THE ORGANIZATION AND DELIVERY OF
VACCINATION SERVICES IN THE EUROPEAN UNION

# GERMANY

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# Germany

*Miriam Blümel*

## Governance

In 2001 the "German Protection against Infectious Diseases Act" (the law on prevention and control of infectious diseases in humans) came into force and defined the basics for vaccinations with the aim of protecting the population from communicable diseases. The Federal Institute for Infectious and Non-Communicable Diseases (Robert Koch Institute) is a subordinated agency of the Federal Ministry of Health. It is the government's central scientific institution in the field of biomedicine and an important body for the safeguarding of public health in Germany. Among other tasks, the Robert Koch Institute is charged with identification, surveillance and prevention of infectious diseases. The tasks of the Robert Koch Institute are specified in § 4 of the German Protection against Infectious Diseases Act (2001).

The Robert Koch Institute is advised in its technical and regulatory tasks by several committees, including the Standing Committee on Vaccinations. The Standing Committee on Vaccinations is an independent advisory group that develops national recommendations for the use of licensed vaccines. It consists of 12 to 18 unpaid members representing different expert fields who are appointed by the Federal Ministry of Health for a period of three years.

Vaccination recommendations by the Standing Committee on Vaccinations apply nationally and are based on the criteria of evidence-based medicine. While the Federal Institute for Vaccines and Biomedicines (Paul Ehrlich Institute) is responsible for licensing vaccines with regard to product-specific efficacy, safety and quality, the

Standing Committee on Vaccinations analyses the individual benefit-risk ratio, but also studies epidemiology at the population level and the effects of a nationwide vaccination strategy for Germany. In addition, the Standing Committee on Vaccinations develops criteria to delineate a common vaccine response from a health impairment beyond the usual extent of a vaccine response. The Committee's recommendations are considered medical standard. While the Committee's recommendations are not binding, they provide the basis for the vaccination guidelines of the Federal Joint Committee. After publication of a new Committee recommendation, the Federal Joint Committee has three months to decide if they will include this recommendation in the vaccination guidelines. If they decide against it, they must provide the arguments that led to the rejection. Once a vaccination is included in the guidelines, it is covered under statutory health insurance. As already mentioned, the recommendations of the Standing Committee on Vaccinations apply nationally. However, the German Protection against Infectious Diseases Act gives the federal states the opportunity to make special arrangements for their own federal state. The federal state recommendations are relevant for the vaccine injury compensation programme.

The Standing Committee on Vaccinations' recommendations are usually published once a year in the *Epidemiological Bulletin* and on the websites of the Robert Koch Institute. Since 2004 detailed explanations of the recommendations have also been published. The recommendations include a vaccination schedule of standard vaccinations for infants, toddlers, children, adolescents and adults, and a table of indication and booster doses with explanatory notes. According to the vaccination schedule, infants receive primary immunization for tetanus, diphtheria, pertussis, poliomyelitis, hepatitis B, *Haemophilus influenzae* type B, pneumococcal disease and rotaviruses. Toddlers should receive primary immunization for meningococcal disease (Serogroup C), **measles**, mumps, rubella and varicella. Human papillomavirus (HPV) is a standard vaccination for girls and boys aged between 9 and 14 years. The Standing Committee on Vaccinations also recommends an annual vaccination against **influenza** and pneumococcal vaccination from the age of 60 (*see* Table 1).

The Standing Committee on Vaccinations gives recommendations for the use of vaccinations for infants, toddlers, children, adolescents, adults, adults older than 60 years and for certain high-risk groups (e.g. patients with chronic conditions). However, there is no mandatory vaccination in Germany. Adults can therefore decide for themselves and parents can decide for their children which vaccinations they receive.

In 2015 the Act to Strengthen Health Promotion and Prevention came into force with the aim to improve disease prevention and health promotion by regulating vaccination policy through a range of legal measures. For instance, children will only be admitted to day-care facilities if the parents can prove that they have taken medical advice from a physician. If this proof is not provided, the responsible health authority will be informed. Parents who refuse the counselling can be fined up to €2500. In case of a measles outbreak in a day-care facility or school, the institution is allowed to exclude unvaccinated children from attendance. Furthermore, the recruitment of employees in medical facilities can be made dependent on their vaccination coverage and immunization status.

According to the "German Health Interview and Examination Survey for Children and Adolescents" (KiGGS) conducted by the Robert Koch Institute, adolescents with a migration background from both parents represent a population group with a relatively low vaccination rate. Various welfare services and non-governmental organizations have developed primary prevention projects in collaboration with the responsible health authorities, the Robert Koch Institute and the Federal Ministry of Health in order to better reach this group. For example, the university medical centre Charité Berlin has launched the *Impfbus* ("vaccination bus") project. This mobile vaccination centre drives to schools, informs pupils about necessary vaccinations, and conducts them (with parental consent). The vaccination bus also supports the medical care of refugees.

In Germany a national immunization register does not exist. However, nationwide and continuous surveillance of vaccination coverage is available from school entrance examinations since 2001. As a second pillar for the nationwide monitoring of vaccine uptake, the Robert Koch Institute coordinates *KV-Impfsurveillance* (KV-Vaccination Surveillance) in cooperation with the 17 Regional Associations of SHI-Accredited Physicians (KV) to monitor vaccination coverage in all age groups, in specific risk groups and at district level. All 17 Regional Physicians' Associations send anonymized payroll data on vaccination services, child and adolescent health check-ups and diagnoses of vaccine-preventable diseases from ambulatory care physicians to the Robert Koch

## **Table 1** Vaccination recommendations 2018/19

| VACCINE \ AGE | INFANTS (Weeks) | | | | TODDLERS (Months) | | CHILDREN (Years) | | | ADOLESCENTS | | | ADULTS | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 6 | 2 | 3 | 4 | 11-14 | 15-23 | 2-4 | 5-6 | 7-8 | 9-14 | 15-16 | 17 | from 18 | from 60 |
| | | | U4 | | U6 | U7 | U7A/8 | U9 | U10 | J1 | | | | |
| **Tetanus** | | G1 | G2 | G3 | G4 | N | | A1 | N | A2 | | N | A [f] | |
| **Diphtheria** | | G1 | G2 | G3 | G4 | N | | A1 | N | A2 | | N | A [f] | |
| **Whooping cough** Pertussis | | G1 | G2 | G3 | G4 | N | | A1 | N | A2 | | N | A [f] | |
| **Polio** Poliomyelitis | | G1 | G2 [a] | G3 | G4 | N | | | | A1 | | N | N (if required) | |
| **Hepatitis B** | | G1 | G2 [a] | G3 | G4 | N | | | | | | | | |
| **Hib** Haemophilus influezae type b | | G1 | G2 [a] | G3 | G4 | N | | | | | | | | |
| **Pneumococcal** [g] **disease** | | G1 | | G2 | G3 | N | | | | | | | | S [c] |
| **Rotaviruses** | G1 [b] | G2 | G3 | | | | | | | | | | | |
| **Meningococcal disease** Serogroup C | | | | | G1 From 12 months | | N | | | | | | | |
| **Measles** | | | | | G1 | G2 | N | | | | | | S [d] | |
| **Mumps Rubella** | | | | | G1 | G2 | N | | | | | | | |
| **Chicken Pox** Varicella | | | | | G1 | G2 | N | | | | | | | |
| **Flu** Influenza | | | | | | | | | | | | | | S (annually) |
| **HPV** Human papillomaviruses | | | | | | | | | | G1 [e] | G2 [e] | N [e] | | |

G **PRIMARY IMMUNISATION**
(up to 4 doses of vaccine G1-G4)

S **STANDARD VACCINATION**

A **BOOSTER VACCINATION**

N **CATCH-UP VACCINATION**
(primary immunisation of persons not yet vaccinated or completion of an incomplete vaccination series)

U **Well-child visit**

J **Well-adolescent visit**
(J1 aged 12-14 years)

a This dose is not required if a monovalent vaccine is administered.

b The 1st vaccine dose should be administered from the age of 6 weeks. Depending on the type of vaccine, 2 or 3 doses are required at intervals of a minimum of 4 weeks.

c Vaccination with polysaccharide vaccine, booster vaccination only recommended for specific indications.

d Single dose vaccinations for all individuals ≥ 18 years with unclear vaccination status and who were born after 1970, who have not been vaccinated or only received one vaccination as a child. Preferably with an MMR vaccine.

e Standard vaccination for girls ages 9-14. For catch-up vaccinations and number of vaccine doses see the summary of product characteristics.

f Td booster vaccination every 10 years. The next Td vaccination that is due is to be administered as a single dose vaccination in the form of Tdap or, if indicated, in the form of a Tdap-IPV combination vaccination.

g Premature infants receive an additional dose of vaccine at the age of three months, i.e. a total of 4 doses.

*Source*: German Standing Committee on Vaccination recommendations, 2018/19

Institute, covering all age groups. Based on these data, vaccination coverage rates can be assessed in a representative manner for different age groups (at least for people who are insured through statutory health insurance, i.e. around 87% of the German population) and at district level. Some of the regionalized data (measles and rotavirus vaccination) are made publicly available online.[2]

## Provision

Every physician in ambulatory care is allowed to provide vaccination services, irrespective of their specialization. Childhood vaccination against measles is usually undertaken by paediatricians as part of routine health check-ups for children. Adult vaccinations against influenza can also be provided by any physician, not only general practitioners. Company physicians are also allowed to conduct general vaccinations, such as against influenza. In addition, vaccinations are also organized and carried out by the health authorities.

## Financing

**Childhood vaccination against measles** is free of charge at the point of delivery and there are no co-payments. Vaccination against measles is included in the vaccination guidelines of the Federal Joint Committee and is therefore a mandatory benefit under statutory health insurance. The statutory health insurance funds cover the costs of vaccinations against measles for children and all adults born after 1970, and for all other vaccinations listed in the guidelines. According to the Association of Private Health Insurance Companies, vaccination coverage is regulated individually by every health insurance company. As a rule, private health insurance companies cover the costs of vaccinations recommended by the Standing Committee on Vaccinations. Health authorities, which also provide vaccination against measles, are financed through the federal state government.

Refugees are also entitled to (childhood and young adult) vaccination against measles, but the regulations are complex and access to health care varies between the federal states. During the first fifteen months of stay (1) some states require prior authorization for any medical treatment beyond emergency treatment (i.e. also for vaccination); (2) some states offer vaccinations in designated facilities; and (3) other federal states have opted for coverage of medical services under the statutory health insurance scheme. Irrespective of the means of access, vaccinations for refugees, as well as other medical treatments, are all financed through the federal state governments. Also nongovernmental organizations play a pivotal role in providing measles vaccinations to migrants and to other children without health insurance coverage.

For **adult vaccinations against influenza**, the same rules apply as in the case of measles vaccination. Vaccination is a mandatory statutory health insurance benefit and free of charge at the point of delivery for those population groups listed in the vaccination guidelines of the Federal Joint Committee. Listed groups include adults aged 60 years and older, pregnant women and all people with an increased health risk due to an underlying disease. Numerous sickness funds offer a range of vaccinations beyond those listed in the guidelines as a voluntary benefit, e.g. vaccination against influenza for insured persons who are not included in the risk groups.

For the upcoming influenza season (2018/19), the Standing Committee on Vaccinations is changing its recommendation on influenza vaccination. According to its assessment published in January 2018, the Committee sees an added benefit of a quadrivalent vaccine compared to a trivalent one. For the 2018/19 season the Joint Federal Committee has included the recommendation in the vaccination guidelines and thus created the conditions for allowing those with statutory health insurance to be vaccinated against seasonal influenza with a quadrivalent vaccine.

People who are not eligible for vaccination against influenza have to pay the physician out-of-pocket. However, many companies provide free-of-charge vaccinations for their employees.

## Key barriers and facilitators

Although vaccination is not mandatory in Germany, measles immunization coverage among 3-year-olds with one vaccine dose has been at about 97%, which is above the EU average. Immunization uptake and paediatric immunization rates have been steadily rising over the last decade. However, gaps still persist in the second dose of measles vaccine. About every third person among people older than 60 years is vaccinated against seasonal influenza, which is close to the EU average (OECD/European Observatory on Health Systems and Policies, 2017).

2 http://www.vacmap.de/

A facilitator for measles vaccination was the harmonization of the immunization schedule with routine health check-ups for children, and moving the second measles vaccine dose from age 6 into the second year of life. After this change in the immunization schedule, second dose coverage especially increased dramatically. A barrier to improved vaccination coverage against measles is the low coverage achieved 20 years ago and earlier, and the lack of a systematic catch-up for these age groups. The decentralized and privatized vaccination system in Germany has problems in actively reaching out to these age groups of adolescents and young adults and in systematically closing the remaining gaps. There is a routine adolescent check-up, but it is only taken up by approximately 50% of adolescent children.

For influenza, important barriers to improved vaccination coverage are the perceptions of the adult population in respect to the need for the vaccine and the severity of the disease, and mistrust in the vaccine and its perceived safety and effectiveness (Bödeker et al., 2015).

To give physicians in ambulatory care a financial incentive to provide vaccinations (or at least not to prevent vaccination for financial reasons), there is a separate remuneration mechanism for all listed vaccinations. Unlike many other primary care services, vaccinations are not tied to budget restrictions.

## References

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