Improving the supply of vaccines

Current challenges and the social value of vaccination prevention

Vaccinations are an effective preventive measure against infectious diseases. High immunisation rates protect various population groups from the onset of diseases and serious illnesses. In addition to reducing the number of cases of illness, vaccinations can lead to direct cost savings through fewer hospitalisations, visits to the doctor and complications, as well as indirect savings from a social perspective. According to the Robert Koch Institute, around one in five people aged 60 and over in Germany have been vaccinated against shingles (Q1 2024) and around two in five against seasonal influenza (2023/24 season). The production, authorisation and distribution of vaccines are subject to strict regulations. The STIKO recommendations and contract negotiations for cost coverage by statutory health insurance are often lengthy. Digitalisation through electronic vaccination cards and data-supported reminder systems offers potential for improving vaccine supply. Low-threshold offers, in particular vaccination in pharmacies, also lead to an increase in vaccination rates with a high level of satisfaction among those vaccinated. In the health economic evaluation of vaccines, long-term social effects are insufficiently taken into account, which is why it is being discussed how a broader evaluation can incorporate the comprehensive value of vaccinations.

>> Vaccinations are among the most effective measures to protect against infectious diseases (Federal Ministry of Health (BMG) 2024a). They can specifically train the acquired immune system by imitating an infection and can protect against severe disease progression and secondary diseases (BMG 2024b).

Vaccine types and technologies

Which vaccine is best suited to prevent a particular disease depends on the characteristics of the pathogen (BMG 2024b). Different vaccine types and technologies are used to protect against infectious diseases. These differ, among other things, in terms of

- their components and the reaction they trigger in the immune system (BMG 2024b),
- the degree of splitting (Schilling 2008),
- the method of production (Leroux-Roels et al. 2011; Strugnell et al. 2011),
- the frequency with which they need to be vaccinated in order to build up sufficient protection (BMG 2024b).

Due to virus mutations, as with influenza, there are also seasonal vaccines that are adapted each season to the circulating virus variations (BMG 2024b). Despite years of research, there is still no vaccine available for a large number of pathogens. Researchers are working to develop effective vaccines using new technologies (BMG 2024b). However, the development of new vaccine types is a costly, complicated and multi-stage process (Leroux-Roels et al. 2011).

Need for high vaccination rates

Vaccinations can protect against diseases or lead to disease progression with less pronounced symptoms. The probability of infecting other people is significantly reduced. A high vaccination rate results in 'community protection', which also protects people who have not been vaccinated or who do not develop an immune response for protection (BMG 2024b). Vaccinations offer great potential for preventing infectious diseases and the associated severe courses of illness, especially for people at risk, such as the elderly and chronically ill (BMG 2024b; Kwetkat 2023). In addition, vaccinations can reduce the number of medical treatments due to severe courses of disease (Deutsches Ärzteblatt 2024).

Vaccination rates

In order to be able to implement, evaluate and optimise vaccination programmes in a targeted manner, vaccination rates in Germany are processed and made available nationwide by the Robert Koch Institute (RKI) as part of the KV (Association of Statutory Health Insurance Physicians) vaccination surveillance (RKI 2024a). In this chapter, German and international vaccination rates are presented using the examples of vaccination against herpes zoster (shingles) and influenza (flu).

Vaccination rates using the example of the herpes zoster vaccination

Herpes zoster, also known colloquially as shingles, is caused by the varicellazoster virus. After surviving chickenpox, the virus remains in the nerve cells for life. At a later point in time, the virus can reactivate and herpes zoster can occur (RKI 2018a). A disease sometimes leads to severe pain in those affected (RKI 2017). Vaccination with the inactivated herpes zoster vaccine is recommended by the Standing Committee on Vaccination at the Robert Koch Institute (STIKO) as a standard vaccination for people aged 60 and over and as an indication vaccination for people aged 50 and over with an increased health risk (RKI 2018b). Since March 2019, the vaccination has been a mandatory benefit of the statutory health insurance funds (RKI 2022).

While the vaccination rate was 0.7% in the first quarter of 2020, it rose slightly but

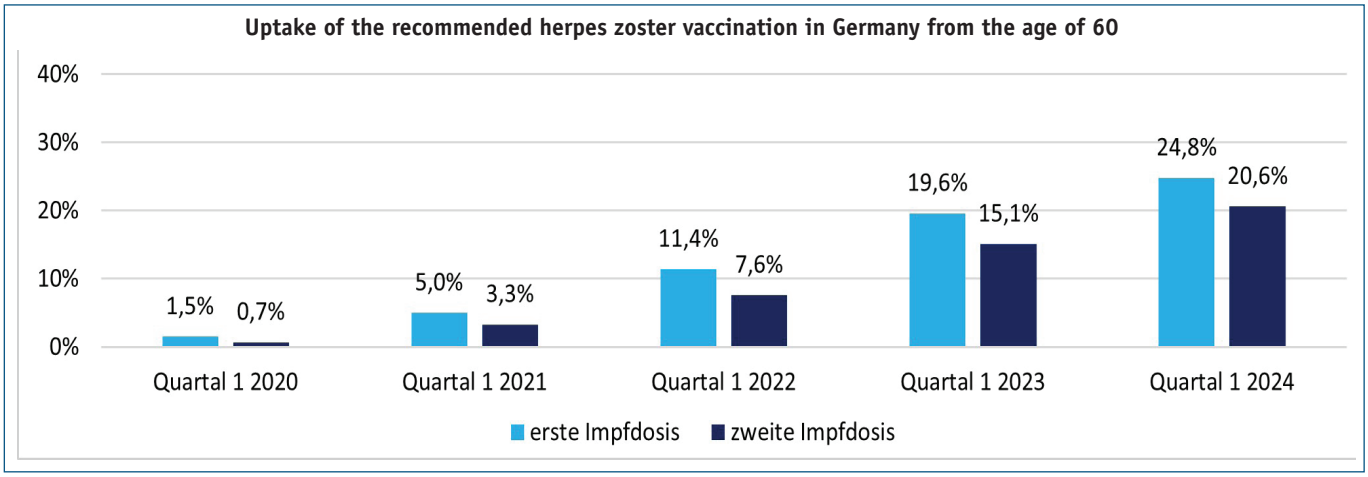


Fig. 1: Uptake of the recommended herpes zoster vaccination in Germany from the age of 60 (based on (RKI 2025), data as of 23 April 2025). Source: own presentation..

continuously to 24.8% by the first quarter of 2024 (RKI 2025) (data as at 23 April 2025). The development of herpes zoster vaccination rates in Germany since the first quarter of 2020 can be seen in Figure 1.

Herpes zoster vaccination is currently recommended in 11 of the 27 member states of the European Union (EU) (Federal Foreign Office 2024; European Centre for Disease Prevention and Control 2024). According to a survey of 3,613 people aged 50 and over in nine European countries published in 2023, the herpes zoster vaccination rate was highest in the UK at 23% (International Longevity Centre UK 2023). No overarching overview could be identified for vaccination rates in other countries, such as for influenza vaccination rates in Europe (European (EU) Commission 2024). Herpes zoster vaccination rates have been published for various countries, but these differ in terms of their data basis, which makes a comparison difficult.

Vaccination rates using the example of influenza vaccination

The real flu, also known as influenza, is transmitted by droplets or through direct contact with contaminated surfaces. The most common symptoms include fever, cough, sore throat, muscle aches and headaches. Other possible symptoms include general weakness, sweating, nasal discharge, nausea, vomiting and diarrhoea. Severe courses with pulmonary and other complications are also possible (RKI 2018c). For people at risk, the STIKO recommends an annual vaccination against seasonal influenza in autumn (RKI 2022).

According to the RKI, in the 2008/09 and 2009/10 seasons, around half of people aged 60 and over were documented to have been vaccinated against influenza. Vaccination rates fell until the 2012/13 season and then remained at a level where around one in three people aged 60 and over had received a seasonal influenza vaccination. In the 2020/21 season, a significant increase in the vaccination rate can be observed, with a downward trend in the following seasons (RKI 2022). The trend in the rate for people aged 60 and over since the 2008/09 influenza season is shown in Fig. 2.

In most EU countries, influenza vaccination rates are only recorded from the age of 65, which makes a direct comparison with the data from Germany difficult (EU Commission 2024). Based on the Eurostat database (data as of 11 December 2024), Figure 3 shows the vaccination rates from the age of 65 in 2022 in the EU countries for which data on influenza vaccination rates are available. It is clear that the influenza vaccination rate

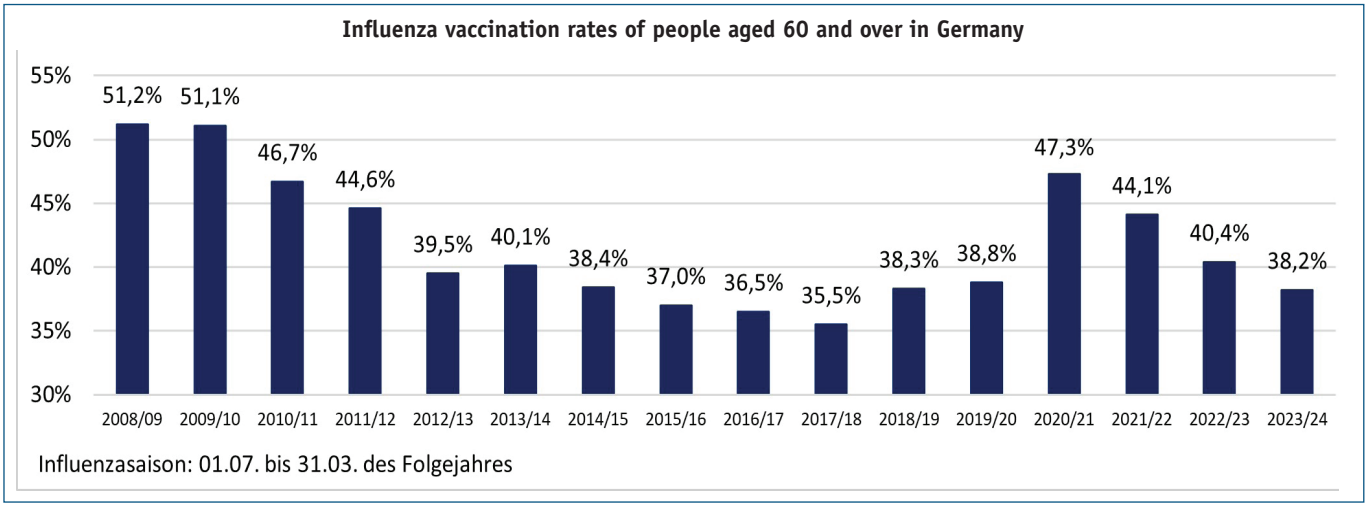


Fig. 2: Influenza vaccination rates of people aged 60 and over in Germany (based on (RKI 2025), data as of 23 April 2025). Source: own illustration.

of older people in Germany in 2022 is slightly below the average of the 27 EU countries (EU Commission 2024).

Health and economic value of vaccines using the example of the herpes zoster vaccination

The evidence on the health and economic value of vaccinations is presented using the example of the herpes zoster vaccination. The standard and indication vaccination with the inactivated herpes zoster vaccine recommended by the STIKO is taken into account (RKI 2018b).

Health benefits of the herpes zoster vaccination

For the incidence of herpes zoster in Germany, which expresses the number of new cases (Kuhn/Bolte 2024), Hillebrand et al. (2015) determined an annual standardised incidence rate of between 10.4 and 10.9 per 1,000 person-years in the years 2006 to 2009. Outpatient and inpatient cases from routine data were taken into account. The incidence rate was around 75% higher in immunocompromised people than in immunocompetent people (Hillebrand et al. 2015). The analysis by Ultsch et al. showed that the incidence and the number of herpes zoster cases leading to hospitalisation increase with age (Ultsch et al. 2011).

The efficacy of a vaccination is determined with the help of controlled clinical studies (WHO 2021). In the ZOE-50 study, an efficacy rate of 97.2% was found in people aged 50 and over (Lal et al. 2015). In people aged 70 and over, the results of the ZOE-70 study showed an efficacy rate of 89.8% and 89.1% in people aged 80 and over (Cunningham et al. 2016). The results of the ZOE-LTFU study, a follow-up study of the ZOE-50 and ZOE-70 studies, showed that even nine years after vaccination with the inactivated herpes zoster vaccine, an effectiveness of 72.7% was achieved (Strezova et al. 2022).

The effectiveness of a vaccination indicates how well vaccines protect against a disease in the real world under realistic conditions (WHO 2021). A systematic literature review with network meta-analysis showed a vaccine effectiveness of 70% for the inactivated herpes zoster vaccine in immunocompetent individuals compared to no vaccination (Xia et al. 2022).

The modelling by Curran et al. shows that in Germany, around two million cases of herpes zoster in the 50+ age group could be prevented by vaccination with the inactivated herpes zoster vaccine. In addition, according to the modelling, 104,586 hospitalisations, 11,154,298 GP visits and 248,159 complications could be prevented in the remaining lifetime.

The modelling is based on the assumption that 40% of people aged 50 and over have received the first vaccination dose and that 70% have received the second vaccination dose. The figures refer to the German population in the respective age group (Curran et al. 2021).

Costs avoided by the herpes zoster vaccination

Against the background of the increase in average sick days per employee in Germany (Federal Statistical Office 2025) and the associated damage to the German economy

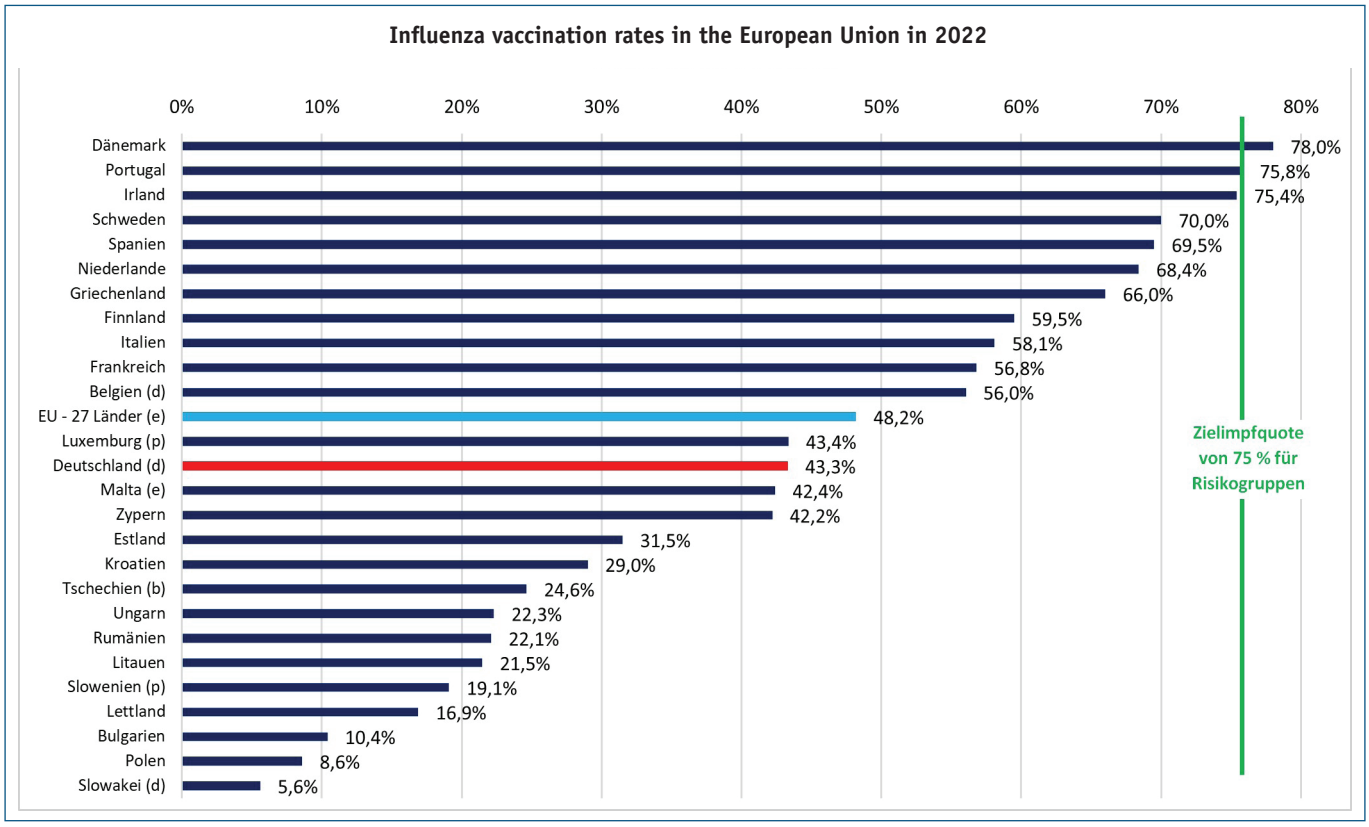


Fig. 3: Influenza vaccination rates in the European Union in 2022 for people aged 60 and over (based on (EU Commission 2024), as at 11.12.2024; sources for the target vaccination rate: (RKI 2009; RKI 2022; World Health Organization (WHO) 2003). Legend: b = break in time series, d = different definition, e = estimated, p = provisional. Source: own representation.

(Federal Institute for Occupational Safety and Health 2024), the relevance of disease prevention measures becomes clear.

In the modelling by Van Oorschot et al., the costs that could be saved by vaccinations with the inactivated herpes zoster vaccine per million people aged 60 and over in the German population were determined. This modelling is based on the assumption that 40% of people aged 60 and over have received the first dose of vaccine and the uptake of the second dose is 70%. The results showed that over the remaining lifetime of the cohort (1 million people aged 60 and over), around Euro 14.9 million in direct costs (payer perspective, discounted) and around Euro 2.8 million in indirect costs (societal perspective, discounted) could be prevented (Van Oorschot et al. 2019).

For the cost-effectiveness of herpes zoster vaccination in Germany, the incremental cost-effectiveness ratio (ICER) was determined as part of the modelling by Curran et al. (Curran et al. 2021). The amount of money that would have to be invested to gain one quality-adjusted life year (QALY) was calculated: if vaccinating people aged 50 and over, the value would be Euro 30,710 per QALY, if vaccinating people aged 60 and over, Euro 32,139 per QALY and if vaccinating people aged 70 and over, Euro 39,107 per QALY. Assuming a threshold of E uro 50,000 per QALY, this intervention was described by the authors as cost-effective by conducting sensitivity analyses (Curran et al. 2021).

Regulatory framework conditions

The authorisation of vaccines in Germany and Europe follows a strictly regulated procedure. Vaccines may only be placed on the market if they have a national marketing authorisation or an authorisation from the European Union (EU) [Section 21 AMG]. Both efficacy and a positive risk-benefit ratio must be proven [Section 25 AMG]. In Germany, the Paul Ehrlich Institute (PEI) is responsible as the higher federal authority [Section 77 AMG]. For EU-wide marketing authorisations, there is the mutual recognition procedure, the decentralised procedure [Section 25b AMG] and the centralised procedure via the European Medicines Agency (EMA) (European Union (EU) 2004). After authorisation, the PEI continuously monitors the vaccines [Section 64 AMG].

The STIKO issues recommendations for vaccinations [§ 20 IfSG]. On this basis, the Federal Joint Committee (G-BA) decides on the inclusion of vaccinations in the Vaccination Guideline (SI-RL) (Federal Joint Committee (G-BA) 2024) and thus in the compulsory catalogue of statutory health insurance (GKV) [Section 20i SGB V]. Since 2007, vaccinations have been a mandatory benefit of statutory health insurance, which guarantees that they are covered for insured persons (Federal Law Gazette (BGBl) 2007). Contracts between health insurance funds and associations of statutory health insurance physicians (KVs) guarantee nationwide coverage and reimbursement [Section 132e SGB V].

Factors for good security of supply

Vaccine production is a highly complex process that is subject to strict national and international regulations such as the German Drug and Active Ingredient Manufacturing Ordinance (AMWHV) (Jung et al. 2020). Because vaccines are produced worldwide in networked structures, stable supply chains are crucial (Grömling/Kirchhof 2020). However, around 68% of active ingredient production is located in Asia (Verband Forschender Arzneimittelhersteller 2022), which can lead to considerable risks in the event of disruptions (Kagermann 2021). Germany could increase its attractiveness as a business location through better industrial policy framework conditions, faster approval procedures and access to international production networks (Kirchhoff 2021a, 2021b).

The EU also categorises complex production processes as a risk factor for supply bottlenecks (EU 2018). Twelve vaccines were affected by shortages in 2023 (Paul Ehrlich Institute 2024). The main reason for this is increased demand, which makes flexible subsequent deliveries more difficult (Miranda-García et al. 2022). A modern industrial policy could help to strengthen the resilience of supply chains (Kirchhoff 2021a).

Vaccinations and digitalisation

The vaccination rate for adults in Germany remains low (RKI 2022). Around 72% of the population have not received vaccination counselling in the last two years (Horstkötter et al. 2017). In addition, a comprehensive reminder system is still lacking (Schrörs/Zollmann 2020). The German government therefore wants to push ahead with the possibilities of digitalisation to target insured persons for vaccinations (Bundestag printed paper 20/9046 2023). Since 2024, the Health Data Utilisation Act (GDNG) has enabled health insurance companies to specifically point out vaccination gaps [Section 25b SGB V]. The Digital Act (DigiG) also integrates electronic vaccination documentation into the electronic patient file (ePA) (BGBl 2024) so that vaccination gaps can be identified and addressed at an early stage (Bitkom 2023).

The Covid-19 pandemic has made it clear how important a functioning digital vaccination management system is. Until now, vaccination rates have been recorded with a considerable delay [Section 13 IfSG]. During the pandemic, the RKI relied on telephone surveys to obtain data (RKI 2021). A digital vaccination register could contribute significantly to a rapid response to outbreaks in the future (Landeszentrum Gesundheit Nordrhein-Westfalen 2019). DigiG and GDNG will enable timely vaccination monitoring (Verband Forschender Arzneimittelhersteller 2023), which will allow health policy measures to be implemented in future on the basis of scientifically sound and up-to-date knowledge (Jochimsen 2022).

Low-threshold vaccination

Low-threshold vaccination services such as those offered in pharmacies have proven their worth during the COVID-19 pandemic. Pharmacists were given permission to carry out COVID-19 vaccinations (BGBl 2021). Important reasons for vaccination in pharmacies are flexible opening hours, short waiting times and good accessibility (Pfizer 2024). Flu vaccinations have also been possible in pharmacies since 2022 (BGBl 2022). By the beginning of 2024, over 600,000 vaccinations had been carried out in pharmacies (Bundesvereinigung Deutscher Apothekerverbände (ABDA) 2024). A survey showed that 94% of patients would continue to use pharmacy vaccinations in the future (Werthner et al. 2025). Vaccination programmes in pharmacies are also helping to increase vaccination rates internationally (Rahim et al. 2024; Spinks et al. 2020).

With the draft bill for a Pharmacy Re-

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form Act (ApoRG), the German government planned to further expand pharmacy vaccinations in order to improve the vaccination coverage rate in the population. Pharmacists were also to be authorised to offer additional vaccinations to people aged 18 and over (BMG 2024c). In the view of the federal government, the supplementary vaccination programme has proven its worth (Bundestag printed paper 20/12696 2024). Following the end of the coalition government, it is currently unclear to what extent many legislative proposals will be pursued further. Politically, it remains to be seen whether the next government will continue the expansion of low-threshold vaccination programmes.

Vaccine prices in Germany

Vaccines are subject to special price regulations. A reference price system for vaccines was introduced in 2011 (BGBl 2010). The core component of the EU reference price system is the comparison of the selling prices for vaccines in Germany with the average prices (reference prices) of vaccines within the European Economic Area. If the price of a vaccine per unit of quantity in Germany is higher than the reference price, the vaccine manufacturers reimburse the pharmacies the discount paid by them to the health insurance funds in the amount of the difference [Section 130a SGB V]. This discount applies to all vaccinations financed by the health insurance funds. Further details are set out in the regulations of the National Association of Statutory Health Insurance Funds (GKV-SV) on the implementation of the manufacturer discount for vaccines (BGBl 2021).

In 2023, expenditure on vaccinations totalled Euro 2.3 billion, which corresponds to 4.6% of total pharmaceutical expenditure (Bundestag printed paper 19/13452). Previous discount agreements have led to bottlenecks in supply (Hillienhof 2012). In order to reduce the risk of supply bottlenecks (ABDA 2021), discount agreements for vaccines are now prohibited (BGBl 2017).

Hurdles

Unlike with other medicinal products, there is no time limit for STIKO to assess new vaccines. For the inactivated herpes zoster vaccine, 9 months passed between EMA authorisation and STIKO recommendation (European Medicines Agency (EMA) 2020; RKI 2018b). It even took 11 years for the meningococcal serogroup B (MenB) 4CMenB vaccine (EMA 2018; RKI 2024b). In comparison, the ACIP issued an initial recommendation for the use of 4CMenB as early as 2015 (Folaranmi et al. 2015). The recommendation for the inactivated herpes zoster vaccine was even made in the USA after just 5 days (Dooling et al. 2018).

According to the STIKO recommendation, it also takes time before vaccinations are available as a benefit in kind. In practice, it has been shown that it can take several months to finalise negotiations between health insurance funds and KVs (Pharma Deutschland e. V. 2025). Until then, the prescription must be issued on a private prescription and the medical vaccination service must be billed privately. Although the invoice can be submitted to the health insurance company for reimbursement (Kassenärztliche Vereinigung Nordrhein 2024), cost reimbursements increase the financial burden for insured persons (Wasem 2000).

Health insurance funds receive lump sums to subsidise preventive services. The amount of these lump sums is divided into three levels, with vaccinations assigned to the lowest level [Section 15 of the Risk Structure Equalisation Ordinance (RSAV)]. For an insured person who received a vaccination in one year, a health insurance fund received an allocation of 95 cents in 2023 (Federal Social Security Office 2024). Discussions about the morbidity-oriented risk structure equalisation scheme (Morbi-RSA) show that the morbidity orientation of the risk structure equalisation scheme reduces the prevention incentives for health insurance funds (Drösler et al. 2017). There is a risk that expenditure on preventive measures will be reduced as health insurance funds lose interest in prevention because allocations increase the more ill the insured person becomes (Wanek/Schreiner-Kürten 2021).

Value4money

Pharmaceutical companies finance research and development through revenue from the sale of their products (Steutel 2021). The development of new vaccines takes an average of 10.7 years with a probability of success of only 6% (Pronker et al. 2013). In view of the importance of vaccinations, the WHO is therefore calling for innovation-friendly framework conditions to promote investment (WHO 2024). Vaccinations are seen as investments in health and the economy that can enable a longer and better life for all (Steutel 2021).

According to Tunder, European reference prices are unsuitable for determining the reimbursement amount, as they do not allow any conclusions to be drawn about the benefits (Tunder/Ober 2020). Assessments of new vaccines should not only take costs into account, but also the overall benefit. At present, this is still not sufficiently captured in current cost-benefit analyses (Beck et al. 2022). In addition to economic aspects, social and ethical effects should therefore also be taken into account (Schwartz/Mahmoud 2016). Effects such as increased productivity in later life after vaccination, better cognitive abilities, higher educational attainment, health benefits at the societal level through community protection and even political stability could be taken into account to reflect the value of vaccination (Deogaonkar et al. 2012). The WHO adapted its guidelines in 2019 to better reflect long-term benefits of vaccination, as vaccines have the potential to generate many long-term health and non-health benefits (WHO 2019). Additional research will help to provide decision-makers with a better understanding of the true value of vaccination, which may currently be underestimated in cost-effectiveness analysis (Biundo et al. 2024).

Conclusion and recommendations for action

Vaccinations are among the most effective and cost-efficient disease prevention measures. They not only protect vaccinated people, but also those around them and can contribute to the eradication of diseases. However, their benefits are often only realised in the long term, which has so far been insufficiently taken into account in economic evaluations. The short-term costs incurred are offset by long-term health, social and economic effects, which are often not fully taken into account (Ultsch et al. 2016). Vaccines are therefore often considered to be at a disadvantage in health economic models (Weber et al. 2021). In order to reflect their actual value, more comprehensive valuation approaches are needed that take into ac-

count society as a whole.

Despite the high value, there are other challenges that influence the vaccination system in Germany. Regulatory framework conditions, pricing mechanisms and supply structures play a decisive role in vaccine availability. Four central strategies can be derived for a sustainable vaccination supply in Germany:

1. holistic evaluation of vaccinations.
2. strengthening public acceptance through transparent communication.
3. digitalisation as a driver for vaccination management and monitoring
4. expansion of low-threshold services to facilitate access and relieve the burden on the healthcare system. <<

by:
Elisabeth Plath MA[1] (ORCID: 0009-0008-0058-3732) /
Michael Minor MA[1] (ORCID: 0009-0007-2138-0304) /
Dr. rer. pol. Christian Speckemeier[1]
(ORCID: 0000-0001-7507-4432) /
Prof. Dr. rer. pol. Jürgen Wasem[2] (ORCID: 0000-0001-9653-168X) /
Dr. rer. medic. Anna Bußmann[1] (ORCID: 0000-0002-9827-9083)

1: Essen Research Institute for Medical Management (EsFoMed) GmbH
2: Chair of Medical Management, University of Duisburg-Essen

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What health insurance companies reimburse for vaccinations

>> The independent comparison portal www.gesetzlichekrankenkassen.de draws attention to the fact that there are sometimes major differences between the statutory health insurance funds when it comes to reimbursing the costs of vaccinations. 'It's worth checking your own health insurance fund for this,' recommends Managing Director Thomas Adolph, who compares the benefits of the 94 statutory health insurance funds. The comparison portal provides an overview of three relevant immunisations as an example of how big these differences can be: Shingles (herpes zoster), human papillomavirus (HPV) and the TBE vaccination against tick-borne encephalitis.

Example herpes zoster:

The Standing Committee on Vaccination (STIKO) recommends this vaccination from the age of 60 and for certain risk groups from the age of 50. In addition to this free standard benefit, however, some health insurance companies offer cost reimbursements even below the age limits: According to the comparison portal, nine health insurers cover the costs in full and some insurers up to a certain maximum amount or a certain proportion. A total of nine health insurance companies provide an annual global budget. One provider covers 100% of the costs up to a maximum of 200 euros, two health insurance funds reimburse up to a maximum of 250 euros in full and one fund up to a maximum of 300 euros. Two further providers contribute up to a maximum of 400 euros, and three providers even reimburse up to 500 euros - two of them in full and one at 80%.

Example HPV

The STIKO recommends the HPV vaccination for girls and boys from the age of nine. This should be done by the age of 17 at the latest. 'Some health insurance companies also cover the vaccination costs for young women and men aged 18 and over, sometimes even in full,' explains Adolph. For women aged 18 and over, for example, 45 health insurance companies reimburse the costs in full (without a maximum amount). As part of the annual global budget, some health insurance companies also contribute up to certain maximum amounts - from 100 to 500 euros. For men aged 18 and over, 41 providers cover the vaccination costs in full and for an unlimited amount. And here too, some health insurance companies reimburse up to 500 euros as part of a global budget of 100 euros.

Example TBE

The TBE viruses cause inflammation of the brain and meninges in some of those infected and are mainly transmitted by ticks. As the little animals like warmer temperatures, more and more risk areas are being added due to climate change. 'Anyone who spends a lot of time outdoors in such an area should consider a vaccination. Bavaria, Baden-Württemberg, southern Hesse, south-east Thuringia, Saxony and south-east Brandenburg in particular are known to be risk areas,' says Adolph. People with statutory health insurance who live in a risk area are reimbursed for the vaccination in full as a standard benefit. However, numerous health insurance funds also cover the costs or part of the costs for insured persons who are only travelling to a German risk area: 44 health insurance funds cover the costs in full and one fund covers 100 percent up to a maximum of 500 euros. Within the scope of the annual global budget that can be called up, 15 health insurance funds offer cost reimbursement. Three providers cover 100% of the costs up to a maximum of 200 euros, three health insurance companies reimburse up to a maximum of 250 euros in full, and three health insurance companies also reimburse up to a maximum of 300 euros. Two other health insurance funds contribute up to a maximum of 400 euros, and four providers even cover up to 500 euros - two of them in full and two at 80%.. <<