccines has led the government to look outside the country to find additional suppliers. As all stakeholders agree that the current system is not sustainable, the government has undertaken changes to the tender procedure it is now possible to have multiple

suppliers qualified in a long-term framework agreement to allow for product differentiation. Moreover, the change in tender legislation, published at the end of 2017 allows the government to consider additional value criteria, such as quality, as part of the tender success criteria, in addition to the existing price criteria [62]. These promising steps toward an improved tendering system shall now be further experimented in coming tender procedures.

There are different ways to ensure that tenders contribute to the sustainability of the vaccine ecosystem. Italy, Spain, and the US all try to encourage suppliers to stay in the market by allowing multiple suppliers on the market, whether through multiple winners per tender or by using multiple tender lots. These mechanisms can also be used to differentiate between the characteristics of vaccines in a single disease area. A more flexible procurement system of multiple winners, shorter tender durations (less than 3 years) and appropriate delivery timelines that take into account the complexity of vaccine manufacturing could help encourage suppliers to remain in the market such that supply issues are not exacerbated by price-based tenders. This has been seen in Germany, where the government first amended the laws for tenders to require two winners per tender contract in a bid to address supply issues and then subsequently abolished tenders for vaccines in 2017, reverting back to the P&R system for vaccines.

For countries that want to increase or maintain vaccination coverage rates, a move to procurement models that place more weight on the concept of value-added services could be useful, especially where issues like lack of awareness and understanding of public health and societal value of vaccination is a main contributor to low vaccination coverage rates. In Spain and Italy, one of the contributing factors to low vaccination coverage rate is the lack of awareness of vaccination value, according to interviewed stakeholders. Some Italian regions indicated that education and awareness campaigns are difficult to sustain due to financial constraints. By considering the provision of value-added services in tender criteria, it is possible to encourage companies to provide educational activities for physicians and patients.

Other than tenders, procurement methods such as price and reimbursement are commonly used for medicines and can also be applied to vaccines (as Germany has done). While a system based on price and reimbursement, focusing on value, may not exploit competition when setting the list price of vaccines, there can be intense competition over market share and services to physicians, pharmacists, and patients which can positively impact the VCR and hence public health.

Our study findings are even more important in the current context of implementation of the EU Council recommendations on strengthened cooperation against vaccine-preventable diseases and Joint Action on vaccination where topics of supply and procurement of vaccines are a key component of the sustainability of vaccination programs and critical to the protection of EU citizens [63].

## 5. Conclusion

Our study shows that the commonly used method of price-based tenders for the procurement of vaccines can have

unintended negative consequences on the vaccine ecosystem and can indirectly affect public health. It demonstrates the importance of a well-balanced and healthy vaccine ecosystem, encompassing appropriate budget allocated to vaccination, as well as procurement methods maximizing the public health goals, in line with EU priorities. Although our approach was exploratory and focused on a selected number of countries and vaccines, our findings were discussed and validated with many experts across Europe. As the publicly available evidence in this domain is limited, we have had to rely on expert interviews, contributing to the expert opinion. As such, further research is encouraged in this area.

## 6. Expert opinion

The current vaccine procurement system in Spain is a tendering framework primarily based on price. This success criteria stem from cost containment being one of the predominant themes across all Autonomous Communities in Spain. However, this focus on price puts the future sustainability of the vaccine market at risk, particularly in terms of incentivizing innovation. Innovation should be rewarded so manufacturers have the right incentives to offer higher quality vaccines that help safeguard public health. Otherwise, there could be future scenarios when only inferior vaccines are purchased. There is already market risk whereby some manufacturers are not participating in the tender bidding system as they do not find it rewarding. This has led to cases of vaccine shortages. This risk is likely to increase if there are no changes made to the current procurement system. There is also a need to change the general mindset about vaccines. Currently, vaccines are seen as an additional public expenditure, rather than an investment in future public health. While the economic landscape plays a key role in spending and budget constraints, with better vaccines reaching the market there is a need to raise public understanding of the health benefits but also the investments needed to bring these vaccines to the market. Over the next 5 years, there is a need to adopt more innovative purchasing agreements and to include innovative value-added services in the vaccine procurement process. This could take the shape of many forms: supporting training of healthcare professionals, awareness campaigns focussed on disease areas with low vaccination rates, improvement in monitoring and vaccine registries, etc. Sustainability can also be improved by having a better dialogue between manufacturers and purchasers, ensuring there is increased awareness of the challenges with current procurement mechanisms and innovation.

In Romania, the current vaccine procurement system awards decisions based on price-based tenders. This mechanism is designed to manage affordability, however does not promote widespread access to vaccines. This procurement system also has supply-side implications, indicated by the supply shortages seen today. There are simple contracting mechanisms that can overcome some of the challenges in the current system, such as implementing multiple winners per contract or split tenders. Ultimately, however, moving to a reimbursement model for vaccines would be more sustainable than the current price-based tender model. Moving to a reimbursement model for vaccines can offer multiple benefits to the long-term

sustainability of the vaccine market, particularly around market attractiveness and innovation. This would be more impactful in certain areas, such as antimicrobial resistance, where reimbursement of vaccines will be critical to encourage future innovation. Additionally, reimbursement of vaccines does not only benefit the availability of products but also acts as a political signal in the promotion of vaccination by the public healthcare system. This is particularly important given the rise in anti-vaccination campaigns. Many people do not understand the science of vaccines and do not understand the level of safety and efficacy a vaccine needs to demonstrate. Similarly, they have preconceived ideas about what a vaccine is and its composition, which is not necessarily correct. The provision of value-added services could offer the opportunity for manufacturers to educate the public and officials, which would be important in vaccination coverage. With budget impact a key concern, there is generally more interest in funding curative services and rather than preventative services. It is therefore important for there to be a change mentality in funding vaccines; illustrating that investing in vaccines can have wider public health benefits. Particularly for some vaccines, like influenza, where there is a rapid return in benefit.

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## Author contributions

T Wilsdon, R Lawlor, and L Li were involved in the conception and design of the study and the drafting of the paper. A Rafila and A García Rojas were involved in the interpretation of the analysis, revising the paper critically for intellectual content and providing the expert review. All authors provide final approval to the version of the study to be published and take accountability for all aspects of work.

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- **This article from the Official Journal of the European Union explains how vaccination is one of the most powerful and cost-effective public health measures and there needs to be strengthened efforts by Member States against vaccine-preventable diseases.**