Identifying efficiencies in the provision of vaccines.
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By protecting children and adults against preventable infectious diseases, vaccines save each year millions of people’s lives. As these products are relatively inexpensive, vaccination is generally considered as one of - if not the - most cost-effective medical intervention available. Although vaccines represent only a small share of total drug expenditure, preventative health-care programmes are most vulnerable to the budget cuts that are currently made across Europe. The benefits resulting from vaccination are not always immediately seen and measurable while cuts are short-term, easily quantifiable and executable. However, by identifying efficiencies in the organisation of vaccine provision, savings are possible while still reaching health goals. This organisation of immunisation programmes varies widely between and even within European countries. Numerous options exist for a policy maker to organise its program in the most efficient way. Not only can he decide which vaccines should be included in the local immunisation schedule, he can also make changes to the way they are procured, distributed and administered. It is within the latter three functions that we identified potential efficiencies and best practices, by comparing vaccination programmes across countries. Based on interviews, observations and what-if analysis, we claim that efficiency gains of 10 EUR to 15 EUR per vaccine dose administered may be achievable in several European countries if the distinct areas of procurement, distribution and administration processes were to be optimised.

The method by which vaccines are purchased and financed does not seem to be a decisive factor in the success of immunisation programmes, as high coverage rates can be achieved in a variety of settings. While a tendering process requires careful planning and preparation, it can provide health care payers with an effective, short term method to obtain lower vaccine purchasing prices. Policy makers should, however, consider that tendering can lead to increased wastage rates, the possible need for stockpiles, and a decrease in social contributions paid by manufacturers due to changes in staffing needs. These 3 costs can offset anticipated budget savings from a reduced purchasing vaccine price. Moreover, tenders may have several negative long term effects on innovation and competition. The main cost benefit typically associated with government-controlled vaccine provision may not result from the procurement phase, but from the organisational structure that is operational further downstream: i.e. an efficient provision of vaccines through alternative distribution and vaccine administration channels. While health care payers in many countries are easily spending many euros on having a single vaccine dose distributed through the standard pharmaceutical distribution channels, specialised cold-chain distributors in countries like the UK, Belgium, and Spain are storing and delivering the same vaccine directly to vaccinators for only a fraction of that cost. Further efficiencies may be achieved by expanding the number and types of vaccinations settings. Non-traditional settings such as pharmacies, schools, well-baby clinics, and vaccination centres can provide an excellent addition to GP and specialist (e.g. paediatricians) offices to increase overall vaccine coverage rates and reach specific target populations in a cost-effective way.

By comparing practices across countries and opting for the most advantageous aspects of vaccine procurement, distribution, and administration processes, policy makers may identify opportunities to organise their immunisation programmes in a more efficient way. They can take those measures to push down the vaccination cost to comply with budget targets while reaching the specific health goals for the population.
The value of vaccines

The introduction of vaccines during the early part of the last century has transformed public health in both the developing and developed world. Wide-spread vaccination campaigns have eradicated smallpox, decreased the global incidence of polio by 99%, and achieved dramatic reductions in the occurrence of diseases such as measles, diphtheria, whooping cough (pertussis), tetanus and hepatitis B. Each year immunisation saves the lives of 2 to 3 million of people and significantly reduces illness and long-term disability. In addition to the medical benefits provided to the individual and his/her community (herd immunity), vaccination also generates substantial short and long term social and economic value.

At the same time, vaccine sales represent only about 3.5% of the global pharmaceutical market. Not surprisingly, immunisation is therefore generally considered as one of the most cost-effective medical interventions available. In a 2005 study, researchers estimated that, for every dollar spent on routine childhood immunisation in the United States, the 7-vaccine program saved more than $5 in direct costs and approximately $11 in additional indirect costs to society.

Downturn forces European health care payers to focus on costs

These excellent returns on investment, however, do not necessarily make vaccine programmes recession-proof. With an emphasis on protecting frontline primary care services and short term budget savings, preventative health programmes are particularly susceptible to healthcare spending cutbacks in times of austerity. Evidence indeed suggests that budgetary constraints as well as the social effects of recent financial crises have adversely affected control of infectious diseases. Although experts advise governments to sustain and, when possible, even increase investments in immunisation, this is hardly an option for countries hardest hit by economic turmoil.

As austerity bites across contemporary Europe, payers in both the eastern and western part of the old continent are currently looking for cost savings and possible efficiency gains in all areas covered by the healthcare budget, including vaccination. In Germany, for example, the pricing processes for both pharmaceuticals and vaccines have recently been drastically revised and distribution margins of wholesalers and pharmacies have been reduced. In addition, there is an increasing trend for sickness funds to use regional tender processes for the procurement of vaccines. Healthcare authorities in several other countries, including the UK, France, and Slovakia, are also contemplating whether they should simply reimburse certain vaccines or take a more active role in the procurement and distribution of these products. Pharmacists in Greece and nurses in France were already allowed to administer flu vaccines at a cost that is significantly lower than a doctor’s consultation fee and recently hundreds of Irish pharmacists have been trained for the same purpose.

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*Herd immunity or community immunity describes a form of indirect protection of unimmunized individual as a result of extensive vaccination in a population.*
The organisation of vaccine provision: a patchwork of systems

Healthcare in Europe is provided and funded through a wide range of systems managed at the national and/or the regional level. Moreover, there are distinct differences between immunisation policies and the extent to which governments want to take control over vaccine provision. As vaccine programmes target different groups of people (i.e. children, adolescents, or adults), various approaches are also required to reach the specific “at-risk” population. As a result, the organisational frameworks in which vaccine programmes are financed and delivered vary substantially between and even within individual European countries.

In most countries, a National Immunization Technical Advisory Group (NITAG) or an equivalent body provides guidance to policy makers enabling them to make evidence-based decisions on immunisation policies. For this purpose, health services/economics experts will evaluate the burden of an infectious disease as well as the safety and efficacy of the vaccine(s) with market authorisation. Products which secure a NITAG recommendation have a higher chance of being included in the local – usually publicly funded – routine immunisation schedule. Nevertheless, short term budget constraints can prevent the actual implementation of such recommendations even when the initial investment would be more than compensated for by averted disease costs in the long run.

That is about as far as similarities between the European vaccination systems go. However, as there are important cultural differences between countries, governments adapt markedly different approaches to domains such as market access, awareness creation, procurement, distribution and vaccine administration. We will take a closer look at various choices that authorities can make in these separate decision areas and discuss their potential advantages and disadvantages.
The aim of this paper is to identify the main factors affecting the cost of vaccination systems and to highlight the options that payers may want to consider when seeking an optimal method to organise vaccine provision systems. With the recent trends in mind, special emphasis is given to the choice between reimbursement and tendering processes in the procurement of vaccines. The scope of the paper is limited to vaccines which could be considered for universal vaccination programs and thus includes most prophylactic, but not travel or therapeutic vaccines. As the terms of tender contracts are often confidential, we will also not focus on the differences in purchase price that may emerge when different procurement methods are used. This paper is based on the conclusions of interviews that were carried out with experts from governmental vaccine procurement departments, vaccine distributors, academic experts, country health policy/economics experts, and current/former executives of major vaccine manufacturers in various European countries (including Belgium, France, Germany, Greece, Romania, and Spain). Additional information was obtained from publicly available sources, publications and the academic literature. A simulation tool was designed to carry out a

**Figure 1.** Major decision areas with impact on the total cost of vaccine provision

**Procurement**
- Government/payer purchase
- Discounts
- Risk-sharing & clawbacks
- Number of competitors

**Market access**
- Price and reimbursement dossier at launch
- Review & decision at launch
- Revision of tender by manufacturer and payer
- (Delay in) time to market
- Legal actions

**Communication**
- Awareness and marketing
- Income tax on employment by companies (sales force)
- Public campaign

**Distribution**
- Wholesaler and pharmacy mark-up
- Taxes on wholesaler and pharmacy
- Third party distributor
- Wastage levels
- Out-of-stock
- Returns/expired vaccines
- In-house costs (stock, storage, transport, order picking, …)
- Parallel trade
- Cost of switching vaccines

**Disease & Other**
- Avoided costs disease treatment
- Productivity loss averted
- Coverage rate
- Vaccination outside target group
- Cost of non-compliance
- Burden of disease
- Post-licensure trials
- Surveillance system
quantitative analysis using the data collected during the research process. This tool was subsequently used to identify major cost components and simulate "what-if" scenarios to estimate potential efficiency gains for the stakeholders.

From the literature and interviews, we identified more than 30 elements that can have an impact on the overall costs of vaccination systems and grouped them into four distinct decision areas: procurement, distribution, vaccine administration and disease & other costs (see Figure 1). Components from this last category can be taken into account when the price of a vaccine is determined (e.g. economic burden of disease, treatment costs and productivity loss averted) or are disease-specific and hard to quantify (compliance, post licensure trials).

Furthermore, the investments required to set up and manage surveillance systems can be significant but are distinct from the costs of vaccine provision. Therefore, the items in the disease & other costs category were not considered in the quantitative analysis. The main cost components of vaccine provision, as suggested by our analysis, in each of the three remaining areas (i.e. procurement, distribution, and vaccine administration) are presented in bold in Figure 1 and will be discussed in further detail below. A detailed, quantitative example of a "what-if" scenario is presented in Figure 4.

\[\text{Surveillance systems are essential in identifying disease trends, monitoring adverse events, and measuring progress towards control and elimination goals.}\]
Public and private markets
Vaccine markets can be characterised as private or public, depending on who the buyers and the payers are. In private markets the buyer is the individual consumer who decides to obtain the vaccine and a payment is made by the consumer and/or his private insurance (out-of-pocket purchase), by the authorities (reimbursed), or by both parties (partially reimbursed plus co-payment). In public markets, national and regional governments commonly take on both roles at the same time by deciding to buy on behalf consumers and pay the vaccines in large quantities, often through tenders. In most European countries, a private and public market coexists but their relative size can vary significantly.

Germany and France exemplify private vaccination systems, which are run with virtually no support from the government. Germany has a highly decentralised system, in which vaccines included in the immunisation schedule have to be reimbursed by all 300 sickness funds. In France, the authorities make recommendations on target groups and assign a reimbursement rate to new vaccines (often 65%), which are subsequently covered by the national health insurance. The remaining sum is paid by consumers or more frequently, their private health insurance. In both countries, the consumer generally decides to opt for vaccination, the physician usually determines/prescribes the brand of the vaccine that will be administered, and health insurers reimburse (part of) the acquisition costs.

At the other end of the spectrum, there are countries in which public buyers play a much more dominant role in vaccine procurement. In Spain and Italy, for example, nearly all vaccines that are deemed beneficial from a public health perspective are included in the immunisation schedule and purchased on a regular basis by regional health authorities. Commonly, these organisations will set up a central procurement or competitive tender process and decide which brand(s) will be provided free of charge to the at risk population in their region.

TENDERS
Tenders can be defined as any formal and competitive procurement procedure through which tenders/offers are requested, received and evaluated for the procurement of goods, works or services, and as a consequence of which an award is made to the tenderer whose offer is perceived as the most advantageous. For procurement agencies, tendering is a useful tool to obtain the lowest possible purchase prices for largely undifferentiated products such as commodities. In the European Union, the legal basis for tendering systems is provided by EU Directive 2004/18/EC which introduces criteria for awarding public contracts.

Within the healthcare sector, tendering is particularly used in hospital settings as well as for the procurement of products for a specific public function (e.g. for army purposes or immunisation campaigns). Although the practice is less common in ambulatory care settings, health insurers in some countries including the Netherlands and Germany apply the process to purchase generic drugs. Unlike for branded pharmaceuticals, it seems generally accepted that both old and novel vaccines can be purchased via a tendering process as soon as competing products become available. As the patentability of biological products like vaccines is fundamentally limited, technical know-how in the domain of production and regulatory requirements usually represent the main barriers to entry for “me too” vaccines.
To tender or to reimburse, that is the question

From the interviews, it became apparent that several European governments are currently considering a revision of their procurement methods and contemplate whether they should be tendering or reimbursing vaccines.

Both approaches do seem to have certain advantages and disadvantages. While tenders may decrease the initial product acquisition costs, they are associated with a high workload, increase the risk of supply interruptions, and require a transparent legal framework in order to avoid litigation. A reimbursed system, on the other hand, offers consumers and their physicians freedom of choice and allows the payer to reimburse vaccines at different rates. At the same time, such voluntary systems might reduce the level of control authorities have over their budget and the public health targets they aim to achieve.

We believe a holistic assessment of which procurement method would be the most suitable should take into consideration the following six aspects:

- Coverage rates
- Vaccine purchase price and budget impact
- Wastage levels
- Administrative burden
- Provision of information
- Risk of supply interruptions

Other effects of different procurement methods, such as the impact on quality, innovation and the speed of availability can be equally important but are not the focus of this paper.

Impact on coverage rates

It seems that both procurement methods can be successfully applied to achieve local vaccination targets. Sometimes it is suggested that publicly-funded, government-controlled (i.e. centralised) systems assure greater vaccination coverage because they allow for the implementation of precise plans concerning immunisation schedules, targets, uptake deadlines and surveillance. It has also been argued that, especially in low-income countries, the uptake of vaccines may be hampered if vaccinees need to make a co-payment. WHO/UNICEF’s most recent statistics on childhood immunisation, however, suggest that high coverage rates can be achieved across a wide variety of settings. Despite the absence of well-defined plans, targets, and deadlines, national coverage rates of $\geq 97\%$ for the third doses of diphtheria, tetanus, pertussis (DTP3), polio (Pol3), and Haemophilus influenzae type B (Hib3) are achieved in France. And although the German system was unsuccessful in achieving high childhood immunisation levels 10 to 15 years ago, it seems this gap has largely been closed in the meantime.

On a less positive note, during the last three to five years, measles outbreaks were reported in countries with a decentralised system (France, Germany) as well as in countries which essentially rely on tender systems for the procurement of childhood vaccines (Bulgaria, Italy, Spain).

So it seems the setup of the system, in itself, can neither prevent nor guarantee the realisation of suitable coverage rates. It will depend more on local situations such as the type of buyer (with short or long term view), the culture (i.e. reaction on "obliged" vaccination) and the view on the healthcare system (i.e. willingness to co-pay). The Society of Independent European Vaccination Experts (SIEVE) believes that clear common goals, the political will to achieve them, and adequate communication are more important factors leading to success in vaccination.
Vaccine purchase price and budget impact

Even though the purchase price of the vaccine itself directly contributes to the costs of immunisation programmes, its proportion to the total programme costs is often limited. It has previously been estimated that vaccine acquisition costs account for about 10-15% of the total cost of any centralised vaccination programme, although this percentage will depend a.o. on the composition of vaccines included in the local schedule.

There are many elements that can be taken into consideration when the price of a vaccine is set and it is clear that reimbursement and tender processes have a different focus. In a typical pricing and reimbursement negotiation, the manufacturer will have the opportunity to provide medical and health economic arguments to demonstrate the value and cost-effectiveness of a new product. The ex-manufacturer’s price that is subsequently agreed upon may be fully or partially reimbursed by the payer and is usually maintained for a considerable period of time. Authorities may decide not to include some products in the list of reimbursed vaccines, in which case the product is usually made available to the private market at a price proposed by the manufacturer and agreed with authorities. Needless to say the products which do not have a favourable reimbursement decision are less likely to be used widely.

In a central purchasing or tender process, the element of competition is introduced and – although other decision criteria are or can be included among the specifications – the focus tends to be on the price rather than on the value of the products. Tender prices can be affected by many factors including the bargaining power of the issuer and suppliers (e.g. concentration of supply and demand, differentiation of products) as well as contractual arrangements concerning logistics, product liability, returns policy, payment terms, length of contract, and guaranteed volumes. The payers’ shift of recent focus towards tendering processes is generated primarily by their expectation that they would be obtaining a lower unit price per vaccine through a tendering process when compared with reimbursing individual vaccine purchases made by vaccinees from retail pharmacies. There are several reasons why tenders may yield lower acquisition prices. First of all, by contracting directly with the issuer, the commercial discounts that were usually passed on to the distribution chain can now be delivered to the payer. Secondly, because market shares are fixed as soon as the contract is awarded, in a purely public market manufacturers can reduce their expenditures on sales and marketing activities (see further). Last but not least, the economic theory suggests that auctions lead to lower prices. As a “single winner takes all” approach may be used by authorities for whom achieving the lowest price is the single most important criterion, vaccine suppliers may prefer to sacrifice part of their profits to increase their chances of winning the tender instead of being kept out of the market altogether.

For health care decision makers, not only the price and cost-effectiveness but also the budget impact of an intervention is important to consider. When vaccines available on the private market are reimbursed, there is a certain level of uncertainty about the uptake and, consequently, about the funds required to acquire the vaccines. As prices and volumes can be stipulated in a so-called ‘fixed-quantity’ contract, it is possible to allocate a specific budget ex-ante to this line item as soon as a tender is awarded.

Therefore, we believe that the tendering process can be an effective, short-term tool for health care payers to obtain lower vaccine prices. However, tendering demands a lot of expertise and impacts the competitive industry landscape. Hence the set-up of a tendering process is complicated and requires a pre-defined and structured framework. Tenders have also other shortcomings, such as lower attention for the cost-effectiveness of a vaccine and for the value of innovation, a risk of reducing market access to low income countries due to international price referencing and a potential negative long term impact on quality, the speed of availability and on competition. Therefore, the impact on the vaccine purchase price is only a part of the procurement consideration between tenders and reimbursement.

Given that there are so many factors that can affect purchase prices and that the terms of tender contracts are generally confidential, we will not focus on the actual cost differences resulting from the method of procurement as such.
Identifying efficiencies in the provision of vaccines

Wastage levels
A clear disadvantage of a fixed-quantity contract, however, is that the specified quantities may either be too high (resulting in overstocks) or too low (resulting in shortages). In a consultation report for the UK Department of Health, it was assumed that wastage levels would increase to 10 % if the procurement of seasonal flu vaccines would be centralised 19. According to the WHO, even wastage rates of 50 % are not uncommon for traditional childhood vaccines 20. And in a more extreme case, over 99 % of the vaccines that were acquired by the Romanian authorities for the launch of a human papillomavirus (HPV) immunisation campaign were left unused (see box "Wastage in Romanian HPV campaign"). For this reason, some public buyers prefer to use ‘estimated-quantity, periodic-order’ contracts. With this type of contract, the quantity of vaccines to be procured via the tendering process is just an estimate and the purchaser can periodically place orders at the agreed price throughout the contract term. This system benefits purchasers, because their financial liability will be limited to each order. In this case the public payers are not obliged to purchase (and neither pay for) the total amount of vaccines mentioned in the contract, however the manufacturer would have to be prepared to deliver that amount of vaccines upon request and in the meantime taking a risk 21. Obviously, this may be reflected in the prices bidders are willing to offer during the tender procedure. In the private market, the financial risk of wastage mainly lies with the manufacturer and other stakeholders in the distribution channel.

Administrative burden
The workload associated with the organisation of tenders is not to be underestimated. A formal tender process including forecasting of required quantities, preparation of tender documents and contracts, the collation of offers, and selection of suppliers may take many months 21. For such a programme to work, a solid legal framework is also required in order to appropriately regulate the tendering process and ensure a fair opportunity to all the participants 24.

Decision criteria have to be transparent and impartial to all participants, which may not always be easy as different vaccine brands may not always be fully interchangeable (e.g. Merck’s Gardasil and GlaxoSmithKline’s Cervarix). Commonly, procurement offices will work together with technical experts to create a point system in which relative weights are assigned to various performance criteria against which the incoming bids will be evaluated (e.g. 40 % costs, 40 % quality, 10 % stability, 10 % other). In Ireland, for instance, experts of the National Immunisation Office will assist members of the dedicated Pharma & Medical Procurement team of the Health Service Executive during the preparation of vaccine tenders.

In countries in which regional authorities are responsible for the healthcare budget, there may be considerable duplication in some activities. In Belgium, both the ‘Cellule vaccination’ and the ‘Flemish Agency for Care and Health’ will issue public offers for the procurement of vaccines in the Walloon and Flemish region of Belgium, respectively.

In Spain, the 19 autonomous Communities each organise their own vaccine tenders. Compared with the other costs that are associated with the organisation of immunisation programmes, however, it seems that these administrative expenses are relatively small.

WASTAGE IN ROMANIAN HPV CAMPAIGN
Cervical cancer is a leading cause of death among women worldwide. In the past few years, however, vaccines have become available that can protect young women from infection with the high-risk strains of human papillomavirus (HPV) which cause approximately 70 percent of all cases.

Romanian incidence and mortality rates of cervical cancer are among the highest in Europe. In November 2008, the Romanian Health Ministry therefore launched a national vaccination campaign targeting 110,000 girls aged 10 and 11. A public budget of approximately 23 million EUR was made available for the acquisition of 164,967 doses of Cervarix and 165,033 doses of Gardasil. Because of low public acceptance, however, only 2,615 girls were vaccinated in the first three months after kick-off and the campaign was suspended. One year later, a second campaign proved equally unsuccessful and most vaccines expired 22,23
Provision of information
Whichever system is used, acceptance of vaccination by the general public and by health-care professionals is instrumental. Public trust in vaccines is influenced by a variety of factors including perceptions about vaccine benefits and risks, historical experiences, supply interruptions, religious or political affiliations, and socioeconomic status. The provision of accurate, scientifically based evidence on the risk–benefit ratios of vaccines is crucial to address several barriers to vaccination. The media plays an important role as a source of information and can have a positive or a negative effect on the public perception of vaccination. Health care professionals, however, are considered as the main advocates for vaccination and the most trusted source of information for the general public. To feel confident in carrying out their responsibilities, they need the support of health authorities and be provided with up-to-date information on infectious diseases and the safety and efficacy of available vaccines. In European private markets, health care professionals will generally obtain such information from health authorities, often supported with disease awareness campaigns by the manufacturers, and from teams of up to 200 representatives and medical liaisons that are employed by vaccine manufacturers in the larger countries. In public markets, on the contrary, pharmaceutical companies have little or no incentive to invest in educational and promotional programs as the market shares will be fixed. A reduction in these expenditures, as well as savings resulting from a decrease in salary expenses and social contributions to the government, may partly explain why prices in tenders are often set lower than in a reimbursed setting. Even so, public health authorities may still decide to fund large-scale advocacy campaigns involving the participation of senior politicians and extensive media coverage (e.g., posters, booklets, radio and TV spots) to inform the general public and health care workers about the decision to introduce a vaccine or to promote immunisation services in general.

Risk of supply interruptions
One of the main concerns for governments using central purchases or tenders is the risk associated with having only one supplier. When these sole suppliers experience manufacturing problems, supply interruptions and vaccine shortages may interrupt immunisation schedules, sometimes leading to children not being immunised. Inevitably the complexities in vaccine production lead to occasional disruption of supply caused by, for example, batch or production failures, quality control issues with bulk or finished products, breakdown of the cold chain in delivery, and failure to predict variations in demand. Because the lead times involved in vaccine production can easily surpass 12 months and the number of manufacturers for any given vaccine is rather limited, it may be very hard to find replacement vaccines in such instances, as experienced by the US health authorities in 2004 (see box “Risk of supply interruptions”).

Although there are no real solutions to this problem, different approaches are used to mitigate the risk. First of all, some procurement programs will routinely split contract awards among two or three suppliers. UNICEF, for example, prefers to procure vaccines from several manufacturers instead of pursuing a winner takes all policy. Secondly, in some countries, such as Belgium and Greece, companies are obliged to establish a stockpile to ensure that some excess vaccine supply is always available to buffer potential supply problems. Commonly these stocks are only used and paid for if the situation requires it. In the Netherlands, where mandatory contingency stocks are particularly large, however, the authorities bear two thirds of the associated costs. Thirdly, a company that is not able or chooses not to fulfil its obligations to deliver tendered vaccines may face penalties that are stipulated in the contract. Generally, these penalties are of a financial nature (e.g., 5 % or 10 % of the vaccine price) but in some Spanish regions manufacturers may even be forced to supply the public buyer with vaccines from a competitor (which it would need to purchase on the private market at retail prices).
RISK OF SUPPLY INTERRUPTIONS
Contamination at Chiron plant in 2004

On the eve of the 2004-2005 flu season, US health officials learned that their supply of flu vaccines was suddenly reduced by 50%. In order to prepare for the annual immunisation campaign, they had ordered approximately 100 million doses of flu vaccines from two multinational corporate manufacturers, i.e. Chiron Corporation and Aventis Pasteur.

At the end of August, however, Chiron detected a contamination problem at its Liverpool production site and British regulators decided to shut down the facility. As the production of flu vaccines easily takes 6 to 9 months, Chiron’s competitors were not able to reach to of this market shortfall and fill the gap of 48 million flu vaccine doses.

CONCLUSIONS ON PROCUREMENT
In conclusion, the method by which vaccines are procured does not seem to be a decisive factor in the success of immunisation programmes, high coverage rates depend more on other organisational and systemic factors. While tenders require careful planning and preparation, they seem to be an effective, short term method for health care payers to obtain lower vaccine unit prices. Authorities may need to consider, however, that increased wastage rates, the possible need for stockpiles, and a loss in social contributions can counterbalance anticipated budget savings. After purchasing large quantities of vaccines, they may also want to take a more active role in advertising the universal mass vaccination campaign to promote vaccine uptake.
Vaccine distribution

Results from our simulations suggest that the main economic benefits associated with tenders may, in fact, lie further downstream: i.e. in a more efficient provision of vaccines to the patient through alternative distribution and vaccine administration channels. A comparison of various European systems shows that both the costs and responsibility of vaccine distribution can lie with different parties. Storage and transport of vaccines can, for example, occur within the existing pharmaceutical distribution networks composed of wholesalers, hospitals and retail pharmacies. On the other hand, authorities may also decide to set up and manage the entire immunisation program including vaccine production, distribution, selection of vaccinators, and immunisation communication.

Wholesaler – pharmacy channel

In the private markets, vaccines are typically distributed through the standard pharmaceutical distribution channels. In countries such as France and Germany, virtually all vaccines are distributed by wholesalers and pharmacies. In most developed markets, retail pharmacies will allow consumers to obtain vaccines for which they are not a member of the at-risk group(s), as well as provide access to brands that are either not part of the publically-funded immunisation programme or which were not recommended for routine use. A benefit of this traditional channel is that it allows pharmacists to collect the consumer’s co-payments for products which are not, or only partially, reimbursed. For the authorities, other important advantages of such a system are that

Figure 2: Mark-ups and VAT differences between countries

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they can rely on the pharmacist’s expertise for informing the general public and they can depend on the existing logistics infrastructure of these private parties without having to make any up-front investment.

It is important to note that not only reimbursed, but also tendered vaccines can be distributed via this route. Recently German sickness funds were authorised to issue regional tenders for the acquisition of e.g. flu vaccines ⁴. After the contract is awarded, these vaccines will be distributed via the regular channel of wholesalers and pharmacies.

For reimbursed products, the majority of European countries have regulated wholesale and retail mark-up/ margin schemes. As distribution margins and taxation rates vary widely across countries, so will the distribution costs that healthcare systems and/or patients need to pay when a pharmacist delivers a vaccine (considering identical ex-manufacturer’s selling prices or MSP; see Figure 2) ²⁹. For cheap vaccines, the costs of distribution may be relatively high compared with the value of the product. More importantly, however, the absolute costs of distribution can become quite significant for more expensive vaccines. This is especially true in countries that do not apply regressive, but linear margins. In Greece, for example, the distribution margins (4.9 % at wholesale and 32.4 % at pharmacy level) and VAT (6.5 %) for a vaccine with an ex-manufacturer’s price of 100 EUR will amount to nearly 48 EUR.

**Direct distribution by specialised companies**

Alternatively, public authorities may also decide to set up a system in which vaccines are directly delivered to the vaccinators. As most vaccine formulations are temperature-sensitive, maintenance of a cold-chain that is robust, reliable, and routinely monitored for possible deviations between the manufacturer and end user is an essential part of the supply process ²⁹. Therefore, the distribution of vaccines in such a system is usually outsourced to private companies that are specialised in cold chain logistics.

In the United Kingdom, for instance, Movianto has won a full tender issued by the Department of Health for a long-term contract to supply childhood vaccines to vaccinators across the country. The data we collected seem to indicate that the distribution costs paid by the British health care payer can be estimated at approximately 0.28 EUR per dose (see box “costs of direct distribution”). In Belgium and Spain, the vaccine manufacturers rather than the public authorities are responsible for the direct distribution of tendered vaccines to general practitioners (GPs) and vaccination centres. During the interviews we conducted, local senior managers mentioned manufacturers typically outsource these services to third-party logistics providers as well and confirmed that the above-mentioned distribution costs are of the right order of magnitude. Even for countries in which distribution is impeded by a less developed road network and/or geographical barriers, rough estimations suggest a similar order of magnitude for these costs.

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⁴From the interviews, we learned that winner-takes-all, estimated-quantity tenders are currently issued most commonly by the German sickness funds. Local experts expressed their concern that these organisations, which are required to be financially self-sufficient may have less of an incentive to reach long-term public health goals for immunization (i.e. adequate coverage rates) than health authorities.

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**Costs of direct distribution**

**Childhood vaccines in the UK**

In 2011, the UK Department of Health renewed its long-term contract for the storage and distribution of the vaccines included in its childhood immunisation programme with healthcare logistics specialists Movianto UK. Under the terms of the contract, the service provider needs to make about 800 cold chain deliveries to 10,000 customers across England (typically GP surgeries, Health Centres and hospitals) and around 730 delivery points in Wales, Scotland and Northern Ireland on a daily basis ³⁰.

Considering that the contract was awarded for a period of 5 years, was valued at £17 million ³¹, and that about 10 to 20 million doses of childhood vaccines are centrally purchased by the NHS Commercial Medicines Unit annually, the distribution cost can be estimated somewhere in the range of £0.17 to £0.34 per dose. For our calculations, we used a point estimate of £0.23 (0.28 EUR) per dose.
Direct distribution by the public authorities
In some countries, governmental institutes manage the distribution of vaccines. In the Netherlands for example, the Rijksinstituut voor Volksgezondheid en Milieu (RIVM) has the responsibility to purchase and distribute the vaccines included in the National Immunisation Programme. All vaccines in Denmark, i.e. both vaccines in the Childhood Vaccination Programme and in the private market, are manufactured or purchased and distributed by the Statens Serum Institut, a public enterprise that operates under the supervision of the local Ministry of Health.
Although it is difficult to estimate the distribution costs that are incurred by such public institutes, it seems likely that the capital costs for the transport (e.g. trucks, cars) and storage (cold rooms, refrigerators, freezers, stand-by generators and cold boxes) of vaccines are substantial.
Health care professionals and general practitioners (GP) in particular, play a central role in the provision of vaccines. They serve as an important source of information for the general public and are the main drivers of vaccination programmes. Physician offices represent the traditional setting in which vaccines are administered. The expenses related to vaccine administration will thus often be determined by the cost of a GP visit which, in most European countries, lies somewhere between 20 EUR and 30 EUR. In some countries, where physician-dispensing is not permitted, patients may even need to make two GP visits: one to obtain a prescription and – after they have collected the vaccine from a pharmacy – a second one for the vaccine administration. German physicians, however, will typically obtain vaccines from a local pharmacy and store them in-house to eliminate the need for such a second visit. In other countries, including Belgium and the UK, the vaccination programme circumvents pharmacies and vaccines included in the local schedule can be delivered to vaccinators directly. In addition to their standard fee, physicians may receive a financial incentive from payers that is aimed at increasing coverage rates. For example, for each flu shot given, physicians in the UK can claim an additional administration fee between £1.87 and £2.11 from the primary care trusts.

Besides the GP practice, there is a variety of other settings in which vaccines can be administered including paediatrician’s offices, early childhood centres, schools, pharmacies, supermarkets and other stores, specialised vaccination centres, the workplace, care homes, hospitals, and elderly homes. These non-traditional settings can provide an excellent addition to GP offices in order to increase overall coverage rates and reach specific target populations. In Belgium, for example, infants are commonly vaccinated against childhood diseases when they visit one of the public healthcare organisations that are charged with the follow-up of babies, infants and children (i.e. Office de la Naissance et de l’Enfance in Wallonia and Kind & Gezin in Flanders). In a similar manner, school-based programmes can be used to administer the HPV vaccine to adolescent girls (a.o. in the UK, Spain, and Belgium). When an elderly population is targeted, as in flu immunisation campaigns, the on-site vaccination of both staff and residents of care homes can be useful to increase coverage rates. In some of the above-mentioned settings, government-employed physicians, pharmacists or paramedics may take care of the vaccinations at a cost lower than the standard GP fee. In the US, all states have been allowing pharmacists to administer vaccines as of June 2009 and this example is being followed in several European countries. In Ireland for example, hundreds of pharmacists have recently been trained to administer flu vaccines at a cost that is significantly lower than a doctor’s consultation fee. Flu vaccines are also commonly administered by pharmacists in Ireland, the UK (at a cost of £8 to £15, including the vaccine), and Greece (service free of charge). In some areas of the UK, travel vaccines and vaccination against cervical cancer are available through community pharmacies as well. When this vaccine administration service is added to an existing organisation or infrastructure, the marginal set-up costs can be limited.

In conclusion, physician offices are and will remain the primary setting in which information about immunisation is provided and vaccines are administered to individuals. Public health authorities can, however, expand the number and types of vaccinations settings in order to increase the speed and rate of vaccination coverage. It seems likely that the use of such non-traditional settings to deliver vaccines during mass vaccination campaigns is cost effective.
Discussion and conclusion

In general, using tender processes for the procurement of certain vaccine products can be an option to reduce purchase prices, taking into account all potential consequences such as wastage levels, supply risk and a decrease in social contributions paid by the manufacturers. If local distribution margins are relatively high (e.g. Greece, Germany), it may be worthwhile to revise these margins and/or consider outsourcing vaccine distribution to a specialised cold-chain distributor as in the UK. The administration of vaccines can be organised through alternative administrators such as pharmacists or other care providers or can be organised differently, for example by eliminating the need for patients to visit their GP twice in order to obtain a prescription and get vaccinated.

However, it is a common misconception that an authority’s choice on procurement (i.e. to tender or to reimburse) should also determine the responsibilities of different stakeholders in the other steps of vaccine provision. Some countries are indeed using a combination of the reimbursement and the tendering processes (see Figure 3).

These examples highlight that there are a number of choices at the disposal of policy makers at the level of vaccine procurement, distribution, and administration. It would be possible to pick the most appropriate method, in each of these distinct areas of vaccine provision, the components they perceive to be most advantageous. By comparing practices in various European countries, it is possible to identify opportunities in one or more of these areas. By testing “what-if” scenarios, we estimate that efficiency gains of 10 EUR - 15 EUR per vaccine dose administered may commonly be achievable by the optimisation of vaccine distribution and administration in many European countries. One such example for a childhood vaccine in France is worked out in a separate box (Figure 4 “Virtual example: a childhood vaccine in France”). In this example we apply only one of the suggested alternatives for procurement, distribution and administration.

Cultural, political and historical differences may constrain the number of choices for a country. For example in France, historical experiences have made authorities hesitant to impose a choice of vaccine through a “single winner takes all” tender, while there is less resistance from German vaccinators on this aspect. And not all countries might have as many options for administering the vaccines as there are in Belgium (GPs, specialists, schools, public health organisations, potentially pharmacists). Still, authorities could improve their processes by looking at other countries and optimise their current organisation of providing vaccines.

This paper is aimed at supporting policy makers and payers in considering alternative options to keep the healthcare budgets under control, whilst still reaching their healthcare outcome targets. It is our opinion that this can be reached by attaining an appropriate rewarding mechanisms for the added value generated by various stakeholders playing significant roles in the distinct areas of vaccine development, distribution and administration.
Some countries are using a combination of the reimbursement and the tendering processes. For tendered vaccines in Spain and Belgium, vaccine manufacturers are generally responsible for the direct distribution of the vaccines to the agencies which then provide the vaccines to the population. A recent change in the system in Germany allowed the sick funds to purchase vaccines via regional tenders. In this new system the vaccines are still distributed via the regular network composed of pharmaceutical wholesalers and retail pharmacies. On the other hand, under the reimbursement systems, alternative vaccine distribution or administration settings can be utilised, such as the administration of the flu vaccine by pharmacists in Ireland, UK and Greece or the administration of the rotavirus vaccine in well-baby clinics in Belgium.
Virtual example: a childhood vaccine in France

Figure 4 shows the main costs (per dose) associated with the provision of vaccines we identified. Taking the perspective of the French authorities, we will attempt to compare the net cost of providing one birth cohort with a new, hypothetical childhood vaccine in the current settings and under the conditions of a possible alternative scenario. In the current setting, we assume the vaccine is fully reimbursed by the national health insurance, distributed by wholesalers and pharmacists, and administered by a GP or pediatrician.

Procurement, including awareness creation and promotion

We are assuming a manufacturer’s selling price of 20 EUR/dose, which is fully covered by the national health insurance in the current situation. In this scenario, the responsible bodies will have determined that this price represents fair value for money from a health economics perspective. The vaccine manufacturer(s) may provide volume discounts to wholesalers and pharmacists, but not the payer. If we presume they would support the launch of new childhood vaccine with a sales team of 75 representatives which spend 1/3 of their time providing information about the novel vaccine to health care professionals, the French authorities would collect social contributions of approximately 1.6 million EUR or 2.09 EUR per dose in the current settings (75 FTEs x 1/3 x 110,000 EUR gross/year x 57 % tax).

Market access

After marketing authorisation was obtained, the clinical value of the vaccine will have been evaluated by the Comité technique des vaccinations (NITAG) and the Commission de la Transparence. In the “as is” scenario, the reimbursement rate and price of the novel childhood vaccine will be determined by/negotiated with two other committees (UNCAM and CEPS, respectively) and revised every 3 to 5 years.

Distribution

Nearly all vaccines in France are distributed by whole-

<table>
<thead>
<tr>
<th></th>
<th>Current settings</th>
<th>Reimbursement</th>
<th>Wholesaler Pharmacy</th>
<th>General Practitioner</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>-2.09 EUR</td>
<td>7.65 EUR</td>
<td>-1.55 EUR</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>16.80 EUR</td>
<td>17.91 EUR</td>
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<td></td>
<td></td>
<td>16.80 EUR</td>
<td>6.10 EUR</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Total: 40.81 EUR</td>
</tr>
</tbody>
</table>

While some vaccines are not reimbursed and others are fully covered by the national health insurance, most vaccines in France are reimbursed at 65 %. The remaining 35 % are covered by private insurance or paid out of pocket by the vaccinee. For reasons of simplicity and because we are comparing against a publicly funded tender, we assume the vaccine is fully reimbursed in the current setting.
## Alternative scenario

<table>
<thead>
<tr>
<th></th>
<th>Manufacturer’s selling price</th>
<th>Discount to payer</th>
<th>Social contributions sales reps</th>
<th>Wastage</th>
<th>Distribution costs &amp; mark-up</th>
<th>Vat &amp; income taxes</th>
<th>Vaccinator fee</th>
<th>Total cost/dose</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Public Tender</strong></td>
<td>20.00 EUR</td>
<td>-2.00 EUR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20.00 EUR</td>
</tr>
<tr>
<td><strong>Direct distribution third-party</strong></td>
<td>1.80 EUR</td>
<td>0.28 EUR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2.08 EUR</td>
</tr>
<tr>
<td></td>
<td>11.00 EUR</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>19.80 EUR</td>
</tr>
<tr>
<td><strong>Vaccination center</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>0.28 EUR</td>
<td>20.08 EUR</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>21.08 EUR</td>
</tr>
</tbody>
</table>

**Market access**

We assume that a member of a procurement team and both a technical and legal expert will, every year, have to spend considerable time preparing the tender procedure and assessing incoming bids (as is the case in Ireland and regions of Belgium and Spain, for example). While the workload involved in both scenarios is not to be underestimated, a personnel cost of 15,000 EUR to 25,000 EUR per evaluation is likely to be negligible on a per dose basis (20,000 EUR/750,000 doses = 0.03 EUR per dose for an annual tender and 0.01 EUR per dose for a scenario in which the price and reimbursement rate is revised every four years). Therefore, the costs related to market access were not shown in the figure.

**Distribution**

We assume a childhood vaccine would be distributed to a number of vaccination centres directly at a cost of approximately 0.28 EUR (as is the case in the UK, Belgium, and Spain).

**Administration**

Government-employed physicians working in vaccination centers (as in Belgium and Spain), or pharmacists (as in UK and Ireland) may be able to administer the vaccine at a cost of only 11 EUR per dose (considering an average fee of 65 EUR/hour and 6 vaccinations per hour).

In conclusion, the current “what if” scenario suggests that the French authorities may be able to provide its infant population with a vaccine in a more cost-efficient manner by centralising its provision processes. While the discounts obtained in the tender process may be partially offset by a loss in social contributions and increased wastage, efficiencies in the distribution and administration of the vaccines might yield a net gain of more than 10 EUR per dose or one fourth of the current vaccine provision costs.

In the alternative scenario, the vaccine is procured via a tender procedure and directly distributed by a third-party distributor to government-employed vaccinators at vaccination centers. Assuming a population of 65,000,000 citizens, a birth rate of 12.7 births/1,000 population and 90 % coverage, the target population is approximately 750,000 newborns.

**Procurement, including awareness creation and promotion**

In the alternative scenario, we assume the authorities have obtained a 10 % discount (2 EUR) from the winner of the public tender. The Institut national de prévention et d’éducation pour la santé (INPES), responsible for implementing policies on disease prevention and health education, may support the public vaccination campaign as it is unlikely that manufacturers will promote the vaccine once market shares have been fixed by the tender. Unless precautions can be taken to prevent over-ordering and/or temperature excursions, wastage rates may easily reach 10 % of the purchase value (benchmarked to UK assumptions; per dose: 10 % of 18 EUR after discount).
References

18. Estimate based on an internal survey among the co-authors of Schmitt et al. 2003 [Personal communication]
30. Contract - The provision of storage and distribution services (including chilled storage and distribution) for vaccines and other medicines - Reference number: CM/PHV/10/5176


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