ROBERT KOCH INSTITUT



CURRENT DATA AND INFORMATION ON INFECTIOUS DISEASES AND PUBLIC HEALTH

Epidemiologisches Bulletin

26. January 2023

2023

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Recommendations by the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute – 2023

Content

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These STIKO vaccination recommendations were endorsed in the 103rd STIKO meeting. This version replaces the previous STIKO vaccination recommendations published in Epidemiologisches Bulletin (Epid Bull) 4/2022 of the Robert Koch Institute (RKI). Differences between this publication and the previous one are marked in blue writing as well as with a blue line on either side of the new text. Major changes to the previous publication of 2022 concern the vaccine preventable diseases of Monkeypox (Mpox) and yellow fever. The respective scientific rationales for the STIKO recommendations have already been published in Epid Bull as well as on the websites of the RKI (www.stiko.de).

STIKO vaccination recommendations were updated on 25.05.2023 and the COVID-19 vaccination recommendation is now included in the main document (s. pages 6, 8, 16 and the Statement on the implementation of the COVID-19 vaccination into the general STIKO recommendations 2023).

Disclaimer

This document is a translation of the original Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute (http://www.rki.de/stiko-empfehlungen) on behalf of the Robert Koch Institute as of 04/2023. The German text is authoritative, and no liability is assumed for any translation errors or for the translation's correctness in case of subsequent revisions to the German original – DOI 10.25646/10829.

Imprint

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General notes/reprint

The issues starting from 1996 onwards are available on the internet: www.rki.de/epidbull

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ISSN 2569-5266



The Robert Koch Institute is an Institute within the portfolio of the Federal Ministry of Health.

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 Statement of the Standing Committee on Vaccination at the Robert Koch Institute (RKI)

Recommendations by the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute – 2023

1. Introduction

The Standing Committee on Vaccination (STIKO) is an independent expert committee, consisting of 12 to 18 members, as set out under the Protection Against Infection Act [Infektionsschutzgesetz (IfSG)]. The members are appointed by the German Federal Ministry of Health in consultation with the supreme federal state health authorities for a period of 3 years. The IfSG requires the commission to provide recommendations on vaccinations and other measures for the specific prophylaxis of communicable diseases. When developing a new vaccination recommendation, the STIKO conducts a medical and epidemiological risk-benefit assessment based on the best available evidence. This takes into account the benefit of the vaccination at population level (e.g. expected epidemiological effects of the vaccination recommendation). The STIKO recommendations serve as a basis for public recommendations from the supreme federal health authorities. In line with Volume V of the Social Insurance Code [Sozialgesetzbuch Fünftes Buch (SGBV)], the STIKO recommendations are the basis for decisions made by the Joint National Committee [Gemeinsamer Bundesausschuss (G-BA)] on whether the costs of the vaccination are covered by statutory health insurance.

Vaccinations are among the most effective and significant medical measures. Modern vaccines are well-tolerated, and irreversible serious adverse events (SAE) are very rarely seen. The immediate goal of vaccination is to protect an individual from a specific disease. A high level of vaccination acceptance allows high vaccination coverage rates to be achieved. It is therefore possible to achieve regional, and eventually global, elimination of certain pathogens. Elimination of measles, rubella, and poliomyelitis are declared and achievable goals of national and international health policy.

In Germany, vaccinations and other means of specific prophylaxis are "publicly recommended" by the health authorities of the federal states on the basis of the STIKO recommendations, in line with § 20 (3) of the Protection Against Infection Act [Infektionsschutzgesetz (IfSG)]. Compensation for vaccineinduced injury caused by "publicly recommended" vaccinations is assured by the federal states.

An important task for physicians is to ensure adequate immunisation of all those under their care. This means starting primary immunisation programmes early, for infants and toddlers, administering these vaccines without delay, and completing vaccination schedules in a timely manner. Following primary immunisation, physicians should use regular booster vaccinations when applicable to ensure that the necessary protection is maintained throughout the life of the individual, and that immunisation against further infectious diseases is initiated when indicated. Every visit to the physician should be used to check the vaccination records of children, adolescents, and adults, and to complete immunisation schedules when necessary.

As well as administering vaccines, the **vaccination services provided by physicians** include:

- Providing information on the disease to be prevented and the benefits of vaccination;
- Providing information on possible adverse events following immunisation;
- Taking the patient's medical and vaccination history, including possible contraindications;
- Determining current health status to exclude acute illnesses;

- Giving recommendations for post-vaccination behaviour;
- Giving information on the commencement and duration of the protective effect;
- Giving advice on booster vaccinations; and
- Documenting the vaccination in the patient's vaccination record or issuing a vaccination certificate.

2. Immunisation schedule (routine vaccinations)

The routine immunisation schedule for infants, children, adolescents and adults (Table 1) includes vaccinations against tetanus (T), diphtheria (D/d), pertussis (aP/ap), *Haemophilus influenzae* type b (Hib), poliomyelitis (IPV), hepatitis B (HB), herpes zoster (HZ), pneumococci, rotavirus (RV), meningo-coccal disease serogroup C (MenC), measles, mumps, rubella (MMR), varicella (V), human papillomaviruses (HPV) and influenza.

The recommended time for vaccination is indicated in weeks, months, and years. For example, "vaccination at the age of 5 to 6 years" means that vaccination should take place between the day of the child's 5th birthday and the day before their 7th birthday. Vaccination should take place at the earliest recommended time. To keep the number of injections as low as possible, combination vaccines should be used if available, and as long as they do not conflict with current STIKO recommendations. It is recommended that physicians check and, when necessary, update vaccination status at every age. Missing vaccinations should immediately be administered in line with the age-related recommendations. Please note that some catch-up vaccinations are only administered until a certain age. Rotavirus vaccination must be completed by the ages of either 24 or 32 weeks depending of the vaccine product used. Vaccination against pneumococci should be administered only until the age of 2 years and vaccination against Hib only until the age of 5 years.

There are some recommended minimum intervals between two vaccinations and it is possible to coadminister some vaccines. To check this, physicians should consult the Summary of Product Characteristics ("physician insert") for the vaccine product. It is particularly important for long-term vaccineinduced protection that the recommended minimum interval between the second-to-last and last vaccination is not shortened for primary immunisations.

Vaccination records should be checked and immunisations provided particularly during routine healthy child visits for infants and children, school entry health examinations, health checks that take place throughout schooling, adolescent health checks, examinations in line with the Young Persons Employment Act [Jugendarbeitsschutzgesetz], preventive medical examinations for adults, and routine examinations of mothers within the first 6-8 weeks after birth. People with chronic diseases should receive the standard vaccinations recommended in the immunisation schedule as long as there are no specific contraindications.

Because of the increased risk of acquiring infectious diseases or developing a severe course of a disease in early childhood, the goal must be to administer recommended vaccinations for infants **as early as possible**. Primary immunisations should be completed by the recommended age of 15 months at the latest. Experience shows that vaccinations started later than recommended are often not continued within the correct timeframe. Until vaccination gaps have been detected and closed, for instance at the school entry health examination, inadequately vaccinated children have insufficient vaccination protection. Age-appropriate full vaccination protection must be ensured before entry to a community facility, and at the latest before starting school.

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Vaccination against	Age in weeks				Age	in mont	sı							Age	in years			
	9	2	3	4	5-10		12	13–14	15	16–23	2-4	5-6	7-8	9–14	15–16	17	≥ 18	≥60
Routine health checks		Ξ	4		U5	ň				U7	U7a/U8	6N	010	ו(/ווח		J2		
Rotavirus (RV)	Γd	7	P2	(P3)														
Tetanus (T) ^b		١d		P2		P3c						B1		B2			B (if nece	ssary, C) ^e
Diphtheria (D/d) ^b		١d		P2		P3c						B1		B2			B (if nece	ssary, C) ^e
Pertussis (aP/ap) ^b		١d		P2		P3c						B1		B2			B3e	
Hib ^b – <i>H. influenzae</i> type b		١d		P2		P3€												
Poliomyelitis (IPV) ^b		١d		P2		P3c								B1				
Hepatitis B (HB) ^b		١d		P2		P3c												
Pneumococci ^b		١d		P2		P3c												S
Meningococcal disease serogroup C	1						Ľ											
Measles						١d			P2								٦	
Mumps, rubella						١d			P2									
Varicella (V)						١d			P2									
HPV – Human papillomaviruses														P1 ^d P2 ^d				
Herpes zoster (HZ)																		P1 ^h P2 ^h
Influenza																		S (annually)
COVID-19																	P1 ⁱ , P2 ⁱ , B1 ⁱ	Si

Recommended time of vaccination

of all individuals not yet vaccinated or completion Catch-up vaccination (primary immunisation of an incomplete series of vaccinations)

(consisting of up to 3 vaccine doses P1–P3) Primary immunisation Explanatory notes ۵

- Booster vaccination Standard vaccination പറ

- The first vaccination should be administered at the age of 6 weeks. Depending on the vaccine used, two or three vaccine doses must be given at least 4 weeks apart b
 - Premature infants should receive an additional vaccine dose at the age of 3 months, to give a total of four doses ٩
 - The previous vaccination should be at least 6 months in the past
- Routine vaccination for children and adolescents aged 9-14 years with two doses given at least 5 months apart. If given as catch-up vaccination, with the vaccination series beginning at age >14 years, or when the first and second doses were administered <5 months apart, a third dose is υυ
 - Td booster vaccination every 10 years. The next due Td vaccination may be administered as a single Tdap vaccination or, if indicated, a Tdap/IPV necessary (note package leaflet/summary of product characteristics) a
- Single vaccination using a MMR vaccine for all those born after 1970 and ≥18 years of age who are of unclear vaccination status, are unvaccinated, combination vaccination 4
 - or who received only one vaccination in childhood
 - Vaccination with 23-valent polysaccharide vaccine <u>ے م</u>
- Double vaccination with the adjuvanted herpes zoster inactivated vaccine at intervals of at least 2 to a maximum of 6 months
- Vaccination interval between P1 and P2 \ge 3 weeks (depending on vaccine licensure), and vaccination interval between P2 and B1 \ge 6 months
 - .__ *
- Repeated booster vaccination at least 12 months after the last antigen exposure, preferably in autumn Vaccinations can be administered at different vaccination appointments. MMR and V can be administered at the same appointment or 4 weeks apart

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3. Standard vaccinations for adults, indication-based vaccines, boosters, and vaccinations to manage travel or elevated job risk

3.1 Overview

For the implementation of the immunisation schedule for infants, children, adolescents and adults (see Table 1) vaccination status should be checked regularly and brought up to date where necessary. All medical consultations provide suitable opportunities.

As well as standard vaccinations (S), other vaccinations may be indicated in particular epidemiological situations or where there is a particular hazard to children, adolescents, and adults. These are known as indicated vaccinations (I). Vaccinations to manage occupational risks (O) and travel vaccinations (T) are particular cases of indicated vaccinations. Travel vaccinations may be required to comply with international health regulations (including yellow fever vaccination) or may be recommended for individual protection while travelling.

Physicians are responsible for recommending the type and chronological order of vaccinations in each individual case, considering the indications and, where applicable, existing contraindications.

If an individual indication for vaccination is not covered by a license valid for Germany or by the Summary of Product Characteristics of the corres-

As well as vaccinations recommended by STIKO, further vaccinations might be indicated based on the existing licensing of a vaccine. These specific indications are not further discussed here, but they can be relevant for the protection of individuals, depending on their health situation. Physicians are responsible for informing patients of these additional protective options. The lack of a STIKO recommendation should not prevent physicians from carrying out further vaccinations when justified. ponding vaccine, this is known as an off-label use. In case of injury, off-label use has consequences for liability and compensation. The physician administering the vaccine therefore has particular obligations for documentation and the provision of information (see chapter 4.1 and chapter 4.2). Benefit claims for a recognised injury from vaccination pursuant to §60 Protection Against Infection Act (Infektionsschutzgesetz [IfSG]) are granted only for vaccinations officially recommended by state health authorities.

The vaccinations in <u>Table 2</u> differ in both their epidemiological relevance and the coverage of costs (see notes on the cost coverage of protective vaccines). They are divided into the following categories:

- **S** Standard vaccinations for universal application (see also Table 1, immunisation schedule)
- **B** Booster vaccinations
- I Indicated vaccinations for risk groups with an individually (not occupationally) increased risk of exposure, illness, or complication, as well as for the protection of third parties
- O Vaccinations due to an increased occupational risk, for example after risk assessment according to the Occupational Health and Safety Act [Arbeitsschutzgesetz]/Ordinance on Biological Substances [Biostoffverordnung]/Ordinance on Occupational Health and Safety Precautions [Verordnung zur arbeitsmedizinischen Vorsorge] and/or for the protection of third parties in the context of occupational activity
- T Travel vaccinations

Table 2 | Recommendations on standard vaccinations for adults, and indication-based vaccines and boosters for all age groups

	Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
	Cholera	т	 travel in areas with a cholera epidemic with unsure/ limited access to clean drinking water long-term occupation in areas with a cholera epidemic work as a disaster relief worker Further information: see recommendations on travel vaccinations of STIKO 	According to the Summary of Product Characteristics.
Updated on 25.05.2023	COVID-19 (Coronavirus Disease 2019)		For the recommended COVID-19 vaccination (indication g publication on implementing COVID-19 vaccination in the	roups, etc.), please refer to <u>table B in the STIKO</u> general STIKO recommendations 2023.
	Diphtheria	S/B	Anyone with absent or incomplete primary immunisa- tion, or if either the last vaccination for the basic immunisation or the last booster vaccination was more than 10 years ago.	Adults should receive the next due diphtheria vaccination as a single Tdap combination vaccination or, if indicated, a Tdap-IPV combination vaccination. Unvaccinated people or those with no vaccination record should receive two vaccine doses at intervals of 4–8 weeks and a third vaccine dose 6–12 months after the second vaccine dose. Travel to an epidemic area should not be undertaken before receipt of two doses.
	Haemophilus influenzae type b (Hib)	I	People with anatomical or functional asplenia (e.g. sickle cell anaemia).	Single dose vaccination. The usefulness of revaccination cannot be assessed at present because of insufficient data.
	Hepatitis A (HA)	I	 People with increased risk of sexual exposure (anogenital-oral transmission) People who frequently receive blood components, e. g., injecting drug users, haemophiliacs, or people with liver disease/general conditions affecting the liver. Residents of psychiatric institutions or comparable welfare facilities for people with behavioural disorders or cerebral damage 	Primary immunisation and booster vaccination according to the Summary of Product Characteristics. Serological screening for anti-HA vaccination is required only for people who have lived for prolonged periods in endemic regions, grew up in families from endemic regions or were born before 1950.
		ο	 People who are at increased risk of occupational exposure, including trainees, interns, students and volunteers with comparable exposure risk, for example: Healthcare workers (including medical and rescue services, kitchen, laboratory, technical and cleaning services, psychiatric and welfare institutions) People in contact with sewage e.g. sewer system and wastewater workers Employment (including kitchen and cleaning) in children's day care centres, children's homes, sheltered employment facilities, refugee shelters, and the like 	
		т	Those travelling in regions with a high prevalence of hepatitis A. Further information: see <u>recommendations on travel</u> vaccinations of STIKO.	

Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Hepatitis B (HB)	I	 People at risk of severe hepatitis B because of an existing or expected immunodeficiency or immuno- suppression, or other pre-existing diseases, for example: HIV-positive or hepatitis C-positive individuals, and patients on haemodialysis.^a People at increased risk of non-occupational exposure, for example: people in contact with HBsAg carriers in the family or flat share, people at high risk of acquiring hepatitis B through sexual contact, injecting drug users, prison inmates, and psychiatric inpatients.^a 	For indication groups 1–4, the following applies: Routine serological testing before hepatitis B vaccina- tion to rule out an existing HBV infection is not necessary. There is no risk in vaccinating someone already infected with HBV against infection, but the vaccination is not effective. Serological testing can be reasonable in specific situations (for example, for financial reasons, to avoid unnecessary vaccinations, or in case of high anamnestic risk of exposure, including if a sexual partner is HBsAg positive).**
	0	3. People at increased risk of occupational exposure, in- cluding trainees, interns, students and volunteers with comparable exposure risk, for example: healthcare personnel (including laboratory personnel and clea- ning personnel), medical and rescue services, occupa- tional first aid providers, police officers, and personnel at facilities with large numbers of hepatitis B-virus (HBV)-infected people (for example, correctional facilities, shelters for refugees, immigrants or asylum seekers, and homes for disabled people). ^{•,•**}	To monitor vaccination success, anti-HBs level should be determined 4–8 weeks after the third vaccine dose (successful vaccination: anti-HBs $\geq 100 \text{ IU/I}$).*** For "low-responders" (anti-HBs 10–99 IU/I), an immediate additional vaccine dose is recommended, with repeated anti-HBs monitoring 4–8 weeks after vaccination. If anti-HBs is still < 100 IU/I, up to two additional doses are recommended with subsequent anti-HBs monitoring 4–8 weeks after each vaccination. There is controversy over reasonable proceedings if the anti-HBs level remains < 100 IU/I after the administrati- on of six vaccine doses; for further explanation, see Epid Bull 36/37 2013. ⁷
	Т	 4. Travel-related indication: an individual risk assessment is required.*** Further information: see recommendations on travel vaccinations of STIKO. * This list of groups provides examples and is not intended to be a be based on assessment of the actual exposure risk (see Epid Bull In the field of occupational health services, the recommendations (Verordnung zur arbeitsmedizinischen Vorsorge] should also be co ** For people in group 4 (travel vaccination), it is necessary. 	For "non-responders" (anti-HBs < 10 IU/I), testing for HBsAg and anti-HBc is recommended to exclude an existing chronic HBV infection. If both parameters are negative, proceed as described for "low-responders" above. After successful primary vaccination, defined as anti-HBs \geq 100 IU/I, routine booster immunisations are usually not necessary. The exceptions are patients with humoral immune deficiency (annual anti-HBs monitoring and a booster dose when anti-HBs < 100 UI/I), and if applicable, people who are at particularly high individual exposure risk (anti-HBs monitoring after 10 years and a booster dose if anti-HBs < 100 UI/I). An additional vaccine dose followed by serological moni- toring, as described above, should be administered to people vaccinated against hepatitis B during infancy but with a newly-developed risk of hepatitis B infection (see indications 1–4) and unknown anti-HBs level.
Herpes zoster (HZ)	S	Adults ≥ 60 years of age	Two vaccinations with the adjuvanted herpes zoster inactivated vaccine at intervals of at least 2 to max. 6 months.
	I	 Adults ≥ 50 years of age in case of increased health risk resulting from an underlying disease, for example: Congenital or acquired immunodeficiency or immunosuppression; HIV infection; Rheumatoid arthritis; Systemic lupus erythematosus; Chronic inflammatory bowel disease; Chronic obstructive pulmonary disease or bronchial asthma; Chronic renal insufficiency; Diabetes mellitus 	
		Vaccination with the live herpes zoster vaccine is not recommended as standard vaccination.	See <u>chapter 3.2</u>

Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Human papilloma- viruses (HPV)			See <u>HPV</u>
Influenza	S	Adults ≥ 60 years of age	Yearly vaccination in autumn with an inactivated quadrivalent high-dose vaccine containing the current antigen combination recommended by the World Health Organization (WHO).
	I	All pregnant women from the second trimester, or from the first trimester in case of an increased health risk resulting from an underlying disease.	Vaccination with an inactivated quadrivalent vaccine containing the current antigen combination recommended by the WHO.
		 People from 6 months of age with an increased health risk resulting from an underlying disease, for example: Chronic diseases of the respiratory tract, including asthma and chronic obstructive pulmonary disease (COPD) Chronic cardiovascular, liver and kidney disease Diabetes and other metabolic diseases Chronic neurological diseases, e.g., multiple sclerosis with relapses triggered by infections Congenital or acquired immunodeficiency or immuno-suppression HIV infection Residents of retirement or nursing homes. People who might act as a potential source of infection for at-risk patients by living in the same household or providing care. People at risk are considered to include anyone with underlying diseases of the above-mentioned examples, who are more likely to experience a reduced response to influenza vaccines. 	Annual vaccination in autumn with an inactivated quadrivalent vaccine containing the current antigen combination recommended by the WHO. Children and adolescents aged 2 to 17 years can alternatively be vaccinated with a live attenuated influenza vaccine (LAIV) if no contraindications exist (see Summary of Product Characteristics). If there are reasons for not using an injection (e.g. injection phobia, coagulation disorders) LAIV should be used preferentially. For persons from the age of 60 and older inactivated quadrivalent high-dose vaccines are recommended.
		If a severe epidemic is considered to be likely, based on experiences in other countries, or is expected following a manifest antigenic drift or antigenic shift, and the vaccine contains the new variant.	According to the recommendations of the health authorities (pandemic plans of the federal states: www.rki.de/pandemieplanung > pandemic plans of the federal states).
	Ο	People at increased risk, e.g., medical personnel, people in establishments dealing extensively with the public, and people who may act as a possible source of infection by caring for individuals at particular risk. People at increased risk because of direct contact with poultry and wild birds.* • Vaccination with the current seasonal human influenza vaccine do influenza virus. It can, however, prevent double infection with the ABAS at www.baua.de > Topics from A-Z > Biological Agents > Tee	Yearly vaccination in autumn with inactivated quadriva- lent vaccine containing the current antigen combination recommended by the WHO. For persons from the age of 60 and older inactivated quadrivalent high-dose vaccines are recommended. es not offer direct protection against infection with the avian currently circulating influenza viruses (see also: TRBA 608 of the chnical Rules for Biological Agents).
	т <i>ү</i> і	Vaccination is generally advisable for travellers aged >60 years and the groups named under I (indicated vaccination) whose influenza vaccination status is not up to date. Further information: see <u>recommendations on travel</u> vaccinations of STIKO.	Vaccination with a quadrivalent vaccine containing the current antigen combination recommended by the WHO. For persons from the age of 60 and older inactivated quadrivalent high-dose vaccines are recommended.
Japanese encephalitis	т	 Periods of residence in endemic areas (South-East Asia, large parts of India, Korea, Japan, China, West Pacific, North Australia) during the transmission period, particularly during travels in current outbreak areas long term visits (>4 weeks) repeated short-term stays expected periods of residence near rice fields and pig farms (not only in rural areas) Further information: see recommendations on travel vaccinations of STIKO. 	Basic (primary) immunisation with two doses; one booster vaccination before re-exposure with a minimum timeframe of 12 months after basic (primary) immunisation
	0	Laboratory staff working specifically with reproductive JEV wild-type strains	

Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Measles	s	Those \ge 18 years and born after 1970 with unclear vaccination status, who have not been vaccinated, or who received only one vaccination during childhood.	Single vaccine dose with an MMR vaccine.
	I	Forthcoming admission or visit to a community facility (e.g. Kindergarten, day care facility for children): ▶ Infants from the age of 9 months	Vaccination with two doses of an MMR/V [*] -vaccine. Provided that the first vaccination was given at the age of 9 to 10 months, the second MMR/V vaccination should be given at the beginning of the second year of life.
		 During an outbreak: Those born after 1970, from the age of 9 months, with unclear vaccination status, who are unvaccinated, or who received only one vaccination during childhood. Exceptionally 6 to 8 month-old infants after individual risk benefit consideration (off-label-use) MMR/V = MMRV or MMR is co-administration with VZV vaccine 	Single vaccination with MMR(V)** vaccine. If necessary complement vaccinations according to the recommendations applying for the relevant age group. Provided that the first vaccination has been given at the age of 9 to 10 months, the second MMR/V* vaccination should be given at the beginning of the second year of life. With first vaccination at the age of 6 to 8 months a second and third MMR/V* vaccination should be administered at the age of 11 and 15 months.
		 MMR(V) = MMR with or without co-administration of VZV vaccine 	
Measles, Mumps, Rubella (MMR)	0	Individuals born after 1970 in the following fields of professional activity (including trainees, interns, students and volunteers): Medical facilities (according to [23 (3) sentence 1)	Vaccination with two doses of an MMR-vaccine (or, if varicella vaccination is indicated at the same time, with a MMR/V-vaccine).
		IfSG) including facilities of other human medical health care professions	component with the least documented vaccinations. For women, each of the three vaccine components
		 Care facilities for mostly elderly people (according to §71 SGBXI) Community facilities e. g. day care facility for children or pupils (according to §33 IfSG) 	(M-M-R) requires vaccination with two doses. For men, the measles and mumps components require vaccination with two doses. For protection against rubella, a single vaccination is sufficient.
		 Institutions housing immigrants, refugees and asylum seekers Technical and vocational colleges, universities 	vaccination(s) with existing immunity against individual components.
Meningo- cocci	I	 Those whose health is at risk: people with congenital or acquired immunodeficiencies, especially those: With complement/properdin deficiencies, Receiving complement C5-inhibitor therapy with e.g. Eculizumab or Ravulizumab With hypogammaglobulinaemia With anatomic or functional asplenia (e.g. sickle cell anaemia). 	Vaccination with meningococcal-ACWY-conjugate vaccine and a men-B vaccine. For further details on implementation of meningococcal vaccination see <u>chapter 3.2</u> .
		During outbreaks or regional clusters upon recommen- dation by the local health authorities. Further information: see Table 6.	In line with the recommendations of the health authorities.
	0	At-risk laboratory personnel (for work involving a risk of <i>N. meningitidis</i> aerosols).	Vaccination with meningococcal-ACWY-conjugate vaccine and a men-B vaccine.
	т	Those travelling to countries with epidemic occurrences, especially if they will be in close contact with the indigenous population (e.g. development aid workers, disaster relief workers, medical personnel, long-term stayer). This also applies to stays in regions with disease outbreaks and vaccination recommendation for the indigenous population (note WHO and country-specific information). Further information: see recommendations on travel vaccinations of STIKO.	Vaccination with meningococcal-ACWY-conjugate vaccine, for disaster relief workers additionally a men-B vaccine.
		Before a pilgrimage to Mecca (Hajj, Umrah). Further information: see recommendations on travel vaccinations of STIKO.	Vaccination with a meningococcal-ACWY-conjugate vaccine. Take note of entry regulations.
		Before long-term stays, especially children and adolescents as well as students or people in training of a specific occupation.	Vaccination with Menigococcal-ACWY-conjugate vaccine and/or men-B vaccine in line with the recommendations of the destination countries.
		Further information: see recommendations on travel vaccinations of STIKO.	

Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Mpox/ Monkeypox and other	1	Men who have sex with men (MSM) and are ≥ 18 years of age and frequently change sexual partners.	Persons ≥ 18 years should receive 2 subcutaneous do- ses of Imvanex [*] vaccine (Modified Vaccinia Ankara, Bavarian Nordic [MVA-BN]) at least 28 days apart
Orthopox- viruses	Ο	Personnel in specialised laboratories who carry out specific activities with infectious samples containing orthopox material and who are classified as at risk of infection after an individual risk assessment by the safety officer.	 For persons who have been vaccinated against smallpox in the past, a single vaccine dose is sufficient. equivalent the vaccine Jynneos of Bavarian Nordic can be used (as good as identical with Imvanex)
Mumps	0	See under Measles, Mumps, Rubella	
Pertussis	S/B	Adults should receive the next due Td vaccine as a single Tdap combination vaccine.	Vaccination with a Tdap combination vaccine, or if indicated, as a Tdap-IPV combination vaccine (for available vaccines, please see Table 11.
	I	Pregnant women at the beginning of the 3 rd trimester (from the 28 th week of pregnancy).	Tdap combination vaccine, if indicated as a Tdap IPV combination vaccine.
		If there is an increased probability of premature birth, vaccination should be administered during the 2 nd trimester.	Vaccination independent of timeframe to a previously administered pertussis vaccine and vaccination in every pregnancy.
		If in the last 10 years there has been no pertussis vaccination, the following groups should receive one dose of pertussis vaccine: ▶ people in close household contact (e.g. parents° and siblings, friends) and caregivers of newborns (e.g. day care providers, babysitters, and where applicable grandparents), if possible at the latest 4 weeks before the birth of the child	Vaccination with a Tdap combination vaccine, or if indicated, as a Tdap-IPV combination vaccine (for available vaccines, please see <u>Table 11</u>).
		\circ $\;$ If a mother was not vaccinated during the pregnancy, she should i	deally be vaccinated in the first few days after the birth of her child.
	0	If in the last 10 years there has been no pertussis vaccination, personnel in healthcare as well as in community facilities should receive one dose of pertussis vaccine.	
Pneumococci	S	Adults ≥ 60 years of age.	Vaccination with 23-valent polysaccharide vaccine (PPSV23). If applicable, repeat vaccinations with PPSV23 at intervals of at least 6 years according to individual indication, see <u>chapter 3.2</u> .
	I	 Children, adolescents and adults at increased health risk as a result of an underlying disease: 1. Congenital or acquired immunodeficiencies, such as: T-cell deficiency or defective T-cell function B-cell or antibody deficiency (e.g. hypogammaglobulinaemia) Deficiency or dysfunction of myeloid cells (e.g. neutropenia, chronic granulomatosis, leukocyte adhesion deficiencies, signal transduction defects) Complement and properdin deficiencies Functional hyposplenism (e.g. sickle cell anaemia), splenectomy," or anatomical asplenia Neoplastic diseases HIV infection After bone marrow transplantation Immunosuppressive therapy" (e.g. because of organ transplantation or autoimmune disease) Immunodeficiency resulting from chronic kidney failure, nephrotic syndrome or chronic liver insufficiency Other chronic diseases, such as: Chronic diseases of the cardiovascular system or of the respiratory tract (e.g. asthma, emphysema, or COPD) Metabolic diseases, e.g. diabetes mellitus treated with metafeatine in the spiratory in cardioastic diseases 	 Sequential vaccination with 13-valent conjugate vaccine (PCV13), followed by PPSV23 after 6–12 months. PPSV23 should only be given to individuals aged 2 years and older.** Update from 17.05.2023: PCV13 or PCV15 can be used for children an adolescents aged 2–17 years Individuals 16 years of age or older should receive a vaccination with PPSV23; those aged 2–15 a sequential vaccination with PCV13, followed by PPSV23 after 6–12 months.**
		 Neurological diseases, e. g. cerebral palsy or seizure disorders 	

Pneumococci (continued) I 3. Anatomical and foreign-material associated risks for pneumococcal meningitis, such as: Cerebral spine fluid fistula Cochlea implant* Sequential vaccination with PCV13 followed PPSV23 after 6–12 months. PPSV23 should given to individuals aged 2 years and older. Professional activity such as welding or separating metal-loading to exposure to metal smoke, including metal-oxidic welding smoke. Polio- myelitis S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. Adults are considered fully immunised of they received primary immunisation as adults in accordance with the of Product Characteristics and have also receive booster vaccination. A vaccination is indicated for the following groups of persons: Those traveling in regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) Immigrants, refugees and asylum seekers who live in	l by only be
Polio- myelitis O Professional activity such as welding or separating metals leading to exposure to metal smoke, including metal-oxidic welding smoke. Vaccination with PSV23 and repeat vaccinations" Polio- myelitis S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. Vaccination with PSV23 and repeat vaccination provide welding smoke. Polio- myelitis S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. Adults are considered fully immunised if they the complete primary immunisation in infanc- childhood and at least one booster vaccinatio adolescence or later, or if they received primar immunisation as adults in accordance with th of Product Characteristics and have also recei booster vaccination. I A vaccination is indicated for the following groups of persons: People with no primary immunisation record receive at least two doses of IPV-vaccine in inf 4 weeks before starting any travels. I A vaccination is indicated for the following groups of persons: People with no primary immunisation record receive at least two doses of IPV-vaccine in inf 4 weeks before starting any travels. Vaccination or booster vaccination with PV, if (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) People with no primary immunisation 4 weeks in Afghanistan Pakistan, the STIKO recommends a poliowy	at intervals of
O Professional activity such as welding or separating metals leading to exposure to metal smoke, including metal-oxidic welding smoke. Vaccination with PPSV23 at minimum intervals of 6 years as lo exposure continues. Poliomyelitis S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. Adults are considered fully immunisation in infanc childhood and at least one booster vaccinatio adolescence or later, or if they received primary immunisation as adults in accordance with th of Product Characteristics and have also receive booster vaccination. I A vaccination is indicated for the following groups of persons: People with no primary immunisation record the Summary of Product Characteristics. Other routine booster vaccination adolescence or leater, or if Nose travelling in regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) People with no primary immunisation record receive at least two doses of IPV-vaccine in immunisation is incomplete or not fully docur for a stay of less than 4 weeks in Afghanistan Pakistan, the STIKO recommends a poliomyer	at intervals of
 Poliomyelitis S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. Adults are considered fully immunisation in infanc childhood and at least one booster vaccination adolescence or later, or if they received primary immunisation as adults in accordance with th of Product Characteristics and have also recei booster vaccination. Missing or not documented primary immunisation record the Summary of Product Characteristics. A vaccination is indicated for the following groups of persons: Those travelling in regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) I Immigrants, refugees and asylum seekers who live in 	on with
Poliomyelitis S/B Anyone with no or incomplete primary immunisation. Anyone without a one-off booster vaccination. Adults are considered fully immunised if they the complete primary immunisation in infanc childhood and at least one booster vaccinatio adolescence or later, or if they received primary immunisation as adults in accordance with th of Product Characteristics and have also receives the Summary of Product Characteristics. I A vaccination is indicated for the following groups of persons: People with no primary immunisation record the Summary. I A vaccination is regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) People with no primary immunisation with IPV, if immunisation is incomplete or not fully docut For a stay of less than 4 weeks in Afghanistam Pakistan, the STIKO recommends a poliomyer	ng as
 Missing or not documented primary immunis vaccinations are reinstated with IPV in accord the Summary of Product Characteristics. Other routine booster vaccinations are not red ded for adults in Germany. A vaccination is indicated for the following groups of persons: Those travelling in regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) Immigrants, refugees and asylum seekers who live in 	received y and n in 'y e Summary ved a
 A vaccination is indicated for the following groups of persons: Those travelling in regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) Immigrants, refugees and asylum seekers who live in 	ation ance with
 A vaccination is indicated for the following groups of persons: Those travelling in regions with risk of infection by wild poliovirus (WPV) or by a mutant vaccine virus strain (circulating vaccine-derived poliovirus [cVDPV]) (the current epidemic situation must be taken into account, especially WHO reports) Immigrants, refugees and asylum seekers who live in 	Johnmen-
communal accommodation, entering from regions at risk of polio; see chapter 4.12	should ervals of primary mented. or slitis las been
Further information: see recommendations on travel vaccinations of STIKO. Stringent temporary recommendations if a sta four weeks, e.g. proof of correct vaccination s (information from the WHO: https://www.wh groups/poliovirus-ihr-emergency-committee).	y exceeds tatus, o.int/
 Personnel in institutions housing immigrants, refugees and asylum seekers from regions at risk of polio Medical personnel who may come into close contact with cases Personnel in laboratories with a risk of infection with poliomyelitis 	primary e primary /as more
Rabies O Veterinarians, hunters, forest workers and other people who handle animals in areas where there is a new occurrence of rabies among wild animals; Dosage schedule according to the Summary of Characteristics.	Product
 People with professional or other close contact with bats; I aboratory personnel at risk of exposure to rabies I aboratory personnel at risk of exposure to rabies 	Summary of
viruses be examined every 6 months for neutralising ar	itibodies.
 T Those travelling in regions with a high risk of rabies and an increased probability of exposure to rabies (e. g. through contact with stray dogs or bats). 	il serum.
vaccinations of STIKO.	
Rubella I Women of childbearing age who are non-immunised or with an unclear vaccination status. ⁴³ Two vaccinations with MMR vaccine. Women of childbearing age only vaccinated once ⁴³ One vaccination with MMR vaccine.	
O See under Measles, Mumps, Rubella	
Tetanus S/B Anyone with no or incomplete primary immunisation, or if the last primary immunisation vaccination or the last booster vaccination was more than 10 years ago. Adults should receive the next due tetanus vac a single Td combination vaccination, or if indic Tdap or Tdap-IPV combination vaccination. Incomplete primary immunisation should be completed by the statement of the stat	

Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)	
TRF	1	Persons exposed to ticks in TBE risk areas.	Primary immunisation and booster vaccinations with a	
(tick-borne encephalitis)	0	Persons at risk of TBE through their profession (exposed laboratory personnel as well as those in risk areas, including forest workers and those exposed during farming).	vaccine authorised for adults and/or children according to the Summary of Product Characteristics. According to the recommendations of the health authorities. Information on TBE risk areas must be	
	т	Tick exposure in TBE risk areas outside Germany.	noted; these are published in Epid Bull 9/2022.	
		Further information: see recommendations on travel vaccinations of STIKO.	 Note seasonality: April – November Risk areas in Germany are currently in particular: Baden-Wurttemberg (except for city district of Heilbronn) Bavaria (except for a few districts in Swabia and western Upper Bavaria) 	
		Following the update of the areas at risk for TBE, the following 3 districts have been	 Brandenburg (new in 2022: district of Oberspree- wald-Lausitz, district of Oder-Spree, district of Spree-Neiße) 	
		added in 2023: Bavaria: SK München, LK Fürstenfeldbruck Sachsen-Anhalt: LK Anhalt-Bitterfeld TBE risk areas (as of January 2023) are published in Epid Bull 9/2023.	Hesse (district of Odenwald, district of Bergstraße, district of Darmstadt-Dieburg, city district of Darmstadt, district of Groß-Gerau, district of Offen- bach, city district of Offenbach, district of Main-Kinzig- Kreis, district of Marburg-Biedenkopf, district of Fulda)	
			 Lower Saxony (district of Emsland) North Rhine-Westphalia (new in 2022: city district of Column) 	
			Solingen) Phinaland-Palatinate (district of Birkenfeld)	
			 Saarland (district of Saar-Pfalz) 	
			 Saxony (city district of Dresden, district of Vogtland- kreis, district of Erzgebirgskreis, district of Bautzen, district of Meißen, district of Zwickau, district of Sächsische Schweiz-Osterzgebirge, district of Mittel- sachsen; new in 2022: city district of Chemnitz, district of Goerlitz) 	
			 Saxony-Annat (city district Dessal-Roislad) Thuringia (city district of Jena, city district of Gera, district of Saale-Holzland-Kreis, district of Saale-Orla- Kreis, district of Saalfeld-Rudolstadt, district of Hild- burghausen, district of Sonneberg, district of Greiz, district of Ilm-Kreis, district of Schmalkalden-Meinin- gen, city district of Suhl, district of Weimarer Land) 	
Tuberculosis		Vaccination with a BCG vaccine is not recommended.		
Typhoid fever	т	When travelling in endemic regions with stays under poor hygienic conditions. Further information: see recommendations on travel vaccinations of STIKO.	According to the Summary of Product Characteristics.	
Varicella	I	I	Seronegative women who wish to conceive,	Two doses of varicella vaccine.
Varicella			 Seronegative patients before planned immunosup- pressive therapy or organ transplantation, Susceptible patients" with severe neurodermatitis, Susceptible persons" in close contact with the two pre- vious groups 	For information on the vaccination of seronegative patients receiving immunosuppressive therapy, please refer to www.rki.de/immundefizienz.
		 "Susceptible persons" are defined as individuals with no vaccinati serological testing 	ion and no history of varicella or no specific antibodies detected upon	
	0	 Seronegative personnel (including trainees, interns, students and volunteers) in the following fields of professional activity: Medical facilities (according to §23 (3) Satz 1 IfSG) including facilities of other human medical health care professions Activities involving contact with potentially infectious material Care facilities for mostly elderly people (according to §71 SGB XI) Community facilities e.g. day care facility for children 	Two doses of varicella vaccine (use of a MMR/V- combination vaccine is recommended if MMR vaccination is indicated at the same time).	
		or pupils (according to §33 IfSG) Institutions housing immigrants, refugees and asylum seekers		

(Table 2 continued)

Vaccination against	Cate- gory	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Yellow fever	0	When working in direct contact with yellow fever virus (e.g. in research institutions or research laboratories).	Vaccination in yellow fever immunisation facilities approved by health authorities. A single booster dose should be administered prior to re-exposure or in case of continued exposure if 10 or more years have passed since the primary vaccination dose. After the 2 nd vaccine dose, no further booster vaccinations are necessary (max. 2 vaccine doses).
	т	 A list of countries with a risk of yellow fever transmission and countries that require a yellow fever vaccination upon entry is provided by the WHO (www.who.int/health-topics/yellow-fever). Further information: see recommendations on travel vaccinations of STIKO and DTG. 	Vaccination in yellow fever immunisation facilities approved by health authorities. A single booster dose should be given prior to re-exposure or in case of continued exposure if 10 or more years have passed since the primary vaccination dose. After the 2 nd vaccine dose, no further booster vaccinations are necessary. Exceptions and particularities for the following groups of people should be noted:
			Pregnant women: If the primary vaccine dose was given during pregnancy a 2 nd vaccine dose (booster dose) should be administered prior to re-exposure or in case of continued exposure regardless of the interval between primary and booster dose (max. 2 vaccine doses).
			Immunodeficient persons: If at the timepoint of the primary vaccination an immunodeficiency exists, a 2 nd vaccine dose should be administered before re-exposure, regardless of the interval between primary vaccination and booster vaccination, in the absence of a contraindication. No serological testing is generally required before or after the 2 nd vaccine dose. Before re-exposure or in case of continued exposure, the administration of further vaccine doses should be decided on an individual basis.
			Children: In case of the 1 st vaccine dose before the 2 nd birthday, a 2 nd yellow fever vaccine dose should be administered before re-exposure or in case of continued exposure, provided that 5 or more years have passed since the primary vaccination. No further vaccine dose is necessary in adulthood, provided 2 vaccine doses have been administered in childhood. If only 1 vaccine dose was administered in childhood, a 2 nd vaccine dose is recommended before re-exposure in adulthood. In case of the 1 st vaccine dose after the 2 nd birthday, a 2 nd vaccine dose should be administered before re-exposure or in case of continued exposure, if 10 or more years have passed since the primary vaccination (max. 2 vaccine doses).
			The International Certificate of Yellow Fever vaccination is valid for life. This applies to new and existing yellow fever vaccination certificates.
			Scientific rationale published in Epid Bull 32/2022.4

3.2 Remarks on individual vaccinations

This chapter discusses immunization schemes and application instructions for individual vaccinations. For follow-up vaccinations and irregular vaccination schemes, please refer to the age-appropriate Tables 10A-E in chapter 6.10. Trade names and age of application for the recommended vaccines are summarized in Table 11 in chapter 6.10. In principle, the information given in the technical data sheet of the individual vaccine is binding. Further helpful information on the use of individual vaccines can be found in the "frequently asked questions" (FAQs) on

the RKI website at www.rki.de/impfungen-a-z. Information on supply bottlenecks and details of alternative vaccines can be found on the websites of the Paul Ehrlich Institute (PEI) and STIKO.

Those insured by statutory health insurance companies are entitled to benefits for protective vaccinations listed in the protective vaccination guidelines of the Federal Joint Committee. Further information on this and on the assumption of costs for vaccinations with professional (occupational) indications can be found in chapter 4.14. In the case of travel vaccinations, the assumption of costs must be clarified on an individual basis; if necessary, the patient must pay for the vaccination himself.

Cholera

In Germany, two cholera vaccines are currently licensed (Dukoral and Vaxchora). Dukoral is an oral vaccination containing attenuated cholera pathogens. In adults and children aged 6 years and older, primary immunisation against cholera consists of two doses, administered with an interval of a minimum of 1 to a maximum of 6 weeks. Children aged 2 to 5 years of age should receive 3 doses (minimum interval of 1 week between vaccine doses). The vaccination should be completed at least 1 week before entering an endemic area. Vaxchora is a live vaccine which is orally administered. In adults and children aged 2 years and older a single dose is sufficient for primary immunisation. Vaxchora should be administered at least 10 days before scheduled departure to an endemic area.

Coronavirus Disease 2019 (COVID-19)

The recommendations for the vaccination against COVID-19 have been included into the current general STIKO recommendations. For COVID-19 vaccination recommendations (indication groups, etc.), please refer to Table B in the STIKO publication on implementing COVID-19 vaccination in the general STIKO recommendations 2023.

Diphtheria

For primary immunization of gestational infants against diphtheria, three doses of vaccine at the ages of 2, 4 and 11 months are recommended (see Epid Bull 26/2020).³ It is advisable to perform these vaccinations with a combination vaccine (e.g. DTaP-IPV-Hib-HepB) which simultaneously protects against tetanus, diphtheria, whooping cough, polio, *Haemophilus influenzae* type b and hepatitis B. For premature babies (born before completed 37 weeks of pregnancy), 4 doses of vaccine at the ages of 2, 3, 4 and 11 months are recommended.

There should be an interval of at least 6 months between the last and the preceding dose of the respective vaccination schedule. Booster vaccinations are recommended at 5-6 years and 9-16 years of age and then at intervals of 10 years. From the age of 5

or older, a vaccine with reduced diphtheria toxoid content (d) is used for booster vaccination and for primary immunisation, generally combined with tetanus toxoid and pertussis antigen (TdaP) or other indicated antigens.

Haemophilus influenzae type b (Hib)

For primary immunization of gestational infants against Hib, three doses of vaccine at the ages of 2, 4 and 11 months are recommended (see Epid Bull 26/2020).³ It is advisable to perform these vaccinations with a combination vaccine (e.g. DTaP-IPV-Hib-HepB) which simultaneously protects against tetanus, diphtheria, whooping cough, polio, *Haemophilus influenzae* type b and hepatitis B. For premature babies (born before completed 37 weeks of pregnancy), 4 doses of vaccine at the ages of 2, 3, 4 and 11 months are recommended.

There should be an interval of at least 6 months between the last and the preceding dose of the respective vaccination schedule. If the first Hib vaccination is administered at the age of 1–4 years, a single vaccination is sufficient. From 5 years of age, Hib vaccination is indicated only in exceptional cases (see Table 2), for example functional or anatomical asplenia. Monovalent Hib vaccines (Act-Hib, Hiberix) are currently not available in Germany, but can be ordered via international pharmacies.

Hepatitis A

For immunisation against hepatitis A, there are monovalent vaccines (Havrix 720 children or Havrix 1440, VAQTA children, VAQTA, HAVpur) and combination vaccines (VIATIM in combination with typhoid fever and Twinrix children/adults in combination with Hepatitis B) licensed in Germany. Twinrix is licensed for the age of 1 - 15 years.

A single dose of Twinrix vaccine both for children or adults does not guarantee adequate protection (e.g. before a trip abroad), since it contains only half as much hepatitis A antigen as the monovalent hepatitis A vaccine. Only after the second dose of the combination vaccine, protection against Hepatitis A can be assumed for about 1 year. The 3^{rd} dose after 6 (– 12) months provides long-lasting protection for hepatitis A. For a regular primary immunisation for adults before a trip abroad, a shortened schedule (o,

Updated on 25.05.2023

7, 21 d) can be applied when using Twinrix vaccine. It should be noted that a fourth vaccination dose after 12 months is necessary to complete the vaccination series.

When using a monovalent hepatitis A vaccine or the combination vaccine with typhoid (licensed from the age of 16 years), there is already full protection given for a timespan of about one year after vaccination with the first dose. Completion of primary immunisation or a long-lasting protection requires two doses at intervals of at least 6-12 months. Only the monovalent vaccine should be used for postexposure prophylaxis. If people are exposed, for which a hepatitis A infection is a particular risk, an immunoglobulin preparation can be given at the same time as the first vaccine dose.

Hepatitis B (HB)

For primary immunisation of infants against hepatitis B, three vaccine doses at the ages of 2, 4 and 11 months are recommended (see Epid Bull 26/ 2020).³ There should be an interval of at least 6 months between the last and second to last dose of the respective vaccination schedule. It is advisable to perform these vaccinations with a combination vaccine (e.g. DTaP-IPV-Hib-HepB) which simultaneously protects against tetanus, diphtheria, whooping cough, polio, *Haemophilus influenzae* type b and hepatitis B.

Pre- and post-vaccination serological testing is not necessary to monitor the success of primary immunisation in childhood, adolescence or adulthood. A booster dose after vaccination in infancy or early childhood is currently not generally recommended for children, adolescents or adults without particular risk factors. Individuals who have been vaccinated against hepatitis B during childhood should only be revaccinated against hepatitis B if a new risk of the disease has developed (for example, new employment in healthcare). In this case, a serological test should be conducted 4-8 weeks after vaccination in line with recommendations in Table 2 and Epid Bull $31/2007^8$ and 36/37.2013.⁷

Post-exposure hepatitis B prophylaxis in newborns of HBsAg-(Hepatitis-B-surface-Antigen-)positive mothers or mothers of unknown HBsAg status

Maternity guidelines state that all pregnant women should have their serum analysed for HBsAg after the 32^{nd} week of pregnancy and as close as possible to their due date. If the result is positive, immunisation of the newborn against hepatitis B must begin immediately postpartum, that is, within 12 hours. The first dose of HB vaccine and HB immunoglobulin should be simultaneously administered to different extremities. Two different vaccination schemes can be applied for primary immunisation with a monovalent vaccine: 0-1-2-12 months or 0-1-6months. The first scheme causes a faster immune response. **Premature babies** should always receive the 0-1-2-12 months scheme.

If the 0-1-2-12 months vaccination scheme is used, the doses can be administered at the age of 2 and 12 months with a hexavalent vaccine.

For infants who have already received 2 HB vaccine doses, the primary immunisation for tetanus, diphtheria, pertussis, *Haemophilus influenzae* type b, and poliomyelitis can be administered with a pentavalent or hexavalent vaccine. The additional HB vaccine doses contained in the hexavalent vaccine do not have negative effects. It is important to keep a minimum interval of 5 months between the last two vaccine doses at the end of the vaccination series.

In newborns of mothers whose HBsAg status is not known and in whom serological testing is not possible before or immediately after delivery, primary immunisation with the HB vaccine should also be started immediately postpartum. If the mother is later determined to be HBsAg positive, passive immunisation with HB immunoglobulin can subsequently be provided for the newborn child within 7 days of birth. Serological testing is required after the completion of primary immunisation in the newborn child of an HBsAg positive mother. HBsAg, anti-HBs, and anti-HBc should be checked 4-8 weeks after the third vaccination dose. If the result of the serological testing shows that there is no immunity an additional vaccine dose should be administered immediately. The success of the vaccination should be monitored with a serological test (see above). Further procedures (e.g. further vaccination) should be decided individually (see Epid Bull 10/2000 and 8/2001).

Herpes zoster (HZ)

In Germany, two vaccines against herpes zoster are licensed and available. Since 2013 an attenuated live vaccine (Zostavax) for people aged 50 years and older and additionally, since 2018 an adjuvanted HZ subunit inactivated vaccine (Shingrix) for peopled aged 18 years and older.

Adjuvanted inactivated herpes zoster vaccine

To prevent HZ and post-herpetic neuralgia (PHN), STIKO recommends the adjuvanted inactivated HZ-vaccine Shingrix as a standard vaccine (S) since December 2018 for all persons \geq 60 years. In addition, STIKO recommends indicated vaccination (I) for people \geq 50 years with an increased health risk of developing HZ resulting from an underlying disease or for people with congenital or acquired immunodeficiency (Epid Bull 50/2018).⁹ These include, amongst others, patients with HIV infection, rheumatoid arthritis, systemic lupus erythematosus, chronic inflammatory bowel disease, chronic obstructive pulmonary disease or bronchial asthma, chronic renal failure or diabetes mellitus.

The vaccination intends to increase the T-cellmediated immune defense against varicella zoster viruses (VZV) and thus to prevent the reactivation of the VZV that remains latently inside the nerve ganglia. The vaccination scheme for the inactivated HZ vaccine consists of two doses administered intramuscularly at intervals of at least 2 to a maximum of 6 months. It can be assumed at the present time that almost every adult grown up in Germany aged ≥ 50 years has undergone an infection with varicella (chicken pox). Therefore, anamnestic or serological information on a previous infection with varicella (chicken pox) is not required prior to vaccination. The inactivated HZ vaccine can be administered according to the Summary of Product Characteristics and in combination with an inactivated, nonadjuvanted seasonal influenza vaccine. No data has yet been published on co-administration with other vaccines than the seasonal influenza vaccines. A history of a HZ disease does not protect from a recurring infection with HZ. The inactivated HZ vaccine

can be administered to people who have undergone HZ in the past. However, the inactivated vaccine is not intended for the therapy of a HZ disease or its late effects. Based on a study in \geq 50-year-old adults, the vaccine is sufficiently immunogenic and safe after a previous HZ disease. Data on the clinical efficacy of the vaccine and on the most favorable point in time of vaccination after a HZ disease is limited. Vaccination should therefore be given after the acute illness is over and the symptoms have subsided.

A live attenuated vaccine (Zostavax) against herpes zoster (HZ) is not recommended by STIKO as a standard vaccination due to limitations in efficacy and duration of protection. Furthermore, the live attenuated vaccine is contraindicated in people with immunodeficiency or receiving immunosuppressive therapy who are at greatest risk of HZ and its complications (see Epid Bull 36/2017).¹⁰

Human papillomaviruses (HPV)

STIKO recommends routine vaccination against HPV) for all girls and boys aged 9-14 years to reduce the burden of disease from HPV-associated tumours. Missing HPV vaccinations should be completed before the age of 17 years. The vaccination series should also be completed before first sexual intercourse. Currently, a two-dose scheme is licensed for children aged between 9 and 14 years (Cervarix, Gardasil 9), with an administration interval of 5 months between the two doses. A third dose is necessary for catch-up vaccinations at age >14 years, or if the time interval between the first and second dose was < 5 months. The Summary of Product Characteristics should be consulted on the number of required vaccine doses and the time intervals between vaccinations.

Once a vaccination series is started, it should be completed with the same vaccine product if possible. Further details on the use of HPV vaccines can be found under Epid Bull 16/2016.

HPV vaccination should be used as an opportunity to update other vaccinations recommended for adolescents by STIKO. The Summary of Product Characteristics should be consulted about simultaneous administration with other vaccines.

Women and men who are older than 17 years and have not received an HPV vaccination can also benefit from vaccination against HPV. However, the effectiveness of vaccination in non-HPV-naive individuals might be reduced. Physicians are responsible to point this out to patients after an individual risk-benefit assessment based on the vaccine licensure. The assumption of costs must be clarified individually.

Vaccinated women and men must be informed that vaccination with one of the currently available vaccines against human papilloma viruses does not protect against all potentially oncogenic HPV types. Therefore, women are still advised to make use of cervical cancer screening services. The scientific rationale for the recommendation of the HPV vaccination for boys – in addition to the rationale for changing the vaccination age (Epid Bull 35/2014),¹² the rationale for HPV vaccination for girls (Epid Bull 12/2007)¹⁴ and the evaluation of the HPV vaccination (Epid Bull 32/2009)¹³ is published in Epid Bull 26/2018.¹¹

Influenza

STIKO recommends annual quadrivalent vaccination in autumn with the current antigen combination recommended by the WHO (Epid Bull 2/2018)¹⁶ as a standard vaccination for everyone aged 60 years and older, and where indicated in specific groups of people (see Table 2). Due to a small but significant superiority in vaccine efficacy in elderly people, a quadrivalent, high-dose vaccine with the current antigen combination advised by the WHO is recommended for all people aged 60 years or older (Epid Bull 1/2021).¹⁵ In addition to the quadrivalent (IIV4) inactivated vaccines for injection, which are licensed for the different age groups, there is a quadrivalent live-attenuated intranasal vaccine (LAIV4) licenced for use in those aged 2 to 17 years. For this age group, the inactivated vaccines or the live-attenuated vaccine can be used. Where there are reasons to avoid injections (for example, a phobia about syringes, or dysfunction of blood coagulation), LAIV4 should be used. Annual vaccination is recommended even when the antigen composition of the vaccine is unchanged from the previous year.

Japanese encephalitis

Currently there is only the inactivated adjuvanted dead vaccine IXIARO licensed in Germany. Vaccination against the Japanese encephalitis virus (JEV) is recommended prior to a stay in endemic regions during the transmission period. The recommendation especially applies if the conditions mentioned under T in Table 2 are met.

In adults, primary immunisation consists of 2 doses (each 0.5 ml) administered 4 weeks or in a fast scheme 7 days apart (fast scheme: do and d7, licensed for adults from 18 until 65 years of age). For children from the age of 2 months to 2 years 2 doses of 0.25 ml are administered 4 weeks apart. From the age of 3 years the regular dose of 0.5 ml per dose should be administered.

In the case of continued risk of exposure to the virus it is recommended that a 1st booster dose should be administered 12–24 months after primary immunisation and a 2nd booster dose (if indication persist) 10 years after the 1st booster dose (Epid Bull 18/2020).²²

Measles

A monovalent vaccine against measles is no longer available in Germany.

For the primary immunisation 2 vaccine doses of a combination vaccine (MMR vaccine) should be administered at the ages of 11 and 15 months. The vaccination interval between the 2 doses should be at least 4 weeks.

The first MMR vaccine dose can be administered from 9 months of age depending on the epidemiological situation, especially in the following situations:

- pending admission to a community facility (e.g. Kindergarten, day care for children);
- after contact with measles cases. If the initial vaccination was given at the age of 9–10 months, the second MMR vaccination must be given at the beginning of the second year of life.

There are no comprehensive data on the safety and efficacy of MMR vaccination in infants younger than 9 months. In the event of an outbreak, these infants must primarily be protected through immunisation

of people with whom they come into contact. Individual risk-benefit considerations can, in exceptional cases, justify vaccination at 6 to 8 months. Infants vaccinated between 6 to 8 months of age should receive two additional doses of MMR/V vaccine at the age of 11 and 15 months to establish longterm immunity.

Following contact with measles cases, passive immunisation with immunoglobulins should be considered up to 6 days after exposure, particularly for unprotected people where active vaccination is contraindicated and who have a high risk of complications, such as infants under 6 months of age, immunodeficient individuals and susceptible pregnant women. This is an off-label recommendation. Infants between 6 and 8 months old can receive immunoglobulins after individual risk-benefit consideration, as an alternative to the first vaccination. After administration of immunoglobulins, the MMR/V vaccination is not reliably effective for 8 months. This should be taken into consideration in the event of an indication for immunoglobulin administration (see also Table 6, and Epid Bull 2/2017).

MMR vaccination is also recommended for all adults born after 1970 who have unknown vaccination status, are unvaccinated, or received only one vaccination in childhood (single vaccination with an MMR vaccine). A background paper and detailed rationale for this recommendation can be found in Epid Bull 32/2010.²⁴

Additionally, two doses of MMR vaccination are indicated for adults born after 1970 in certain fields of professional activity. This includes staff in healthcare institutions, nursing homes, community facilities, institutions housing immigrants, refugees and asylum seekers, as well as in technical and vocational colleges and universities (see Epid Bull 2/2020).²⁵

In March 2020 the measles protection act was inaugurated. Therefore, children enlisted in a kindergarten, a day care facility for children or a school must be able to provide documentation of the recommended STIKO vaccinations or a medical certificate that declares sufficient immunity against measles. Children of the age 12–23 months must be able to provide documentation for at least 1 vaccine dose against measles and children from the age of 24 month onwards must be able to provide documentation of 2 vaccine doses against measles. As an alternative a medical certificate that declares sufficient immunity against measles can be provided regardless of the age of the child. Unvaccinated/Children without sufficient immunity against measles, can be excludes from the right to be enlisted in a kindergarten/day care facility for children.

Employees in kindergartens, schools or other community facilities, asylum seeker and refugee accommodations as well as day care workers must be vaccinated against measles or be immune – provided they were born after 1970. The same applies to professionals in medical facilities born after 1970, e.g. hospitals or medical practices (see also: www.masernschutz.de/).

Meningococcal disease

Meningococcal B (menB)

In Germany, two meningococcal serogroup B vaccines are licensed: Bexsero is licensed for people from the age of two months and Trumenba is licensed from the age of 10 years. STIKO currently considers that the available study results and evidence are not sufficient for a conclusive decision about a universal menB vaccination recommendation. A STIKO comment on the status of the meningococcal B vaccine assessment was published in Epid Bull 36/2014 and updated in 2018 (Epid Bull 3/2018).

STIKO recommends vaccination against serogroup B meningococci (menB) in addition to menACWY vaccination for people with certain underlying diseases (e.g. people with congenital or acquired immunodeficiency, (see Table 2). There is no data on the efficacy of the menB vaccine in these people, but a smaller study found lower immune responses in children and adolescents with complement defects than in healthy or asplenic subjects. In the scientific rationale "Update of meningococcal vaccination recommendations in Germany" it is noted that the risk of invasive meningococcal disease (IMD) varies according to the underlying disease (see Epid Bull 37/2015).²⁶ For disaster relief workers and if exposed also for medical personal and development aid wor-

kers a menB vaccination is recommended (see: recommendations for travel vaccinations of STIKO)

Physicians should therefore base their decisions about menB vaccination on an individual risk assessment.

Meningococcal C (menC)

STIKO recommends the vaccination against serogroup C meningococcal disease with a meningococcal C conjugate vaccine for all children at the age of 12 months. MenC conjugate vaccines are licensed and can be administered from the age of 2 months.

In Germany, there is a subsequent and lower disease incidence peak in adolescents. A detailed justification for the vaccination recommendation can be found in Epid Bull <u>31/2006</u>.³⁰ Children and adolescents aged up to 17 years with missing vaccinations should receive a catch-up vaccination. A booster vaccination is at this point of time not recommended by STIKO. The recommendations on vaccination of people at increased risk should also be followed (see Table 2).

Meningococcal ACWY (menACWY)

A meningococcal vaccination against serogroups ACWY is recommended for certain indications, e.g. for people with a congenital or acquired immunodeficiency or for travellers (see Table 2 and Table 6). No meningococcal C vaccination is required for children and adolescents who have not yet received a meningococcal vaccination and who receive an ACWY vaccination because of an indication (e.g. travel). In Germany, menACWY conjugate vaccines are licensed from the age of 6 months (Nimenrix), 12 months (MenQuadfi) and 2 years (Menveo).

Mpox/Monkeypox

In Germany, the vaccine Imvanex (Modified Vaccinia Ankara, Bavarian-Nordic [MVA-BN]) is licensed for vaccination against monkeypox. This is a 3^{rd} generation smallpox vaccine that cannot replicate in humans. For persons ≥ 18 years of age without a history of smallpox vaccination, primary immunisation is administered subcutaneously with 2 vaccine doses of Imvanex (MVA-BN) at least 28 days apart. For persons who have been vaccinated against smallpox in the past, a single dose of vaccine is sufficient. The vaccination can be administered to persons with immunodeficiency. The vaccine is not licensed for pregnant women, children or adolescents. Equivalently, the vaccine Jynneos from Bavarian-Nordic can be used (almost identical to Imvanex). The corresponding detailed scientific rationale can be found in Epid Bull 25/26/2022.¹

Mumps

A monovalent mumps vaccine is no longer available in Germany. For the primary immunisation against mumps 2 vaccine doses of a combination vaccine (MMR vaccine) should be administered at the age of 11 and 15 months. The vaccination interval between the 2 doses should be at least 4 weeks. Pre-existing immunity against one or two of the antigens included in the MMR vaccine is not a contraindication for vaccination with MMR.

Additionally, two doses of MMR vaccination are indicated for adults born after 1970 in certain fields of professional activity. This includes staff in healthcare institutions, nursing homes, community facilities, institutions housing immigrants, refugees and asylum seekers, as well as in technical and vocational colleges and universities (see Epid Bull 2/2020).²⁵

Pertussis

Primary immunisation during infancy: Given the epidemiological pertussis situation in Germany and the severity of the clinical course of pertussis in infancy, it is advisable to start primary immunisation of infants and toddlers at the earliest possible point in time, that is, immediately after 2 months of age, and to continue vaccination in a timely manner.

For primary immunisation of infants born at term, 3 vaccine doses are recommended at the age of 2, 4 and 11 months (see Epid Bull 26/2020).³ It is reasonable to use a combination vaccine (e.g. DTaP-IPV-Hib-HepB) which simultaneously protects against tetanus, diphtheria, whooping cough, polio, *Haemophilus influenzae* type b and hepatitis B. For premature babies (born before 37 completed weeks of gestation) 4 vaccine doses at the chronological ages of 2, 3, 4 and 11 months are recommended.

The interval between the last and second to last dose of the respective vaccination schedules for primary immunisation should be at least 6 months.

Booster vaccinations are recommended at 5-6 years of age and 9-16 years of age. Vaccines with reduced pertussis antigen content (ap instead of aP) are used from 5 to 6 years of age for both booster vaccinations and, where applicable, catch-up primary immunisations (for available vaccines see Table 11).

Standard vaccination of adults: STIKO recommends administering the next due Td vaccine for all adults as a single Tdap combination vaccination (see Epid Bull 15/2019) or a Tdap-IPV combination vaccination if indicated. A monovalent pertussis vaccine is no longer available, so administration of combination vaccines is recommended on the required vaccination dates. If there is an existing indication for pertussis vaccination, a Tdap combination vaccine can be used, even if a Td-containing vaccine has recently been administered. A placebo-controlled study has demonstrated that one of the available Tdap combination vaccines can be administered within 1 month of a previous Td vaccination without causing increased side effects (see Epid Bull 33/2009).³³

Indicated vaccination for pregnant women: Vaccination with a Tdap combination vaccine is recommended at the beginning of the 3rd trimenon. In case of an increased probability for premature birth, vaccination should be administered during the 2nd trimester. This vaccination should be administered in every pregnancy, regardless of the interval to previously administered pertussis vaccinations. The aim of pertussis vaccination in pregnancy is to reduce the incidence of disease in newborns and young infants (see Epid Bull 13/2020).³²

Procedure for recognized pertussis clusters: In the context of recognised pertussis clusters, vaccination can also be considered for fully vaccinated children and adolescents in close contact with cases in the household or in community facilities, if the last vaccination occurred more than 5 years ago. Before the birth of a child, it is especially important that people in close household contact and caregivers of the newborn should be checked for adequate immuno-

logical protection against pertussis, defined as vaccination within the past 10 years (see Table 2).

Pneumococcal disease

Primary immunisation during infancy: Infants born at term aged 2 months and older should receive two vaccine doses of pneumococcal conjugate vaccine in an interval of 8 weeks for primary immunisation up to the age of 12 months. Preterm infants (born before 37 completed weeks of gestation) from the chronological age of 2 months should receive a total of 3 vaccine doses in intervals of 4 weeks. Primary immunisation will be completed with a further dose at the age of 11 months (minimum interval to previous vaccination is 6 months). The recommendation for preterm babies is based on the licensure of the pneumococcal conjugate vaccines, which restricts the use of the 2+1 scheme to full-term infants (as of November 2020). A detailed justification for the pneumococcal vaccine recommendation can be found in Epid Bull 36/2015.³⁹ Toddlers aged 12 months to 24 months without previous pneumococcal vaccination should receive only two doses at intervals of at least 8 weeks as catch up vaccinations.

The primary goal of universal vaccination of all children up to 24 months of age with pneumococcal conjugate vaccine is to reduce morbidity from invasive pneumococcal diseases (IPD) and resulting consequences such as hospitalisation, disability and death.

Standard vaccination of older adults: Use of the 23valent pneumococcal polysaccharide vaccine (PPSV23) (Pneumovax 23) is recommended as a standard vaccination (category "S") for people aged ≥ 60 years who do not belong to any of the risk groups listed under "l" or "O" in Table 2.

Indicated vaccinations: For people with certain risk factors for pneumococcal diseases (Categories "I" and "O"), vaccination against pneumococcal disease is recommended at any age. For those with an immune deficiency (Group 1) and people with anatomical and foreign-material associated risk factors (e.g. cochlear implant) and therefore an increased risk of pneumococcal meningitis (Group 3), sequential immunisation with 13-valent conjugate PCV13 (Prevenar 13), followed by PPSV23 (Pneumo-

vax) is recommended. PPSV23 is approved from the age of 2 years (see Table 3). Before that age, only PCV13 can be used. For people with chronic diseases, that are not associated with an immune suppression (Group 2) and those with a professional indication, exclusive vaccination with PPSV23 is recommended. Sequential immunisation should be conducted for those in Group 2 aged 2 to 15 years.

Update from 17.05.2023: PCV13 or PCV15 can be used for children and adolescents aged 2 – 17 years (Update 17.05.2023), see Epid Bull 20/2023.

Booster vaccinations: Vaccine-induced protection is not permanent, so for all groups listed in Table 2, STIKO considers it expedient from a medical/epidemiological point of view to administer booster vaccinations with PPSV23 at intervals of at least 6 years. According to the Summary of Product Characteristics for PPSV23, however, "healthy adults should not routinely be given booster vaccinations". "In the case of individuals with an increased risk of serious pneumococcal disease," however, the Summary of Product Characteristics states that booster vaccinations "could be considered". This regularly applies to people in categories "I" and "O". Older people who do not belong to either of these categories should be considered on a case-by-case basis. Patients must be informed about the increased reactogenicity of the booster vaccination in comparison to

the primary vaccinations, as well as the possible loss of protection if booster vaccinations are not given.

Detailed scientific justifications for these recommendations can be found in Epid Bull 36/2016 and 37/2016.^{37,38}

Poliomyelitis

The wild poliovirus type 2 and 3 have been eradicated worldwide. There is still a risk of infection by wild poliovirus types 1 and by genetically-mutated circulating vaccine-derived polioviruses (cVDPV) of all three types when travelling to some regions. Since 1998, the oral polio vaccine (OPV) is no longer recommended because of the risk - albeit very low - of vaccine-associated paralytic poliomyelitis (VAPP). For protection against poliomyelitis, an injectable inactivated polio vaccine (IPV) (if indicated, as combination vaccine) is recommended. For primary immunisation against poliomyelitis, infants should receive 3 vaccine doses at the ages of 2, 4 and 11 months (see Epid Bull 26/2020).³ The interval between the last and second to last dose of the respective vaccination schedule for primary immunisation should be at least 6 months. It is reasonable to use a combination vaccine which simultaneously

Vaccination status	Recommended vaccination sch	PPSV23 follow-up vaccination at least 6 years after last PPSV23 vaccination	
vaccination status	First vaccination Second vaccination		
No vaccination	PCV13#	PPSV23 at intervals of 6–12 months®	Yes
PCV13	PPSV23 at intervals of 6 –12 months	Not applicable	Yes
PCV7 or PCV10	PCV13#	PPSV23 at intervals of 6−12 months®	Yes
Previous PPSV23 less than 6 years ago	PCV13 [#] at intervals of 12 months	PPSV23 at interval of 6 years of the previous PPSV23 vaccine dose	Yes
Previous PPSV23 6 or more than 6 years ago	PCV13#	PPSV23 at intervals of 6–12 months*	Yes
PCV13 + PPSV23	Not applicable	Not applicable	Yes

Table 3 | Administering sequential indication-based pneumococcal vaccination from the age of 2 years, following consideration of the current vaccination status

PPSV23 (23-valent polysaccharide vaccine) can be administered, at the earliest, 2 months after PVC13 vaccination (13-valent conjugate vaccine) (e. g. vaccination before planned immunosuppressive therapy). A longer interval of 6–12 months is immunologically more useful.
 PCV13 or PCV15 can be used for children and adolescents aged 2–17 years (Update 17.05.2023), see Epid Bull 20/2023.

protects against tetanus, diphtheria, whooping cough, polio, *Haemophilus influenzae* type b and hepatitis B. From 9 to 16 years of age, a booster vaccination containing IPV is recommended. Primary immunisation started with OPV should be completed with IPV (see also Table 2).

Rabies

According to WHO criteria, Germany has been free of terrestrial rabies since 2008. However, illegal importation of pet animals (dogs and cats) from countries with endemic terrestrial rabies still poses a risk. Germany is one of the European countries with the highest recorded number of bat rabies cases caused by bat lyssaviruses, which are also transmissible to humans. Prophylactic pre-exposure immunisation consists of three doses given by intramuscular injection on days 0, 7 and 21 (Rabipur) or days 0, 7, and 21 or 28 (Tollwut-Impfstoff (HDC) inaktiviert). To maintain long lasting protection, a booster dose is recommended 1 year after the first dose and then every 5 years (Tollwut-Impfstoff (HDC) inaktiviert) or every 2-5 years (Rabipur), respectively. For post-exposure prophylaxis, see chapter 5.5.

Rotavirus (RV)

The RV vaccines are live oral vaccines. Depending on the vaccine brand, 2 (Rotarix) or 3 doses (Rota-Teq) are administered to the infant starting at the age of 6 weeks, with at least 4 weeks between doses. There is a slightly elevated risk for intussusception (estimated at 1–2 cases per 100,000 infants vaccinated) within the first week after the first RV vaccine dose, which increases with age of the child. STIKO therefore strongly recommends beginning the vaccination series as early as possible, and by the age of 12 weeks at the latest, and completing it by the age of 16 weeks (Rotarix) or 20–22 weeks (RotaTeq). The vaccination series must be completed by the age of 24 weeks when using Rotarix or 32 weeks for RotaTeq.

The background paper and detailed scientific rationale can be found in Epid Bull 35/2013.⁴⁶ The Summary of Product Characteristics should be consulted about simultaneous administration with other vaccines.

RV immunisation is recommended for preterm infants at their chronological age and for full-term

infants, even if hospitalized. The benefits of RV vaccination in neonatal intensive care units (NICU), providing protection against nosocomial RV infection, significantly outweigh the low risk of RV gastroenteritis in other hospitalized patients through nosocomial vaccine virus transmission. The risk of vaccine transmission is low and is sufficiently reduced by common infection control measures on NICUs. A joint statement from STIKO, the German Academy for Pediatrics and Adolescent Medicine (DAKJ) and the German Society for Neonatology and Pediatric Intensive Care Medicine (GNPI) on RV vaccination of preterm infants and neonates during hospitalization is published in Epid Bull 1/2015.

Rubella

A monovalent rubella vaccine is no longer available in Germany. For the primary immunisation against rubella 2 vaccine doses of a combination vaccine (MMR vaccine) should be administered at the age of 11 and 15 month. The vaccination interval between the 2 doses should be at least 4 weeks.

Pre-existing immunity against one or two of the antigens included in the MMR vaccine is not a contra-indication for MMR. The primary objectives of the vaccine recommendation are to prevent congenital rubella syndrome (CRS) and to eliminate rubella in Germany.

Mothers with a seronegative rubella test in pregnancy should be given 2 MMR vaccinations postpartum at an interval of at least 4 weeks between the doses. The first vaccine dose can be administered with the postpartum examination at the end of the postpartum period.

Additionally, two doses of MMR vaccination are indicated for adults born after 1970 in certain fields of professional activity. This includes staff in healthcare institutions, nursing homes, community facilities, institutions housing immigrants, refugees and asylum seekers, as well as in technical and vocational colleges and universities (see Epid Bull 2/2020).²⁵

Tetanus

For primary immunisation of infants born at fullterm, 3 vaccine doses are recommended at the age

of 2, 4 and 11 months (see Epid Bull 26/2020).³ It is reasonable to use a combination vaccine which simultaneously protects against tetanus, diphtheria, whooping cough, polio, *Haemophilus influenzae* type b and hepatitis B. For premature babies (born before completed 37th week of pregnancy) 4 vaccine doses at the chronological ages of 2, 3, 4 and 11 months are recommended.

The interval between the last and second to last dose of respective vaccination schedules for primary immunisation should be at least 6 months. Booster vaccinations are recommended at 5-6 years of age and 9-16 years of age. Further booster vaccinations should be administered in intervals of 10 years. Each booster vaccination with Td (including in case of an injury) should be used as an opportunity to check whether pertussis vaccination is indicated and, if applicable, to administer a combination vaccine (Tdap) or if indicated Tdap-IPV.

Tick-Borne encephalitis (TBE)

Vaccination against TBE should be completed by the beginning of the tick season, because about 95% of cases in Germany are notified in the months of May to November. Please note the current information on risk areas in Germany. Both child vaccines (FSME-IMMUN Junior, Encepur Children) and adult vaccines (FSME-IMMUN adults, Encepur adults) are available for vaccination. Incomplete primary immunisation should be completed with missing vaccine doses. In the Summary of Product Characteristics of FSME-IMMUN it is written that a primary immunisation can only be completed by an additional vaccination after two already administered vaccine doses. However, in the opinion of STIKO, the principle "every vaccination counts" also applies here: Once a primary immunisation has been started, it can be continued at any time and NO new primary immunisation is required. Even if a booster vaccination is administered years after the recommended date of vaccination, it offers 3-5 years of protection, depending on the age of the vaccinated person (see Summary of Product Characteristics). Both vaccines licensed in Germany protect against the Central European TBE virus subtype as well as the Far Eastern and Siberian TBE virus subtypes.

Typhoid fever

In Germany one live vaccine and three inactivated vaccines are available for vaccination against typhoid fever. The oral live vaccine (Typhoral L capsules) should be administered in 3 doses on days 0, 2 and 4. The vaccination series should be completed at least 10 days before traveling to an endemic area. The parenteral inactivated vaccines (Typhim Vi and Typherix) are to be administered once i.m. at least 2 weeks before entry into an endemic area. If an additional indication for hepatitis A exists, the inactivated combined vaccine against typhoid and hepatitis A (Viatim) can be used.

Varicella (V)

For primary immunisation of infants, two vaccine doses are recommended at the age of 11 and 15 months. A minimum interval of 4 weeks between the two vaccinations is required. Vaccination can be administered either at the same time as the first MMR vaccination or, at the earliest, 4 weeks later. These intervals are required as both vaccines are live vaccines. Regarding the first vaccination dose against varicella and measles, mumps, rubella, it is preferable for children below the age of 5 years to simultaneously administer a single varicella vaccine dose and an MMR combination vaccine dose at different body sites. The rationale for this recommendation is a slightly increased risk of febrile seizures 5-12 days after application of the combined MMRvaricella (MMRV) vaccine compared with the simultaneous vaccination with a varicella and MMR vaccine. This increased risk was only observed after the first vaccination. The second dose of varicella vaccine should be administered at the age of 15 months and a MMRV combination vaccine can be used. See the STIKO statement on "Combined vaccination against measles, mumps, rubella and varicella (MMRV)" in Epid Bull 38/2011.

In all unvaccinated children and adolescents with no history of varicella, catch-up vaccination should take place using 2 doses. The minimum interval between the two doses of varicella or MMRV vaccine is 4 to 6 weeks (depending on the Summary of Product Characteristics provided by the manufacturer). Children and adolescents who have only been vaccinated once against varicella should receive a second dose of varicella or MMRV vaccine.

The background paper and detailed scientific rationale for the varicella vaccination recommendation was published in Epid Bull 32/2009,⁴⁹ and an evaluation of the recent varicella vaccination strategy is in Epid Bull 1/2013.

Two doses of varicella vaccination are indicated for seronegative personnel working in medical institutions, healthcare institutions, nursing homes, community facilities, institutions housing immigrants, refugees and asylum seekers, or who are in contact with potentially infectious material (see Epid Bull 2/2020).²⁵

Yellow fever

Vaccination with the attenuated yellow fever live vaccine (Stamaril) is recommended when traveling to countries where yellow fever is endemic, and is necessary in countries that require proof of yellow fever vaccination as a condition of entry. Other countries require proof of yellow fever vaccination only with entry from yellow fever endemic countries or after an airport transit >12 h in a yellow fever endemic country.

The WHO list (www.who.int/health-topics/yellowfever) of countries in which there is a risk of yellow fever transmission or an obligation to provide proof of vaccination on entry, was included in the country table of the recommendations of the STIKO and the German Society for Tropical Medicine, Travel Medicine and Global Health (DTG) on travel vaccinations.

In 2013, the WHO decided that one vaccine dose against yellow fever is for almost all people sufficient for a lifelong protection. In 2015, the STIKO went along with the WHO recommendation and recommended that only certain groups of people such as pregnant women or people with immune deficiency (e.g. HIV) should receive a yellow fever vaccine booster dose. Based on an updated evidence review and new assessment of the analysed data,^z the STIKO discussed and adjusted the yellow fever vaccination recommendations together with the DTG. Since, on the basis of the newly evaluated evidence, lifelong immunity cannot be concluded after just one vaccine dose and the extent of the declining immunity depends on age and the immune status at the time of the first vaccination, a one-time booster vaccination is recommended before re-exposure or in case of continued exposure, provided that 10 or more years have passed since the primary vaccination. After administration of the 2nd vaccine dose no further booster vaccinations are necessary. There are exceptions and particularities for the following groups of people: pregnant women, people with immunodeficiency and children.

The complete and updated recommendations can be found in <u>Table 2</u> and the corresponding detailed scientific rationale in Epid Bull 32/2022.⁴

For further information also see <u>recommendations</u> on travel vaccinations of STIKO.

4. Notes on administering vaccinations 4.1 Information requirements before vaccinations

General information

Providing information is an important part of the immunisation service offered by physicians (German Civil Code [BGB] §630e)

Before administering a vaccine, the physician is obliged to inform the person to be vaccinated or their accompanying parent or legal guardian or person who has the power of attorney (German Civil Code [BGB] §630d, para.1, sentence 2) about the disease to be prevented and the vaccination itself, so that an effective declaration of consent can be given. Furthermore, the person to be vaccinated should be informed about the consequences of a forborne vaccination. This information should be provided by the physician regardless of personal medical opinions, possible reservations or misgivings.

Extent of the information

This information should include:

- background on the disease to be prevented and treatment options;
- the benefits of the vaccination;
- the contraindications;
- the administration of the vaccine;
- when vaccination protection starts and how long it lasts;
- what to expect and what to do after immunisation;

- possible side effects and vaccine-associated complications; and
- the need for any follow-up and booster vaccinations and when.

However, the precise scope of the information required always depends on the specific circumstances. The principle of patient-related information applies here, i.e. it should be appropriate to the understanding of the individual patient or person giving consent. Decisive criteria can include age, level of education, previous experience and medical knowledge. It is therefore always necessary to tailor the message to the individual patient or the person giving consent. A general picture of the severity and direction of the risk spectrum associated with vaccination must be provided by the physician. In exceptional cases, a waiver for an explicit explanation can be declared by the person to be vaccinated or the person giving consent and with this, information provision may be unnecessary.

According to $\S630e$, para.3, German civil Code (BGB) giving out information by the physician can be waived, if there are special circumstances, especially if the procedure cannot be delayed or the patient declares explicitly to forgo the information to be provided. The occurrence of such an exception should be documented by the physician very precisely for reason of proof.

Form and timing of the information

The **information must be** provided **orally** under $\S630e$, para. 2, no. 1, BGB, by the person administering the vaccination or by a person who has received the training required to carry out the measure. Additional reference may be made to written information given to the patient.

Care must be given to ensure that the information is provided in good time and in a way that the person being vaccinated or their accompanying parent or guardian or person who has the power of attorney (German Civil Code [BGB] §630d, para. 1, sentence 2) can understand the content. Particularly in the case of language barriers, the physician must ensure that the explanation has been understood. In case of doubt, the physician should consider whether an interpreter should be consulted, which may be at the expense of the person to be vaccinated.

Information sheets

Information sheets on vaccinations by registered physicians are available free of charge on the website of the "Forum for vaccinating doctors" (www. forum-impfen.de, after password-protected registration). In some cases, information sheets are sold by providers (e.g. the German Green Cross or Thieme Compliance). To support people who do not speak German, the Robert Koch Institute offers translations of information sheets on many different vaccinations to download free of charge in various languages (www.rki.de). The Federal Center for Health Education (BZgA) also provides a wide range of information materials on vaccination and vaccinepreventable diseases for laypeople via its homepage www.impfen-info.de.

The leaflets also contain a questionnaire on the state of health of the person being vaccinated and previous immunisations which specifically relate to the vaccine under consideration. Those being vaccinated or their parents or guardians must also have the opportunity to have their questions and issues addressed. Most information sheets include declarations of consent which can be signed by the person being vaccinated or their parent or guardian.

Form of consent and documentation

Written consent is not required by law, but can be useful in certain cases. The information provided and record of consent must be documented in the patient's files (\S 630f, para. 2, sentence 1, BGB), regardless of the form in which they were provided. If the information is based on a specific information sheet, this should be mentioned in the documentation. It can also be useful to make a note in the patient's file if the relevant person or their parent or guardian has refused a vaccination. The patient or the person giving consent must receive a copy of any documents that were signed in the context of information or consent (\S 630e, para. 2, sentence 2, BGB).

Minor patients

In the case of minors, the consent of the parent or guardian must be routinely obtained. In cases of opposite opinions of parties in shared custody cases, it can be assumed that in a law suit the party gets decision-making authority that is in favour of the vaccination (see also: Higher regional court (OLG) Frankfurt Main, ruling from 17.08.2021, file number (Az.) 6UF 120/21). Adolescents can give their own consent if they have acquired the necessary cognitive and decision-making ability; this is usually the case at 16 years of age. Physicians must determine whether the individual adolescent "can, according to his [or her] mental and moral maturity, understand the significance and scope of the intervention and the nature of the consent" (Federal Court of Justice in civil matters (BGHZ) 29, 33-37). According to $\S 6_{3}$ oe, para. 5, sentence 1, BGB sets out that people unable to give consent have to be informed in a way that fits with their understanding, as long as they are in a position to understand the explanations and this is not against their best interests.

Public vaccination appointments

For public vaccination appointments (e.g. school immunization programs), it is recommended that physicians provide information in written form in advance and, if appropriate, obtain a written declaration of consent. This does not, however, absolve physicians from their legal obligation to provide the person being immunised or their accompanying parent or guardian with oral information and the opportunity to ask questions.

4.2 "Off-label" use

"Off-label" use is the prescription of a licensed medical product outside the use for which licensure has been approved by national or European regulatory authorities. This may apply, for example, to the scope of application (indication), age restrictions, dosage, or duration of treatment. For any off-label use, the physician concerned is liable for the medical appropriateness of the treatment and any potential adverse events. Medical associations recommend that off-label use should be based on valid guidelines or recommendations, or acknowledged scientific literature. For off-label use, it is essential to provide comprehensive information to the patient or their legal guardian of the risks and benefits of the vaccination, and explain that the vaccine is being used off-label. Medical treatment and the information provided must be fully documented with an explicit explanation that the treatment is an off-label use in the patient's file.

4.3 Documenting the vaccination

General information

According to § 22, para. 1, IfSG, the vaccination has to be immediately documented in the patient's vaccination card or if not applicable in a vaccination certificate by the person authorized to administer the vaccination.

The patient's vaccination card or vaccination certificate has to comply with the requirements of § 22, IfSG and needs to include the following information per vaccination: date of vaccination, name (brand) and batch number of the vaccine, name of the disease to be prevented, name (birth name) of the person to be vaccinated as well as the name and address of the person authorized to administer the vaccination. Any form that meets WHO requirements and is in accordance with § 22, IfSG, such as the "International certificates of vaccination and shot record" ("Yellow vaccination card"), can be used as a vaccination card.

Missing vaccination documentation

Vaccination documents are often missing or incomplete. This is not a reason for postponing necessary vaccinations, not catching up on missing vaccinations, or not starting primary or basic immunisation. No particular risk arises from additional vaccinations when vaccine-induced protection already exists. This also applies to multiple vaccinations with live virus vaccines. Serological tests to check the immune status of an individual are indicated only in exceptional cases (e.g. anti-HBs antibodies for people at increased risk of hepatitis B infection).

4.4 Vaccination management in the physician practice

A well-established vaccination management system in physicians' practices and other medical facilities plays an important role in promoting vaccinations and achieving vaccination targets. This type of management system helps to coordinate workflows and establish responsibilities.

Patient contact and invitation systems

Patient vaccination status should be monitored and updated, if applicable, at each visit to the doctor. Opportunities to assess immunisation status include screening examinations (e.g. "U" examinations in

childhood, "J1/J2" examinations for adolescents, health check-ups and screening examinations for adults as well as routine examinations of mothers within the first 6-8 weeks after birth), initial contact with new patients, special events (treatment after accidents or injuries, start of kindergarten, health certificates for internships or new jobs), or seasonal visits (travel vaccinations, tick-borne encephalitis or influenza vaccinations). A recall system can help to remind patients when vaccinations are due, and therefore increase uptake. Reminders can be sent via email, post, or telephone by e.g. health insurances, public health authorities or physicians. In the latter case patient consent (signature) is required before they are enrolled in a recall system. Templates for a recall consent form are available from the Association of Statutory Health Insurance Physicians (ASHIPs).

Organizational responsibilities and logistics

To run an efficient and successful vaccination management in the doctor's office, it can be helpful to assign organizational responsibilities to individual employees. The routine tasks of these individuals include monitoring inventory and ordering vaccines, training other employees, and practical vaccination management. Many practice administration systems offer useful tools for managing vaccine inventory.

Responsibilities of practice staff

Practice staff can support practical vaccination management through targeted actions. When arranging appointments, they can remind patients to bring their vaccination records to be checked at the next visit, or they can add a reminder to an appointment slip. Trained staff can record the current vaccination status based on entries in the vaccination records, identify any missed vaccinations, and create an individual vaccination plan if needed. When talking to patients, practice staff can remind them of any outstanding vaccinations, encourage them to be vaccinated and hand out relevant information. Medical personnel can inform physicians of any missed vaccinations when handing over patient records. Practice staff can prepare vaccines and vaccination records if any vaccinations are planned during the visit. Injecting the vaccine can be delegated to qualified medical personnel after the physician has

approved the indication, but the liability remains with the physician.

Storing vaccines

Vaccines are sensitive biological products and must above all be protected from light and heat. All vaccines should be stored in their original packaging in a separate refrigerator at +2°C to +8°C. Vaccines should never come into contact with the external wall of the refrigerator or be stored in the refrigerator door. Special refrigerators for vaccines are particularly suitable, but household refrigerators without a freezer can also be used. The refrigerator should be used exclusively for cooling vaccines and other medicines. The temperature should be monitored by regular checks, preferably every morning and evening, but at least once a day. A thermometer that shows the minimum and maximum temperatures, or a thermometer data logger that continuously measures temperatures, are suitable. The thermometer should be positioned in the middle of the refrigerator. The observed temperatures should be documented. Vaccines that were accidentally stored incorrectly or have been frozen must be discarded. Freezing can lead to hairline cracks in the ampoules and the vaccine could become unsterile. Slightly or completely frozen adsorbed vaccines are less well tolerated and can lead to purulent inflammation or injection abscesses. Live vaccines (MMR, varicella, herpes zoster, LAIV, rotavirus, yellow fever) containing viruses capable of reproduction are especially sensitive. An uninterrupted cold chain must be maintained for these vaccines.

Preparing and injecting the vaccine

The vaccine should only be removed from the refrigerator shortly before administration. Vaccines must not come in contact with disinfectants. The rubber stoppers must be dry. The needle should be dry, and no vaccine should be on the outside of the needle. That would make the injection painful and can lead to inflammation at the injection site. After filling the syringe with the vaccine and removing any air, attach a new needle for the injection. The vaccine should usually be used quickly after filling the syringe. The injection site should be disinfected, taking the (minimum) exposure time indicated by the manufacturer into account. The skin should have dried before the injection is administered.

The preferred site for the intramuscular administration of vaccines is the *M. deltoideus*. If this muscle has not yet developed sufficiently (e.g. in infants and toddlers), injection into the *M. vastus lateralis* (anterolateral thigh) is recommended. The risk of damaging nerves or vessels here is low. Aspiration is not necessary for these injection sites. When injecting adsorbed vaccines into subcutaneous fatty tissue, painful inflammation or the formation of granuloma or cysts can occur. The success of the vaccination is also questionable when injecting into fatty tissue.

4.5 Vaccination intervals

General information

The vaccination intervals shown in the immunisation schedule (Table 1), Table 2 and Tables 10 A-E as well as in the Summary of Product Characteristics sheets should generally be complied with.

For urgently-indicated vaccinations, such as postexposure rabies prophylaxis or postnatal immunoprophylaxis for hepatitis B in newborns, physicians must strictly adhere to the recommended vaccination schedule.

For long-lasting vaccination protection, it is particularly important that the recommended minimum interval in primary immunisation between the secondlast and last vaccination (generally 6 months) is not shortened.

However, on the other hand there is generally nothing like an unacceptably long interval between vaccinations. **Every vaccine dose counts.** Additional vaccine doses are not required if intervals between vaccine doses that have already been administered are longer than recommended. Where primary immunisation has been out of date for many years or a booster vaccination has not been carried out in a timely manner, for example against diphtheria, tetanus, poliomyelitis, hepatitis B, or TBE (see www. rki.de), the immunisation **does not have to be started again** from the beginning. Instead, it should be updated with the missing vaccine doses. This also applies to infants and toddlers. To provide vaccination protection as early as possible, exceeding the recommended vaccination intervals should be avoided, especially in young children.

The following applies to intervals between different vaccinations: Live vaccines (attenuated, replicationcompetent viruses) can be administered simultaneously. If they are not administered simultaneously, there must usually be a minimum interval of 4 weeks between the two vaccine administrations.

Immunisation with inactivated vaccines (inactivated pathogens, their antigen components, and toxoids) requires no minimum time interval between the two vaccinations, even if one of the vaccines is a live attenuated vaccine. Possible adverse reactions to preceding vaccinations should have completely subsided before any new vaccinations. The Summary of Product Characteristics should be consulted on the minimum interval between two vaccinations and the co-administration of vaccines.

Interval between vaccination and surgical interventions

If the indication is urgent, surgical procedures can be carried out at any time, even if preceded by a vaccination. For elective procedures, a minimum interval should be allowed of 3 days after the administration of inactivated vaccines, and 14 days after the administration of live vaccines.

Neither clinical observations nor theoretical considerations suggest that vaccinations and surgical procedures are incompatible. However, to distinguish between possible vaccination reactions and surgical complications, it is recommended that these minimum intervals between vaccinations and operations be maintained.

After surgical procedures, vaccinations can be given as soon as the patient is stable. Vital vaccinations (such as tetanus, rabies, and hepatitis B vaccination) can be given at any time. Following operations associated with immunosuppressive treatment, e.g. transplantations, vaccinations must be planned in cooperation with the attending physician.

4.6 Notes on reducing pain and stress during vaccination

Background

It is not unusual for pain and stress reactions to be triggered when vaccines are injected. Fear or worry about potential pain can have a lifelong negative impact on attitudes to visiting the doctor, vaccinations and the acceptance of vaccinations amongst both children and their parents.

Nowadays, there are several evidence-based sets of recommendations for reducing pain and stress connected with vaccinations. These include particular injection techniques, age-related distraction methods and other behaviours that can lessen the pain of vaccination. These recommendations are summarised in this section. Physicians are encouraged to apply these techniques on reducing vaccination-related pain in their everyday practice to promote public acceptance of vaccination. Additional information can be found in the publications cited.^{B-H}

General recommendations

During vaccination, healthcare professionals should be calm, cooperative and competent. When describing the vaccination procedure to the person being vaccinated, it is important to use neutral language and choose words carefully to avoid increasing the individual's fear or distrust. It is essential to avoid using falsely reassuring or dishonest phrases like "It won't hurt at all!"

Painkillers

- In some cases, lidocaine patches or creams under occlusive dressing can be used for children from birth to reduce the pain caused by the injection. In children aged <12 months, the patches and creams should not be used concomitantly with drugs (such as sulphonamide) that contribute to the formation of methaemoglobin. Pain patches can also be helpful for adolescents and adults who are afraid of injections. The minimum time required to achieve the optimal pain relief (30–60 minutes) must be taken into account during planning.
- An ice spray can also be used to reduce pain. It should be sprayed for 2–8 seconds and the vaccination can be administered immediately after skin disinfection.

Other support procedures

- Even before their children's first vaccination appointment (from 2 months of age), parents should be informed about forthcoming vaccinations and the concomitant pain and pain-reducing options. This means that the information could be given at the U3 examination to promote the use of pain-reducing strategies at the vaccination appointment.
- Parents of children aged <10 years should be present in the room during their child's vaccination.
- Children aged ≥ 3 years, adolescents and adults should all receive information about what will happen during the vaccination and how they can best deal with pain or fear, e.g. by holding their parent's hand immediately before the injection. Children aged ≤ 6 years should have their attention diverted from the pain by suitable tactics (e.g. blowing up a balloon, pinwheels, blowing bubbles, toys, videos, conversations or music) immediately before and after the injection. Adults can be encouraged to cough slightly or hold their breath.
- If infants are still being breastfed, mothers can nurse them during the vaccination. Alternatively sucking on a dummy can be used to calm the infant and reduce pain.
- Children aged < 2 years who are no longer being breastfed can be given 2 ml of 25 % glucose solution or another sweetened liquid a minute or two before the vaccination. As rotavirus vaccines contain sucrose, this should be given first if it is one of several vaccinations being administered at the same time.

Recommended body position

- Small children aged < 3 years should preferably be carried or sit on their parents' lap during the vaccination and be gently rocked and stroked afterwards.
- Children aged ≥ 3 years, adolescents and adults should sit as upright as possible during the vaccination. Children can sit on their parents' laps so that their parents can help to keep their limbs still.
- People who have experienced fainting during vaccinations or other medical interventions should be vaccinated lying down.

Recommended injecting techniques

- For infants aged <2 months, the length of the needle should be 15 mm. For older infants and small children, it should be 25 mm and for adolescents and adults, 25–50 mm.
- Irrespective of age, intramuscular injections should be administered without aspiration. Aspiration is unnecessary because there are no major blood vessels in the body parts where the injection is administered (*M.vastus lateralis* or *M. deltoideus*).
- If several vaccinations are being given at the same time, the most painful injection should be given last. Pneumococcal and MMR injections can be particularly painful.
- A rapid injection can reduce pain for intramuscular injections.

Pain-reducing techniques that are not recommended

- Warming the vaccine.
- Manual stimulation of the area to be injected, e.g. by rubbing or pinching.
- Administering oral analgesics before or during the vaccination.

4.7 Contraindications and false contraindications

Contraindications

Children, adolescents, and adults with acute diseases requiring treatment should only be vaccinated after recovery, with the exception of post-exposure vaccination.

Depending on the diagnosis, adverse events temporally correlated with a vaccination are not an absolute contraindication against a further vaccination with the same vaccine. Obstacles to vaccination can include allergies to components of the vaccine. These may include neomycin, streptomycin, and egg protein in rare cases. Persons who react with anaphylactic symptoms after oral consumption of egg protein should not be vaccinated with vaccines that contain egg protein (yellow fever and influenza vaccine).

For congenital or acquired immunodeficiency, the physician treating the immunodeficiency should be

consulted before vaccination with a live vaccine. Serological monitoring of the success of vaccination is under certain constellations indicated in patients with immunodeficiency. (Further information see: www.rki.de)

Vaccinations that are not recommended or not urgently indicated should not be carried out during pregnancy. Live vaccines against measles, mumps, rubella, and varicella are contraindicated in pregnancy. It is permissible to administer a yellow fever vaccination in pregnancy where there is a clear indication and following careful risk-benefit consideration. A yellow fever vaccination should not be carried out in breastfeeding women. Worldwide, there have been reports of sporadic cases of breastfed infants developing an encephalitis after their mothers had received a yellow fever vaccination.

False contraindications

Indicated vaccinations are often omitted because certain conditions are erroneously considered contraindications. These include:

- Common infections, even if they are accompanied by subfebrile temperatures (<38.5°C);
- Possible contact between the person to be vaccinated and people with contagious diseases;
- Seizures in the family;
- Febrile convulsions in the medical history of the child to be vaccinated;
- Eczema including dermatoses and localised skin infections;
- Treatment with antibiotics;
- Treatment with low doses of corticosteroids or locally applied steroid-containing preparations;
- Pregnancy of the mother of the child to be vaccinated (including varicella vaccination after risk assessment)*;
- Congenital or acquired immunodeficiencies upon vaccination with inactivated vaccines;
- Neonatal jaundice;
- Premature birth: premature babies should be vaccinated at the recommended vaccination age re-

Considering the current vaccination coverage for varicella, the risk of connatal varicella syndrome in a seronegative pregnant woman in contact with her unvaccinated child (that is therefore at risk of being infected), is greater than the risk of a complication due to the vaccination of the child and transmission of vaccineinduced varicella via the child to the pregnant mother.

gardless of their gestational age and current weight;

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- Breastfeeding women: they can receive every required vaccination except for yellow fever (see above: Contraindications)
- Breastfed infants: infants who are exclusively or partially breastfed can be vaccinated in line with the STIKO recommendations, like infants who are fed formula or other baby food.

Indicated vaccinations should also be undertaken in people with chronic diseases, including neurological diseases, as these people are especially endangered by severe courses and complications of vaccinepreventable diseases. People with chronic diseases should be informed of the benefits of vaccination compared with the risk of the disease. There is no evidence that flare-ups or progressions of chronic diseases, which may occur in temporal association with vaccination, can be causally linked to vaccination.

4.8 Vaccinations to protect reproductive health, for women with the wish to have children and during pregnancy and lactation

Certain vaccine-preventable infections before and during pregnancy and in the postpartum period are associated with increased risks for women's health, the course of pregnancy and the health of the unborn or newborn child.¹ Timely administration of the recommended standard vaccinations from infancy onwards and avoidance of vaccination gaps in childbearing age offer the best protection against the impact of vaccine-preventable diseases on women's health and the health of their children.

Vaccinations to protect against sexually transmitted diseases

Vaccination against the sexually transmitted diseases **hepatitis B** and **HPV** are part of the standard immunisation schedule for **infants** aged 1 year (hepatitis B) and **children aged 9–14 years** (HPV).

The majority of acute hepatitis B cases are observed after sexual transmission in young adults. Infections are also possible, e.g. in families or in communal facilities for children, due to other possible transmission routes, e.g. through contact of infected body fluids with mucous membranes or minor injuries or otherwise damaged skin. The reason for a hepatitis B vaccination recommendation in infants is, among other things, a particularly high risk of a chronic form of progression among the rare cases of the disease in infants and toddlers, which can lead to liver cirrhosis or hepatocellular carcinoma. While in adults a chronic course of the disease occurs in 10% of cases, the proportion of cases in infants and children amounts up to 90%. If the vaccination was missed in infancy, a catch-up vaccination is recommended until the age of 17.

The goal of HPV vaccination of girls and boys is to reduce the burden of disease from HPV-induced tumours. Besides causing genital warts, persistent HPV infections can lead to cell changes in the area of the cervix, vagina and vulva, penis, anus and throat. Over time, these cell changes can lead to cancer and may therefore have a relevant, long-term influence on the sexual and reproductive health of both men and women. The timing of the vaccination is crucial for reliable protection: the vaccination series should ideally be completed before any sexual contact occurs. A catch-up vaccination is recommended until the age of 17.

Catch-up vaccinations in women of childbearing age and vaccinations for women with the wish to have children

Rubella and varicella infections of pregnant women can result in a congenital rubella syndrome (CRS) or a congenital varicella syndrome with involvement of single or multiple organs in the unborn child. A peripartum varicella infection of the mother can lead to life-threatening neonatal varicella. The STIKO recommends women of childbearing age who are unvaccinated or with unclear vaccination status to be vaccinated against rubella with 2 doses of an MMR vaccine. Women of childbearing age with one previous dose should receive a second MMR vaccination. In addition, the STIKO recommends two vaccinations against varicella for seronegative women of childbearing age. Pregnant women who contract measles have an increased risk of developing pneumonia, furthermore increased preterm labour, premature births and spontaneous abortions have been observed. A measles infection at the end of the 3rd trimester or around birth can lead to neonatal measles (see Epid Bull 32/2010).

Against measles, mumps, rubella and varicella only live vaccines are available that bear a contraindication during pregnancy. Therefore, any vaccination gaps that may exist in women of childbearing age should be closed in a timely manner. After vaccination with a live vaccine, pregnancy should be avoided for one month. Accidental vaccination with a live vaccine during early pregnancy does not constitute an indication for an abortion.

As part of the spontaneous recording of adverse events after vaccination¹ and a systematic literature review of epidemiological studies, that covered more than 3,500 documented vaccinations during pregnancy with monovalent rubella or measles-rubella or measles-mumps-rubella (MMR) vaccines, no case of congenital rubella disease caused by the vaccine virus^K was observed.

Missing or incomplete vaccinations against **tetanus**, **diphtheria** and **polio** should be completed according to the general recommendations of the STIKO (see Table 10E). If applicable, vaccination against hepatitis B should be given before conception (see Table 2). Vertical transmission from the most often chronically infected mother to the child is the main cause of hepatitis B in infected children,^L which leads to a chronic course in about 90 % of cases of perinatal infection.^M

In contrast to live vaccines, after vaccination with an inactivated vaccine, no time interval has to be considered before a potential conception.

Vaccinations during pregnancy

Due to theoretical considerations, vaccinations with a **live vaccine**, such as against measles, mumps, rubella or varicella, **generally poses a contraindication** in pregnancy.

Vaccination with the live vaccine against **yellow fever** may be administered during pregnancy in the presence of an unambiguous indication and after a careful risk-benefit assessment.

Inactivated vaccines are considered **safe** for the pregnant woman and fetus.^N Therefore, pregnancy is not a contraindication for the administration of inactivated vaccines (such as those against influen-

za, tetanus, diphtheria, pertussis, hepatitis A and B). In the first trimester of pregnancy, only urgently indicated vaccinations should be administered to avoid that spontaneous abortions, which are frequent in early pregnancy, are associated with the vaccination.

Vaccination against seasonal **influenza** and **pertussis** is explicitly recommended by the STIKO during every pregnancy (see Table 2). The primary vaccination goal of influenza vaccination of pregnant women is to prevent a severe course of disease progression, whereas the goal of pertussis vaccination in pregnancy is to reduce the disease burden in newborns and young infants.

If the pertussis vaccination recommended during pregnancy has not been administered, the mother should preferably be vaccinated in the first days after birth. Especially before the birth of a child, it should be reviewed whether close household contacts and close contacts of the newborn have sufficient immunological protection (vaccination within the past 10 years) against pertussis (see Table 2).

Vaccinations during lactation

Breastfeeding women can receive all vaccinations recommended by the STIKO with the exception of the yellow fever vaccination (see chapter 4.7 "Contraindications and false contraindications"). The postnatal examination at the end of the postpartum period is particularly useful for vaccination prophylaxis. Mothers who do not have 2 documented doses of rubella vaccine or who tested seronegative for rubella during pregnancy should be administered 2 MMR vaccine doses postpartum at a (minimum) interval of 4 weeks.

4.9 Vaccinating patients with immunodeficiency

Patients with immunodeficiency frequently suffer from infectious diseases. These diseases often have a particularly severe course in this group. People with immunodeficiency should therefore be given as much protection as possible by vaccination. It is also important for infection protection that those who come into household contact with people with immunodeficiency are properly protected by vaccination in line with STIKO recommendations. This also applies to other people in the patient's direct environment (for example in the health service, day care centre for children or school).

Table 2 of the STIKO recommendations already lists some groups of patients with a congenital or acquired immunodeficiency. When planning and carrying out vaccinations, special attention must be paid to some particularities in these patient groups. This may involve:

- Recognition and assessment of the severity of the immune defect;
- Assessment of indications and contraindications for specific vaccinations or vaccine types, depending on the type and severity of the underlying disease or if applicable the immunosuppressive medication and the thereof resulting immune deficiency;
- Considering the time of vaccination (e.g. before a planned iatrogenic immunosuppression);
- The comprehensive provision of information to the patient, especially if an off-label application is necessary.

To assist vaccinating physicians with the mentioned points above and to provide decision-making assistance, a group of experts has developed vaccination guidelines for patients with immunodeficiency under the leadership of STIKO. These instructions are published in four themed documents and are available online (www.rki.de/immundefizienz.de, in German only). This includes the basic paper (Paper I), the application instructions for vaccinating patients with primary immunodeficiency diseases (including autoinflammatory diseases) and HIV infection (Paper II), the instructions for vaccination against haematological and oncological diseases (antineoplastic therapy, stem cell transplantation), organ transplantation and asplenia (Paper III) and the instructions for vaccination against autoimmune diseases, other chronic inflammatory diseases and under immunomodulatory therapy (Paper IV).

4.10 Vaccination complications and reporting

Criteria for differentiating normal vaccine reactions from potential complications

Under the Protection Against Infection Act (IfSG) (§6, para.1, sentence 1, no.3), every suspected vaccine-

associated complication must be notified to the responsible local public health authority. This notification is a medical duty. Complications are defined as damage to health that goes beyond the usual reaction to vaccination. To differentiate vaccinationassociated complications, which must be reported, from normal vaccination reactions, STIKO has defined the characteristics of normal reactions to vaccination, as requested by IfSG (§ 20, para. 2, sentence 3).

Normal vaccination reactions that are exempt from notification are defined as temporary local and systemic reactions that do not go beyond the usual dimensions of a reaction to vaccination and can be seen as the expression of the interaction between the organism and the vaccine. STIKO has set out the following criteria for **normal reactions to vaccines**:

- Over a period of 1-3 days (occasionally longer): prolonged reddening, swelling or pain around the injection site;
- Over a period of 1–3 days: fever <39.5°C (rectal measurement), headache and joint pain, tiredness (fatigue), discomfort (malaise), nausea, restlessness, swelling of regional lymph nodes;
- 1-3 weeks after administration of attenuated live vaccines: symptoms of an ascribable "vaccination illness" such as mild parotid swelling, short-term arthralgia or a temporary exanthema after measles, mumps, rubella or varicella vaccinations, or mild gastrointestinal complaints, e.g. following oral rotavirus or typhoid vaccinations.
- Symptoms which are obviously ascribable to a cause other than the vaccine are also exempt from notification. All other reactions should be reported.

Reporting the suspicion of vaccine-associated complications

Under the Protection Against Infection Act (IfSG) (\S 6, para.1, sentence 1, no.3), any suspicion of damage to health (suspicion of vaccine-associated complications) that goes beyond normal vaccine reactions must be reported within 24 hours by name to the local public health authority (\S 9, para.1 and 3 IfSG). The physician's notification must immediately be forwarded by the local public health authorities under \S 11, para.2 (IfSG) and from there to the respective fe-

deral authority (PEI) under §77 of the German Drug Law. The obligation to notify was made statutory to ensure immediate triggering of the relevant immunological tests (e.g. to exclude an immune defect) or microbiological tests (e.g. to exclude an intercurrent infection by differential diagnosis) required to clarify adverse drug reactions and to acquire and store the necessary test materials such as serum or stool samples.

The notification obligation applies whether or not the vaccine is publicly recommended. To ensure uniform reporting of suspected cases nationwide, PEI has developed a report form in collaboration with STIKO and the German Ministry of Health entitled, "Bericht über Verdachtsfälle einer über das übliche Ausmaß einer Impfreaktion hinausgehenden gesundheitlichen Schädigung" (Report of suspected cases of damage to health going beyond the usual reaction to vaccination). This is available online at: www.pei.de/SharedDocs/Downloads/DE/ arzneimittelsicherheit/pharmakovigilanz/ifsg-meldebogen-verdacht-impfkomplikation.pdf and can also be obtained from the health authorities. The reports help to improve the pool of data on vaccineassociated complications.

Under §6 of their professional code, physicians are also obliged to report any adverse drug reactions they encounter in the course of providing treatment to the Drug Commission of the German Medical Association (www.akdae.de). The manufacturer can also be informed.

Vaccination damage and its recognition under the Infection Protection Act (IfSG)

IfSG, § 2, no. 11 defines vaccination damage as a health or economic consequence of harm attributable to the vaccination and which goes beyond the normal reaction to the vaccination. Vaccination damage is also considered to have occurred if pathogens capable of reproduction are administered (live vaccine), and someone other than the person vaccinated is harmed because the vaccine virus is transmitted. Anyone who suffers vaccination damage resulting from a vaccination publicly recommended by a competent state authority of the area where they are living, is eligible for benefits based on the health and economic consequences, as defined by the Federal Benefit Act (§ 60, para.1, sentence 1, no.1 IfSG). The person affected or their parents or guardians must submit an application for care to the responsible pension office of their state of residence. The same applies in the case of health damage caused by a vaccination against the SARS-CoV-2 coronavirus on the basis of a statutory order pursuant to section 20i, paragraph 3, sentence 2, number 1, letter a, also in conjugation with number 2, Book V of the Social Code [SGB V] (§ 60, para.1, sentence 1, no.1a, IfSG).

The procedure differs and is separate from the process of reporting a suspected vaccination complication (see previous sections). Local public health authorities or attending physicians should inform people affected or their parents or guardians of statutory provisions for compensation following vaccination damage (IfSG, \S 60–64), the responsible authority of the federal state as descripted in the Federal Benefit Act (\S 64, IfSG) and the procedure. Information on this can also be obtained from the regional pension offices themselves.

4.11. Vaccination of personnel in medical facilities

Vaccination of personnel in medical facilities is of particular importance. On the one hand, due to their professional activity, medical workers are exposed to an increased risk of exposure to certain infectious agents. In this case the occupational indicated vaccination serves to protect the individual worker against infections. On the other hand, the personnel themselves can become a source of infection for the patients they care for or for colleagues. The vaccination of medical personnel can thus serve to avert vaccination-preventable nosocomial infections of the patients (so-called third-party protection). Recommendations of the STIKO according to §20, para.2, IfSG generally consider both aspects. The STIKO has published a statement on vaccinations for personnel in medical facilities to support managers and directors of medical facilities and those responsible for implementing vaccinations, in reducing the transmission of vaccinepreventable infectious diseases in their areas of responsibility and to ensure that the personnel working in medical facilities have adequate vaccination protection in accordance with their area of application. The statement includes a table with information on selected vaccine-preventable infectious diseases and the occupationally indicated vaccination recommendations as well as information on postexposure prophylaxis (PEP) (see Epid Bull 4/2021).

4.12 Vaccination recommendations for migrants and refugees living in Germany

Migrants and refugees living in Germany should be vaccinated according to the STIKO recommendations for their age. Refugees often come from countries or demographic groups with limited access to medical care and vaccinations. An overview of the vaccinations recommended in individual countries can be found on the websites of the European Centre for Disease Prevention and Control (ECDC) (https://vaccine-schedule.ecdc.europa.eu/) or WHO (https://immunizationdata.who.int/listing.html?topic=vaccine-schedule&location=).

Any available vaccination documents should be used to assess the individual's vaccination status. Any missing vaccinations should be administered (see chapter 6). Often, vaccination status cannot be assessed because of a lack of documents. Vaccinations that are not documented are considered not to have been administered, and should be administered following STIKO recommendations. However, credible oral statements on prior vaccinations should be taken into account.

- Children and adolescents who are unvaccinated or whose vaccination status is not clear should receive vaccinations against diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella, varicella, hepatitis B, meningococcus C, and HPV (from the age of 9 years). Infants should also be vaccinated against rotaviruses, with the vaccination course completed by the age of 24 weeks (Rotarix) or 32 weeks (RotaTeq). Infants and toddlers should be vaccinated against pneumococci (up to the age of 24 months) and Haemophilus influenzae type b (up to the age of 4 years). Children with documented primary immunization against tetanus, diphtheria, pertussis, and poliomyelitis need one booster 5 years after their primary immunisation.
- Unvaccinated adults or adults whose vaccination status is not clear should receive initial immunisation against diphtheria, tetanus, pertussis, and poliomyelitis. Adults who already have primary

immunisation against tetanus, diphtheria, pertussis, and poliomyelitis should receive a Tdap-IPV booster 10 years after the previous vaccination. People born after 1970 should receive a single vaccination against measles (MMR). Women of child-bearing age should be vaccinated twice against rubella (MMR), and seronegative women who wish to have children should be vaccinated twice against varicella. From the age of 60 years, a pneumococcal vaccination (see chapter 3.2) and an annual influenza vaccination (in autumn) should also be administered.

So that people can be informed about the diseases to be prevented and the vaccination planned, the RKI provides an educational package, including consent forms for various vaccinations in several languages on the internet (COVID-19, hepatitis A, hepatitis B, herpes zoster (inactivated vaccine), HPV, influenza, MMR, meningococci C, varicella, pneumococci, rotavirus, Tdap-IPV, and 6-in-1 vaccination [DTaP-IPV-Hib-HepB]): www.rki.de.

Invoicing for publicly recommended vaccinations for refugees is regulated by the Benefits for Asylum Seekers Act (AsylbLG, §4, para. 3). Health insurance normally pays for vaccinations for all other migrants.

Recommended vaccinations for refugees in reception centres and other shared accommodation facilities with crowded living conditions

Living together for extended periods in crowded conditions (e.g. in reception centres for asylum seekers) increases the probability of outbreaks of infectious diseases. A growing number of inadequatelyvaccinated people can lead to the development of an epidemiologically relevant, unprotected demographic group. Closing gaps in the vaccination coverage of these groups can be difficult because of the decentralized healthcare system and the required selfresponsibility in Germany. However, public health workers or contracted physicians have good access to reception centres and shared accommodation facilities, where they can implement targeted measures to close vaccination gaps. Administering vaccinations soon after arrival in Germany can achieve the following aims:

individual protection and closing vaccine gaps;

- limiting or preventing outbreaks of diseases preventable by vaccination in facilities;
- preventing demographic groups that are unvaccinated and difficult to reach.

The situation (size of the facility, length of stay, resources) and the organization of vaccination appointments vary widely among the reception centres and shared accommodation facilities. If possible, all vaccinations recommended by STIKO should be included in vaccination appointments. In facilities in which it is difficult to implement the STIKO recommendations because stays tend to be short, only one vaccination appointment may be possible. In that case, vaccinations should be prioritized.

Table 4 lists high-priority vaccinations that should be started soon after arrival and admission to the facility, if possible in the first few days. After leaving the facilities, licensed physicians or public health workers at the refugee's next destination should com-

plete the primary immunisation or start new ageappropriate vaccinations based on catch-up vaccination recommendations (see chapter 6.10).

General information provided by STIKO on vaccinations should be taken into account (see <u>chapter 4.1</u>). If there are not enough vaccines in the facility, children should be given priority. Vaccinations to control outbreaks of diseases preventable through vaccination should be given first priority, and if applicable, combined with other required vaccinations.

There is an elevated risk of influenza outbreaks in reception centres and shared accommodation facilities because of the crowded living conditions. Beyond STIKO recommendations, local public health authorities can consider offering vaccinations against seasonal influenza in the autumn and winter months to all residents, and not only to groups at high risk.

Age at first vaccination First vaccination appointment# 2-8 months DTaP-IPV-Hib-HepB¹ DTaP-IPV-Hib-HepB 9 months - 4 years MMR-V² Tdap-IPV 5-17 years MMR-V Tdap-IPV³ Adults born after 1970 MMR⁴ Tdap-IPV³ Adults born before 1970 Additional indicated vaccinations for: • Pregnant women from the 2nd trimester Influenza (in addition to the above vaccinations) People aged 60 years and older Children and adults with chronic diseases⁵

Table 4 | Prioritizing vaccinations for the first vaccination appointment soon after arrival for unvaccinated refugees and refugees whose vaccination status is not clear

The vaccines mentioned here can be administered simultaneously.

A pentavalent vaccine can also be used.

2 In children aged < 5 years, it may be better to separate the first dose of MMR and V vaccines, instead of using the MMR-V combination vaccine.

3 Pregnancy is not a contraindication.

4 Contraindicated during pregnancy.

5 In case of unclear anamnesis, set indication to vaccinate generously.

Employees (including e.g. volunteers) in reception centres or shared accommodation facilities should be vaccinated following the STIKO vaccination recommendations for their age. Vaccination status for tetanus, diphtheria, poliomyelitis, pertussis, measles (for people born after 1970), mumps, and rubella should be assessed based on entries in vaccination records whenever possible. Vaccination for protection against varicella is recommended for all seronegative persons (see Epid Bull 2/2020²⁵). The ArbMedVV (Ordinance on Occupational Health Care) should be followed for those employed.

STIKO also recommends the following vaccinations for employees with elevated risk of exposure in these facilities. Indications should be defined based on an estimation of the actual risk of exposure:

- hepatitis A
- hepatitis B
- poliomyelitis booster if the last vaccination was more than 10 years ago
- influenza (in season)

4.13 Vaccine supply shortages

Since October 2015, the PEI website has included information about shortages in the supply of vaccines and the probable duration of non-availability (www.pei.de/lieferengpaesse). This information is derived from notifications from pharmaceutical companies, which report shortages as soon as the delivery chain for supplying a vaccine is interrupted for a period of at least 2 weeks. PEI also announces on their website if one or more alternative vaccines with the same composition are available and can be used instead.

If no licensed vaccine with comparable antigen composition is available for the respective indication and age, the STIKO gives recommendations on how protection through vaccination can be ensured alternatively – using other available vaccines. Even though there are no unacceptably long vaccination intervals and every vaccination counts, a timely immunisation in accordance with the recommendations – especially in infants and toddlers – is preferable from the STIKO's perspective. This also applies to the influenza vaccination, where immunity through vaccination should ideally be achieved before the start of the influenza season. Booster vaccinations may be postponed if primary immunisation is complete, since the time intervals recommended by the STIKO for booster vaccinations allow a certain degree of flexibility.

Table 5 lists recommendations for the most frequent or relevant supply shortages for which no alternative vaccine with comparable composition is available. The alternative recommendation should be applied as soon as the PEI website mentioned above informs about a supply shortage of the originally recommended vaccine. A query in several regional supply pharmacies can clarify whether, despite the supply shortage declared by the PEI, residual stocks of this vaccine are still available regionally. For the application of the alternative recommendations, the information on the PEI website is authoritative; in addition, the STIKO provides information on its website (www.stiko.de > Lieferengpaesse). The alternative recommendation loses its validity as soon as the PEI cancels the determination of the supply shortage on its website (see above). In addition, the STIKO will also remove the reference of the applicability of the alternative recommendation from its website. For further information, see Epid Bull 23/2021.²³

4.14 Notes on invoicing for vaccinations

There are various possible options for covering the cost of vaccinations. Under § 20I, para.1 first sentence of Book V of the Social Code [SGB V], insured people are entitled to vaccination under §2 no.9 of the Protection Against Infection Act (IfSG). Based on STIKO recommendations, the Federal Joint Committee (G-BA) must provide vaccination guidelines (see www.g-ba.de) that establish the details of the obligation to reimburse the cost of vaccinations (including requirements, type and scope). Therefore the significance of the vaccinations for public health should be considered. According to §20i para.1 first sentence of SGB V, immunisations indicated because of an increased health risk from a non-workrelated stay abroad (travel vaccinations) are excluded from this entitlement, unless there is special interest in preventing the introduction of a transmissible

Vaccination against ^a	Recommended vaccine affected by supply shortage ^a	Recommended alternative(s) ^b
Diphtheria, tetanus, pertussis, poliomyelitis, <i>Haemophilus</i> <i>influenzae</i> type b, hepatitis B	Hexavalent vaccine (DTaP-IPV-Hib-HepB)	Pentavalent vaccine (DTaP-IPV-Hib) plus monovalent HB vaccine Alternative: DTaP vaccine (trivalent) plus monovalent vaccines IPV, Hib and HB
Hepatitis A, hepatitis B	Combination vaccine HA+B	Monovalent vaccine HA plus monovalent vaccine HB
Hepatitis B	Monovalent HB vaccine	Combination vaccine HA+B
Herpes zoster	Adjuvanted herpes zoster inactivated vaccine	No alternative (postponement of the vaccination appointment)
Haemophilus influenzae type b	Monovalent Hib vaccine	No alternative ${}^{\varepsilon}$ (postponement of the vaccination appointment)
Influenza (standard vaccina- tion for persons ≥60 years)	Inactivated, quadrivalent, high-dose influenza vaccine, with current antigen combination recommended by WHO	Inactivated, quadrivalent influenza vaccines (cell culture based, split virus, subunit, recombinant and adjuvanted vaccines)
Measles, mumps, rubella	MMR combination vaccine	MMR-V combination vaccine ^d
Measles, mumps, rubella, varicella (MMR-V)	MMR-V combination vaccine	MMR combination vaccine plus monovalent varicella vaccine
Pneumococcal disease	23-valent polysaccharide vaccine	No alternative [®] (postponement of the vaccination appointment)
Tetanus, diphtheria, pertussis	TdaP/Tdap combination vaccine	Tdap-IPV combination vaccine

Table 5 | Alternatively recommended vaccines in case of supply shortages

a According to immunisation schedule (standard vaccinations) for infants, children, adolescents and adults in Table 1, recommendations on standard vaccinations for adults and indication and booster vaccinations for all age groups in Table 2, postexposure vaccinations in Table 6, and age-dependent recommendations for the implementation of catch-up vaccinations in Table 10 A-E, respectively.

b In compliance with license restrictions and according to the Summery of Product Characteristics.

c Does not apply to children <5 years of age, here DTaP-IPV-Hib or DTaP-IPV-Hib-HepB can be used as an alternative.

d Note slightly increased risk of febrile convulsions in children <5 years of age 5–12 days after initial administration of combined MMR-V vaccine (see Epid Bull 30/2012); however, the STIKO considers this slightly increased risk to be secondary to timely MMR immunisation in the event of a supply shortage.

e Because of the broader coverage of pneumococcal serotypes, it is not appropriate to replace the 23-valent polysaccharide vaccine with another, lower-valent pneumococcal vaccine; when availability is limited, remaining doses of vaccine should be prioritized for the following groups: patients with immunodeficiency (to complete sequential vaccination); seniors ≥ 70 years of age; patients with a chronic cardiac and respiratory diseases.

Abbreviations: diphtheria: D or d (depending on antigen concentration); *Haemophilus influenzae* type b: Hib; hepatitis A: HA; hepatitis B: HepB and HB; measles mumps rubella: MMR; pertussis: aP or ap (depending on antigen concentration); poliomyelitis: IPV: tetanus: T; varicella: V

disease into the Federal Republic of Germany, for the protection of public health. Under §20i para.1 first sentence of SGB V, the Federal Joint Committee determines individual requirements, type and scope of services in guidelines following §92 SGB V on the basis of the STIKO recommendations according to §20 para.2 IfSG with special consideration of the importance of protective vaccinations for public health (§20i, para.1, sentence 3 and 4 SGB V). Any deviations from the STIKO recommendations must be specifically justified.

If a GB-A decision is not made within 2 months following publication of the STIKO recommendations, vaccinations recommended by STIKO must be provided by health insurance companies until the guideline comes into existence. The optional benefits coverage provided by health insurance companies can also include the reimbursement of the cost for further vaccinations that are not part of the guidelines of the Federal Joint Committee. The health insurance company associations have to jointly and uniformly make agreements regulating the funding of protective vaccinations and the reimbursement of vaccine costs at the regional level with the regional authorities responsible for carrying out vaccinations.

Apart from the health insurance companies, other payers can cover the cost of protective vaccinations.

The vaccinations denoted "O" in the STIKO recommendations also include those for professional groups that are not subject to the named ordinances. This category includes vaccinations that are primarily indicated for the protection of third parties. Even if no regulations apply in these cases, it is in the interests of employers to offer these vaccinations, because this allows them to counter possible claims for regress and avoid the costs of employee absenteeism. The protective vaccination guidelines of the Federal Joint Committee determine how far the recommendations denoted "O" are standard services for the statutory health insurance companies.

5. Post-exposure vaccinations and other measures for specific prophylaxis of communicable diseases

5.1 Overview

As well as recommendations for standard and indicated vaccinations, STIKO issues recommendations about post-exposure vaccinations and other measures for specific prophylaxis among those in contact with diseases in private and occupational settings or community facilities. These recommendations include advice on how insufficiently-protected individuals can be protected after exposure to specific infectious agents to prevent further spread of the disease or to mitigate the course of the disease. Postexposure vaccination, passive immunisation by administration of immunoglobulins, and chemoprophylaxis are specified as preventive measures. Information on post-exposure prophylaxis of specific infectious diseases can also be found in the "RKI Guidebooks" ("RKI-Ratgeber", www.rki.de/ratgeber).

5.2 Vaccinations in cases of clusters or outbreaks of meningococcal diseases

- A "meningococcal disease outbreak" is defined as two or more cases of the same serogroup within 4 weeks in a children's facility, school class, playgroup, or a community facility with a householdlike character (for example, student dormitories, boarding school, or barracks);
- A "regionally-clustered occurrence" is defined as three or more cases of the same serogroup within 3 months:

- in a restricted age group of the population (e.g., adolescents) in one place; or
- in a region with a resulting incidence $\geq 10/100,000$ in the relevant population.

As well as antibiotic prophylaxis for close contacts (see Table 6, and the recommendations of the German Society of Paediatric Infectious Diseases [Deutsche Gesellschaft für Pädiatrische Infektiologie (DGPI)], or the National Reference Centre for Meningococci, and the RKI-Ratgeber "Meningokokken" ["Meningococcal Disease Guide"] of the RKI), the responsible health authorities can recommend prophylactic vaccination if the clustered occurrence or the outbreak was caused by a strain preventable by vaccination. This is justified by the possibility of further cases occurring up to a few months after the onset of the first illnesses.

As with antibiotic prophylaxis, close contacts in the households of patients, their intimate partners, and close contacts in children's facilities, school classes, playgroups, and community facilities with a household-like character can be included in prophylactic vaccination if there is an outbreak.

For a regionally-clustered occurrence, the responsible health authorities must decide on recommendations considering the epidemiological and temporal correlations of the cases, their age distribution, the level of public concern, and the feasibility of the measures.

For vaccination, the licenced vaccines for the meningococcus serogroup causing the outbreak can be used (see notes on use in Table 2 and notes on vaccination against meningococcal infection in chapter 3.2).

Whenever meningococcal meningitis is suspected, a specimen for isolation of the pathogen should immediately be sent to a suitable laboratory. The responsible local Public Health Department should urge that samples of isolated meningococci be sent as rapidly as possible to the National Reference Centre to ensure typing and to permit preventive vaccination to be recommended in the event of a clustered occurrence.

Table 6 | Post-exposure vaccinations and other measures for specific prophylaxis

Disease	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Diphtheria	For people in close (face-to-face) contact with cases.	Chemoprophylaxis: Independent of vaccination status, preventive antibiotic treatment is recommended, e.g., with erythromycin (see RKI's Guidebook for Physicians, on diphtheria, www.rki.de/ratgeber > Diphtherie). Post-exposure vaccination is indicated if the most recent vaccination was > 5 years ago.
	During epidemics or increased morbidity in the region.	Vaccination in line with health authority recommendations.
Haemophilus influenzae type b (Hib)	 Chemoprophylaxis is recommended after close contact (face-to-face) with a patient with invasive Haemophilus influenzae type b infection: For all household members at least 1 month old, if either an unimmunised or insufficiently immunised child aged up to 4 years or someone with a relevant immunodeficiency is present; For unimmunised exposed children up to 4 years of age in community facilities; For all children, regardless of vaccination status and age, as well as for caregivers of the same group in a community facility for young children, if ≥ 2 cases have occurred within approximately 2 months and children of the facility are unvaccinated or incompletely vaccinated 	Chemoprophylaxis: Rifampicin: From 1 month old: 1 x 20 mg/kg body weight (up to a maximum of 600 mg) per oral for 4 days Adults: 1 x 600 mg per oral for 4 days Administration of rifampicin is contraindicated in pregnant women, so ceftriaxone could be considered instead for prophylaxis (1 x 250 mg, given intramuscularly). If prophylaxis (1 x 250 mg, given intramuscularly). If prophylaxis is indicated, it should be started as soon as possible, and at the latest 7 days after the onset of disease in the index case. In addition to chemoprophylaxis, unvaccinated or incompletely vaccinated children ≤ 4 years old should be revaccinated against Hib.
Hepatitis A (HA)	Contact with hepatitis A patients (especially in community facilities).	Post-exposure vaccination with monovalent hepatitis A vaccine within 14 days of exposure: Following exposure in people in particular danger from hepatitis A (e.g., those chronically infected with HBV or HCV), an immunoglobulin preparation should be given simulta- neously with the first vaccination. See also "Ratgeber Hepatitis A" ["Hepatitis A Guide"] at www.rki.de/ratgeber > Hepatitis A.
Hepatitis B (HB)	Injuries from objects potentially containing HB virus (e.g., a needle) or blood contact with mucous membranes or broken skin.	See post-exposure hepatitis B immune prophylaxis (chapter 5.3 and Figure 1)
	Newborn babies with HBsAg-positive mothers or mothers with unknown HBsAg status (regardless of birth weight).	See comments on specific vaccinations (chapter 3.2)
Measles	 People with unclear vaccination status, who have not been vaccinated, or who received only one vaccination during childhood after contact with measles cases: At the age of 6 to 8 months: exceptionally after individual risk-benefit consideration (off-label-use). At the age of 9 to 10 months At the age of 11 months to 17 years. At the age of 18 years or more, born after 1970 	 Vaccination with MMR(V)* vaccine preferably within 3 days of exposure. For the number of vaccine doses and the time of administration, please consider the following age-specific recommendations: Vaccination; Vaccination; A second and third vaccine dose should be given at the ages of 11 and 15 months. First vaccination; The second vaccination should be given at the beginning of the second year of life. People with unclear vaccination status or who have not been vaccinated should be given two vaccine doses, administered at least 4 weeks apart; People who have received only one vaccination should be given one more vaccination. People who have not been vaccinated, with unclear vaccination, who were given only one vaccination during childhood should be given one vaccination.
	* MMR(V) = MMR with or without co-administration of varicella vaccine	

Disease	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
	Unprotected people with a high risk of complications and for whom active immunisation is contraindicated after exposure to measles: Infants < 6 months of age susceptible pregnant women immunodeficient individuals 	Post-exposure administration of immunoglobulins <i>(off-label-use)</i> as soon as possible, preferably within 6 days of exposure: 1 x 400 mg/kg body weight, intravenously. For infants between 6 to 8 months of age, passive immuniza- tion with immunoglobulins can be considered instead of the first vaccination, based on an individual risk-benefit assess- ment, for instance if the contact happened more than 3 days before. After administration of immunoglobulins, the MMR vaccination is not reliably effective for 8 months. This should be taken into consideration in the event of an indication for immunoglobulin administration (see also Epid Bull 2/2017).
Meningo- cocci	 Chemoprophylaxis is recommended for all those in close contact with someone with invasive meningococcal infection (all serogroups). This includes: All household contacts of patients; People directly exposed to the patient's oropharyngeal secretions; Contacts in childcare facilities for children under 6 years of age (if the groups are well-separated, only in the affected group); People with close contacts in community facilities with a household-like character (boarding schools, student dormitories and barracks) Chemoprophylaxis is indicated if close contact with the index patient took place in the 7 days preceding the onset of illness. Chemoprophylaxis, post-exposure vaccination is recommended for unvaccinated household contacts or close contacts in similar settings, if the infection of the index case was caused by serogroups A, C, W, Y or B. The vaccination should be given as soon as possible after the serogroup of the pathogen has been determined for the index case. 	Chemoprophylaxis: <i>Rifampicin</i> : Newborn babies: 2 x 5 mg/kg body weight per oral for 2 days Infants, children and adolescents up to 60 kg: 2 x 10 mg/kg body weight (max. dosage 600 mg) per oral for 2 days Adolescents and adults from 60 kg: 2 x 600 mg per oral for 2 days. Eradication rate: 72–90% Or: <i>Ciprofloxacin</i> : From 18 years of age: 1 × 500 mg per oral Eradication rate: 90–95% Where applicable, <i>Ceftriaxone</i> : From 2 to 11 years of age (<50 kg): 1 x 125 mg, given intramuscularly From 12 years of age (≥50 kg): 1 x 250 mg, given intramuscularly From 13 years of age (≥50 kg): 1 x 250 mg, given intramuscularly From 13 years of age (especially for pregnant women after exposure): 1 x 500 mg per oral Eradication rate: 97% Where applicable, <i>Azithromycin</i> : From 13 years of age (especially for pregnant women after exposure): 1 x 500 mg per oral Eradication rate: 93 % Administration of rifampicin and gyrase inhibitors is contraindicated in pregnant women, so ceftriaxone (1 x 250 mg, given intrawnuscularly or intravenously) or azithromycin (1 x 500 mg per oral) can be used as prophylaxis if necessary. An index case with an invasive meningococcal infection should also receive rifampicin after completion of therapy, unless given intravenous treatment with a third-generation ceephalosporin
Mumps	 People with unclear vaccination status, who have not been vaccinated, or who received only one vaccination during childhood, who have been in contact with mumps cases 	Single vaccination with an MMR vaccine (if possible within 3 days of exposure).

Disease	Indication	Notes on use (Note package leaflet/ Summary of Product Characteristics)
Mpox/ Monkeypox	 After close physical contact via non-intact skin (skin lesions) or mucous membranes (e. g. sexual contact, interpersonal contact between family members) or after prolonged unprotected face-to-face contact <1 m with a person who is infected with monkeypox (e. g. household contacts). After close contact without adequate personal protective equipment (gloves, FFP2 mask/medical face mask and protective gown) with a person with confirmed monkeypox infection, their bodily fluids (e. g. needlestick injury) or contaminated potentially infectious material (e. g. clothing or bedding of infected people) in medical care. Laboratory personnel having accidental unprotected contact with laboratory samples containing non-inactivated monkeypox material; especially when virus enrichment is carried out in cell cultures. 	 Post-exposure vaccination with Imvanex* (Modified Vaccinia Ankara, Bavarian-Nordic [MVA-BN]) from asymptomatic persons aged ≥ 18 years as early as possible within a period of up to 14 days after exposure. In people who have had a smallpox (Variola maior) vaccination in the past, a single dose of vaccine is sufficient. In the event of a local infection cluster (outbreaks), adults can be given a vaccination without proven direct or indirect contact with an infected index case (ring vaccination). * equivalent the vaccine Jynneos of Bavarian Nordic can be used (as good as identical with Imvanex)
Pertussis	 People without vaccination protection in close contact with a case in the family, a shared accommodation, or a community facility. Vaccinated persons with close contact to a pertussis case, if there are persons at risk in their environment (e.g. unvaccinated or incompletely vaccinated infants, children with basic cardiac or pulmonary diseases or pregnant women during the last trimester). 	Chemoprophylaxis with a macrolide is recommended (see also RKI-Ratgeber "Pertussis" ["Pertussis Guide"] at <u>www.rki.de/</u> ratgeber > Pertussis).
Poliomyelitis	All contacts of a poliomyelitis cases regardless of their vaccination status. A secondary case is a cause for ring vaccinations.	Immediate post-exposure vaccination with IPV. Immediate extensive investigations and establishment of measures by the health authorities. Ring vaccinations with IPV and establishment of further measures by decree of health authorities.
Tetanus	See Table 8	
Rabies	See Table 9	
Varicella	1. Unvaccinated people without prior history of varicella and in contact with people at increased risk.	Post-exposure vaccination within 5 days of exposure ^{**} or within 3 days of rash onset in the index case. Additionally, contact with people at risk (for example, those listed in point 2) should be avoided at all costs
	 Persons at increased risk of varicella complications, including: Unvaccinated pregnant women with no history of varicella; Immunodeficient patients with uncertain or absent varicella immunity; Newborn babies whose mothers became ill with varicella between 5 days before and 2 days after delivery; Preterm babies born in or after the 28th gestation week, whose mothers are not immune, if exposed in the neonatal period; Preterm babies born before the 28th gestation week if exposed in the neonatal period regardless of their mother's immune status. 	Post-exposure administration of varicella zoster immunoglo- bulin (VZIG) as soon as possible and no later than 96 hours after exposition. ^{**} VZIG can prevent or markedly alleviate the disease. Please follow the Summary of Product Characteristics for the administration and dosing of VZIG! Post-exposure administration of VZIG can be given in combination with antiviral chemoprophylaxis, if applicable
	Exposure is defined as. I nour or more with an infectious person if	r a room, race-to-race contact, mousefiold contact.

5.3 Post-exposure hepatitis B immunoprophylaxis

Prompt prophylaxis is required following exposure to the hepatitis B virus (HBV). The following notes were compiled for application in the field of occupational health and can be transferred to other health service fields.

Lacerations and puncture wounds (especially with hollow needles) and blood contact with mucosa or broken skin provide a risk of infection. Any such event (for example, during patient care of an "index case") should be reported as an occupational accident by the employees (the "exposed people"). The HBsAg status of the index case and the HBV vaccination status of the exposed people should be determined.

Further measures depend on the HBsAg status of the index case:

 If the index case is HBsAg-negative: Further measures to prevent hepatitis B are superfluous.* If the exposed people have not been vaccinated or vaccination is incomplete, primary immunisation should be started or completed.

- 2. If the index case is HBsAg-positive: Further measures depend on the vaccination status of the exposed people and are explained below.
- 3. If the HBsAg status of the index case is unknown: The HBsAg level of the index case should be determined immediately (within 48 hours). Depending on the result of the HBsAg testing, intervention should proceed as described in 1 or 2, above. If testing is not possible within 48 hours or at all (e. g., injury from a hollow needle in a rubbish bag), the index case is classified as HBsAg-positive, and further measures depend on the vaccination status of the exposed people. **

The process described below is also shown in a flow chart (see Figure 1).



Figure 1 | Procedure for post-exposure hepatitis B immunoprophylaxis (see text for details)

* In incompletely vaccinated or unvaccinated persons vaccination schedule should be completed.

Very rarely, HBsAg-negative people can be infectious. From a cost-benefit point of view, routine testing for HBV-DNA of all index cases does not seem practicable.

An isolated positive result of an anti-HBc test possibly necessitates further diagnostic clarification. However, required vaccination should not be delayed.

For exposed people with complete vaccination: The measures to be taken depend on the most recent anti-HBs level.

- ▶ Anti-HBs was determined within the last 10 years:
 - · Anti-HBs was ≥ 100 IU/l: No action.
 - Anti-HBs was 10–99 IU/l: Immediate determination of the current anti-HBs level, with further action depending on the test result (see Table 7).
 - Anti-HBs was <10 IU/l: Blood withdrawal (testing for HBsAg, anti-HBc, and anti-HBs), followed by immediate simultaneous administration of HB vaccine and HB immunoglobulin without waiting for the test results.** *Exception*: If at a point more than 10 years ago, an anti-HBs ≥100 IU/l was recorded, only HB vaccine (not HB immunoglobulin) should be given (see the flow chart in Figure 1).
- Last anti-HBs testing was more than 10 years ago or never (or if test result is unknown): Immediate testing of the current anti-HBs level. Further action depends on the test result (see Table 7).

For exposed people with incomplete vaccination:

- Immediate testing of the current anti-HBs level.
 Further action depends on the test result (see Table 7).
- Administration of missing vaccinations (where applicable, a shortened vaccination schedule can be used; see Summary of Product Characteristics).

For unvaccinated exposed people and known "nonresponders" (individuals with permanent anti-HBs <10 IU/l):

- Blood withdrawal (testing for HBsAg, anti-HBc, anti-HBs), and subsequent immediate simultaneous administration of HB vaccine and HB immunoglobulin without waiting for the test results.**
- For unvaccinated people, two additional vaccine doses (after the initial dose) should be given following the standard immunisation schedule, to achieve a complete primary immunisation. Antibody response following HB vaccination is not affected by simultaneous administration of immunoglobulin.

5.4 Post-exposure tetanus immunoprophylaxis following injury

Even trivial injuries can be entry points for *Clostridium tetani* and its spores. Following any injury, the treating physician should always verify the current tetanus vaccination status (see Table 8).

Post-exposure tetanus vaccinations, where necessary, must be carried out immediately. Missed primary immunisation vaccinations must be reinstated (see chapter 6.10 "Age-dependent recommendations for conducting catch-up vaccinations").

Table 7	Hepatitis	B immunoprop	hylaxis after	exposure, d	lepending on	current anti-HBs	value
(Note f	lowchart in	figure 1 and tex	t!)				
•		•	· ·				

		Required administration of		
Current anti-HBS level	HB vaccine*	HB immunoglobulin		
≥100 IU/I		No	No	
10–99 IU/l		Yes	No	
<10 IU/l, or not determinable	Anti-HBs was previously ≥ 100 IU/I	Yes	No	
within 48 hours, AND	Anti-HBs was never ≥ 100 IU/I, or is unknown	Yes	Yes	

* Not all HB vaccines are licenced for immunoprophylaxis.

An isolated positive result of an anti-HBc test possibly necessitates further diagnostic clarification. However, required vaccination should not be delayed.

	Documented tetanus vaccination status	Time since last tetanus vaccination	DTaP/ Tdap ^{2,5}	Tetanus immuno- globulin (TIG) ³
Clean, negligible	Unvaccinated or unknown		Yes	Yes
wounds	Less than three vaccine doses		Yes ⁴	No
	At least three vaccine doses	≥ 10 years	Yes	No
		< 10 years	No	No
All other wounds ¹	Less than three vaccine doses or unknown		Yes ⁴	Yes
	At least three versions doeses	≥5 years	Yes	No
	At least three vacchie doses	<5 years	No	No

Table 8 | Tetanus immunoprophylaxis following injury

1 This includes wounds that are deep and/or soiled (contaminated with dust, earth, sputum, or stool), and injuries with tissue fragmentation and reduced oxygen supply or penetration of foreign bodies (e.g., contused, lacerated, bite, puncture, or gunshot wounds), severe burns and frostbite, tissue necrosis, and septic abortions.

2 Children under 6 years of age receive a combination vaccine with DTaP, and older children and adolescents receive Tdap. Adults also receive Tdap if they have not yet received a pertussis vaccination as adults (≥ 18 years of age) or if there is a current indication for pertussis vaccination (see Table 2).

3 TIG = Tetanus immunoglobulin. Generally, 250 IU are used; TIG is administered simultaneously with a DTaP/Tdap vaccine in contralateral parts of the body. The TIG dose can be increased to 500 IU for: (a) infected wounds (that do not receive adequate surgical treatment within 24 hours); (b) deep or contaminated wounds with tissue damage and reduced oxygen supply; (c) foreign body penetration (e.g. bites, stab or bullet wounds); (d) severe burns and frostbite, tissue necrosis and septic abortions.

4 For patients who have started but not completed primary immunisation (e.g. infants), the interval to the last dose must be taken into account. Post-exposure vaccination on the day of wound treatment is expedient only if the interval to the previous vaccine dose is at least 28 days. The STIKO catch-up vaccination recommendations apply to completing primary immunisations.

5 According to information issued by the Deutsche Gesetzliche Unfallversicherung (DGUV) [German Statutory Accident Insurance] in April 2018, the costs of combined tetanus vaccinations will generally be covered if in line with STIKO recommendations a tetanus prophylaxis is required after an occupational accident.

5.5 Post-exposure rabies immunoprophylaxis

Detailed information on the epidemiology of rabies in Germany can be found in Epid Bull 8/2011.

Notes on post-exposure rabies immunoprophylaxis

- Potentially contaminated body sites and all wounds must be cleaned immediately and generously with soap or detergent for at least 15 minutes, rinsed thoroughly with water, and treated with 70% alcohol or an iodine preparation. When possible, wounds should not primarily be sutured.
- From exposure level II, immunisation with a rabies vaccine is carried out according to a schedule indicated for post-exposure prophylaxis, following the Summary of Product Characteristics.
- From exposure level III, both immunisation with a rabies vaccine and application of human rabies immunoglobulin (20 IU/kg body weight) are initiated for persons without active rabies protection. As much rabies immunoglobulin as possible is instilled in and around the wound, and the remaining amount is administered intramuscularly into *M. vastus lateralis*.
- If an indicated administration of rabies immunoglobulin was missed at first vaccination, it can still

be given until 7 days after the first dose of rabies vaccine.

- If someone who was previously vaccinated with rabies cell culture vaccines is newly exposed, the Summary of Product Characteristics must be followed.
- If the vaccination history shows incomplete vaccination, full immunoprophylaxis should be carried out in line with Table 9.
- If indicated, immunoprophylaxis must be carried out immediately. There should be no delay while waiting for clarification of a suspected infection in the animal. If the suspicion of rabies in the animal is not confirmed by veterinary examination, immunoprophylaxis can be discontinued or continued as pre-exposure vaccination.
- Because of the great variability in the incubation period, which can last between <10 days and >1 year, post-exposure prophylaxis is still useful for weeks to months after exposure, if there is a reasonable suspicion that it may be necessary.
- Care must be taken to check tetanus vaccination documentation and if necessary to administer simultaneous tetanus immunoprophylaxis (see Table 8).

Level of exposure	Type of exposure from a wild	Post exposure immunoprophylaxis (Note the Summary of Product Characteristics)		
	animal, pet, or bat with suspected or confirmed rabies	Unvaccinated or incompletely vaccinated persons	Persons with complete primary immunisation ²	
I.	Touching/Feeding of animals; licking of intact skin.	No vaccination.	No vaccination.	
П	Superficial scratches or abrasions without bleeding; licking or nibbling on broken skin.	Rabies vaccination schedule. ¹	Immunisation with 2 vaccine doses at an interval of 3 days. ^{2,3}	
ш	Bites or scratches; sputum contact with mucous membranes or wounds (e.g., through licking); suspected bite or scratch from a bat or mucous membrane contact with a bat.	Rabies vaccination schedule, ¹ simultaneously administration of rabies immunoglobulin (20 IU/kg body weight).	Immunisation with 2 vaccine doses at an interval of 3 days. ^{2,3}	

Table 9 | Indications for a post-exposure rabies immunoprophylaxis (rabies PEP) in immune-healthy persons

1 Two vaccines are licenced and available for immunisation in Germany: Rabipur and Tollwut-Impfstoff (HDC) inaktiviert. According to the Summary of Product Characteristics, the following vaccination schedules can be used for the rabies PEP in unvaccinated or incompletely vaccinated persons: Essen schedule: 1 vaccine dose each on days 0, 3, 7, 14 and 28

Shortened Essen schedule: 1 vaccine dose each on days 0, 3, 7, 14. Only licenced for Rabipur in healthy, immunocompetent persons. Zagreb schedule: 2 vaccine doses on day 0 (simultaneously), 1 additional vaccine dose each on days 7 and 21 (0, 0, 7, 21). Only applicable in healthy immunocompetent people.

2 In persons with a completed primary immunisation with 3 vaccine doses before exposure (pre-exposure prophylaxis, PrEP), immunoprophylaxis should consist of 2 vaccine doses administered on day 0 and 3 in case of a level II or III exposure. Administration of immunoglobulins in not required.

3 In persons with a PrEP consisting of 2 vaccine doses of Tollwut-Impfstoff (HDC) inaktiviert, a 3rd vaccine dose should be administered at least 1 year apart. If this 3rd vaccine dose was not administered, there is currently no data if a boostability is given with a 2 dose PEP, if PEP is required after exposure. However, administration of immunoglobulin is not required.

People with immunodeficiency should always be vaccinated according to a rabies vaccination schedule (number of doses and time intervals between the vaccine doses according to the Summery of Product Characteristics) from exposure level II onwards, even if the pre-exposure primary immunisation has been fully completed. Simultaneous administration of the rabies immunoglobulin on day o is indicated for this group of people from exposure level II onwards. Two to four weeks after the last vaccine dose, an antibody check should be carried out to determine whether an additional vaccine dose is required.

6. Recommendations on catch-up vaccinations for children, adolescents and adults with incomplete or unknown vaccination status

6.1 Introduction

These notes are based on the recommendations for routine vaccination of infants, children, adolescents and adults (see immunisation schedule). These notes are intended to help physicians to decide which vaccinations are required for unvaccinated, delayed, or incompletely vaccinated individuals to achieve the vaccination protection recommended for their age. Evidence supporting this guidance is often limited, because there are few studies of high methodological quality examining vaccine effectiveness under irregular immunisation schedules. The recommendations given here are therefore mainly based on the long-term experience and expertise of STIKO members.

The recommendations also took into account expert opinions and the recommendations of other international immunisation technical advisory groups.^{O,P,T-X} References to the literature are given at the end of the <u>chapter 6</u> "Recommendations on catch-up vaccinations".

All consultations with physicians, whether involving children, adolescents or adults, should be used to check the individual's vaccination status and to prompt catch-up of missing vaccinations.

6.2 Unvaccinated people and those with unclear vaccination status

An overview of the recommended catch-up vaccinations and the corresponding immunisation schedule for different age groups is given in Tables 10 A–E. Age groups were chosen to incorporate age-related particularities in vaccination recommendations and application notes in the Summary of Product Characteristics of licensed vaccines. The relevant age for the required vaccinations is the **age at the start of the catch-up series**.

6.3 People who have been partially vaccinated

For partly immunised children, adolescents, and adults, all documented vaccinations to date are counted, provided the interval between single doses was not shorter than the recommended minimum interval. For long-lasting vaccination protection, it is especially important that the recommended minimum interval between second-to-last and last vaccinations (6 months for most vaccines) is not shortened during primary or basic immunisation (P). Based on this condition, the following applies:

Every vaccination counts!

This means that there are, in principle, no illegitimately long intervals between vaccinations. Usually, a primary immunisation series that has been interrupted for many years – for example, against diphtheria, TBE, tetanus, poliomyelitis, or hepatitis B – does not have to be started again from scratch. A booster vaccination that has not been administered according to schedule can also be administered at a later point in time.

Individual immunisation schedules should be compiled, considering the individual's current **age**, and the number and timing of previous vaccines.

For vaccinations that are recommended only until a specific age (pneumococcal for infants/children, Hib, rotavirus), an interrupted primary immunisation series should not be continued if the person is now beyond this specific age.

An incomplete HPV vaccination series, however, should be completed even after the age of 18. Care is needed to clarify who will bear the cost.

6.4 Procedure when vaccination documents are missing

If the vaccination card is not traceable or lost, medical files should be used to identify previous vaccinations. Where appropriate, a new vaccination card can be issued based on the documented history of vaccinations.

Missing vaccination cards are a frequent problem among recently immigrated children, adolescents, and adults. A summary of up-to-date vaccination recommendations by country of origin can be found on the WHO (https://immunizationdata.who.int/ listing.html?topic=vaccine-schedule&location=) and ECDC (http://vaccine-schedule.ecdc.europa. eu/Pages/Scheduler.aspx) websites, which list all national immunisation schedules. In principle, however, all vaccinations that are not documented should be administered following the STIKO recommendations.

For people with unknown vaccination status, including missing or incomplete documentation of vaccinations, it is in the interest of the individual to be protected. It should therefore be assumed that the relevant vaccinations are missing. Anamnestic information on vaccination or disease history (including measles, mumps and rubella) is, with the exception of varicella, often unreliable and should not be incorporated into the planning of catch-up vaccinations. Deviations from this principle are justifiable in individual cases.

6.5 Medical history information on varicella

Anamnestic information on varicella (chicken pox) is mostly reliable. Studies show that information about a previous history of varicella with typical clinical manifestations is highly valid.^Q A varicella vaccination is not required after an anamnestic response indicating a prior varicella disease. If in doubt, a varicella vaccination should be administered, especially because varicella complications (including pneumonia, encephalitis, and the risk of fetopathy if contracted during pregnancy) increase among adolescents and young adults.^R It should be noted that adolescents and young adults coming from tropical countries, especially Southeast Asia, are less frequently immune to varicella than individuals in Europe.

6.6 Indication of serological titre determination

Serological testing to determine the need for catchup vaccinations based on antibody titres only makes sense in exceptional cases, because the test methods used in clinical laboratories often do not have sufficient sensitivity and specificity. For some vaccinepreventable diseases (e.g., pertussis), no reliable serological correlate exists that would be suitable as a surrogate marker for the presence of immunity. Antibody titre levels also do not allow conclusions to be drawn about potential cellular immunity. In principle, routine antibody testing is not appropriate before or after routine vaccinations. Exceptions are verifying vaccination success in people with immunodeficiency (see "Grundlagenpapier mit Anwendungshinweisen für Impfungen bei PatientInnen mit Immundefizienz" [Framework paper on immunisation of immunocompromised people] (www. rki.de/immundefizienz), and confirming protection against hepatitis B among those for whom vaccination is indicated under Table 2. Serological testing is also recommended to confirm protection against varicella among women who wish to conceive and who have unclear anamnesis of varicella.

6.7 Is "over-vaccination" dangerous?

In general, there is no elevated risk of side effects resulting from excess vaccine doses. To limit the number of injections, it is therefore possible to use combination vaccines even if not all antigens or vaccine components are needed (see also "Choice of vaccines", below). On rare occasions, the repeated administration of inactivated vaccines can cause adverse events such as pronounced local reactions including painful swelling and reddening of the affected extremity (called the "Arthus reaction"). This self-limiting reaction is most likely to occur in case of high individual serum antibody concentrations in combination with very frequent vaccination with tetanus and/or diphtheria toxoid. In this case, antibody testing should be conducted before the administration of further Td vaccines. This risk does not exist for pertussis antigens.^s

6.8 Choice of vaccines

Combination vaccines should be used instead of monovalent vaccines as this can reduce the number of injections, the vaccination goal can be reached at an earlier date, and vaccination acceptance can be increased. In Germany, there are currently no monovalent vaccines available against certain diseases (childhood diphtheria, measles, mumps, rubella, and pertussis). In these cases, combination vaccines must be used (for example, to catch up a missing mumps or rubella vaccination with an MMR vaccine). Individual immunisation schedules are often necessary because of age-dependent changes in vaccination indications (for example, vaccination for *Haemophilus influenzae* type b until the 5th birthday, and pneumococci until the 2nd birthday) and the restriction of licensed vaccine administration to certain age groups.

The current Summary of Product Characteristics states that the hexavalent vaccines Infanrix hexa (DTaP-IPV-Hib-HepB), Vaxelis and Hexyon can be used for primary immunisation and booster vaccinations for infants and small children. No concrete age limit is given. In its function as national regulatory authority, the PEI states that in this context there is no binding definition of the term "small child". The current Summary of Product Characteristics notes that the pentavalent vaccines Infanrix-IPV+Hib (DTaP-IPV-Hib) and Pentavac are suitable from the age of 2 months and no upper age limit is given (see Table 11). For primary immunisation against Haemophilus influenzae type b, a single dose of vaccine from 12 months of age is sufficient. The usual pentavalent or hexavalent vaccines DTaP-IPV-Hib(-HepB) can, however, continue to be administered if this is necessary to complete the other vaccinations. No negative effects from excess Hib vaccine doses are expected. Alternatively, missing vaccinations can be completed with the trivalent vaccine Infanrix (DTaP, licensed until the 6th birthday) and, simultaneously or sequentially, with monovalent vaccines against hepatitis B and poliomyelitis. A vaccination series started with a specific combination vaccine can be completed using vaccines from a different manufacturer.

Depending on age, vaccines with different dosages are used for hepatitis B vaccination (for more details see the Summary of Product Characteristics).

6.9 Vaccinations against tetanus, diphtheria, poliomyelitis and pertussis from the age of 5 years

In older children and adults, protection against pertussis can be achieved with a single dose of a combination vaccine including the pertussis component, because the current prevalence of *Bordetella pertussis* means that few people are immunologically naïve against pertussis. A study showed that one vaccine dose induced an immunological response in more than 90 % of vaccinated individuals aged 11 years and older.^P Equivalent information can also be found in the relevant Summary of Product Characteristics of the vaccines.

Starting at the age of 5 years, vaccines with reduced antigen content (d instead of D and ap instead of aP) should be used for vaccinations against diphtheria and pertussis. Whilst the Td vaccines (Td-Impfstoff Mérieux, Td-pur) and the monovalent IPV vaccine (IPV-Mérieux) are licensed for primary immunisations according to the Summary of Product Characteristics, the combination vaccines with pertussis components (**Tdap:** Boostrix, Covaxis, **Tdap-IPV:** Boostrix-Polio, Repevax) are mainly intended for booster vaccinations.

The PEI defines the term "primary immunisation" as first-time immunisation during infancy and early childhood, for which vaccines with higher antigen content (upper case D and P) should be used. In its function as the national regulatory authority for vaccines in Germany, the PEI has determined that the ap-containing vaccines above can be used for the first-time immunisation of older children, adolescents and adults whose vaccination status is unknown or who have not been previously vaccinated against Tdap-(IPV).

The use of Boostrix (Tdap), Boostrix-Polio (Tdap-IPV), Covaxis (Tdap) and Repevax (Tdap-IPV) is covered by licensing for primary immunisation from the adolescent age of \geq 12 years.

When these vaccines are used outside the relevant age group, information about off-label use should be provided (see chapter 4.2 for off-label use), and this should also be documented in writing.

For booster vaccinations, all these vaccines can be used without restrictions for the age stated in the relevant licence. This includes the completion of previously-initiated vaccination series.

STIKO has published information on the "Use of Tdap and Tdap-IPV vaccines for the primary vaccination of individuals" in a statement in Epid Bull 4/2016.

6.10 Age-dependent recommendations for the implementation of catch-up vaccinations

Tables 10 A-E list the recommended catch-up vaccinations for children, adolescents and adults with missing primary or basic immunisation. The respective **table for the current age is to be used**.

С	Catch-up vaccination
В	Booster vaccination
Р	Primary vaccination
Hib	Haemophilus influenzae type b
MMR	Measles, mumps, rubella

HPV Human papilloma virus

Vaccination	Minimum interval in months after previous vaccination dose			Age in years	
against	0	2	6	5-8	9–16
Tetanus	C1	C2	C3	В1	B2
Diphtheria (D)	C1	C2	C3	В1	B2
Pertussis (aP)	C1	C2	C3	В1	В2
НіЬ	C1	C2	C3		
Poliomyelitis	C1	C2	C3		B1
Hepatitis B	C1	C2	C3		
Pneumococcus	C1	C2	C3		

Table 10A | Catch-up and booster vaccinations for children aged <12 months

Children aged <12 months

Missing DTaP-IPV-Hib-HepB and pneumococcal conjugate vaccine doses should be administered. To complete primary immunisation against DTaP-IPV-Hib-HepB and pneumococcal disease, 2 vaccine doses should be given at 2 months intervals and a 3^{rd} dose with the respective vaccine after an interval of ≥ 6 months since the previous vaccination (use vaccines with age-appropriate antigen content, see Table II).

There is only a short time slot for catch-up of the rotavirus immunisation series, because administration of the first dose should take place before the age of 12 weeks and the last dose preferably before the ages of 16 weeks (Rotarix) or 20–22 weeks (RotaTeq) depending on the vaccine brand (see Summary of Product Characteristics). The vaccination series must be completed by the age of 24 (Rotarix) or 32 (RotaTeq) weeks.

Additional vaccinations are carried out according to the general STIKO immunisation schedule.

Vaccination	Minimum interval in months after previous vaccination dose			Age in years	
against	0	1-2ª	6	5-	16
Tetanus	Cl	C2	C3	B1 ^b	B2 ^b
Diphtheria (D)	Cl	C2	C3	B1b	B2 ^b
Pertussis (aP)	Cl	C2	C3	B1b	B2 ^b
Hib	Cl				
Poliomyelitis	Cl	C2	C3		Blc
Hepatitis B	Cl	C2	C3		
Pneumococcus ^d	Cl	C2 (Vaccination interval ≥8 weeks)			
Meningococcus C	Cl				
MMR ^e	C1	C2			
Varicella ^e	C1	C2			

Table 10B | Catch-up and booster vaccinations for children aged 12 months to <5 years

a Interval depends on vaccine or indication.

b Booster vaccination 5–10 years after the last dose of the primary immunisation, or after a previous booster vaccination.

c The booster vaccination should be administered at the age of 9–16 years.

d The pneumococcal vaccination is not recommended as a routine vaccination after the age of 24 months; there is no need for catch-up vaccination.

e Starting at the age of 11 months.

Children aged 12 months to < 5 years

To complete primary immunisation against DTaP-IPV-Hib-HepB and pneumococcal disease 2 vaccine doses should be given at an interval of 2 months, plus a 3^{rd} vaccination after an interval of ≥ 6 months since the previous vaccination (use vaccines with age-appropriate antigen content, see Table 11). Booster vaccinations are given at the ages of 5-6 years (at the earliest, 2 years after the third dose) and 9-16years. From the age of 12 months, Hib only requires 1 vaccine dose, and pneumococci only 2 vaccine doses at an interval of 8 weeks. From the age of 2 years, a pneumococcal vaccination is only recommended for children in a risk category (indication vaccination). Additionally, 2 MMR and varicella vaccinations should be given at intervals of 4-6 weeks as well as a meningococcal C conjugate vaccination. There is a slightly increased risk of febrile convulsions after the first MMRV combination vaccine dose, in comparison with the simultaneous administration of the

MMR vaccine and the V vaccine, so preference should be given to separate MMR and V vaccines for the first dose in children aged <5 years. For the second vaccination against MMR and V, either the MMRV combination vaccine or separate MMR and V vaccines can be used.

Vaccination	Minimum interval	Age in years		
against	0	1	6	10–17
Tetanus	C1	C2	C3	Blª
Diphtheria (d)	Cl	C2	C3	Bla
Pertussis (ap) ^b	C1	C2	C3	Bla
Poliomyelitis	Cl	C2	C3	В1
Hepatitis B	C1	C2	C3	
Meningococcus C	Cl			
MMR	C1	C2		
Varicella	Cl	C2		
HPV ^c (children and adolescents) from 9 years	РІ		P2	

Table 10C | Catch-up and booster vaccinations for children aged 5 to <11 years

a Depending on the age at completion of the primary immunisation, two booster vaccinations may be appropriate before adulthood (the interval between P and B1 and between B1 and B2 is 5–10 years).

b There is no monovalent pertussis vaccine available in Germany, so only Tdap or Tdap-IPV combination vaccines can be used.

c Primary immunisation (P) with two doses at least 5 months apart (note Summary of Product Characteristics).

Children aged 5 to <11 years

Missing polio vaccinations and DTaP or Tdap vaccine doses should be administered using vaccines with an antigen content appropriate for the age (see Table 11). Until the sixth birthday, the Summary of Product Characteristics states that it is possible to administer the trivalent vaccine Infanrix (DTaP) and simultaneously inject an IPV vaccination against polio into the other arm.

From the age of 5 or 6 years (depending on the Summary of Product Characteristics), a vaccine with a reduced concentration of diphtheria toxoid (d) and pertussis antigen (p) should be given (3 vaccine doses in intervals of o-1-6 months).

In Germany, however, no Tdap or Tdap-IPV vaccine is currently licenced for primary immunisation in the age group 6-11 years. An off-label use of one of the vaccines that are approved from the age of 12 is required for children in this age group. Appropriate information of patients and documentation is required.

Depending on age on completion of the primary immunisation series, it might be appropriate for this age group to receive one or two Tdap booster vaccinations between the ages of 10 and 17 years. A booster vaccination should be given at the earliest 5 years after the last dose of the primary immunisation or the previous booster vaccination. Primary immunisation against hepatitis B consists of three vaccinations (0-1-6 months). Two MMR and varicella vaccinations should also be given at an interval of 4-6weeks and one dose of a conjugate vaccine against meningococcal C.

Children and adolescents aged 9–14 years should receive two HPV vaccinations at least 5 months apart (note the Summary of Product Characteristics).

Vaccination against		Minimun	Vaccination interval		
		0	1	6	5–10 years
Tetanus		C1	C2	C3	В1
Diphtheria (d)		C1	C2	C3	В1
Pertussis (ap)ª		C1			В1
Poliomyelitis		Cl	C2	C3	В1
Hepatitis B		Cl	C2	C3	
Meningococcus C		Cl			
MMR		Cl	C2		
Varicella		С1	C2		
HPV [♭] (children and adolescents)	9–14 years	P1		P2	
	>14 years	C1	C2	C3	

Table 10D | Catch-up and booster vaccinations for children/adolescents aged 11 to < 18 years

a There is no monovalent pertussis vaccine available in Germany, so only Tdap or Tdap-IPV combination vaccines can be used.

b If first vaccine dose is administered at the age of 9–14 years: Primary immunisation (P) consists of two doses, given at least 5 months apart. For catch-up vaccinations (C) with the first vaccination at the age of > 14 years, three doses are necessary (note Summary of Product Characteristics).

Children/adolescents aged 11 to <18 years

Where there is a missing vaccination against pertussis, protection can be achieved with one dose of a Tdap or Tdap-IPV vaccine.^Y If primary immunisation against tetanus, diphtheria and poliomyelitis is also indicated, the first of the required three vaccinations (o-1-6 months) should be conducted with a Tdap or Tdap-IPV vaccine (see Table 11).

A booster vaccination with Tdap or Tdap-IPV should be administered 5 to 10 years after completion of the primary immunisation series and if possible before reaching adulthood.

Primary immunisation against hepatitis B should be conducted with three vaccine doses (o-1-6 months) using the vaccine licensed for that age group.

Additionally, two MMR and varicella vaccinations should be given with an interval of 4-6 weeks, and one dose of a conjugate vaccine against meningo-coccal C.

Children and adolescents under the age of 15 years should receive a two-dose HPV vaccination in an interval of at least 5 months. Catch-up vaccinations should be offered until the age of 17 years. Three doses are necessary for catch-up vaccinations when the first does of the primary vaccination was administered at the age of >14 years (note the Summary of Product Characteristics).

Vaccination	Minimum interval in months after previous vaccination dose				Vaccination interval
against	0	1	2	6	Every 10 years
Tetanus	C1	C2		C3	В
Diphtheria (d)	C1	C2		C3	В
Pertussis (ap)ª	C1				B1 (one-time)
Poliomyelitis	C1	C2		C3	B1 (one-time)
Measles for people born after 1970	Cl				
Rubella for women in childbearing age ^b	Cl	C2			
Varicella for sero- negative women who wish to conceive	CI	C2			
Pneumococcal for adults ≥ 60 years of age	CI				Repeat immunisation only where there is an individual indication, see <u>Table 2</u> , (after 6 years at the earliest)
Herpes zoster for adults ≥60 years of age ^c	Cl		С	2	

Table 10E | Catch-up and booster vaccinations for adults aged ≥ 18 years

a There is no monovalent pertussis vaccine available in Germany, so only Tdap or Tdap-IPV combination vaccines can be used.

b Unvaccinated women or women without documented vaccinations should be given two doses. Women who have been vaccinated once should be given one dose. In the absence of a monovalent rubella vaccine, an MMR vaccine can be used.

c Two vaccine doses with inactivated herpes zoster vaccine in an interval with at least 2 months to a maximum of 6 months in between vaccinations.

Adults from 18 years of age

Adults should receive all vaccinations recommended for their age group, including catch-up vaccinations for tetanus, diphtheria, pertussis and poliomyelitis if necessary. Unvaccinated people or those with unknown vaccination status can receive three vaccine doses of a Td or Td-IPV combination vaccine (o-1-6 months). To achieve protection against pertussis, the first vaccination should be given as a Tdap or Tdap-IPV combination vaccine (see Table II).^U Td booster vaccinations should be administered 10 years after the previous vaccination in all cases. For the first booster, a Tdap combination vaccine should be used once.

People born after 1970 and \geq 18 years of age should receive a single dose of a vaccine containing measles virus, preferably an MMR vaccine. Women of childbearing age should be given two rubella vaccinations with an MMR vaccine.

Varicella vaccination (two doses with an interval of 4-6 weeks) is recommended for seronegative women who wish to conceive.

From the age of 60 years, STIKO recommends routine vaccination against pneumococcal disease with a polysaccharide vaccine (PPSV23), vaccination against herpes zoster with the inactivated vaccine (two vaccinations in intervals of at least 2 to a maximum of 6 months) and yearly vaccination with a quadrivalent high-dose vaccine against seasonal influenza. A repeated vaccination against pneumococci should be given at the earliest 6 years after routine vaccination and should be determined on a case-by-case basis (see <u>chapter 3.2</u> and <u>Table 2</u>).

	Antigens	Trade name	Market authorization from ^a	Approved up to the age of ^a	
	Cholera	Dukoral	2 years	No information (limited data for persons aged 65 and older)	
		Vaxchora	2 years	No information (limited data for persons aged 65 and older)	
	COVID-19	s. Table C of the STIKO recommendation for COVID-19 vaccination.			
	DTaP	Infanrix	2 months	<6 years	
		Infanrix-IPV + Hib	2 months	No information	
	Diar-irv-rid	Pentavac	2 months	No information	
	DTaP-IPV-Hib-HepB	Infanrix hexa	Infant age	Infants and small children ^b	
		Hexyon	6 weeks	Infants and small children ^b	
		Vaxelis	6 weeks	Infants and small children ^b	
	Haemophilus	Act-Hib	2 months	<5 years ^c	
	influenzae type b	Hiberix	2 months	Infants and small children ^c	
		Avaxim Junior	1 year	< 16 years	
		Avaxim	16 years	No upper age limit	
	Llonatitic A	Havrix 720 Junior	1 year	< 15 years	
	riepatitis A	Havrix1440	15 years	No upper age limit	
		VAQTA Paediatric 25 E	1 year	< 18 years	
		VAQTA 50 E	18 years	No upper age limit	
	Hepatitis A/ Typhoid fever	Viatim	16 years	No upper age limit	
		Twinrix Paediatric	1 year	< 16 years	
	перації Атв	Twinrix	16 years	No upper age limit	
		Engerix-B Paediatric	Birth	< 16 years	
		Engerix-B	16 years	No upper age limit	
		Fendrix ^e	15 years	No upper age limit	
	Henatitis B	HBVAXPRO 5 micrograms	Birth	< 16 years	
		HBVAXPRO 10 micrograms	16 years	No upper age limit	
		HBVAXPRO 40 micrograms ^d	18 years	No upper age limit	
_		HEPLISAV B	18 years	No upper age limit	
		PreHevbri ^k	18 years	No upper age limit	
	Herpes zoster	Shingrix	50 years	No upper age limit	
	HPV IPV (Poliomyelitis)	Cervarix	9 years	No information	
		Gardasil 9	9 years	No information	
		IPV-Mérieux	2 months ^f	No upper age limit	
	Japanese encephalitis	lxiaro	2 months	No upper age limit	
	MMD	M-M-RVaxPro	(9–) 12 months ^g	No upper age limit	
		Priorix	9 months	No upper age limit	
		Priorix-Tetra	(9–)11 months ^g	No upper age limit	
	IVI IVI IC-V	ProQuad	(9–)12 months ^g	No upper age limit	
		MenQuadfi	\geq 12 months	No upper age limit	
	Meningococcus ACWY	Menveo	2 years	No upper age limit	
	2 C S S T T				

6 weeks

No upper age limit

Nimenrix

Table 11 | Trade names and age of administration in Germany for vaccines mentioned in the text (there is no guarantee that this list is complete, please note product information; influenza vaccines are not listed)

(Table 11 continued)

Antigens	Trade name	Market authorization from ^a	Approved up to the age of ^a
Meningococcus B	Bexsero	2 months	No upper age limit
Weiningococcus b	Trumenba	10 th birthday	No upper age limit
Meningococcus C	Menjugate 10 micrograms	2 months	No upper age limit
Weiningococcus C	NeisVac-C	2 months	No upper age limit
Mpox/Monkeypox	Imvanex/Jynneos ⁱ	18 years	No upper age limit
	Apexxnar	18 years	No upper age limit
	Pneumovax 23	2 years	No upper age limit
Pneumococcus	Prevenar 13	6 weeks	No upper age limit
	Synflorix	6 weeks	5 th birthday
	Vaxneuvance	6 weeks	No upper age limit
	Rabipur	Birth	No upper age limit
Rabies	Tollwut-Impfstoff (HDC) inaktiviert	Birth	No upper age limit
Deterious	Rotarix	6 weeks	24 weeks
Rotavirus	RotaTeq	6 weeks	32 weeks
	Td-Immun (currently not available)	5 th birthday (60 months)	No upper age limit
Td	Td-Mérieux	5 th birthday (60 months) ^f	No upper age limit
	Td-pur	5 th birthday (60 months) ^f	No upper age limit
	Boostrix	4 th birthday (48 months) ^h	No upper age limit
Tdap	Covaxis	4 th birthday (48 months) ^h	No upper age limit
	TdaP-IMMUN (currently not available)	4 th birthday (48 months) ¹	No upper age limit
Tdan IDV	Boostrix Polio	3 rd birthday (36 months) ^h	No upper age limit
iuap-ir v	Repevax	3 rd birthday (36 months) ^h	No upper age limit
Td-IPV	Revaxis	5 th birthday (60 months)	No upper age limit
	Encepur Children	1 year	11 years
Tick-borne	Encepur Adults	12 years	No information
encephantis (TBE)	FSME-IMMUN 0,25 mL Junior	1 year	< 16 years
	FSME-IMMUN	16 years	No information
Typhoid fever	Typhoral L Capsules	5 years	No upper age limit
	Typhim Vi	2 years	No upper age limit
Yellow fever	Stamaril	6 months	No upper age limit
Verleelle	Varilrix	(9–)11 months	No upper age limit
Valleella	Varivax	(9–) 12 months	No upper age limit

a See also Summary of Product Characteristics (as of January 2023).

b The Summary of Product Characteristics states that the vaccine can be used to vaccinate "infants and small children". According to the licensing authority (PEI), there is no binding definition of the term "small child".

c From the age of 5 years, Hib vaccination is only indicated in exceptional cases (e.g. functional or anatomical asplenia).

d Vaccine for predialysis and dialysis patients.

e Vaccine for patients with renal insufficiency and for pre-dialysis and dialysis patients.

f Also licensed for primary and first-time immunisation.

Equivalent the vaccine Jynneos of Bavarian Nordic can be used (as good as identical to Imvanex).

k Availability is expected in the 2nd half of 2023.

g If earlier immunisation protection is considered necessary, the vaccination can be given starting at the age of 9 months; see recommendations for measles in chapter 3.2.

h Primary immunisation of individuals from 12 years of age whose vaccination status is unknown or who have, so far, not been vaccinated complies with licensing.

i Primary immunisation of individuals from the age of 4 years whose vaccination status is unknown or who have so far not been vaccinated complies with licensing. N.B. Despite the upper case "P" in the name of the compound TdaP-IMMUN, it is one of the pertussis vaccines with reduced antigen content (ap).

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List of STIKO recommendations and their scientific rationales

Mpox/Monkeypox

 Wissenschaftliche Begründung der STIKO für die Empfehlung zur Impfung gegen Affenpocken mit Imvanex (MVA-Impfstoff); publiziert im Epid Bull 25/26/2022

Cholera

2 Änderung der Empfehlungen zur Impfung gegen Cholera; publiziert im Epid Bull 31/2010

DTaP-IPV-HIB-HepB

Wissenschaftliche Begründung für die Empfehlung zur Grundimmunisierung gegen Diphtherie, Tetanus, Pertussis, Poliomeyelitis, Haemophilus influenzae Typ b und Hepatitis B mit dem 6-fach-Impfstoff im Säuglingsalter nach dem 2+1-Impfschema; publiziert im Epid Bull 26/2020

Yellow fever

- 4 Wissenschaftliche Begründung der STIKO für die Empfehlung zur Gelbfieber-Auffrischimpfung vor Reisen in Endemiegebiete und für exponiertes Laborpersonal; publiziert im Epid Bull 32/2022
- 5 Wissenschaftliche Begründung zur Änderung der Gelbfieber-Impfempfehlung aufgrund der Änderungen in den Regelungen der Internationalen Gesundheitsvorschriften zu Gelbfieber; publiziert im Epid Bull 35/2015

Hepatitis **B**

- 6 Wissenschaftliche Begründung für die Anpassung der Empfehlungen zur Impfung gegen Hepatitis A und B; publiziert im Epid Bull 35/2017
- 7 Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen Hepatitis B; publiziert im Epid Bull 36/37/2013
- 8 Hinweise zur Notwendigkeit der Wiederimpfung
 10 Jahre nach erfolgter Grundimmunisierung

gegen Hepatitis B (HB) im Säuglings- bzw. Kindesalter; publiziert im Epid Bull 31/2007

Herpes zoster

- 9 Wissenschaftliche Begründung zur Empfehlung einer Impfung mit dem Herpes zostersubunit-Totimpfstoff; publiziert im Epid Bull 50/2018
- 10 Wissenschaftliche Begründung zur Entscheidung die Herpes zoster Lebendimpfung nicht als Standardimpfung zu empfehlen; publiziert im Epid Bull 36/2017

HPV

- Wissenschaftliche Begründung für die Empfehlung der HPV-Impfung für Jungen im Alter von 9–14 Jahren; publiziert im Epid Bull 26/2018
- 12 Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen humane Papillomviren; publiziert im Epid Bull 35/2014
- Impfung gegen HPV Aktuelle Bewertung der STIKO; publiziert im Epid Bull 32/2009
- Impfung gegen humane Papillomaviren (HPV) für Mädchen von 12 bis 17 Jahren – Empfehlung und Begründung; publiziert im Epid Bull 12/2007

Influenza (seasonal)

- 15 Wissenschaftliche Begründung für die Aktualisierung der Influenza-Impfempfehlung für Personen im Alter von ≥60 Jahren; publiziert im Epid Bull 1/2021
- Wissenschaftliche Begründung für die Empfehlung des quadrivalenten saisonalen Influenzaimpfstoffs; publiziert im Epid Bull 2/2018
- Wissenschaftliche Begründung für die geänderte Empfehlung zur Anwendung von Influenzaimpfstoffen bei Kindern und Jugendlichen im

Alter von 2–17 Jahren; publiziert im Epid Bull 35/2017

- 18 Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen Influenza; publiziert im Epid Bull 36/37/2013
- 19 Änderung der Empfehlungen zur Impfung gegen Influenza; Empfehlung zur Impfung von Schwangeren; publiziert im Epid Bull 31/2010
- 20 Begründung der STIKO für die Influenza-Impfung bei PatientInnen mit Multipler Sklerose (MS) mit durch Infektionen getriggerten Schüben; publiziert im Epid Bull 32/2004
- 21 Wirksamkeit und Sicherheit der Influenza-Impfung für PatientInnen mit chronischen Lungenerkrankungen (online verfügbar unter: www.rki.de > Kommissionen > STIKO > Empfehlung der STIKO > Begründung > Influenza)

Japanese encephalitis

22 Wissenschaftliche Begründung für die Empfehlung zur Impfung gegen Japanische Enzephalitis bei Reisen in endemiegebiete und für Laborpersonal; publiziert im Epid Bull 18/2020

Supply shortage

23 Empfehlung und wissenschaftliche Begründung zum Beschluss der STIKO zu Lieferengpässen von Impfstoffen; publiziert im Epid Bull 23/2021

Measles

24 Änderung der Empfehlung zur Impfung gegen Masern; publiziert im Epid Bull 32/2010

Measles Mumps Rubella and Varicella

25 Empfehlung und wissenschaftliche Begründung für die Angleichung der beruflich indizierten Masern-Mumps-Röteln-(MMR-) und Varizellen-Impfung; publiziert im Epid Bull 2/2020

Meningococci

- 26 Aktualisierung der Meningokokken-Impfempfehlung: Indikationsimpfung – Postexpositionelle Impfung – Berufliche Indikation; publiziert im Epid Bull 37/2015
- 27 Änderung der Empfehlungen zur Indikationsimpfung gegen Meningokokken; publiziert im Epid Bull 32/2012

- 28 Änderung der Empfehlungen zur Impfung gegen Meningokokken; publiziert im Epid Bull 32/2010
- 29 Empfehlung und Begründung einer postexpositionellen Meningokokken-Impfung; publiziert im Epid Bull 31/2009
- 30 Begründungen zur allgemeinen Empfehlung der Impfung gegen Meningokokken im Säuglings- und Kindesalter – Impfung der Kinder im 2. Lebensjahr mit konjugiertem Meningokokken-Impfstoff der Serogruppe C; publiziert im Epid Bull 31/2006

Mumps

26. January 2023

31 Änderung der Empfehlung zur Impfung gegen Mumps; publiziert im Epid Bull 31/2012

Pertussis

- 32 Wissenschaftliche Begründung für die Empfehlung der Pertussisimpfung mit dem Tdap-Kombinationsimpfstoff in der Schwangerschaft; publiziert im Epid Bull 13/2020
- 33 Zusätzliche Pertussis-Impfung im Erwachsenenalter als Tdap-Kombinationsimpfung bei der nächsten fälligen Td-Impfung – Empfehlung und Begründung; publiziert im Epid Bull 33/2009
- 34 Klinische Studien mit azellulären Pertussiskomponenten-Impfstoffen bei Erwachsenen: Anlage zum Epid Bull 31/2009
- 35 Erweiterung der beruflichen Indikationen für eine Pertussis-Impfung; publiziert im Epid Bull 31/2009
- 36 Begründung für die STIKO-Empfehlung einer Pertussis-Auffrischimpfung im Vorschulalter; publiziert im Epid Bull 3/2006

Pneumococci

- 37 Wissenschaftliche Begründung zur Aktualisierung der Empfehlung zur Indikationsimpfung gegen Pneumokokken für Kinder und Erwachsene; publiziert im Epid Bull 37/2016
- 38 Wissenschaftliche Begründung zur Aktualisierung der Pneumokokken-Impfempfehlung bei Senioren (Standardimpfung ab 60 Jahren); publiziert im Epid Bull 36/2016
- 39 Wissenschaftliche Begründung zur Änderung der Pneumokokken-Impfempfehlung für Säuglinge; publiziert im Epid Bull 36/2015

- Wissenschaftliche Begründung für die Änderung der Empfehlung zur Indikationsimpfung gegen Pneumokokken; publiziert im Epid Bull 36/2014
- 41 Begründungen zur allgemeinen Empfehlung der Impfung gegen Pneumokokken im Säuglings- und Kindesalter – Pneumokokken-Impfung mit 7-valentem Konjugat-Impfstoff für Kinder unter 2 Jahren; publiziert im Epid Bull 31/2006
- 42 Zur Impfung gegen Pneumokokken-Krankheiten; publiziert im Epid Bull 31/2005
- 43 Begründung der STIKO-Empfehlung zur Pneumokokken-Impfung; publiziert im Epid Bull 28/2001

Travel vaccinations

 Empfehlungen der Ständigen Impfkommission (STIKO) zu Reiseimpfungen; publiziert im Epid Bull 14/2021

Rubella

45 Änderung der Empfehlungen zur Impfung gegen Röteln; publiziert im Epid Bull 32/2010

Rotavirus

46 Empfehlung und wissenschaftliche Begründung der Empfehlung zur Rotavirus-Standardimpfung von Säuglingen; publiziert im Epid Bull 35/2013

Rabies

47 Änderung der Empfehlungen zur Impfung gegen Tollwut; publiziert im Epid Bull 31/2010

Varicella

- 48 Wissenschaftliche Begründung für die Änderung der Empfehlung zur passiven Immunisierung mit Varizella-Zoster-Immunglobulin (VZIG); publiziert im Epid Bull 35/2015
- 49 Impfung gegen Varizellen im Kindesalter: Empfehlung einer zweiten Varizellenimpfung; publiziert im Epid Bull 32/2009
- 50 Begründung der STIKO für eine allgemeine Varizellenimpfung; publiziert im Epid Bull 49/2004

National immunisation schedule available in 21 languages: www.stiko.de/en

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- RKI-Ratgeber zu einzelnen Infektionskrankheiten www.rki.de/ratgeber
- Kurz & Knapp: Faktenblätter zum Impfen (www.rki.de/impfen-infomaterial)
 - Faktenblatt zur HPV-Impfung
 - Faktenblatt zur FSME-Impfung
 - Faktenblatt zur Herpes-zoster-Impfung
 - Faktenblatt zur Masern-Impfung

- Faktenblatt zu Impfungen in der Schwangerschaft
- Faktenblatt zur Influenza-Impfung
- Faktenblatt zur COVID-19-Impfung
- Fremdsprachige Informationsmaterialien zu

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- Aufklärungsinformationen zu folgenden Impfungen in Fremdsprachen: COVID-19-Impfung mit mRNA-Impfstoff (BioNTec/Pfizer, Moderna); COVID-19-Impfung mit Vektor-Impfstoff (Janssen/Johnson&Johnson); COVID-19-Impfung mit proteinbasiertem Impfstoff (Nuvaxovid/ Novavax); COVID-19-Impfung mit Ganzvirus-Impfstoff (COVID-19-Impfstoff Valneva/Valneva); Mpox-/Affenpocken-Impfung; Hepatitis-A-Impfung; Hepatitis-B-Impfung; Herpes-zoster-Impfung mit dem Totimpfstoff; HPV-Impfung; Influenza-Impfung; Influenza-Impfung mit dem Lebendimpfstoff (nasal); Meningokoken-C-Impfung; MMR-Impfung; Pneumokokken-Impfung; Rotavirus-Impfung; TdaP-IPV-Impfung; 6-fach-Impfung (DTaP-IPV-Hib-HepB); Varizellen-Impfung
- Glossar medizinischer Begriffe zum Thema Impfen in 15 Sprachen
- Informationen zu Kinderlähmung (engl., franz., arab.)
- Praxis-Plakat zur Aufklärung über das schmerzreduzierte Impfen "Wie helfen Sie Ihrem Kind beim Impfen?", finden Sie auf der Seite www.rki.de/impfen
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Ständige Impfkommission: Empfehlungen der Ständigen Impfkommission (STIKO) beim Robert Koch-Institut 2023

Epid Bull 2023;4:3-68 | DOI 10.25646/10829

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