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A review of the sustainability of vaccine funding across Europe and implications for post-COVID policymaking

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ABSTRACT

Background: Approaches to routine vaccine funding and the underlying budget-setting process vary greatly across European countries. The ongoing COVID-19 pandemic has put enormous pressure on healthcare systems, affecting resilience of the overall vaccine ecosystem.

Methods: This article reviews how vaccine budgets are structured across 8 European countries (England, Finland, France, Germany, Italy, Norway, Romania, and Spain). First a literature review of the landscape was undertaken, followed by expert interviews to review the findings and consider policy principles to secure prioritisation and sustainability of routine vaccination budgets post-COVID.

Results: The organisation of budgets and vaccine spending varies greatly across Europe. In 2/8 countries (France and Germany) vaccine spending is subsumed into a wider healthcare budget. In 2/8 countries (Italy and Romania) the budget differentiates public health and prevention spending from other areas of healthcare, though there is no standalone vaccine budget. In 4/8 countries (England, Finland, Norway and Spain) there is a standalone vaccine budget, however this may not cover all elements needed for immunisation delivery and is not always transparent.

Conclusion: Ensuring adequate and dynamic country vaccine budgets, with horizon scanning approaches like in England and Finland, or flexible vaccines expenditures like Germany, would greatly help the timely availability of public funding for new vaccines and strengthen vaccines supply security in Europe through a more virtuous European vaccine ecosystem.

1. Introduction

1.1. Aim

Vaccines are among the most cost-effective healthcare interventions, providing direct and indirect benefits to both individuals and society and bringing value for money [1]. The benefits for the vaccinated individual can range from preventing infection from communicable diseases, minimising disease severity, and in some cases, even preventing the development of certain cancers. For the society as a whole, vaccination leads to enormous cost-savings in the form of reduced mortality and morbidity, in addition to broader economic benefits from increased productivity of the country workforce. In the most successful cases, vaccination results in disease elimination and eventual eradication

through the phenome of “herd immunity”. As of 2021, more than 20 life-threatening diseases can be prevented by vaccination, including major disability agents or killers like polio, pneumococcal pneumonia, cervical cancer, typhoid, meningitis and, most recently, COVID-19 [2]. The value of vaccination is broadly recognised with children in all countries routinely immunised, and vaccines have become a central plank of global public health efforts [3].

Despite the overwhelming benefits of vaccines on population health and economy, only a small fraction of healthcare budgets is currently allocated to vaccines in Europe. It has been recently estimated that 20 of the 27 Member States of the European Union spend less than 0.5% of their healthcare budget on immunisation [4]. Approaches to routine vaccine funding and the underlying budget-setting process vary greatly across European countries, affecting resilience of the overall vaccine

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ecosystem and its flexibility to integrate new vaccines in national immunisation programmes (NIPs). Funding for vaccines may compete with the rest of the healthcare budget, which in turn, competes with other sectorial needs. To date, there has been a lot of research on the amount of money countries spend on vaccination and prevention [5,6], but little attention has been given to how the corresponding budget is determined.

The aim of this article is to review how vaccine budgets are structured across 8 European countries (England, Finland, France, Germany, Italy, Norway, Romania, and Spain) and understand differences in the role of key stakeholders, how the budget is organised and factors that feed into the budget-setting process. By reviewing the advantages and limitations of different approaches, we suggest policy principles to secure prioritisation and sustainability of routine vaccination and NIP budgets in a post-COVID recovery context.

1.2. Background

In Europe, access to vaccines is broadly reliant on NIPs. The drafting, development and updating of recommendations for NIPs is usually the responsibility of an independent technical body known as the National Immunisation Technical Advisory Group (NITAG). These programmes are typically approved and mandated by the Ministry of Health to homogenise access to vaccines within a country in line with public health objectives. In most cases, inclusion of a vaccine into the NIP grants nation-wide reimbursement, facilitating adequate and equal uptake. However, studies have indicated high variability in the time to accessing new vaccines in Europe, with a range of 2 to 6 years following marketing authorization [7]. National assessments underlying immunisation policy decisions are a significant contributor to this access delay. A necessary enabler for access is timely availability of funding. This means budgets need to be able to flexibly adapt to new immunisation priorities in accordance with the availability of new vaccines and their integration into the NIP.

The number of available vaccines has increased rapidly in the recent years. Vaccine development continues to be a focus of innovation, with many new vaccines being developed for diseases previously thought to be non-preventable [8]. As of April 2020, 258 vaccines in development by biopharmaceutical research companies are being investigated to treat or prevent infectious diseases, cancers, allergies and Alzheimer's disease. These also include novel mechanisms of action such as using messenger-RNA. It is estimated that, for respiratory syncytial virus (RSV) alone, there are approximately 60 immunisation measures in development as either maternal vaccines, infant vaccines or prophylactic monoclonal antibodies [9]. In this fast-moving and expanding context, ensuring the long-term sustainability of vaccine budgets will be crucial to secure full and equal access to future innovative vaccines while ensuring the availability of current routine vaccines.

The ongoing COVID-19 pandemic has put enormous pressure in healthcare systems, leading to delayed delivery of care services in many industrialised countries [10]. It has also highlighted the fragility of our current systems for vaccines development, manufacturing and delivery. The WHO European Region saw a 1% decrease in routine immunisation coverage, from 95% in 2019 to 94% in 2020 [11]. Though a smaller decrease compared to other regions, there are large variations amongst countries and a lack of reported data from some countries where COVID-19 disruptions have also affected capacity to collect and report routine immunisation coverage data [12].

In addition to the pressure on provision of healthcare services, the economic implications of the pandemic had put pressure on healthcare budgets. In the EU alone, the government debt to GDP ratio in the EU increased from 77.5% in Q4 2019 to 90.7% in Q4 2020, mostly due to government debt increasing and GDP decreasing [13]. During the last financial crisis, governments implemented austerity measures that significantly reduced the amount of funding allocated to prevention, resulting in negative growth for 4 consecutive years across OECD

countries [14]. Socioeconomic and health inequalities widened during this period and the continuity of vaccinations reaching vulnerable sub-groups was threatened [15].

The introduction of COVID vaccines creates additional challenges. Key uncertainties remain around the potential need for seasonal vaccination or for new vaccines addressing the challenge of new variants. If COVID vaccines were to be administered routinely and integrated into NIPs, this could put significant pressure on existing vaccines budgets, potentially impacting funding for existing vaccines and access to future innovative vaccines. It is also important to acknowledge that vaccine funding sustainability is also impacted by fiscal rules for healthcare spending. Research has shown there is a clear relationship between the potential of fiscal rules and controlling the level of healthcare expenditure [16]. However, given that the level of spending dedicated to vaccines and prevention ultimately reflects a political choice, our analysis focuses on the prioritisation and sustainability of vaccine budgets. The huge health, economic, and social consequences of epidemics, and the substantial cost of pandemic response, shows investments in immunisation infrastructures during interpandemic periods and measures to prevent infectious diseases will be crucial to increase health systems resilience [17].

2. Methods

The vaccine funding landscape was reviewed across 8 European countries: England, Finland, France, Germany, Italy, Norway, Romania, and Spain. Countries were selected to represent a range of healthcare systems and approaches to vaccine procurement. To structure the analysis across countries we developed a standardised framework which considered: the role of key stakeholders involved in the process, how the budget is organised and the funding flow, factors that feed into the budget-setting process, how funding has changed over time and the approach to COVID vaccine funding (see Appendix 1 for Research framework). The framework was developed drawing on the literature gaps and key formulation and classification issues for health budgets set out by the WHO [18]. Within each area of the framework, critical elements for analysis were set out to ensure a structured and targeted approach to researching the funding environment across those countries.

To populate the framework, a literature review was first undertaken. The literature review was conducted over the period from November 2020 to March 2021. Government websites, academic journals, NGO publications, industry reports and online newspaper articles were searched for information on funding policies related to vaccines. Websites of national health ministries were searched for funding-related policy and strategy documents published over the past five years. 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 five years. Government websites, databases and key media sources were searched using a variety of key words, including: “vaccines”; “immunisation”; “prevention”; “funding”; “financing”; “budget-setting”; “budget structure” and “reimbursement”. National websites across countries were searched in the local language. In total, the literature review included over 200 publications. Relevant publications were selected for this paper that emphasize the critical areas of policy development across the framework and illustrate evidence of impact of different approaches.

To complement the literature review, an interview program was conducted to review the findings and discuss the pros and cons of the funding landscape with national experts. A total of 8 interviews were conducted, which included stakeholders from 7 countries and 1 above-country European expert. No interview was conducted with a German stakeholder as the analysis revealed Germany does not follow a budget-setting process for vaccines, but rather mandated funding following national recommendations on use. Interviews were held between January to September 2021. Experts contacted included: policy advisors

to the national Ministry of Health or Finance, public payers, vaccine specialists or leading academics in the field of Public Health. Each country interview followed a structured discussion guide that focused on: (1) reviewing and validating the funding and budget-setting process for vaccines in that country; (2) discussing the pros and cons of the budget-setting process; and (3) considering policy recommendations to ensure future budget sustainability (see [Appendix 2](#) for an example of the high-level discussion guide tailored for the Romanian expert). The above-country interview focussed on reviewing our framework for mapping countries rather than the funding and budget-setting process in a particular country.

The analysis was presented at the European Health Forum (Gastein) 2021 in the session “Vaccines funding in Europe: Ensuring sustainability in a post-pandemic world.” Feedback from the session was taken into account in the synthesis of this article.

3. Results

3.1. The role of key stakeholders

The first question to be addressed is who is involved in the decision to allocate resources to vaccines. Looking across the 8 countries the key stakeholders involved in determining the budget affecting the funding of vaccines are described in [Appendix 3](#). Across most countries the key decision-makers are at national level. Generally, the respective Ministry of Health is the key stakeholder in the decision-making process for budgetary allocations to vaccines. This is the case in England, Finland, France, Germany, Norway and Romania.

In Italy and Spain, the stakeholders involved depends on how the regional healthcare system is organised. In Spain, for example, the 17 regional healthcare authorities are responsible for establishing the necessary budget items for healthcare provision in their regions. Each regional government decides how to allocate the available budget across the different sectorial departments (mainly healthcare, education and social services) and sets their expenditure limits. The key stakeholder in this case is the Public Health Secretary or Directorate within each of regional governments [\[19\]](#).

Often, legislation exists that provides an overarching framework to fund vaccines and establish immunisation programmes. This is the case in England, Finland, France, Germany and Italy. Attempts to introduce better legislation supporting the funding of vaccines has been debated in other countries. In Romania, the NITAG (The Technical Working Group for Coordination of Vaccination Activities [GTCAV]) has not been functional since 2015. Since then, any change to the NIP has been enabled through recommendations from both the Ministry of Health and the National Institute of Public Health (INSP). In 2017, Romania drafted a new law on the organization and financing of vaccination activities [\[20\]](#). The draft law would ensure sufficient funding for all the aspects related to vaccination service delivery: vaccines purchasing for the NIP under the responsibility of the Ministry of Health; activities necessary to ensure the continuity of transportation and storage of vaccines; the functioning of the GTCAV; support for training of staff involved in the delivery of vaccination services; and development of the National Electronic Vaccination Register (RENV).

3.2. How the budget is organised

The second question is whether the vaccine spending is part of the healthcare budget or of the prevention budget, and whether there is a specifically defined budget for vaccines /vaccination. This varies from one country to another and is summarised in [Appendix 4](#).

In some countries (France and Germany), vaccine spending is subsumed into a wider healthcare budget. In Germany, funding of healthcare provision and delivery is under the responsibility of the multiple statutory and private health insurances (KKs). Health insurances are the main budget holders and are obliged to reimburse healthcare

technologies approved by the Federal Joint Committee (GBA). For vaccines, the Standing Vaccination Commission (STIKO) is responsible for assessing new vaccines and for updating the national vaccination schedule. STIKO’s recommendations provide the basis for the vaccination directives of the GBA [\[21\]](#). Due to the use of legislation to mandate funding, there are no vaccine budgets *per se*, but rather vaccine expenditures out of the wider healthcare budget in a pay-as-you go manner [\[22\]](#). The French healthcare budget-setting framework is fragmented in two separate budget legislations presented and approved by the Parliament each year: the State Budget Act and Social Security Financing Law (LFSS). The LFSS determines the conditions for the financial balance of Social Security, including universal healthcare coverage, and fixes expenditure targets based on revenue forecasts [\[23\]](#). Thus, the entire healthcare budget, including vaccines and vaccination services falls within the LFSS.

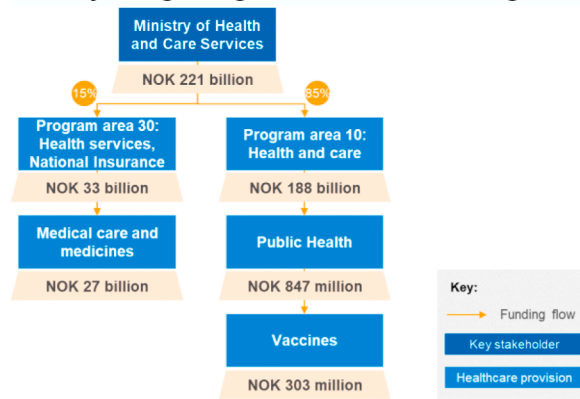
In other countries, there is more granularity to the vaccines budget item. In Norway, the overall healthcare budget is set by the Ministry of Health and Care Services (HOD). HOD separates overall healthcare spending between two budgets: Program area 10 (Health and care spending – equates to around 85% of healthcare spending and covers areas such as care services, primary care and public health) and Program area 30 (Health services and National Insurance – accounts for the remaining 15% of healthcare spending and covers medical treatment that is reimbursed by the National Insurance Scheme, primarily medicines) [\[24\]](#). In principle, preventive services are not financed by the National Insurance Scheme. This means vaccines are funded separately to medicines and sit within the program area 10.

Where countries have more regional level decision-making, it directly impacts the way the vaccines budget is organised. The Italian healthcare system is funded through the National Health Fund i.e., the state’s health budget. The Ministry of Health (MoH) is responsible for managing the National Health Fund and for allocating it across the 21 regions. Regions are prompted to distribute their health budget in proportions defined by the MoH: outpatient care (51%), hospital care (44%) and prevention (5%) – including for vaccines, personnel and services [\[25\]](#). Percentages have remained constant over the years and regional prevention budgets are calculated purely on a per-capita basis. In reality, regions have complete freedom over the allocation of funds among the various services and the percentages set out by the MoH can be modulated at regional level [\[26\]](#). Since 2017, the National Health Fund includes an additional dedicated budget item for each region to support reimbursement of vaccine purchasing. The Fund also includes a dedicated budget for innovative drugs and innovative oncology drugs [\[27\]](#). Though, vaccine procurement occurs at regional level, the delivery falls under the responsibility of the Departments of Prevention within Local Health Units (ASLs). Regional Health Departments are also responsible for funding ASLs through capitated budgets.

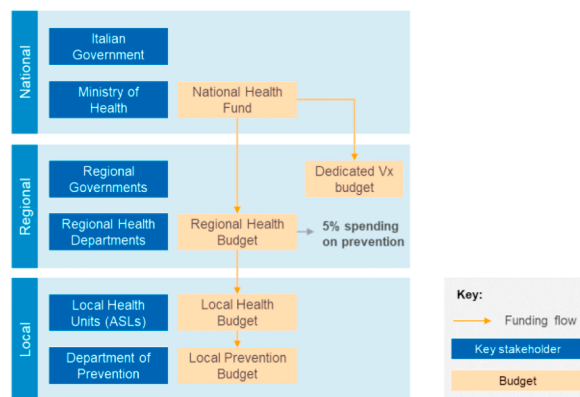
In other countries, although granularity of the vaccines budget exists, the information is not always transparent. In England, the NHS Public Health Functions Agreement sets out the arrangements under which the Secretary of State delegates responsibility to NHS England for certain public health services, including vaccination. These are known as Section 7A services (S7a) [\[28\]](#). All funding is centrally allocated to NHS England’s Area Teams, and each will get a share of the allocation for local commissioning, depending on population. This share is used to establish local immunisation programmes. Each immunisation programme under Section 7A will have a specified budget that considers all necessary elements for vaccine service delivery. There is no overall budget for S7a *per se*, this is just how the allocation of funds for these programmes are reported in the public domain. The provision of Section 7A services is legally bound under the National Health Service 2006 Act. In addition, the Government’s 2020–21 mandate to NHS England includes a specific objective to deliver services under S7a [\[29\]](#).

Overall, the organisation of budgets and vaccine spending varies greatly across Europe (see [Fig. 1](#)):

Norway budget organisation and funding flow (with 2020 budget allocation)



Italy budget organisation and funding flow



England budget organisation and funding flow (with 2019/2020 NHS commissioning budget)

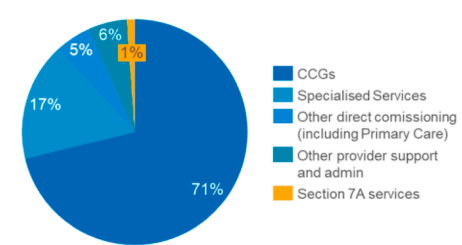
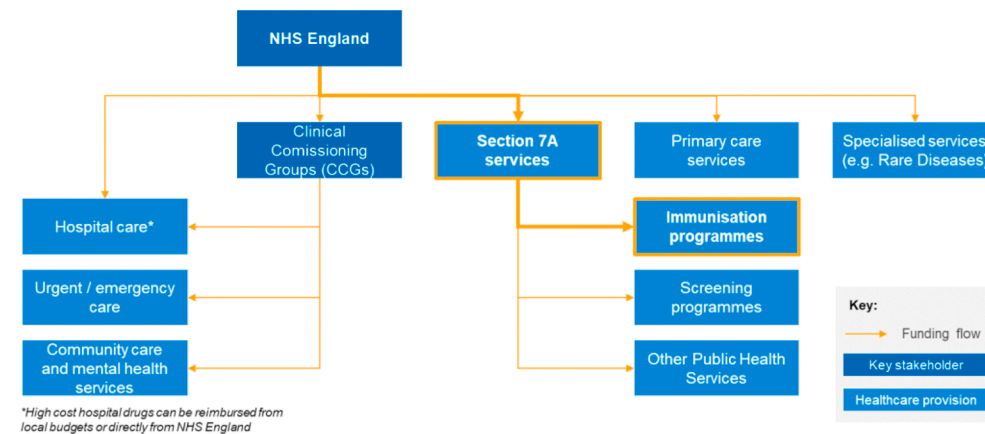


Fig. 1. Comparison of budget organisation across example countries.

- In 2/8 countries (France and Germany) vaccine spending is subsumed into a wider healthcare budget.
- In 2/8 countries (Italy and Romania) the budget differentiates public health and prevention spending from other areas of healthcare, though there is no standalone vaccine budget.
- In 4/8 countries (England, Finland, Norway and Spain) there is a standalone vaccine budget, however this may not cover all elements needed for immunisation delivery and is not always transparent.

3.3. Factors that feed into the budget-setting process

The third area we study are the factors that are taken into consideration for determining vaccination budgets. They are summarised in [Appendix 5](#). All countries (with the exception of Germany) revise budgets on an annual basis. In some countries, budget revisions are primarily based on population changes. In Romania, for example, budgets are based on historical figures adjusted to increases in volume [30]. Within the prevention budget, however, it is possible to re-allocate funds across different programmes depending on demand.

Additionally, there is a lack of transparency of the key determinants of how funds are allocated to categories of vaccines. Though in some countries performance and coverage targets are considered when establishing budgets. In France, vaccine funds represent an expenditure target and is set out to cover costs of the NIP and other social security targets. Each year, a new Social Security Financial Law (LFSS) is drafted and is accompanied by a Social Security Policy Assessment Report (REPSS) [formerly known as Quality and Efficiency Programs] where the Social Security objectives from the last cycle are evaluated based on performance indexes [31]. This assessment report constitutes the basis for increasing or decreasing expenditure targets for each objective in the next cycle. For example, “developing prevention” has been set as the second objective in the draft LFSS for 2021, with the specific sub-objective to increasing vaccination coverage for routine immunisation of the 24-month-old children and for influenza vaccines in over 65-year-olds and other risk groups [32]. In England, budgeting for each immunisation programme is based on regional forecasting uptake and public health performance targets. This results in the setting of performance indicators and key deliverables in order to effectively implement the changes highlighted in the annual NHS public health functions agreement [33]. Performance targets are guided by the Green Book issued by Public Health England, which considers recommendations from the JCVI.

Only two countries incorporate a forward-looking view when updating their health budget: England and Finland. In England, horizon scanning is performed both at national and local levels, typically about 1–2 years in advance. Local commissioning leads work closely with JCVI so as new technologies are being reviewed, they understand the funding implications and plan for the service to be implemented. In Finland, the Ministry of Finance estimates the national vaccine procurement budget according to future orders needed for the supply of vaccines included in the NIP [34]. The Finnish Institute for Health and Welfare (THL) continuously develops and updates the NVP in consultation with National Expert Group on Vaccination (KRAR). The THL formally introduced horizon scanning in their process of updating the NVP, which was piloted in 2019 [35].

3.4. Approach to COVID-19 vaccine funding

Countries have adopted different approaches to fund COVID-19 vaccines through the pandemic. Many countries have supported access to COVID-19 vaccines through use of emergency funds or supplementary budgets. Italy established several Decree-Laws early in the pandemic period, committing the regions to set up COVID-19 response programmes with specific funds, under joint monitoring by the Ministry of Health and the Ministry of Economy and Finance [36].

Similarly, many countries have not yet integrated COVID-19

vaccination into their NIP. Norway is one of the few countries which did, where additional funds were allocated to the vaccine budget for COVID-19 vaccines. In October 2020, HOD published the budget for 2021, which included NOK 3.77 billions for the advance purchase agreements (APAs) established for COVID-19 vaccines and NOK 30 millions to support distribution [37]. These additional funds resulted in a 1 261% budget increase between 2020 and 2021. This highlights the impact that the COVID-19 pandemic had on the sustainability of vaccine funding.

4. Discussion

It is clear that European countries adopt a variety of approaches to determining public health budget for vaccines. Two overall characteristics were identified to allow a systematic way to compare approaches to vaccine funding:

- **The way the budget is structured:** Countries differ in terms of whether the budget is part of the healthcare budget or the prevention budget, whether there is a defined budget for vaccines or not, and the expected consumption of the budget. Countries are often grouped together, so that we can classify countries by whether their budget is “closed” or “open”.
- **The way the budget is updated over time:** Countries differ in terms of the deciding stakeholders, the criteria for budget allocation and what is driving changes of this budget. As before, countries are often grouped together and in this case we can classify countries by whether their budget-setting process in “ad hoc” or “dynamic”.

Mapping countries according to their budget structure and how budgets are updated is summarised in [Fig. 2](#).

Based on this mapping exercise, we have categorised countries as having a budget structure to be “open” or “closed” and the budget-setting process to be “ad hoc” or “dynamic” across countries. This provides two overall dimensions we can use to categorize countries according to vaccine budgets with similar characteristics (see [Fig. 3](#)).

We discuss each of these categories in turn to understand the advantages and limitations of each approach, drawing on country examples. For some countries, there is also some variation for paediatric and adult vaccines. In this analysis we have considered the overall approach.

Type A: Dynamic vaccine budgets updated by new priorities

This first category includes both England and Finland. The key feature of these budgets is that they are usually established based on what is required for local delivery; this includes annual revisions drawing on public health performance targets and future needs. In Finland the Ministry of Social Affairs and Health (STM) is responsible for direct funding of vaccines and allocation of healthcare funds across municipalities, and the individual municipalities who are responsible for funding and organising vaccination services [38]. The dedicated budget item for vaccine purchasing sits within the budget for Promoting Health and Functional Capacity [39].

This focus on local delivery in these 2 countries can be advantageous in the roll-out of new vaccines, as funding is considered for broader elements of vaccine service delivery and not only limited to vaccine procurement. This allows funding to be available to support local education and community-engaging activities; key enablers for vaccination uptake [40]. School-based HPV immunisation delivery has successfully achieved high coverage in England and reduced inequalities at area level since the start of the programme in 2008 [41]. Full course coverage in the routine programme was just over 80% in the first year of the programme; higher than any other European country. In fact, both England and Finland consistently demonstrate higher than average vaccination coverage rates for HPV compared to the rest of Europe and are close to reaching the WHO vaccination target of 90% [42].

As the other focus in these countries is on optimizing service delivery, vaccine budgets can be supplemented with additional funds in a flexible and on-demand manner to support access. The budget-setting

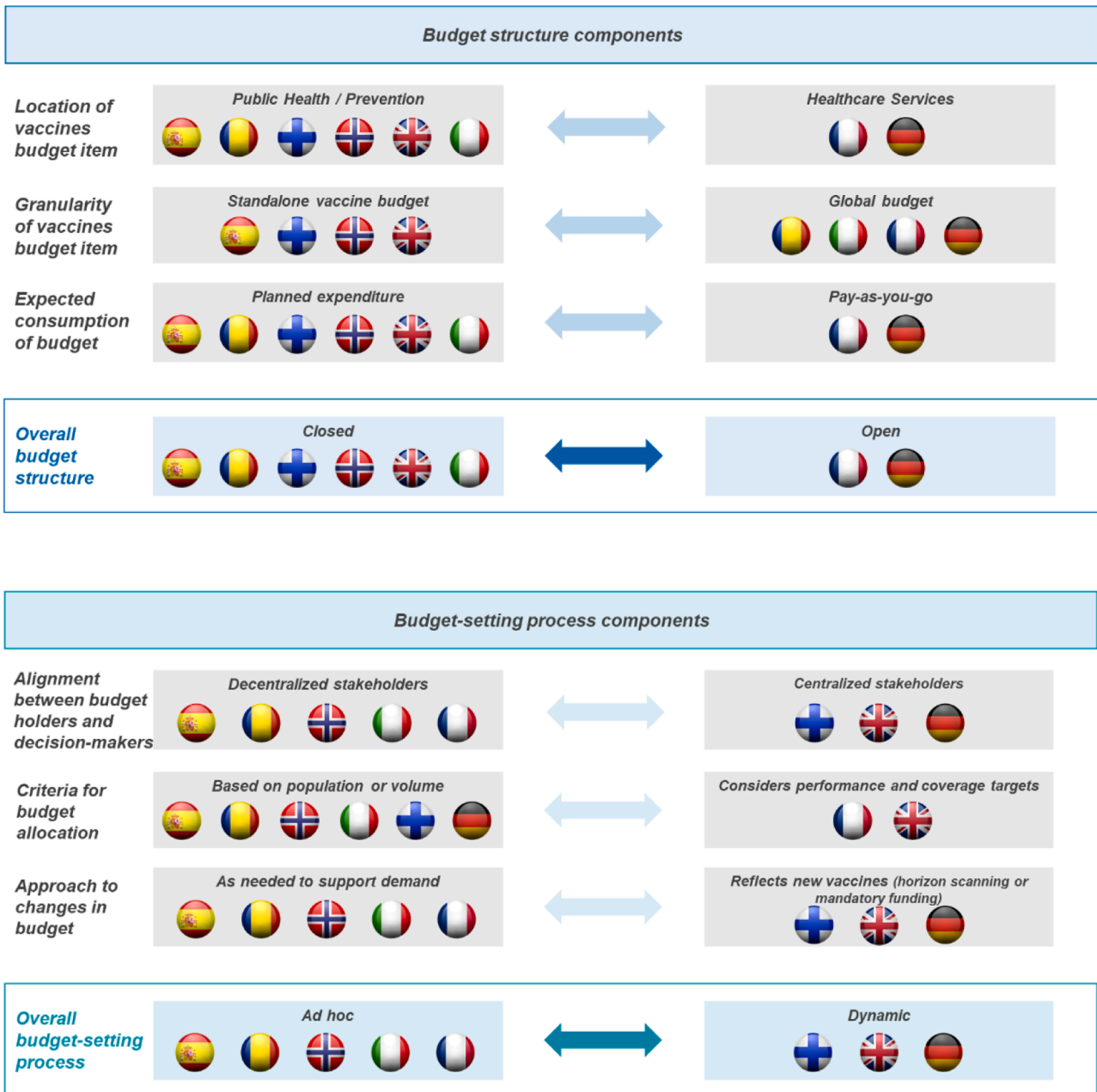


Fig. 2. Country mapping.

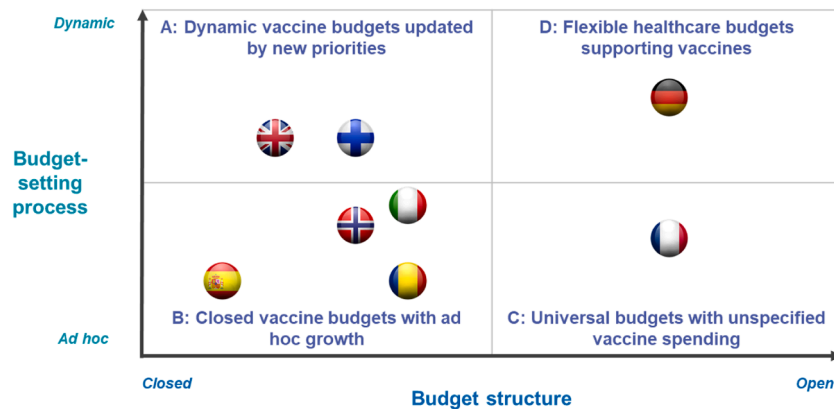


Fig. 3. Categorisation of vaccine budgets.

process is also more dynamic compared to other countries, which is reflected by their forward-looking nature. These countries are the only ones to actively adopt horizon scanning in their budget-setting process, allowing them to anticipate for increases in demand. Since the horizon scanning pilot scheme was implemented in Finland, there was an increase in the vaccine purchasing budget for 2019–20 [43]. However, there is a lack of transparency to how far into the future demand for new vaccines is being considered.

One of the limitations of this category is the lack of transparency as to what is driving funding changes in the vaccine budget. Spending on England’s Section 7A services has seen a steady increase over the last four years in line with overall budget increases in NHS commissioning. However, it is not clear whether this increase in funding has impacted the NIP or been directed towards other programmes under Section 7a (e.g., population screening).

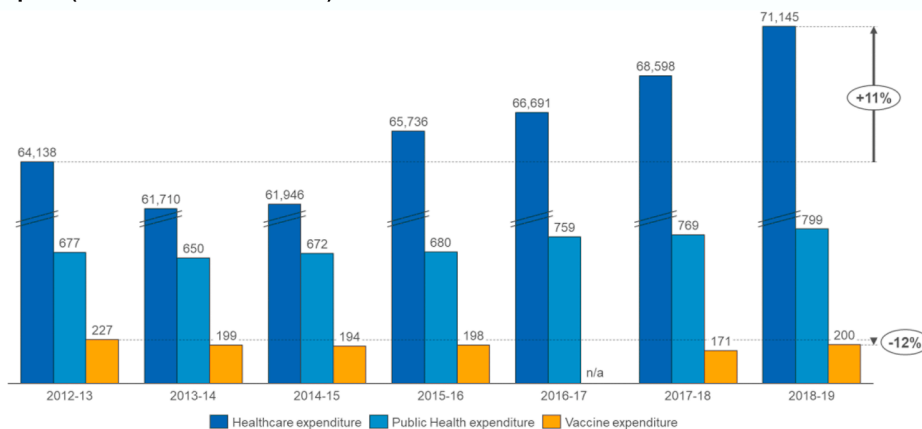
Type B: Closed vaccine budgets with ad hoc growth

Half of the countries in scope fall in the “closed vaccine budgets with ad-hoc growth” category, namely Spain, Norway, Romania, and Italy. Here, spending requirements for vaccines and medicines fall under separate budgets. Consequently, vaccine budgets are normally ring-fenced from healthcare spending needs outside public and prevention. One of the benefits is reduced risk that vaccines have their budget redirected to respond to budgetary challenges impacting other areas of healthcare.

One observed clear advantage of this category compared to the previous one is that the vaccine budget is much more transparent. This means stakeholders are able to monitor changes in budgets over time. This is useful as it allows growth in different areas of healthcare and prevention to be compared, which can be an indicator of policy prioritization. In Spain, Public Health expenditures have represented between 1.05% and 1.12% of the total healthcare expenditures, with a slight increase in the recent years. However, the proportion of vaccine expenditures has been decreasing steadily, falling from representing 0.35% of the total healthcare expenditure in 2012 to 0.28% in 2018 (see Fig. 4) [44]. According to local experts, the budget-setting in Spain is a rigid process resulting from negotiations between regional sectorial counsellors (education, health, infrastructure, etc.) and the regional finance counsellor; vaccines must compete for budget against the rest of Public Health services [45]. As a result, the limitation of this funding approach is that vaccine budget growth may be restricted by upstream budgetary limits imposed by the Public Health or Prevention budgets. In practice ad hoc growth may be more flexible when there is greater pressure, as seen in Norway when additional funds were allocated to the vaccine budget for COVID-19 vaccines.

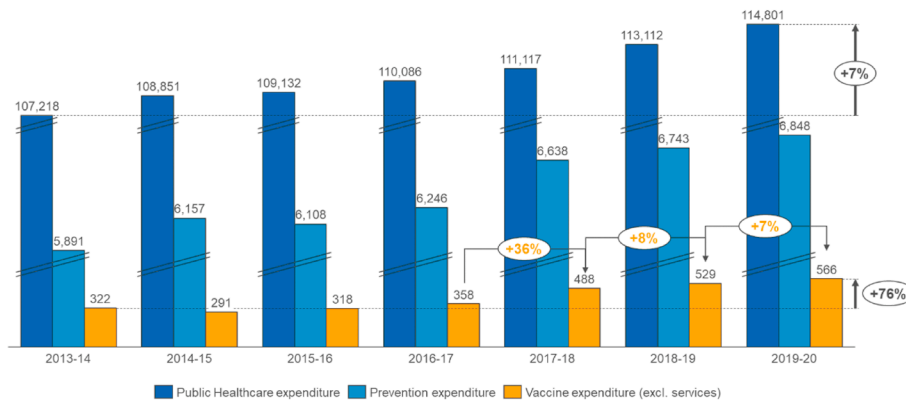
In term of decision making, the characteristics of this category are decentralized stakeholders, meaning there can be challenges in aligning budget holders and access decision-makers, with implications for vaccination coverage [46]. Countries have used policy tools and legal

Spain (between 2012 and 2019)



Sources: *Estadística de Gasto Sanitario Público 2019, Ministerio de Sanidad, Consumo y Bienestar Social and Las vacunas en España; Situación actual y perspectivas de futuro (Deloitte, 2017)*

Italy (between 2013 and 2019)



Source: *AIFA Rapporto OsMed 2013 – 2019*

Fig. 4. Change in vaccine expenditure in Spain and Italy (€bn).

frameworks to improve vaccine funding and coverage. For example, in Italy until 2017, only 4 vaccines were mandatory: diphtheria, polio, tetanus and hepatitis B. A steady decline in vaccine coverage rates since 2010 led to a measles outbreak in 2017, where 88% of the cases were observed in unvaccinated individuals [47]. This raised social awareness and called the attention of the mainstream media across Europe [48]. To address this issue; policymakers introduced the National Plan of Vaccine Prevention (PNPV) 2017–2019, updating the previous plan from 2002. The PNPV updated the national vaccination schedule to include 10 mandatory vaccines, set targets for vaccine coverage, identified key priorities across disease areas and developed actions to reduce disparities between Italian regions [49]. The PNPV was financially supported by the Lorenzin decree, which became law in July 2017 (Law 119/2017), and introduced dedicated budget item for vaccine reimbursement within the National Health Fund. This intends to help regions cope with the additional mandated vaccines. The consequence was increased vaccine expenditures that correlated with an increase in vaccination coverage rates (see Fig. 4). The most significant increases were seen in measles-containing vaccine (MCV) and Rubella-containing vaccine (RCV) (see Fig. 5).

Type C: Universal budgets with unspecified vaccine spending

Of the 8 studied European countries, only France sits in this category. Here, vaccine spending is diluted within a broad envelope that provides flexibility for relatively large increases. This means vaccines can be funded as needed, out of the overall healthcare budget, which can help keep up with changing vaccine demand [50]. This is a very different budget structure to the previous category. The only vaccine expenditures that are regularly reported are the ones for organised vaccinations (ONDAM estimates) as part of institutional prevention campaigns (like for COVID-19) and are therefore excluding routine vaccination performed in primary care settings [51]. According to the National Agency for Medicines and Health Products Safety (ANSM), vaccine consumption amounted to more than €547 million in 2016 [52]. The nature of the budget means there is a lack of transparency as to how, or if, any priorities for vaccines are reflected when setting the overall healthcare budget.

However, in 2018, ONDAM vaccine expenditures increased significantly following the proposal of Agnès Buzyn, Minister of Solidarity and Health, to make compulsory 8 additional vaccines previously recommended for early childhood, in addition of the only 3 compulsory vaccines at that time [53]. Like Italy, this decision responded to a need to curb certain infectious diseases, such as measles [54]. Though vaccination coverage rates have increased, France still lags behind many other countries in this analysis (see Fig. 6). In addition, during the revision of the annual global healthcare budget, unfortunately, no

priorities are defined for different types of vaccines or vaccination groups. As demonstrated in England and Finland, adopting such a prioritisation approach could ensure funding allocation aligns with public health performance objectives.

Type D: Flexible healthcare budgets supporting vaccines

The final category we describe as “flexible healthcare budgets supporting vaccines,” where Germany falls. The structure of the vaccine budgets in this category is similar to that of the previous one, in that any expenditure amounts specified represent guidance rather than expenditure ceilings and can therefore be exceeded allowing flexibility. This “pay-as-you-go” approach in Germany is enabled by having a mandate to fund new vaccines that have been recommended. STIKO’s recommendations provide the basis for the vaccination directives GBA. After publication of recommendation, the GBA has two months to decide inclusion of the recommendation into the (NIP) vaccination guidelines [55]. If the GBA does not follow the STIKO recommendation, this has to be justified by the GBA.

Consequently, increases in vaccine expenditures are driven by expansion of vaccine recommendations, e.g., varicella-zoster virus, human papillomavirus in boys, switch from trivalent to quadrivalent influenza vaccine, and switch from Tdap (tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis) to Tdap-IPV. However, like the previous category, there is no evidence of priorities for specific vaccine types being taken into consideration when establishing budgets. The nature of expenditures means funding does not support any enabling factors for vaccine service delivery outside of product purchasing, such as education or monitoring; these are the responsibility of other groups. For example, “Infect Control” is a research alliance dedicated to combatting infectious diseases that is supported by the Federal Ministry of Education and Research (BMBF). One of the aims is to develop education campaigns for the public to combat declining vaccination rates [56]. Where funding is organised in this type of manner, dialogue between stakeholders is vital to ensure alignment of funding priorities.

5. Recommendations

Given the varying advantages and limitations identified across categories of vaccine budgets in the studied European countries, it is clear there is no specific “gold standard” for vaccine funding sustainability. Though approaches to vaccine funding is a competency at Member State level, the European Commission can have a role to play in the development and sharing of best practices. COVID-19 has driven an expansion of the European Commission’s role in health policy, and the new European Health Union provides a framework for further centralisation,

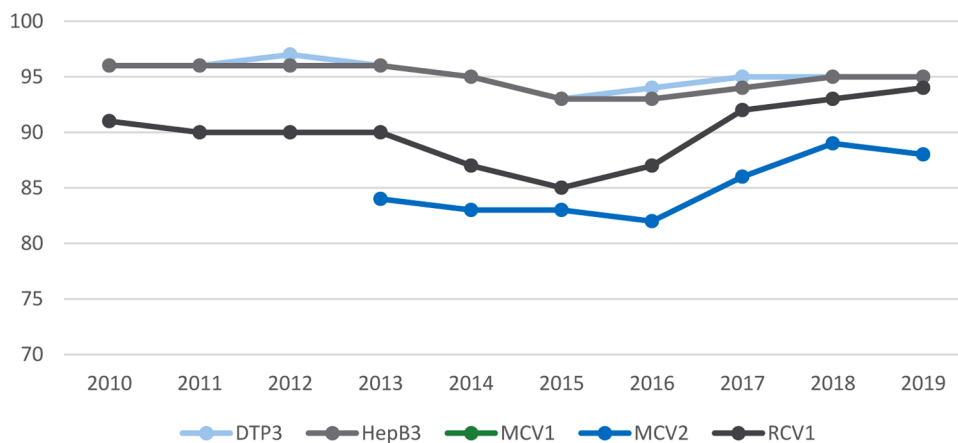


Fig. 5. Vaccine coverage rates in Italy between 2010 and 2019 (%).

Notes: Coverage rates for MCV1 and RCV1 were the same over the period, which is why a single line is shown.

Source: WHO and UNICEF estimates of immunisation coverage: 2020 revision

Country	HepB3	MCV1	MCV2	RCV1
Spain	96	98	94	98
Norway	96	97	95	97
Finland	n/a	96	93	96
Germany	87	97	93	97
Italy	95	94	88	94
UK	93	91	87	91
France	91	90	83	90
Romania	90	90	76	90

Fig. 6. Vaccination coverage rates for HepB3, MCV1, MCV2 and RCV1 in 2019. Source: WHO and UNICEF estimates of immunisation coverage: 2020 revision.

allowing opportunities for European collaboration and lessons to be learnt across countries [57]. This is a hallmark feature of the EU's Recovery Plan for Europe. The EU4Health programme, running from 2021 to 2027, sets out the EU's ambitious response to the COVID-19 pandemic. With a budget of €5.1 billion, more than ten times that of previous EU health programmes, its objectives include increasing the EU's role in responses to cross border health threats; encouraging sustainable production, supply chain and innovation of medicinal products in the EU; and financing additional emergency reserves of medicines and other health supplies to complement national reserves [58]. There are also opportunities for Member States to use the Commission's Recovery and Resilience Facility to strengthen immunisation systems to ensure more resilient health systems.

Drawing on best practices identified in this analysis and the discussion at the European Health Forum Gastein 2021, we suggest 6 key principles to secure prioritisation and sustainability of vaccine budgets in a post-COVID recovery context:

- 1. Accountability:** Increase policy prioritisation of vaccines at national level (e.g., setting targets for vaccines expenditure, having vaccines expenditure per capita as EU indicator of Member States HCS performance) and a mandate to fund the vaccines recommended by NITAGs. There needs to be timely political will to ensure access to vaccines.
- 2. Cooperation:** Ensure a forward-looking view in budget-setting (e.g., multi-annual plans or annual budget horizon scanning) through effective stakeholder collaboration, involving vaccine manufacturers, and ensuring systems reward innovation and foster development of next-generation vaccines.
- 3. Flexibility:** Ensure vaccine funding flexibility and no strict caps on spending, allowing reallocation of healthcare funds to support unforeseen changes to vaccine demand (e.g., during epidemics). There needs to be a patient-centred approach rather than a budget-centred approach.
- 4. Transparency:** Increase transparency of monitoring and reporting vaccine budgets and expenditures. Defined vaccination expenditure could be a key health indicator to measure national healthcare system efficiency.
- 5. Allocation:** Ensure funding supports changes in immunisation priorities by implementing outcome/performance indicators (i.e., vaccine coverage target reach) to align funding allocation with desired future health outcomes.
- 6. Equity:** Ensure equity of access to vaccines across Europe through cross-country sharing and adoption of best funding practices. Leveraging the role of the Directorate-General for Structural Reform Support (DG Reform) can support Member States in sharing,

identifying and implementing structural reforms to improve their immunisation systems.

Though these principles have been developed for a European context, the COVID-19 pandemic has prompted many healthcare stakeholders to acknowledge “diseases do not respect borders” and “no one is safe until everyone is safe”. It is therefore vital that countries beyond Europe also strive to secure prioritisation and sustainability of vaccine budgets going forward.

6. Conclusion

To ensure equitable access to vaccines across Europe, a sustainable approach to vaccine funding is critical to improve the timely access to innovative vaccines for the European population. It could also be considered as a key element for strengthening European countries' pandemic preparedness plans, as required by the COVID-19 experience, in complement to the coordinated efforts that are being deployed by the European Commission.

Ensuring adequate and dynamic country vaccine budgets, with horizon scanning approaches like in England and Finland, or flexible vaccines expenditures like Germany, would greatly help the timely availability of public funding for new vaccines, reinforce effective NIPs and strengthen vaccines supply security in Europe through a more virtuous European vaccine ecosystem. There are also opportunities for Member States to use the Commission's Recovery and Resilience Facility to strengthen immunisation systems to ensure more resilient health systems.

Disclosures

Ryan Lawlor and Tim Wilsdon, of Charles River Associates, were commissioned by Sanofi to support this analysis and they assume editorial responsibility as contributors to the study. Charles River Associates is an economic consultancy company with a long-established reputation for independent analysis. Agustín Álvarez Nogal and Adrian Pana received no financial support for this study. Vanessa Rémy-Blanc is a Sanofi employee and may hold shares in the company. The remaining authors reported no potential conflicts of interest.

Author contributions

Ryan Lawlor, Tim Wilsdon and Vanessa Rémy-Blanc were involved in the conceptualization of the study and writing the paper. Agustín Álvarez Nogal and Adrian Pana were involved in expert interviews, validation of the analysis and the final review.

Approval

All authors provided final approval of the final version of the manuscript submitted for publication and take accountability for all aspects of the work.

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Appendix

Appendix 1. Research framework

Key research question	Elements for analysis
Who determines funding (decision-makers)?	Key stakeholders involved in determining funding The role of National vs regional decision-makers
How is funding organised and what is the vaccines budget flow?	Prevention and vaccines budget flow and any differences per vaccine-type or separate funding for the administration of the national immunisation programme The degree to which there is a separate budget for vaccines, innovative medicines and other prophylactic treatments (including spending on prevention) The degree to which the budget is ring-fenced
On what basis is funding determined?	Criteria for funding and price-setting Timeline for the budget-setting process (including key milestones for budget decisions) The degree to which this is forward looking and takes into account future launches and horizon scanning
How has funding changed over time?	The extent the vaccines budget has changed in relation to the overall healthcare budget Understanding the drivers of vaccines budget change
Are there any COVID implications?	Whether there have been any contingency funds for COVID-related healthcare needs The approach to funding COVID-19 vaccines

Appendix 2. High-level discussion guide (Romania example)

Introduction

1. To begin with, could you give a quick overview of your role and previous experience with funding and budget-setting processes for vaccines in your country?

Funding and budget-setting process for vaccines

Who determines funding?

1. The Ministry of Health establishes the national vaccination schedule, approves the national immunization programme and organizes the centralized procurement of vaccines.
 - a No technical working group anymore - NITAG not functional since 2015. Changes are now made by MOH by Institute of Public Health (such as pregnancy vaccination included 2 years ago)?
2. In 2017, Romania introduced a new law on the organization and financing of vaccination activities. The law stipulates financing of vaccination activities shall be carried out by the Ministry of Health.
 - a Currently the draft vaccination law is stuck in parliament. Any signs of pushing along?

How is vaccine funding organised?

1. Healthcare is split in curative and preventive program. Preventive program is financed by MOH
 - a There is no specific budget for vaccines. Vaccines are paid for with other prevention and healthcare services?
 - b The budget does not make any distinction between vaccine type. Are there any budget or spending considerations for types of vaccines? (e.g. paediatric vs adult vaccinations)
 - c Is the budget for vaccines and medicines ring-fenced for other areas of healthcare spending?

On what basis is funding determined?

1. How does vaccine spending work in practice? Is there planned expenditure or it is more pay-as-needed for different vaccines?
2. There is an overall lack of transparency regarding how vaccine funding is determined. Healthcare budgets are revised annually, however there is no indication of priorities or implications for vaccines
 - a Are budget holders and decision-makers on vaccine recommendation siloed?
 - b How does input from the National Institute of Public Health (INSP) on newly recommended vaccines and changes to coverage recommendations feed into the budget-setting process?
3. On what basis is funding determined and key indicators. Is this based on population and volume or considers any performance and coverage targets?
 - a Is there any criteria for funding of vaccines or sufficient budget allocation?
 - b Is allocation mainly considering what is needed to support demand, or does this reflect new vaccines? Is there use of horizon scanning?
 - c What happens if vaccine spending is higher than expected?

How has funding changed over time?

1. There is no publicly available data on vaccine spending and how this has changed over time. How has spending on vaccines changed over time?
 - a Do you know of any examples of previous vaccines or drivers where there has been a significant increase in the vaccines spending?

What are the implications of COVID-19?

1. Considering the upcoming Covid-19 vaccines and the potential requirements for multiple doses or seasonal vaccinations, how do you expect the budgets are going to cope with this?

Pros and cons of the budget setting process

Present slide showing the pros and cons of the budget setting process.

Pros	Cons
<ul style="list-style-type: none"> ✓ Vaccines are funded nationally by the Ministry of Health through a centralized procedure and distributed to ensure no regional variation (that could limit coverage and uptake) ✓ Vaccines can be funded as needed out of the overall healthcare budget to keep up with changing demand 	<ul style="list-style-type: none"> × There is a lack of transparency regarding the criteria for the budget-setting process and allocation of funds to vaccines × Upon revision of the annual healthcare budget there are no priorities or implications for vaccines × No clear process for how input from Vaccine Technical Committees on newly recommended vaccines and how changes to coverage recommendations feed into the budget-setting process

1. Based on our review of the vaccine funding and budget setting process in Romania we have identified a number of pros and cons. Do you agree with the list?

Probe on where they don't agree and ask why

1. Are there any pros and cons missing from the list which you think are important given the budget setting process in Romania?

Policy recommendations for sustainable vaccines funding

Present slide showing policy recommendations to ensure future budget sustainability and walk-through the recommendations we have drafted.

<p>Key policy recommendations</p> <ul style="list-style-type: none"> ➢ Increase policy prioritisation of vaccines at national level (e.g., by developing legal frameworks for funding vaccines) to ensure sufficient allocation of funds ➢ Increase transparency of reporting vaccine expenditure to ensure accountability ➢ Ensure a forward-looking view in the budget-setting process to ensure new vaccines and immunization priorities are reflected in the overall healthcare budget
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1. Do you agree with this list of policy recommendations?
 - a Do any go too far / not far enough?
2. Are there any critical areas missing? Would you suggest any additional recommendations for how policies should adapt in the medium and longer-term to ensure future sustainability?

Conclusion and next steps

1. As a next step, the insights from this discussion will be pooled with insights from other stakeholders across European countries to develop a manuscript with recommendations of how to sustainably fund vaccines post-COVID. There may be opportunities for publication of the research in the public domain. Is this something you would be interested in being involved in as a potential co-author?

Close the interview and thank the participant

Appendix 3. Comparison of stakeholders involved in decision-making and determining funding across countries

England	Finland	France	Germany	Italy	Norway	Romania	Spain
The UK Treasury sets the Departmental Expenditure Limit for each country and each	The Ministry of Social Affairs and Health (STM) is responsible for direct funding of vaccination,	The Ministry of Solidarity and Health (MoSH) is responsible for approving national	The GBA is the highest decision-making body in the German healthcare system and is responsible for	In Italy, the responsibility of healthcare budget allocation is shared between	The Ministry of Health and Care Services (HOD) directs healthcare services by means of legislation and	The Ministry of Health (MoH) establishes the national vaccination schedule, approves the national	In Spain, the responsibility of healthcare budget allocation lies within the 17 regional

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England	Finland	France	Germany	Italy	Norway	Romania	Spain
administration allocates resources to fund services under their control. The responsibility for immunisation is based on a tripartite agreement between the Department of Health and Social Care, Public Health England and NHS England. The overall NHS budget has been set up to 2023-24, taking into account objectives the NHS Long Term Plan.	covering vaccine acquisition and purchasing, distribution, staff training and surveillance. However, the costs of organisation of vaccination administration fall within the municipalities; allocation of funds for social and healthcare across municipalities is responsibility of the Ministry of Finance.	vaccination strategies and for establishing the necessary budget items (“expenditure targets”) for ambulatory care services, including vaccinations; however, the ultimate budget holder is Social Security. The Regional Health Agencies (ARs) have very limited flexibility to divert funding from one item to another as this is defined at the national level.	approving national vaccination guidelines, which are to be mandatorily funded by all statutory health insurances. The GBA guidelines are based on vaccination strategies and recommendations issued by the Standing Vaccination Commission (STIKO) within the Robert Koch Institute (RKI).	the MOH and the 21 regions. Vaccine procurement is decentralised and takes place at the level of the regional health department.	annual budgetary allocations through various governmental institutions. The Norwegian Institute of Public Health (FHI) is the central body for the municipalities and health authorities that coordinates vaccination. The Department of Vaccines arranges for the purchase (through tendering), storage and distribution of vaccines for the national vaccination program.	immunization programme and organizes the centralised procurement of vaccines. Romania’s NITAG has not been functional since 2015. Since then, all recommendations are made by the MoH. In 2017, Romania drafted a comprehensive new law on the organisation and financing of vaccination activities, however as of 2021 this has not been adopted yet and is still awaiting a parliamentary vote.	governments. The Public Health Commission within the Interterritorial Council of the National Health System (CISNS) is the ultimate responsible for developing vaccination policies and is supported by technical assessments from the Vaccine Committee.

Appendix 4. Comparison of how funding is organised and the vaccines budget flow

England	Finland	France	Germany	Italy	Norway	Romania	Spain
Vaccines under the NIP are commissioned nationally by NHS England through Section 7A services, these also include population screening programmes and other public health services for children and adults. Some vaccines sit outside the remit of S7a. Each immunisation programme under Section 7A will have a specified budget. The budget for the vaccine programme considers all elements that are part of the vaccine service delivery (e.g., vaccine purchasing, supporting administration, incentives to improve administration, local education etc.). There is no overall budget for Section 7A services, this is just how the allocation of funds for these	Vaccines have a standalone budget item (€31M in 2019) within the state budget; this budget item covers the costs of vaccine acquisition, purchasing, distribution, staff training and surveillance. As such, vaccination services (administration) are organised and funded directly by the municipalities’ budget. The budget includes an annual “pandemic fee” of €5M to cover for national-scale outbreaks.	Each year, a new Social Security Financing Law (LFSS) is drafted by the Social Security Directorate within the MoSH and is voted and approved by the Parliament. The LFSS includes the so-called ONDAM which defines the healthcare expenditure target at a national level. The ONDAM is broken down by settings of care (‘objectives’) and specific expenditure items (‘sub-objectives’) such as physician honoraria, healthcare interventions etc. Vaccines are not specifically defined within the ambulatory care envelope, and are therefore diluted within medicines used in the ambulatory setting. The ONDAM includes estimations of	The national prevention strategy specifies that statutory health insurances are to provide funding for all vaccination services and do not set any expenditure limit. Due to the nature of the German funding scheme, there are no vaccine budgets per se, but rather vaccine expenditure as these are procured in a pay-as-you-go manner. While physicians are bound to prescribe vaccines sustainably, vaccines do not impact their quarterly drugs budgets and can prescribe as many as necessary without cost containment measures.	The Regional Health Budget comes is distributed from the National Health Fund, which defines levels of spending in each region: outpatient care (51%), hospital care (44%) and preventive services (5%). The regional governments, however, are free to allocate their regional budget across their local health units (ASLs) in a manner that best supports their organisation needs. Since 2017 under the Lorenzin Decree, the National Health Fund includes an extra quota for each region to support vaccine purchasing. In addition, the National Prevention Plan (PNP) 2020-2025 is endowed with a total of €200M to be distributed	Healthcare funding in Norway is organised at the national level. Vaccines are funded separately to medicines. They sit as a dedicated budget item within the Public Health budget. There is no separate budget for innovative prophylactic treatments. The Vaccines budget covers the acquisition of all Vaccines in Norway, including those not routinely offered as part of the national vaccination program (e.g., travel vaccines). Administration costs and operating expenses associated with the NIP are covered under a different budget item. The budget appears to be ring-fenced and is not restricted by any upstream budgetary limits imposed by the Public Health budget or overall	Vaccines under the national immunisation programme are funded and procured nationally by the MoH through a centralized procedure and distributed to the District Public Health Authorities. Healthcare funding is split between the curative and preventive programs. The preventive program is financed by the Ministry of Health and includes vaccines for children, pregnancy and flu (adult vaccines are excluded). The prevention budget supports purchasing of products only. Administration costs and operating expenses associated with the national vaccination program are covered under a different budget item.	The regional healthcare authorities are responsible for establishing the necessary budget items for healthcare provision in their regions. Vaccines have a standalone budget that sits within the Public Health budget at regional level and represents the largest share of the Public Health budget. The current budgets are considered too low for the regions to have enough flexibility to add new vaccines to the regional vaccination schedule or include innovative vaccines with high cost. The granularity of the vaccine budget depends on the regions; some have specific budget

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England	Finland	France	Germany	Italy	Norway	Romania	Spain
programmes are reported in the public domain (i.e., there is a lack of transparency on programme-specific spending).		institutionally organized vaccines, typically regional campaigns organised by ARSs that fall outside the NIP.		across regions for the purposes of health prevention.	healthcare budget under HOD.		for each type of vaccine while others have a single budget item.

Appendix 5. Comparison of the basis funding is determined across countries

England	Finland	France	Germany	Italy	Norway	Romania	Spain
All funding is centrally allocated by NHS England and the regions get a share of the allocation depending on population and then the region allocates funds to the different immunisation programmes based on local needs. The budget is revised annually and considers recommended improvements to the provision of services for the following year. Budgeting for each immunisation programme is based on regional forecasting uptake and public health performance targets. Horizon scanning is performed, both at the national and local level, typically about 1-2 years in advance.	The National Vaccination Program (NVP) defines the vaccines that are to be provided free-of-charge to all Finland residents; NVP's validity is evaluated by the THL and considers new developments in the field of vaccines and changes in international vaccination programs. The vaccines budget item is estimated according to future vaccine orders to meet the goals of the NVP; inclusion of new vaccines to the NVP will be accompanied with a detailed evaluation of the budget needs and a subsequent update of the vaccines budget. The THL formally introduced horizon scanning in their process of updating the NVP, which was piloted in 2019.	Theoretically, the expenditure target defined in the ONDAM is based on a thorough review of the past year's objectives and how well these were met according to performance indexes and also intends to cover the costs for vaccination of the national immunization plan (NIP); however, there is no evidence that these reviews are really used to modify the expenditure targets defined in the ONDAM. The draft LFSS for 2021 includes the sub-objectives of increasing vaccination coverage among the 24-month old children and the 65+ year old population and other risk groups.	The Standing Vaccination Commission (STIKO) is responsible for assessment of new vaccines and for updating the national vaccination schedule. It is mandatory for statutory health insurances (Kks) to fund vaccines recommended by STIKO and included into vaccination guidelines by the GBA. The STIKO considers new developments in the field of vaccines when prioritizing which vaccines to assess. In addition, the Robert Koch Institute (RKI) holds annual Horizon Scanning meetings with vaccine manufacturers.	The National Plan of Vaccine Prevention (PNPV) 2017–2019 has enforced mandatory vaccination in Italy, sets targets for vaccine coverage, identifies the main priorities and also sets out actions to reduce regional differences. Inclusion of vaccines in the national vaccination schedule take into consideration the feasibility of implementation based on the costs of vaccines.	The budget is revised on an annual basis. During each budget revision, HOD lists key priorities compared with the previous budget and this has included specific points on vaccine spending. Spending on vaccines can extend beyond the budgeted amount if necessary. In 2019, the proposed vaccines budget was NOK 336 million, but spending on vaccines reached NOK 456 million. This suggests the budget does not impose a hard cap on spending. No evidence of horizon scanning or taking into account future launches.	Prevention budgets are revised annually, however is primarily based on historical figures adjusted based on population/volume. Budget reviews are not forward looking and do not take into account future launches. This is also no evidence of horizon scanning in the budget setting process.	Regional budgets are revised annually but often face delays due to political instability. In practical terms, this results in budgets being revised every 2 or 3 years. Budget-setting is a very rigid process that results from negotiations between regional sectorial counsellors (education, health, infrastructure, etc.) and the regional finance counsellor; vaccines must compete for budget against the rest of healthcare services as well as other sectorial priorities. The amount allocated to the vaccine budget is based on historic expenditure, population growth and a review of vaccine coverage rates. Horizon scanning is not part of the vaccine budget setting process.

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