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Statement of the German Standing Committee on Vaccination at the RKI

Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute – 2017/2018

These STIKO vaccination recommendations were endorsed during the 85th and 87th STIKO meetings and are considered enacted upon their publication on 24 August 2017. This 2017 version replaces the previous STIKO vaccination recommendations published in Epidemiologisches Bulletin (Epid. Bull.) 34/2016 of the Robert Koch Institute (RKI). The scientific rationale for the modified STIKO recommendations will be available in Epid. Bull. 35/2017 and 36/2017 on the RKI website (www.stiko.de/en).

Disclaimer

This document is a translation of the original Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute (www.rki.de/stiko-empfehlungen) on behalf of the Robert Koch Institute as of August 2017. 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.

1. Introduction

The Standing Committee on Vaccination (STIKO) is an independent expert committee, consisting of 12 to 18 members, as stipulated in the Infection Against Protection Law [Infektionsschutzgesetz (IfSG)]. The members are appointed by the German Federal Ministry of Health in consultation with the federal state health authorities for a period of 3 years. In accordance with the IfSG the committee provides 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 means beyond individual aspects the benefit of the vaccination at population level (e. g. expected epidemiological effects of the vaccination) is taken into account. STIKO recommendations serve the federal health authorities as a basis for their public recommendations. Following Volume V of the Social Insurance Code ([Sozialgesetzbuch Fünftes Buch (SGB V)] the STIKO recommendations are also the basis for the decision of the Joint National committee [Gemeinsamer Bundesausschuss (G-BA)] whether the costs of the vaccination are covered by the 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 observed only in very rare cases. The immediate goal of vaccination is to protect an individual from a specific disease. Given a high level of acceptance within the population high vaccination coverage rates can be attained. Consequently, it is possible to achieve regional elimination of single pathogens, and eventually to eradicate them worldwide. 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 according to § 20 (3) IfSG]. Compensation of vaccine-induced injury caused by "publicly recommended" vaccinations is assured by the federal states.

This week 34/2017

Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute – 2017/2018

Contents

Overview of new or updated recommendations in 2017:

- Withdrawal of the preferential recommendation of the live attenuated influenza vaccine (LAIV) for children at the age of 2 to 6 years (see table 2, p. 340)
- Considering voluntary helpers for vaccinations against Hepatitis A and B due to an increased occupational risk (see table 2, p. 339)
- Live attenuated Herpes zoster vaccine is not recommended as a standard vaccination (see table 2, p. 340 and notes p. 345)
- Editorial revision of chapter 4.1 "Obligation to inform patients or legal gardians prior to immunization" (see p. 349 ff.)

Table of Contents

An important task for a physician is to ensure adequate immunisation for all persons under his care. This means starting primary immunisation early in infants and toddlers, administering these vaccines without delays, and completing vaccination schedules in a timely manner. Following primary immunisation, using regular booster vaccinations when applicable, the physician must ensure that the necessary protection is maintained throughout the life of the individual, and that immunisation against further infectious diseases is initiated when indicated. Therefore, 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.

In addition to administering the vaccine, the **vaccination services provided by the physician** 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 existing contraindications;
- ▶ Determining current health status in order to exclude acute illnesses;
- ▶ Giving behavioural recommendations subsequent to the vaccination;
- ▶ 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 (standard vaccinations)

The standard 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), pneumococci, rotavirus (RV), meningococcal C, measles, mumps, rubella (MMR), varicella, Human Papillomaviruses (HPV) and influenza.

The recommended time of 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 the 7th birthday. Vaccination should take place at the earliest recommended time. To keep the number of injections as low as possible, combination vaccines should preferably be used if available and as long as they do not conflict with current STIKO recommendations. It is recommended to check and, when necessary, update the vaccination status at every age. Missing vaccinations should immediately be administered in accordance with the recommendations for the respective age. 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 Hib should be administered only until the age of 5 years and vaccination against pneumococci only until the age of 2 years.

Regarding minimum intervals between two vaccinations and the possibility of co-administering vaccines, the Summary of Product Characteristics ("physician insert") for the respective vaccine product should be consulted. It is of particular importance for long-term vaccine-induced protection that, for primary immunisation, the recommended minimum interval between the second-to-last and last vaccination is not shortened.

Vaccination records should be checked and immunisations provided especially during the healthy-child visits that infants and children routinely undergo, the school-entry health examination, health checks that take place throughout schooling, adolescent health checks, examinations in accordance with the Young Persons Employment Act [Jugendarbeitsschutzgesetz], and preventive medical examinations for adults. All persons with chronic diseases should receive the standard vaccinations recommended in the immunisation schedule as long as there are no specific contraindications.

Because of the particular 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** and to complete primary immunisations by the recommended ages of 14 months (for MMR and Varicella by 23 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, at the latest prior to starting school. In adolescents, missed vaccinations must be reinstated by the age of 18 at the latest (that is, by the day before their 18th birthday).

Table 1: Immunisation schedule (vaccinations) for infants, children, adolescents and adults

Vaccination against	Age in weeks	Age in months					Age in years					
	6	2	3	4	11–14	15–23	2–4	5–6	9–14	15–17	≥ 18	≥ 60
Tetanus (T)		P1	P2	P3	P4	C	C	B1	B2		B (if necessary, C) [e]	
Diphtheria (D/d)		P1	P2	P3	P4	C	C	B1	B2		B (if necessary, C) [e]	
Pertussis (aP/ap)		P1	P2	P3	P4	C	C	B1	B2		B (if necessary, C) [e]	
H influenzae b (Hib)		P1	P2 [c]	P3	P4	C	C					
Poliomyelitis (IPV)		P1	P2 [c]	P3	P4	C	C		B1		if necessary, C	
Hepatitis B (HB)		P1	P2 [c]	P3	P4	C	C					
Pneumococcus [a]		P1		P2	P3	C						S [g]
Rotavirus (RV)	P1 [b]	P2	(P3)									
Meningococcal C					P1 (from 12 months)		C					
Measles					P1	P2	C				S [f]	
Mumps, Rubella					P1	P2	C					
Varicella					P1	P2	C					
Influenza												S (yearly)
HPV									P1 [d]	P2 [d]	C [d]	

Explanatory notes for Table 1

P Primary immunisation (consisting of up to 4 inoculations P1–P4)

B Booster vaccination

S Standard vaccination

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

a Premature infants should receive an additional vaccine dose at the age of 3 months for a total of 4 doses.

b The 1st vaccination should be administered at the age of 6 weeks. Depending on the vaccine used, 2 or 3 doses must be given at least 4 weeks apart.

c This dose can be omitted when using a monovalent vaccine.

d Vaccination for girls aged 9–14 years with 2 doses given 5 months apart. If given as catch-up vaccination with the vaccination series beginning at age > 14 years, or when the 1st and 2nd doses were administered < 5 months apart, a 3rd dose is necessary (note package leaflet / summary of product characteristics).

e Booster vaccination in each case is to occur 10 years after the last preceding dose. The next due Td vaccination may be administered as a single Tdap vaccination or, if indicated, a Tdap/IPV combination vaccination.

f One-time vaccination for all persons born after 1970 of ≥ 18 years of age who are of unclear vaccination status, are unvaccinated, or who have received only one vaccination in childhood, preferably using an MMR vaccine.

g One-time vaccination with 23-valent polysaccharide vaccine.

3. Adult vaccinations: standard, indicated, and booster vaccinations, and vaccinations for increased occupational risk or travel

3.1 Overview

To comply with the immunisation schedule for infants, children, adolescents and adults (see Table 1, p. 336) vaccination status should be checked regularly and brought up to date where necessary; each medical consultation should be utilised for this.

Beside standard vaccinations (S), other vaccinations may be indicated in a particular epidemiological situation or where there is a particular hazard to children, adolescents, and adults; these are referred to as indicated vaccinations (I). Vaccinations due to 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.

It is the physician's responsibility to recommend the type and chronological order of vaccinations in each individual case, considering the indications and, where applicable, existing contraindications.

In addition to vaccinations recommended by STIKO, further vaccines might be indicated based on the existing licensure of a vaccine. These specific indications are not discussed further below, but they can be useful for the protection of an individual, depending on his or her individual health situation. It is the physician's responsibility to inform patients of these additional protective options. The lack of a STIKO recommendation should not prevent a physician from carrying out further vaccinations when justified.

If the individual indication for vaccination is not covered by a licensure valid for Germany or by the Summary of Product Characteristics of the corresponding vaccine, it comprises an off-label use. In case of injury, off-label use has consequences for liability and compensation and places particular obligations on the physician administering the vaccine regarding documentation and the provision of information. Benefit claims for a recognised injury due to vaccination pursuant to § 60 standard IfSG are granted only for vaccinations officially recommended by state health authorities.

The vaccinations mentioned in Table 2 differ both in terms of their epidemiological significance and in terms of the coverage of their cost (see notes on the cost coverage of protective vaccines, p. 356); they are divided into the following categories:

S **Standard** vaccinations for universal application (see also Table 1, p. 336, immunisation schedule)

B **Booster** vaccinations

I **Indicated** vaccinations for risk groups with a personally (rather than professionally) increased risk of exposure, illness, or complications, as well as to protect third parties

- **O** Vaccinations due to an increased **occupational/professional** risk, for example after risk assessment in accordance with the Occupational Safety and Health Act [Arbeitsschutzgesetz], the Biological Agents Ordinance [Biostoffverordnung, the Regulation Concerning Occupational Healthcare [Verordnung zur arbeitsmedizinischen Vorsorge (ArbMedVV)], and the 'G 42' screening, as well as for hygiene reasons
- **T** **Travel** vaccinations

Tabelle 2: Recommendations on standard vaccinations for adults as well as on indicated and booster vaccinations for all age groups

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Cholera	T	Periods of residence in infected areas, especially with inadequate hygiene conditions in current outbreaks, e. g., in refugee camps or during natural disasters.	According to the Summary of Product Characteristics.
Diphtheria	S/B	All persons with absent or incomplete primary immunisation, or if either the last vaccination for the basic immunisation or the last booster vaccination occurred more than 10 years previously.	Adults should receive the next due diphtheria vaccination as a one-time Tdap combination vaccination, if indicated as a Tdap-IPV combination vaccination. If diphtheria vaccination is indicated and adequate vaccination protection against tetanus and pertussis is in place, a monovalent diphtheria vaccine should be given. Unvaccinated persons or those with no vaccination record should receive 2 vaccinations at intervals of 4–8 weeks and a 3rd vaccination 6–12 months after the 2nd vaccination. Travel to an epidemic area should not be undertaken prior to receipt before of 2 doses.
***Haemophilus influenzae* type b** (Hib)	I	Persons with anatomical or functional asplenia.	One-time vaccination. Whether revaccination is useful can currently not be assessed because of insufficient data.
Hepatitis A (HA)	I	▶ Persons with a sexual behaviour with increased risk of exposure; **for example Men who have sex with men (MSM)** ▶ Persons frequently receiving blood components, e. g., haemophiliacs, or persons with liver diseases/diseases involving 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-HAV is required only for persons who have lived for prolonged periods in endemic regions **or** grew up in families from endemic regions **or** were born before 1950.
	O	Persons who are at increased risk of occupational exposure, including trainees, interns, students and volunteers with comparable exposure risk, for example: ▶ Health care workers (including medical and rescue services, kitchen, laboratory, technical and cleaning services, psychiatric and welfare institutions). ▶ Persons 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, asylum seekers' shelters, and the like.	
	T	Those travelling in regions with a high prevalence of hepatitis A.	
Hepatitis B (HB)	I	1. Persons who are at risk of severe hepatitis B owing to an existing or expected immunodeficiency or immunosuppression, or owing to other pre-existing diseases, for example: HIV-positive individuals, hepatitis C-positive individuals, and patients on haemodialysis.* 2. Persons who are at increased risk of non-occupational exposure, for example: persons in contact with HBsAG carriers in the family or flat share, persons at high risk to acquire hepatitis B through sexual contact, injection drug users, prison inmates, and if applicable psychiatric inpatients.*	**For indication groups 1–4, the following applies:** Routine serological testing to rule out an existing HBV infection prior to hepatitis B vaccination is not necessary. It is riskless to vaccinate persons already infected with HBV against hepatitis B; however, 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).**
	O	3. Persons who are at increased risk of occupational exposure, including trainees, interns, students and volunteers with comparable exposure risk, for example: Health care personnel (including laboratory personnel and cleaning personnel), medical and rescue services, occupational first aid providers, police officers, and personnel at facilities where an increased prevalence of hepatitis B-virus (HBV)-infected persons is likely to be present (for example, correctional facilities, shelters for asylum seekers, and homes for the handicapped).*,**	To monitor vaccination success, anti-HBs level should be determined 4–8 weeks after the 3rd vaccine dose (successful vaccination: anti-HBs ≥ 100 IU/l).*** For "low-responders" (anti-HBs 10–99 IU/l) an immediate additional vaccine dose is recommended in connection with repeated anti-HBs monitoring 4–8 weeks after vaccination. If anti-HBs is still < 100 IU/l, up to 2 additional doses are recommended with subsequent anti-HBs monitoring 4–8 weeks after each vaccination. There is contro-

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Hepatitis B (HB) (continued)	T	4. Travel-related indication: an individual risk assessment is required. * *This list of groups of persons provides examples and is not intended to be a definitive list of indicated groups. The vaccination indication shall be based on the assessment of the actual exposure risk. (see Epid. Bull. 36/2013).*[4] ** *In the field of occupational health services, the recommendations of the ArbMedVV should be attended as well.* *** *For persons belonging to indication group 4 (travel vaccination) it is necessary to evaluate whether, in view of the real risk of exposure and the individual risk of non-responding, serological monitoring is necessary.*	versy over reasonable proceedings if the anti-HBs level remains < 100 IU/l after the administration of in total 6 vaccine doses; for further explanation see *Epid. Bull.* 36/2013.[4] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 36/2013) In the case of "non-responders" (anti-HBs < 10 IU/l) it is recommended to test for HBsAG and anti-HBc 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 ≥ 100 IU/l, 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/l), and if applicable, persons who are at particularly high individual exposure risk (anti-HBs monitoring after 10 years and a booster dose if anti-HBs <100 UI/l). An additional vaccine dose followed by serological monitoring described above should be administered to persons vaccinated against hepatitis B during infancy with a newly arisen risk for hepatitis B infection (see indications 1–4) and with unknown anti-HBs level
Herpes zoster		The live-attenuated herpes zoster vaccine is not recommended as a standard vaccination.	See also information on individual vaccine indications in the box in chapter 3.1 at page 337.
Human papilloma-viruses (HPV)			Please see p. 345
Influenza	S	Adults ≥ 60 years of age.	Yearly vaccination in autumn with an inactivated vaccine containing the current antigen combination recommended by 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 vaccine containing the current antigen combination recommended by the WHO.
		Persons of all ages with an increased health risk resulting from an underlying disease, such as: ▶ Chronic diseases of the respiratory tract (including asthma and COPD;) ▶ Chronic cardiovascular, liver and kidney diseases ▶ Diabetes and other metabolic diseases ▶ Chronic neurological diseases, e.g., multiple sclerosis with relapses triggered by infections ▶ Persons with congenital or acquired immunodeficiencies with residual T- and/or B-cell function ▶ HIV infection. Residents of retirement or nursing homes. Persons who might act as a potential source of infection for at-risk patients by living in the same household or by taken care of them. At risk are considered persons with underlying diseases, who are more likely to experience a reduced response to influenza vaccines, e.g. patients with dialysis-dependent renal disease or persons with congenital or acquired immunodeficiency or immunosuppression.	Annual vaccination in autumn with a vaccine containing the current antigen combination recommended by the WHO. Children and adolescents aged 2 to 17 years can be vaccinated with an inactivated influenza vaccine or a live attenuated influenza vaccine (LAIV) if no contraindications exist (see Summary of Product Characteristics). If there are obstacles for an injection (e.g. injection phobia, coagulation disorders) LAIV should be used preferred. ~~LAIV should be preferred in children aged 2 to 6 years.~~
	O	Persons at increased risk, e.g., medical personnel, persons in establishments dealing extensively with the public, as well as persons who may act as a possible source of infection by caring for individuals at particular risk. Persons at increased risk by direct contact with poultry and wild birds*.	Yearly vaccination in autumn with inactivated vaccine containing the current antigen combination recommended by WHO. *Vaccination with the current seasonal human influenza vaccine does not offer direct protection against infection with the avian influenza virus. It can, however, prevent

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Influenza (continued)			double-infection with the currently circulating influenza viruses (see also: TRBA 608 of the ABAS at www.baua.de > Topics from A–Z > Biological Agents > Technical Rules for Biological Agents).
	T/I	For travellers aged > 60 years and the groups of persons named under I (indicated vaccination) whose influenza vaccination status is not up to date, vaccination is generally advisable. For other travellers an influenza vaccination may be advisable after a risk assessment depending on exposure and vaccine availability.	Vaccination with a vaccine containing the current antigen combination recommended by the WHO.
	I	If a severe epidemic based on experiences in other countries is impending or is to be expected following a manifest antigenic drift or antigenic shift and the vaccine contains the new variant.	According to the recommendations of the health authorities.
Measles	**S**	Those ≥ 18 years and born after 1970 with unclear vaccination status, who have not been vaccinated, or who received only one vaccination during childhood.	One-time vaccination, preferably with a MMR vaccine.
	I	With forthcoming admission or visit of a community facility (e.g. Kindergarten): ▶ Infants from the age of 9 months	Vaccination with 2 doses of a MMR/V*-vaccine. Provided that the first vaccination has been given at the age of 9 to 10 months, the 2nd MMR/V vaccination should be given at the beginning of the 2nd year of life.
	I	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. ▶ 6 to 8 month-old infants exceptionally after individual risk benefit consideration (Off-label-use).	One-time vaccination with MMR(V)** vaccine If necessary complement vaccinations according to the recommendations applying for the respective age group. Provided that the first vaccination has been given at the age of 9 to 10 months, the 2nd MMR/V* vaccination should be given at the beginning of the 2nd year of life. With first vaccination at the age of 6 to 8 months a 2nd and 3rd MMR/V* vaccination should be administered at the age of 11 to 14 and 15 to 23 months * *MMR/V = MMRV or MMR in co-administration with VZV vaccine* ** *MMR(V) = MMR with or without co-administration of VZV vaccine*
	O	Those born after 1970 with unclear vaccination status, who have not been vaccinated, or who received only one vaccination during childhood and who are working in health care or community facilities, or who care for immunodeficient or immunosuppressed individuals.	One-time vaccination with a MMR vaccine.
Meningococcal infections	**I**	Those whose health is at risk: Persons with congenital or acquired immunodeficiencies with residual T- and/or B-cell function, especially ▶ complement/properdin deficiencies, ▶ Treatment with Eculizumab (monoclonalal antibody against terminal complement component C5) ▶ hypogammaglobulinaemia ▶ asplenia	Vaccination with a quadrivalent ACWY-conjugate vaccine and a Men-B-vaccine. For further details regarding implementation of meningococcal vaccination see p. 346 f.
	I	During outbreaks or regional clusters upon recommendation by the local health authorities (see p. 360).	In accordance with the recommendations of the health authorities.
	O	At-risk laboratory personnel (in the case of work involving a risk of *N. meningitidis* aerosols).	Vaccination with quadrivalent ACWY-conjugate vaccine and a Men-B-vaccine.
	T	Those travelling to countries with epidemic/hyperendemic occurrences, especially in close contact with the indigenous population (e.g. development aid workers, disaster relief workers, medical personnel, long-term stays); this also applies to stays in regions with disease outbreaks and vaccination recommendation for the indigenous population (note WHO and country-specific information).	Vaccination with a quadrivalent ACWY-conjugate vaccine (see p. 346).

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Meningococcal infections (continued)	T	Before a pilgrimage (Hajj, Umrah).	Vaccination with a quadrivalent conjugate vaccine (serogroups A, C, W, Y) (see p. 346). Take note of entry regulations.
	T	Students before long-term stays in countries with recommended standard vaccination of adolescents or selective vaccination of students.	In accordance with the recommendations of the destination countries.
Mumps	O	Individuals born after 1970 with unclear vaccination status, who have not been vaccinated, or who received only one vaccination in childhood and who are working in health care with direct patient contact, in community facilities, or in educational establishments for young adults.[21]	One-time vaccination with MMR vaccine.
Pertussis	S/B	Adults should receive the next due Td vaccine as a one-time Tdap combination vaccine.	Vaccination with a Tdap combination vaccine, if indicated as a Tdap-IPV combination vaccine. (For available vaccines, please see Table 8, p. 372).
	I	If in the last 10 years there has been no pertussis vaccination, the following groups should receive one dose of pertussis vaccine: ▶ women of childbearing age; ▶ persons in close household contact (parents and siblings) and caregivers (e.g. day nannies, babysitters, and where applicable grandparents), if possible 4 weeks before the birth of the child. If a mother was not vaccinated before conception, she should preferably be vaccinated during the first days following the birth of her child.	
	O	If in the last 10 years there has been no pertussis vaccination, personnel in health care as well as in community facilities should receive one dose of pertussis vaccine.	
Pneumococcal diseases	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 p. 347).
	I	Children, adolescents and adults at increased health risk as a result of an underlying disease: 1. **Congenital or acquired immuno-deficiencies or immunosuppression,** 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. due to organ transplantation or autoimmune disease) ▶ Immunodeficiency in the context of chronic kidney failure, nephrotic syndrome or chronic liver insufficiency 2. **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 oral medication or insulin ▶ Neurological diseases, e.g. cerebral palsy or seizure disorders	1. 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.** 2. Individuals older than 16 receive a vaccination with PPSV23; those aged 2–15 receive a sequential vaccination with PCV13, followed by PPSV23 after 6–12 months.**

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Pneumococcal diseases (continued)		**3. Anatomical and foreign-material associated risks for pneumococcal meningitis,** such as ▶ Cerebral spine fluid fistula ▶ Cochlea implant* * *vaccination preferably before intervention*	3. Sequential vaccination with PCV13 followed by PPSV23 after 6–12 months. PPSV23 should only be given to individuals aged 2 years and older.** ** *As these vaccines provide only temporary protection, the vaccination with PPSV23 should be repeated in all three risk groups at intervals of at least 6 years.* *For information on practical implementation, see chapter "Notes on individual vaccinations", p. 347*
	O	Professional activity such as welding or separating metals leading to exposure to metal smoke, including metal-oxidic welding smoke.	Vaccination with PPSV23 and repeat vaccination with PPSV23 at minimum intervals of 6 years as long as exposure continues.
Poliomyelitis	S/B	All persons with no or incomplete primary immunisation. All persons without a one-time booster vaccination	Adults are considered fully immunised if they have received the complete primary immunisation in infancy and childhood and at least one booster vaccination in adolescence or later, or if they have received primary immunisation as adults in accordance with the Summary of Product Characteristics and have received a booster vaccination. Missing primary immunisation vaccinations are reinstated with IPV in accordance with the Summary of Product Characteristics. Beyond the above, a routine booster vaccination is not recommended for adults.
	I	A vaccination is indicated for the following groups of persons: ▶ Those travelling in regions with risk of infection (the current epidemic situation must be taken into account, especially the WHO reports); ▶ Immigrants, refugees and asylum seekers who live in communal accommodation, entering from regions at risk of polio (see p. 355).	Vaccination or booster vaccination with IPV, if primary immunisation is incomplete or not fully documented or the last vaccination dates back longer than 10 years. Persons with no primary immunisation record should receive at least 2 doses of IPV before starting their travels.
	O	▶ Personnel of the above-mentioned institutions; ▶ Medical personnel who may have close contact with cases; ▶ Personnel in laboratories with a poliomyelitis risk.	Vaccination or booster vaccination with IPV, if primary immunisation is incomplete or if the last of the primary or the last booster vaccination dates back longer than 10 years.
Rubella	I	Women of childbearing age that are non-immunised or with an unclear vaccination status.[33] Women of childbearing age vaccinated once.[33]	Two vaccinations with MMR vaccine. One vaccination with MMR vaccine.
	O	Non-vaccinated persons or persons with an unclear vaccination status in paediatrics, obstetrics and pregnancy care institutions as well as in community facilities.	One vaccination with MMR vaccine.
Tetanus	S/B	All persons with no or incomplete primary immunisation, if the last primary immunisation vaccination or the last booster vaccination dates back longer than 10 years.	Adults should receive the next due tetanus vaccination as a one-time Tdap combination vaccination, if indicated as a Tdap-IPV combination vaccination. Incomplete primary immunisation should be completed, booster vaccination should occur at 10-year intervals.
TBE (tick-borne encephalitis)	I	Persons exposed to ticks in TBE risk areas.	Primary immunisation and booster vaccinations with a 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 noted; these are published in *Epid. Bull.* 17/2017.
	O	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).	

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
TBE (tick-borne encephalitis) (continued)	T	Tick exposure in TBE risk areas outside Germany.	Note seasonality: April – November **Risk areas in Germany** are currently in particular: ▶ **Baden-Wurttemberg** ▶ **Bavaria** (except for a few districts in Swabia and western Upper Bavaria) ▶ **Hesse** (district of Odenwald, district of Bergstraße, district of Darmstadt-Dieburg, city district of Darmstadt, district of Groß-Gerau, district of Offenbach, city district of Offenbach, district of Main-Kinzig-Kreis, district of Marburg-Biedenkopf) ▶ **Rhineland-Palatinate** (district of Birkenfeld) ▶ **Saarland** (district of Saar-Pfalz) ▶ **Saxony** (district of Vogtlandkreis) ▶ **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 Hildburghausen, district of Sonneberg, district of Greiz)
Rabies	O	▶ Veterinarians, hunters, forest workers and other persons who handle animals in areas where there is a new occurrence of rabies among wild animals ▶ Persons with professional or other close contact with bats ▶ Laboratory personnel at risk of exposure to rabies viruses	Dosage schedule according to the Summary of Product Characteristics. Persons with a continued exposure risk should regularly receive a booster vaccination according to the Summary of Product Characteristics. Laboratory personnel working with the rabies virus should be examined every 6 months for neutralising antibodies. A booster vaccination is indicated at < 0.5 IU/ml serum.
	T	Those travelling in high risk rabies regions (e.g. from stray dogs).	
Tuberculosis		Vaccination with a BCG vaccine is not recommended.	
Typhus	T	When travelling in endemic regions with stays under bad hygienic conditions.	According to the Summary of Product Characteristics.
Varicella	I	▶ Seronegative women who wish to conceive ▶ Seronegative patients prior to planned immunosuppressive therapy or organ transplantation ▶ Susceptible patients* with severe neurodermatitis ▶ Susceptible persons* in close contact with the two previously mentioned groups	According to the Summary of Product Characteristics. For information on the vaccination of seronegative patients receiving immunosuppressive therapy, please refer to *Epid. Bull.* 39/2005 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 39/2005). *"Susceptible persons" are defined as individuals with no vaccination and no history of varicella or no specific antibodies detected upon serological testing.
	O	▶ Seronegative personnel in health care and new workers in community facilities for preschool-age children.	
Yellow fever	R	▶ Before staying in endemic regions in Africa and Latin America; please consult publications of the World Health Organization (WHO) with information on yellow fever endemic areas; or ▶ according to the vaccination requirements of the destination or transit countries.	One-time vaccination in yellow fever immunisation facilities approved by health authorities. The International Certificate of the Yellow Fever vaccination is valid for life. This applies to already issued and newly issued yellow fever vaccination certificates. According to the WHO, since 2016 travellers who have a yellow fever vaccination certificate can no longer be rejected from entry for the reason that the certificate has been expired after 10 years. A list of countries with the risk of yellow fever transmission and the countries that require a yellow fever vaccination upon entry is provided by WHO (www.who.int/ith/2017-ith-country-list.pdf?ua=1; www.who.int/ith/2017-ith-annex1.pdf?ua=1).
	O	When working with contact to Yellow Fever Virus (e.g. in research institutions or research laboratories).	One-time vaccination in yellow fever immunization facilities approved by health authorities.

3.2 Anmerkungen zu einzelnen Impfungen

Cholera

The strict compliance of safe food, sanitation of water, and personal hygiene is the most important measure in the prevention of cholera infection. Generally, the risk is very low to suffer from cholera while travelling. However in case of travels in regions with current infections, the cholera vaccination can be indicated for individual protection, particularly at stays with poor sanitation and hygiene, for example during cholera outbreaks in refugee camps or after natural disasters. In Germany, there is recently one cholera vaccine (Dukoral®) licensed. This vaccine is an oral vaccination containing attenuated cholera pathogens. In adults and in children of 6 years age and older, primary immunisation against cholera consists of 2 doses, which are administered in an interval of at least 1 week to maximum 6 weeks.

Diphtheria

From the age of 5 or 6 years, 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 or other indicated antigens.

Haemophilus influenzae type b (Hib)

From 5 years of age, Hib vaccination is indicated only in exceptional cases (see Table 2, p. 338), for example functional or anatomical asplenia.

Hepatitis A

For immunisation against hepatitis A, there are monovalent and combination vaccines licensed in Germany. Monovalent hepatitis A vaccines are available in a dosage for children and in one for adults. For primary immunisation using one of the monovalent hepatitis A vaccines, there are 2 doses with an interval of 6–12 months necessary. For the primary immunisation using the vaccine combined with hepatitis B, there are 3 doses at months 0, 1, and 6 necessary (as used the monovalent hepatitis B vaccine). The combination vaccine contains only half of hepatitis A antigen as the monovalent hepatitis A vaccine; therefore, the combination vaccine should be not used in case of postexpositional prophylaxis.

Hepatitis B (HB)

Pre- and post-vaccination serological testing is not necessary to monitor the success of primary immunisation in childhood and adolescence. Revaccination 10 years following vaccination of infants and toddlers is currently not generally recommended for children and adolescents. Individuals who have been vaccinated against hepatitis B during childhood should be revaccinated against hepatitis B if a new risk for hepatitis B has evolved (for example, new employment in health care). A serological test should be conducted 4–8 weeks after vaccination according to recommendations in Table 2 (see p. 338 f.) as well as *Epid. Bull.* 31/2007[5] and 36/2013[4].

Post-exposure Hepatitis B prophylaxis in newborns of HBsAg positive mothers or of mothers of unknown HBsAg status

According to the maternity guidelines, all pregnant women should have their serum analysed for HBsAg after the 32nd week of pregnancy and as close as possible to the 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 are thereby simultaneously administered. Primary HB immunisation thus started should be completed with a 2nd active vaccination 1 month after the 1st vaccination, and with a 3rd vaccination 5 months at the earliest after the 2nd vaccination.

In newborns including premature babies 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 regardless of birth weight. If the mother is later determined to be HBsAg positive, passive immunisation subsequently can be performed in the newborn child within 7 days after birth.

Serological testing is required after the completion of primary immunisation in the newborn child of an HBsAg positive mother: 4–8 weeks after the 3rd vaccination dose, HBsAg, anti-HBs, and anti-HBc are to be checked.

Because a lower birth weight can cause a reduced antibody response, in infants of less than 1,000 gr a serological test (anti-HBs) should be conducted 4 weeks after the 2nd vaccination. If the anti-HBs level is ≥100 IE/l, the 3rd vaccination is given 5 months after the 2nd vaccination. If the anti-HBs level is <100 IE/l, the 3rd vaccination should be administered immediately. Another anti-HBs serological test should be conducted 4 weeks later in those infants. If levels are ≥ 100 IE/l, a 4th vaccination should be given 9 months after the last immunisation. If no immunity exists after the 3rd vaccination, the 4th dose is to be administered immediately. Vaccination success is checked by serological testing (see above). Further measures (including possible 5th and 6th vaccinations) need to be decided on an individual basis (see *Epid. Bull.* 10/2000 and 8/2001, www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issues 10/2000 and 8/2001).

Herpes zoster

A live attenuated vaccine (Zostavax®) against herpes zoster (HZ) and postherpetic neuralgia (PHN) was licensed for persons 50 years of age and older in 2006 and became available in Germany in September 2013. Based on the conclusion, that an effective and sustainable reduction of the HZ disease burden cannot be achieved with this vaccine, the STIKO decided against issuing a recommendation for standard HZ vaccination at this time. This decision is based on a systematic review of available data on the efficacy, duration of protection, and safety of the vaccine, and is supported by the results of health economic modelling. Both, the risk of developing HZ and the severity of the illness increase markedly with age. The

efficacy of the vaccine, however, decreases with advancing age, from 70 % for persons in their 50s to 41 % for persons in their 70s to less than 20 % for persons 80 years of age and older. The duration of vaccine related protection is limited to only a few years. The modelling results show only a slight, age-dependent reduction in the total number of HZ cases through vaccination with the live attenuated vaccine. The reduction ranged from 2.6 % for persons vaccinated at the age of 50 to 0.6 % for those vaccinated at the age of 80. Finally, the live attenuated vaccine is often contraindicated in persons who are at greatest risk of HZ and its complications. Thus, in the overall appraisal, the epidemiological benefit-risk assessment of the HZ vaccination did not lead to a recommendation for standard vaccination with the live attenuated vaccine. An individual benefit-risk assessment may, however, lead to a different decision in individual patients (see *Epid. Bull.* 36/2017)[6].

Human papillomaviruses (HPV)

STIKO recommends standard vaccination against HPV (types 16 and 18) for all girls aged 9–14 years to reduce the burden of disease due to cervical cancer. Missing HPV vaccinations should be completed before the age of 18 years (that is, the day before the 18th birthday). The vaccination series should be completed before first sexual intercourse. Currently, a 2-dose scheme is licensed for children aged between 9–14 years (Cervarix®, Gardasil® 9), with an administration interval of 5 months between the 2 doses. A 3rd dose is necessary for catch-up vaccinations at the age > 14 years, or if the time intervals between the 1st and 2nd dose was < 5 months. Regarding the number of necessary vaccine doses as well as the required time intervals between vaccinations, STIKO refers to the respective Summary of Product Characteristics.

Since April 2016 the nonavalent HPV vaccine Gardasil® 9 is available on the market in Germany in addition to Cervarix®. Both vaccine products can be used to obtain the goal of reducing the incidence of cervical cancer and pre-cancer lesions. 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: "Statement of STIKO at RKI: Use of the nonavalent vaccine against human papillomaviruses (HPV)".

HPV vaccination should be utilised as an opportunity to bring other vaccinations for adolescents recommended by STIKO up to date. Concerning simultaneous administration with other vaccines, STIKO refers to the respective Summary of Product Characteristics.

Women who are older than 17 years and have not received a HPV vaccination can also benefit from vaccination against HPV. It is within the physician's responsibility to point this out to patients after an individual risk-benefit assessment based on the vaccine licensure.

Vaccinated persons 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 and that they must therefore still make use of cervical cancer screening services. A scientific evaluation of the changed HPV vaccination recommendation, supplemental to the scientific rationale (*Epid. Bull.* 12/2007)[9] and the assessment of vaccination (*Epid. Bull.* 32/2009)[8] was published in *Epid. Bull.* 36/2014[7] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issues 12/2007, 32/2009, 36/2014).

Influenza

STIKO recommends annual vaccination in autumn with the current antigen combination recommended by the WHO as a standard vaccination for all persons aged 60 years and older, and where indicated in specific groups of persons (see Table 2, p. 339). In addition to the trivalent (IIV3) and quadrivalent (IIV4) inactivated vaccines for injection, there is a quadrivalent live-attenuated intranasal vaccine (LAIV4) for the age group 2 to 17 years licensed. For this age group the inactivated vaccines or the live-attenuated vaccine can be used. In case of barriers for an injection (for example phobia about syringe, dysfunction of blood coagulation) LAIV should be preferred. Annual vaccination is recommended even when the antigen composition of the vaccine is unchanged compared with the previous season.

Measles

Vaccination against measles should be performed with a combination vaccine (MMR vaccine), usually at the age of 11–14 months. The 2nd MMR vaccination should be completed by the age of 2 years to attain the earliest possible vaccination protection.

The 1st 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. Kita)
- after contact with measles cases

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, such infants must primarily be protected through immunisation of contact persons in their environment. 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 2 additional doses of MMR vaccine at the age of 11 to 14 and 15 to 23 months to establish long-term immunity.

Following the contact with measles cases, passive immunisation with immunoglobulins should be considered up to 6 days after exposition particularly for unprotected people with contraindicated vaccination and a high risk of complications, like infants less than 6 months of age, immunodeficient individuals and pregnant women. This is an off-label recommendation. Infants between 6 to 8 months of age can receive immunoglobulins after individual risk-benefit consideration alternatively to the 1st vaccination. 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 Table 3, p. 357 and *Epid. Bull.* 2/2017).

MMR vaccination is also recommended for all adults born after 1970 who have an unknown vaccination status, are unvaccinated, or have received only one vaccination in childhood, especially if they work in the health care or in community facilities, or if they care for immunodeficient or immunosuppressed individuals (one-time vaccination, preferably with an MMR vaccine). A background paper and detailed rationale for this recommendation can be found in *Epid. Bull.* 32/2010[15] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 32/2010).

Meningococcal disease

Meningococcal B

A vaccine against serotype B meningococcal disease (Bexsero®) was licensed in Europe in January 2013 for persons from the age of two months and has been available in Germany since December 2013. STIKO currently concludes that the available study results and resulting evidence are not sufficient for a conclusive decision regarding a universal vaccination recommendation. An updated STIKO comment regarding the status of the meningococcal B vaccine assessment was published in *Epid. Bull.* 36/2014 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 36/2014)

However, STIKO recommends vaccination against sero-group B meningococci (MenB) in addition to MenACWY vaccination for persons with certain underlying diseases. (see Table 2, p. 340). Data regarding immunogenicity and efficacy of the MenB vaccine in these persons are lacking, but the immune response is likely to be weaker and of shorter duration than in healthy individuals. In addition, as detailed in the Background Paper "Update of meningococcal vaccination recommendations in Germany: Use of the serogroup B vaccine in persons at increased risk for meningococcal disease", the risk for IMD varies according to the underlying disease in question (see Bundesgesundheitsblatt. 2015;58: 1314–43). Persons with terminal complement defects and properdin deficiency have by far the highest risk – up to 10,000-fold higher than background risk. IMD risk in persons with asplenia, on the other hand, is much lower, around 20- to 30-fold higher than background risk. The risk for persons with other immune defects, such as HIV infection or hypogammaglobulinemia is lower still. Thus the physician should base the decision for MenB vaccination on an individual risk assessment.

Meningococcal C

STIKO recommends the earliest possible vaccination against serogroup C meningococcal disease with a meningococcal C conjugate vaccine for all children aged 12 to 23 months. The primary goal of the vaccination is to reduce morbidity due to invasive serogroup C meningococcal diseases and sequelae such as hospitalisation, severe complications, disability and death.

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.* 31/2006.[20] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 31/2006).

Children aged up to 17 years with missing vaccinations should receive a catch-up vaccination. Concerning simultaneous administration with other vaccines, STIKO refers to the respective Summary of Product Characteristics.

In addition to this note, the recommendations on vaccination of persons at increased risk should be followed (see Table 2, p. 340). For protection against MenC disease, MenC conjugate vaccines can be administered from the age of 2 months onwards.

Meningococcal ACWY

A meningococcal vaccination against serogroups ACWY is recommended for certain indications (see Table 2, p. 341 and Table 3, p. 358). No meningococcal C vaccination is required for children and adolescents who have not yet received a meningococcal vaccination and who receive an ACWY vaccination due to an indication (e.g. travel). In Germany, tetravalent MenACWY conjugate vaccines are licensed from the age of 6 months (Nimenrix®) and 2 years (Menveo®), according to the Summary of Product Characteristics (July 1, 2017). In the US, Menveo® is licensed for children aged 2 months or older.

Mumps

Monovalent mumps vaccine is no longer available in Germany. Instead, MMR vaccine should be used. Pre-existing immunity against one or two of the antigens included in the MMR vaccine is not a contra-indication for MMR.

Pertussis

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.

Booster vaccinations are recommended at 5–6 years of age and 9–17 years of age. Vaccines with reduced pertussis antigen content (Tdap or Tdap-IPV) are used from 5–6 years of age both for booster vaccinations and, where applicable, for catch-up primary immunisations.

STIKO recommends administering the next due Td vaccine for all adults as a **one-time** Tdap combination vaccination or a Tdap-IPV combination vaccination if indicated. Because a monovalent pertussis vaccine is no longer available, administration of combination vaccines is recommended on the respective 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 previously been administered.** A placebo-controlled study has demonstrated that one of the available Tdap combination vaccines can be administered within 1 month after a previous Td vaccination without causing increased side effects; see *Epid. Bull.* 33/2009, p. 340–341. (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 33/2009).

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

longer than 5 years ago. Before the birth of a child, it is especially important that persons in close household contact with and carers of the newborn baby be checked for adequate immunological protection against pertussis defined as vaccination within the past 10 years (see Table 2, p. 341 f.).

Pneumococcal disease

Primary immunisation during infancy: 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 sequelae such as hospitalisation, disability and death. **Infants born at term** should receive 3 vaccine doses at the ages of 2, 4, and 11–14 months (so-called 2+1 scheme). The minimum interval between the 1st and 2nd dose is 2 months, and the minimum interval between the 2nd and 3rd dose is 6 months. **Preterm infants** (born before 37 completed weeks of gestation) should receive a total of 4 vaccine doses at the ages of 2, 3, 4, and 11–14 months (3+1 scheme). The deviant recommendation for preterm babies is due to the licensure of the pneumococcal conjugate vaccines, which restricts the use of the 2+1 scheme to term infants so far (as of July 2017). A detailed justification of the pneumococcal vaccine recommendation can be found in *Epid. Bull.* 36/2015[28] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 36/2015).

Standard vaccination of older adults: People aged ≥ 60 years who do not belong to any of the risk groups listed under "I" or "O" in Table 2 (p. 341) are recommended to be vaccinated with the 23-valent pneumococcal polysaccharide vaccine (PPSV23) (Pneumovax® 23) (Category "S").

Indication 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 or suppression (Group 1) as well as for those with an increased risk of pneumococcal meningitis (Group 3), sequential immunisation with 13-valent conjugate (PCV13) (Prevenar 13®), followed by PPSV23 is recommended. For people in Group 2 and for those with a professional indication, exclusive vaccination with PPSV23 is recommended. Only if aged 2 to 15 years, sequential immunisation should be conducted in Group 2.

For people who are recommended to have sequential immunisation (PCV13 followed by PPSV23), the following applies:

- PPSV23 may be given as early as 2 months after PCV13 according to the prescribing information (e. g. in case of vaccination before a planned immunosuppressive treatment).
- If they have already had a PCV13 vaccination, they should only be given the PPSV23 vaccination.
- If previously vaccinated with a lower-valent conjugate vaccine (PCV7 or PCV10), they should receive PCV13 followed by PPSV23.
- If they have already had a PPSV23 vaccination, a PCV vaccination should be administered with a minimum interval of 1 year.

Booster vaccinations: Due to the fact that vaccine-induced protection is not permanent, 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 (SPC) 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," on the other hand, the SPC states that booster vaccinations "could be considered". This regularly applies to people in categories "I" and "O". In respect to seniors who do not belong to either of these categories, the indication should be considered on a case-by-case basis. Patients must be informed about the increased reactogenicity of the booster vaccination in comparison with 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 [26,27] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issues 36 and 37/2016).

Poliomyelitis

The oral polio vaccine (OPV) is no longer recommended owing to the risk – although very low – of vaccine-associated paralytic poliomyelitis. For protection against poliomyelitis, an injectable vaccine – inactivated polio vaccine (IPV) – is recommended. From 9 to 17 years of age, a booster vaccination containing IPV is recommended for adolescents. Primary immunisation started with OPV is to be completed with IPV. Additional information on vaccination against poliomyelitis is displayed in Table 2 (see p. 342 f.).

Rabies

According to WHO criteria, Germany has been free of terrestrial rabies caused by classical rabies virus since 2008. However, it is among the European countries with the highest recorded number of bat rabies cases caused by bat lyssaviruses, which are also transmissible to humans. In addition, illegal importation of pet animals (dogs, cats) from countries with endemic terrestrial rabies still poses a risk. Prophylactic pre-exposure immunisation consists of 3 doses given by intramuscular injection on days 0-7-21 (Rabipur®) or days 0-7-28 (Tollwut-Impfstoff HDC®), respectively. In order to maintain long lasting protection with Tollwut-Impfstoff HDC®, a booster dose 1 year after the first dose is recommended. For post-exposure prophylaxis see page 363.

Rotavirus (RV)

The RV vaccines are oral live vaccines. Depending on the used vaccine brand, 2 doses (Rotarix®) or 3 doses (RotaTeq®) are given to the infant starting at the age of 6 weeks, with at least 4 weeks between the vaccine doses. There is a possible slightly elevated risk for intussusception (estimated at 1–2 cases per 100,000 infants vaccinated) within the 1st week after the 1st RV vaccine dose, which increases with age of the vaccinee. Therefore, STIKO strongly recom-

mends beginning the vaccination series as early as possible – by the age of 12 weeks at the latest – and to complete it **preferably** 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 at the age of 32 weeks when using RotaTeq®.

The background paper and detailed scientific rationale can be found in *Epid. Bull.* 35/2013[34] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 35/2013). Concerning simultaneous administration with other vaccines, STIKO refers to the respective Summary of Product Characteristics.

RV-immunization 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 of the 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 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 1/2015).

Rubella

Monovalent rubella vaccine is no longer available in Germany. Instead, MMR vaccine should be used. 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.

Tetanus

Each booster vaccination with Td (including in case of an injury) should be used as a reason to check whether pertussis vaccination is indicated and, if applicable, to administer a combination vaccine (Tdap).

Tick-Borne Encephalitis (TBE)

TBE illnesses in children generally have a milder course than in adults, predominantly presenting symptoms of meningitis and more rarely symptoms of encephalitis. Residual neurological damage has been reported only in isolated cases. As febrile reactions of > 38°C have been observed in 15 % of 1- to 2-year-old vaccinated children (as opposed to 5 % of 3- to 11-year-old children), the recommendation is to carry out a particularly careful assessment of the indications together with the parents prior to vaccination of children under 3 years of age. Otherwise, the basic principles of indicated vaccination presented in Table 2, p. 342 apply to the paediatric vaccine and to the adult vaccine, including the information contained in the Table on risk areas and on the seasonality of the disease. In addition, vaccination should be completed by the beginning of the tick season – about 95 % of cases are notified in the months of May to November.

Tuberculosis

In Germany, vaccination against tuberculosis with BCG is no longer recommended by STIKO since 1998. No BCG vaccine is licensed in Germany.

Varicella

The 1st dose of the vaccination against varicella (V) is generally administered at age 11 to 14 months, either at the same time as the 1st MMR vaccination or, at the earliest, 4 weeks after it. For the 1st vaccine dose against varicella and MMR, the simultaneous application of a single varicella vaccine dose and an MMR combination vaccine at different body sites is preferable. The rationale for this recommendation is a slightly increased risk of febrile seizures 5–12 days after application of the combined MMR-varicella (MMRV) vaccine compared with the simultaneous vaccination with a varicella and MMR vaccine. This increased risk was only observed after the 1st vaccination. The 2nd dose of varicella vaccine should be administered between ages 15 to 23 months and can be conducted with a MMRV combination vaccine; see the STIKO statement on "Combined vaccination against measles, mumps, rubella and varicella (MMRV)" in *Epid. Bull.* 38/2011 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 38/2011).

In all non-vaccinated 9- to 17-year-old adolescents with no history of varicella, catch-up vaccination should also take place with 2 doses, in accordance with the Summary of Product Characteristics. The minimum interval between 2 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 2nd 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[37], and an evaluation of the recent varicella vaccination strategy is found in *Epid. Bull.* 1/2013. (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issues 32/2009 and 1/2013).

Yellow fever

Yellow fever vaccination 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. After reviewing the available evidence, World Health Organization (WHO) has declared in 2014 that a single dose of yellow fever vaccine provides lifelong protection. The validity period of an international certificate of yellow fever vaccination is changed from 10 years to lifelong. This applies already issued certificates of yellow fever vaccination as well as new ones. A list of countries with risk of yellow fever transmission as well as a list of countries that

require proof of yellow fever vaccination as a condition for entry can be found on the WHO web site: (www.who.int/ith/2017-ith-country-list.pdf?ua=1; www.who.int/ith/2017-ith-annex1.pdf?ua=1).

Following persons may benefit from a booster dose because their immune response may be weakened and therefore a protection after a single vaccination will eventually not last lifelong: (1) children who were vaccinated for the first time at the age < 2 years, especially those who have been vaccinated against yellow fever and MMR simultaneously, (2) women who have been vaccinated during pregnancy, (3) HIV-infected people.

The detailed scientific rationale for the adaption of the yellow fever vaccination recommendation can be found in *Epid. Bull.* 35/2015[2] (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 35/2015).

4. Practical issues related to the application of vaccines

4.1 Obligation to provide information prior to immunisation

General information

Providing information is an important part of the immunization service offered by the physician. The physician's obligation to provide the patient or person to be vaccinated with information was re-defined in 2013 in the "Law on the Improvement of Patients' Rights" (Patient Protection Act) (German Civil Code [BGB], Art. 1 § 630e).

Before administering a vaccine, the physician is obliged to inform the vaccinee or their accompanying parent or guardian about the disease to be prevented and the vaccination itself so that an effective declaration of consent can be given.

Extent of the information

This information should include the following content:

- 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,
- how the recipient should behave after immunization
- as well as the necessity for follow-up and booster vaccinations and when they should be administered.

However, the precise scope of the necessary information always depends on the specific circumstances of the individual case. The principle of patient-related information applies here, i.e. the understanding of the individual patient or consent person is to be taken as a basis. Decisive criteria can be the age, the level of education, previous experience and medical knowledge. It is therefore always necessary to set up an individual scale which is appropriate for the patient or the person entitled to consent. The enrolled physician must provide a general picture of the severity and direction of the specific risk spectrum with regard to vaccination. If a waiver for an explicit explanation is declared by the patient or consent person information can become unnecessary.

Form and timing of the information

The information must be provided verbally in accordance with § 630e, 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. In the justification of the law (Bundestag printed paper 17/10488, p. 24, on § 630e, BGB), this point is explained as follows: "The patient should be given the opportunity to ask questions during a face-to-face discussion with the person administering the treatment so that the information provided is not reduced to simply ticking a box on an information sheet."

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 can understand the content. Information may be given immediately before immunization provided that the patient or the accompanying parent or guardian is not under pressure to make a decision. Particularly in the case of language barriers, the physician must ensure that his explanations are understood. In case of doubt it should be clarified whether an interpreter – possibly at the expense of the patient – should be consulted.

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 various providers (e. g. the German Green Cross or by Thieme Compliance).To support the information of persons who do not speak German the RKI offers translations of information sheets on many different vaccinations to download free of charge in up to 20 languages (www.rki.de > Infektionsschutz > Impfen > Informationsmaterialien in verschiedenen Sprachen). In addition, the Federal Center for Health Education (BZgA) provides numerous information materials on vaccination and vaccine-preventable diseases for laypersons via its homepage www.impfen-info.de.

The leaflets also contain a questionnaire on the state of health of the person being vaccinated and on previous immunizations which specifically relate to the vaccine under consideration. Subsequently, the physician must offer an opportunity to address any questions and issues raised by the person being vaccinated or their parent or guardian. Most information sheets include already formulated 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, i. e. it is sufficient if a verbal consent is noted in the patient's files. In certain cases, however, a written declaration of consent can be useful. The vaccinating physician should also note in the patient's files that the information no matter in which form it has been provided (§ 630 para. 2 p.1 BGB). If the information is based on the relevant information sheet, the vaccinating physician should draw attention to this in his files. Moreover, it can be useful to make a note in the patient's file if the relevant person or the parent or guardian has refused a vaccination. A copy of the documents that has been signed by the patient or consent holder in the context of the information must to be handed over to him (§ 630e para. 2 p. 2 BGB).

Vaccination of minor children

In the case of minor children, the parent's or guardian's consent must be routinely obtained. 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. However, it is always the task of the vaccinating physician to determine for every individual case whether the adolescent "can, according to his mental and moral maturity, understand the significance and scope of the intervention and his allowance" (BGHZ 29, 33–37). Corresponding to § 630e, para. 5, p. 1, BGB also the person unable to give her/his consents is to inform according to his/her understanding so far that he is in a position to understand the explanations and so far this is in his/her best interests.

Public vaccination appointments

In the case of public vaccination appointments (e. g. at school immunization programs), it is recommended to provide information in written form in advance and, if appropriate, acquire written consent. This does not, however, absolve the physician from the legal obligation to provide the person being immunized or their accompanying parent or guardian with verbal information, as well, in order to give them the opportunity to ask questions.

4.2 Off-label use

The term "off-label use" refers to the prescription of a licensed medical product outside of the use for which licensure had been applied and approved by national or European regulatory authorities, for example in respect to the scope of application (indication), age restrictions, dosage, or duration of treatment. In case of off-label use, the physician is liable for the medical appropriateness of the treatment as well as for potential adverse events. Medical associations recommend that off-label use should only be conducted based on valid guidelines or recommendations or acknowledged scientific literature. For off-label use, it is indispensable to comprehensively inform the patient or legal guardian of risks and benefits of the respective vaccination, and that the vaccine is being used off-label. Medical treatment and provided information have to be documented comprehensively in the patient's file.

4.3 Documentation of the vaccination

General information

IThe batch number, vaccine name (brand), date of vaccination and disease vaccinated against must be documented in the patient's vaccination card and in the medical record of the physician administering the vaccine, in accordance with the specifications of the IfSG § 22. The stamp and signature of the physician are likewise part of the vaccination documentation. This applies to all vaccines and can make retrospective investigation easier, should questions arise about the efficacy and safety of particular vaccines or individual vaccine batches. Any form that meets WHO requirements and that also makes allowance for the provisions of the IfSG, such as "International certificates of vaccinations and shot record", can be used as a vaccination card.

Annex 2 of the immunisation guideline of the Federal Joint Committee (G-BA) designates a standard documentation code for vaccinations that has had to be used since 1 July 2008 when billing statutory health insurance companies.

Missing vaccination documentation

The physician is frequently confronted with missing, untraceable or incomplete vaccination documents. This is not a reason for postponing necessary vaccinations, not catching up on missing vaccinations, or not starting primary 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 persons at increased risk of hepatitis B infection); serological tests to detect previous vaccinations in the case of unclear vaccination status are generally not useful.

4.4 Vaccine procedure and handling of vaccines

Vaccines are sensitive biological products that must be especially protected from a rise in temperature. Vaccines containing replication-competent viruses are particularly sensitive. All vaccines should be stored in the refrigerator at 2–8°C. The storage temperature must be checked regularly. Vaccines that, by mistake, were stored incorrectly or frozen must be discarded. Vaccines should not come into contact with disinfectants. The stoppers of injection vials must be dry!

The needle should be dry; in particular, the outside of the cannula should not become wet with vaccine. This causes the injection to be painful and can lead to inflammation in the region of the injection canal. After drawing the vaccine into the syringe and removing any air that might be present, a new needle should be fitted for the injection. The injection site must be disinfected prior to injection. The skin should be dry again at the time of injection.

For vaccines injected via the intramuscular route, the preferred injection site is the deltoid muscle. If this muscle is not sufficiently developed, injection into the vastus lateralis muscle (anterolateral thigh) is recommended. The risk of injury to nerves or vessels there is low. Injection of adsorbate vaccines into the subcutaneous fatty tissue can lead to painful inflammations and to the formation of granulomas or cysts. In addition, there is doubt about the success of vaccinations when injected into fatty tissue.

4.5 Intervals between vaccinations

General information

The vaccination intervals shown in Tables 1, 2, and 7 and in Summary of Product Characteristics sheets should generally be complied with and neither be shortened nor prolonged. In the case of urgently indicated vaccinations, such as post-exposure rabies prophylaxis or postnatal immunoprophylaxis of hepatitis B in the newborn, the recommended vaccination schedule must be strictly adhered to. Minimum intervals should be shortened only in urgent exceptional cases (for example, a trip abroad at short notice).

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

On the other hand, every vaccine dose counts! Additional vaccine doses are not required if intervals between already administered vaccine doses are longer than recommended. Even a primary immunisation that has been out of date for many years or a booster vaccination not carried out in a timely manner, for example against diphtheria, tetanus, poliomyelitis, hepatitis B, or TBE (see www.rki.de > Infektionskrankheiten > FSME > Antworten auf häufig gestellte Fragen zur FSME-Impfung), **does not have to be started again from the beginning,** but is updated with the missing vaccine doses. This also applies to infants and toddlers. In the interest of providing vaccination protection as early as possible, exceeding the recommended vaccination intervals should be avoided in young children.

The following applies to intervals between different vaccinations: Live vaccines (attenuated, replication-competent viruses or bacteria) can be administered simultaneously. If they are not administered simultaneously, there must be a minimum interval of 4 weeks between the 2 vaccine administrations. In the case of immunisation with inactivated vaccines (inactivated pathogens, their antigen components, and toxoids) no minimum time interval between 2 vaccinations is necessary, even if one of the vaccines is a live attenuated vaccine. Possible adverse reactions following preceding vaccinations should have completely subsided prior to a new vaccination.

With regard to the minimum interval between 2 vaccinations as well as the co-administration of vaccine, note should be taken of the Summary of Product Characteristics for the respective vaccine.

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. In the case of elective procedures, a minimum interval of 3 days should be allowed after the administration of inactivated vaccines and a minimum interval of 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. With the exception of vital vaccinations (such as tetanus, rabies, and hepatitis B vaccination), these minimum intervals also apply to vaccination following major surgical procedures. Following operations associated with immunosuppressive treatment, e.g. transplantations, vaccinations must be planned in cooperation with the attending physician.

4.6 Guidance on reducing vaccination-related pain and stress

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 both amongst children and their parents.

Several evidence-based sets of recommendations for reducing pain and stress related to vaccinations have been published. These include certain injection techniques, age-related distraction methods and other behaviours which can lessen the pain of vaccination. These recommendations are summarised in the following. Physicians are encouraged to apply these techniques on reducing vaccination-related pain in their everyday practice and thus to promote public acceptance of vaccination. Additional information can be found in the publications cited.[1-7]

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 in order to avoid increasing the individual's fear or suspicion. It is essential to avoid using falsely reassuring or dishonest phrases like "It won't hurt at all!"

Painkillers

- In individual cases, lidocaine patches or creams under occlusive dressing can be used for children from 4 months of age to reduce the pain caused by the injection. In children aged < 12 months, the patches and creams should not be used concomitantly with drugs like sulphonamide which contributes to the formation of methaemoglobin. Pain patches can also be helpful for adolescents and adults who are afraid of injections. The minimum time of 30–60 minutes to achieve the optimal pain relief must be taken into account during planning. The costs of the patches (approx. € 5 each), which are freely available in pharmacies, usually have to be borne by the parents or the person being vaccinated.
- To reduce pain an ice spray can also be used. It should be sprayed for 2-8 seconds; after disinfection, the vaccination can be administered immediately.

Other support procedures

- Even before their children's first vaccination appointment (from 2 months of age), parents should be informed about the forthcoming vaccinations and the concomitant pain and pain-reducing options. This means that the information could already been given at the U3 examination in order to promote the use of pain-reducing strategies at the vaccination appointment itself.
- Parents of children aged < 10 years should be present in the room during their child's vaccination.
- Children aged ≥ 3 as well as adolescents and adults should receive information about what will happen during the vaccination and how they can best deal with pain or fear, e.g. by clasping their mother's or father's hand immediately before the injection. Children aged ≤ 6 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. To distract adults, they can be encouraged to cough slightly or hold their breath.

Recommended body position

- Sucking on a dummy will also help to reduce pain in infants.
- If infants are still being breastfed, mothers can nurse them during the vaccination. If, however, the infant is being vaccinated against rotavirus at the same time, the mother should not breastfeed before and during the RV vaccination because concurrent breastfeeding can potentially weaken the effect of the RV vaccination (see FAQ on rotavirus vaccination and breastfeeding *Epid. Bull.* 39/2013, www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 39/2013). Alternatively, a dummy can be used.
- Children aged < 2 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, it should be given first if it is one of several vaccinations being administered at the same time.
- Small children aged < 3 should preferably be carried or sit on their parents' lap during the vaccination and be gently rocked and stroked afterwards.
- Children aged ≥ 3 as well as 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 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 (M. vastus lateralis or M. deltoideus) in the parts of the body that are used for the injection.
- 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.

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
- Rapid injection can reduce pain during intramuscular injection.

Literature

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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 second vaccination with the same vaccine. Obstacles to vaccination can include allergies to components of the vaccine. Neomycin and streptomycin are important considerations, as well as 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).

In the case of 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 indicated in patients with immunodeficiency.**

Vaccinations that are not urgently indicated should not be carried out during pregnancy. Live vaccines against measles, mumps, rubella, and varicella are contraindicated in pregnancy. It is allowed to administer a yellow fever vaccination in pregnancy in case of clear indication and merely after careful risk-benefit consideration. A yellow fever vaccination should not carried out in breastfeeding women. Worldwide there are reported sporadic cases of breastfed infants who came down with a meningoencephalitis after their mother had received a yellow fever vaccination.

False contraindications

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

- Commonplace infections, even if they are associated with subfebrile temperatures (< 38.5°C);
- Possible contact of the person to be vaccinated with people with contagious diseases;
- Seizures in the family;
- Febrile convulsions in the medical history of the child to be vaccinated (as febrile vaccination reactions can provoke seizures, administering antipyretics to children who are prone to seizures should be considered, for example, in the case of inactivated vaccines, at the time of vaccination and again 4 and 8 hours after the vaccination, as well as between the 7th and 12th day following MMR vaccination in the case of a rise in temperature);
- Eczema including dermatoses and localised skin infections;
- Treatment with antibiotics or 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; see below*);
- Congenital or acquired immunodeficiencies upon vaccination with inactivated vaccines;
- Neonatal jaundice;
- Premature birth: premature babies should be vaccinated according to the recommended vaccination age regardless of their age of maturity and current weight;
- Breastfeeding women: they can receive every required vaccination except a yellow fever vaccination (see above: Contraindications)
- Breastfed infants: infants who are exclusively or partially breastfed can be vaccinated in accordance with the STIKO recommendations just the same as infants who are fed formula or other baby food.

* Currently, the risk of connatal varicella syndrome in a seronegative pregnant woman in contact with her non-vaccinated child thus at risk of being infected is greater than the risk of such a complication through vaccination and, where applicable, transmission of vaccine-induced varicella via her child.

Indicated vaccinations should also be undertaken in persons with chronic diseases, as these persons are especially endangered by severe courses and complications of vaccine-preventable diseases. Persons with chronic diseases should be educated on the benefits of vaccination compared with the risk of 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 Immunization in immunodeficiency or immunosuppression

Patients with immunodeficiency and/or immunosuppression often suffer from infectious diseases. In comparison to immunocompetent persons these diseases often have a particularly severe course. Therefore people with immunodeficiency or immunosuppression should be given as much protection as possible by vaccination. In addition it plays a central role for infection protection that household contact persons are properly protected by vaccination according to the STIKO recommendations as well as other persons from the direct environment of the patient (for example in the health service, day care center or school). Table 2 of the STIKO recommendations already lists some patients with congenital or acquired immunodeficiency or -suppression. When planning and carrying out vaccinations, special attention must be paid to this particular patient clientele, such as:

- the recognition and assessment of the severity of the immune defect;
- indications and contraindications for specific vaccinations or vaccine types, depending on the type and severity of the underlying disease and the resulting immune deficiency;
- the time of vaccination (e.g. before a planned iatrogenic immunosuppression);

- the comprehensive information of the patient, especially if an off-label application is necessary.

With the aim of assisting vaccinating doctors in the above-mentioned points and providing decision-making assistance a group of experts is currently working under the leadership of STIKO to provide vaccination guidelines for patients with immunodeficiency or immunosuppression. These application instructions are to be published in four thematically separate documents. The basic paper is already published and available at: (www.rki.de/stiko > STIKO Recommendations > Notices). Documents ii–iv are to be published by the end of 2017 and early 2018 respectively.

4.9 Vaccine-associated complications and its reporting

Criteria for differentiating normal vaccine reactions from potential complications

Der In accordance with the Protection Against Infection Act (IfSG) (§ 6 para. 1, no.3), every vaccinating physician is required to notify the responsible health authority if the suspicion of vaccine-associated complications arises. Such complications are defined as damage to health that goes beyond the usual dimensions of a reaction to vaccination. In order to differentiate vaccination-associated 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).

Normal vaccination reactions that are **exempted from notification** are defined as temporary local and general reactions that do not go beyond the usual dimensions of a reaction to vaccination and can be seen as the expression of the organism's interaction with the vaccine. STIKO has elaborated 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, discomfort, 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 pain, e. g. following rotavirus or typhoid vaccinations.

Also exempted from notification are symptoms which are obviously ascribable to a cause other than the vaccine; all other reactions should be reported.

Reporting the suspicion of vaccine-associated complications

In accordance with the Protection Against Infection Act (IfSG) (§ 6 para. 1, no.3), the suspicion of damage to health (suspicion of vaccine-associated complications) that goes beyond the normal dimensions of vaccine reactions must be reported to health authorities. The respective physician's notification must immediately be forwarded by the health authorities to the relevant state authorities in accordance with § 11, para. 2 (IfSG) and from there to the respective federal authorities (Paul Ehrlich Institute, PEI) in accordance with § 77 of the German Drug Law. The notification obligation was made statutory in order to immediately trigger 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 irrespective of whether or not the vaccine under discussion is publicly recommended. In order to ensure uniform reporting of a suspected case nationwide, PEI has developed a report form in collaboration with STIKO and the Ministry of Health entitled, "Bericht über Verdachtsfälle einer über das übliche Ausmaß einer Impfreaktion hinausgehenden gesundheitlichen Schädigung" (Report on suspected cases of damage to health going beyond the usual dimensions of a reaction to vaccination) which is available online at www.pei.de/SharedDocs/Downloads/vigilanz/pharmakovigilanz/ifsg-meldebogen-verdacht-impfkomplikation.html or can be obtained from the health authorities. The reports help to improve the pool of data on vaccine-associated complications. In addition, the health authorities should inform the person concerned or the parent or guardian about the statutory provisions for compensating the victims of vaccine-related damage (§§ 60–64 IfSG). The relevant application should be made to the appropriate pension office.

In addition, pursuant to § 6 of their professional code, physicians are obliged to report any adverse drug reactions they encounter in the course of conducting treatment to the Drug Commission of the German Medical Association (www.akdae.de > Arzneimittelsicherheit > Unerwünschte Arzneimittelwirkung melden). The manufacturer can also be informed.

4.10 Shortages of vaccines

Since October 2015, the Paul Ehrlich Institute (PEI) has included information about shortages in the supply of vaccines and the probable delivery waiting times on its website (www.pei.de/lieferengpaesse-impfstoffe-human). This information derives from notifications from pharmaceutical companies which report shortages as soon as the delivery chain for supplying a vaccine is broken for a period of at least 2 weeks. In agreement with RKI and STIKO, PEI also announces which alternative vaccines with the same composition are available and can be used.

If no vaccines with the same antigenic composition are available, STIKO is being asked to recommend a course of action involving the use of other vaccines which can also

achieve the required immunity (www.rki.de > Kommissionen > Ständige Impfkommission > Lieferengpässe).

Unavailability of Tdap and IPV vaccines

The supply of Tdap and Tdap-IPV vaccines is particularly challenging because of increased demand worldwide for acellular pertussis vaccine and inactivated polio vaccine. As production capacity cannot keep pace, this situation could continue for several years. STIKO has published a statement on the issue entitled "Handlungsempfehlungen bei Nicht-Verfügbarkeit von Tdap- bzw. IPV-haltigen Impfstoffen" (Recommendations in case of unavailability of Tdap- or IPV-containing vaccines) *Epid. Bull.* 14/2016 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 14/2016). This describes basic procedure if there is a shortage of these vaccines and how the groups of individuals to be vaccinated can be prioritised.

4.11 Vaccination recommendations for immigrants, refugees, or asylum seekers in communal accommodation

It is recommended to begin immunising residents of communal accommodation as soon as possible through the local health authorities (öffentlicher Gesundheitsdienst [ÖGD]) or through physicians commissioned by the ÖGD. Primary immunisation should be completed by private physicians in the most recent place of residence or by the ÖGD after leaving communal accommodation.

Available vaccination documentation should, where possible, be taken into account; the procedure should be based on the STIKO recommendations.

- Unvaccinated adults and adults with unclear vaccination status should receive vaccinations against diphtheria and tetanus, against poliomyelitis and, in seronegative persons, against hepatitis B. Adults should receive the next due Td vaccination (booster vaccination) as a one-time Tdap combination vaccination. Individuals born after 1970 should be vaccinated once against measles (MMR). Women of childbearing age should receive 2 vaccinations against rubella (MMR), and seronegative women who wish to conceive should be vaccinated twice against varicella. It is recommended that persons over the age of 60 receive a pneumococcal vaccination and each autumn an annual influenza vaccination.
- Unvaccinated children and children with unclear vaccination status should receive vaccinations against diphtheria, tetanus, and pertussis, as well as against poliomyelitis, measles, mumps, rubella, varicella, hepatitis B, meningococcal C, and HPV (girls only); in addition, infants and toddlers should be vaccinated against rotavirus, *Haemophilus influenzae* type b, and pneumococci

4.12 Information on cost coverage of immunisations

There are various possible payers for covering the cost of vaccinations. New regulations were established in 2007 that define which vaccinations are covered by all statutory health insurance companies in Germany. According to § 20d of Book V of the Social Code [SGBV], insured persons are entitled to vaccination pursuant to § 2 no. 9 of the Protection Against Infection Act (IfSG). Based on STIKO recommendations, the Federal Joint Committee (GBA) must determine, in a vaccination guideline (see www.g-ba.de), the details of the obligation to reimburse the cost of vaccinations (including requirements, type and scope). In doing so the particular significance of vaccinations for public health should be taken into account. Immunisations indicated owing to an increased health risk from a non-work-related stay abroad (travel vaccinations) are excluded from this entitlement, unless, for the protection of public health, there is special interest in preventing the introduction of a transmissible disease into the Federal Republic of Germany (for example, travel vaccinations). If a GB-A decision is not made within 3 months following publication of the STIKO recommendations, those vaccinations recommended by STIKO must be provided by health insurance companies until the guideline comes into existence.

Health insurance companies can also include in their optional benefits coverage the reimbursement of the cost for further vaccinations that are not part of the guideline of the Federal Joint Committee. In addition, 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 are able to cover the cost of protective vaccinations. These include ÖGD for vaccinations pursuant to § 20 5 of the IfSG, as well as other named entities based on legal regulations (e.g., employers). For example, in accordance with § 3 3 of the Occupational Safety and Health Act [Arbeitsschutzgesetz], an employer is not permitted to impose the costs of occupational safety measures on an employee. Occupational safety measures include vaccinations that must be offered in accordance with the Occupational Safety and Health Act [Arbeitsschutzgesetz]/Biological Agents Ordinance [Biostoffverordnung]/Regulation Concerning Occupational Healthcare [Verordnung zur arbeitsmedizinischen Vorsorge (ArbMedVV)]. The vaccinations offered are specifically determined by the outcome of a risk assessment.

The vaccinations denoted "O" in the STIKO recommendations also include those for professional groups that are not subject to the named ordinances. In this category, vaccinations are also listed that are primarily indicated for the protection of third parties.

Even if the named regulations do not apply in these cases, it is in the interests of the employer concerned to offer these vaccinations, because in doing so the employer can counter possible claims for redress or save on the costs of down-time among employees. How far the recommendations denoted "O" are standard services for the statutory health insurance companies is determined by the protective vaccination guidelines of the Federal Joint Committee. At present, this does not regularly provide for an entitlement to statutory health insurance company reimbursement in cases where the employer is responsible. However, for vaccinations recommended by STIKO that do not have to be covered by the employer, the statutory health insurance companies are obligated to reimburse the cost, based on the vaccination guideline.

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

5.1 Overview

In addition to the recommendations for standard and indicated vaccinations, STIKO issues recommendations regarding post-exposure vaccinations and other measures of specific prophylaxis of contact persons in private and occupational settings and in community facilities. Those recommendations include advice on how insufficiently-protected individuals can be protected after exposure to specific infectious agents in order to prevent further spread of the disease or to mitigate the course of the disease. Post-exposure 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-Guidebook for physicians" ("Ratgeber für Ärzte" des RKI) (www.rki.de/ratgeber).

Table 3: Post-exposure vaccinations and other measures of specific prophylaxis of communicable diseases

Vaccination against	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Diphtheria	For persons in close (face to face) contact with cases.	**Chemoprophylaxis:** Independent of vaccination status, preventive antibiotic treatment is recommended, e. g., with Erythromycin (see RKI-Guidebook for physicians "diphtheria", www.rki.de > Infektionskrankheiten A–Z > Diphtherie). Post-exposure vaccination is indicated if the most recent vaccination occurred > 5 years previously
	During epidemics or regionally increased morbidity.	In accordance with the recommendations of the health authorities.
Haemophilus influenzae type b (Hib)	Chemoprophylaxis is recommended after close contact with a patient with invasive *Haemophilus influenzae* type b Infection: ▶ For all household members starting at age 1 month, if either an unimmunised or insufficiently immunised child aged up to 4 years or a person with a relevant immunodeficiency is present; ▶ For unimmunised exposed children up to 4 years of age in community facilities.	**Chemoprophylaxis:** *Rifampicin:* **From 1 month of age:** 1 x 20 mg/kg body weight (up to a maximum of 600 mg) p. o. for 4 days **Adults:** 1 x 600 mg p. o. for 4 days As administration of rifampicin is contraindicated in pregnant women, ceftriaxone can be used for prophylaxis instead, if necessary (1 x 250 mg i. m.). If prophylaxis is indicated, it should be started as soon as possible, and at latest 7 days after the onset of disease in the index case.
Hepatitis A (HA)	Contact with hepatitis A patients (especially in community facilities).	**Post-exposure vaccination with monovalent Hepatitis A-vaccine within 14 days after exposure:** Following exposure in persons for whom hepatitis A presents a particular danger (e. g., those chronically infected with HBV or HCV), an immunoglobulin preparation should be given simultaneously with the 1st vaccination. See also "Ratgeber Hepatitis A" ["Hepatitis A Guide"] at www.rki.de > Infektionskrankheiten A–Z > Hepatitis A.
Hepatitis B (HB)	Injuries from objects potentially containing HBV (e. g., a needle stick) or blood contact with mucosa or non-intact skin.	See post-exposure hepatitis B immune prophylaxis, p. 360 f.
	Newborn babies either of HBsAg positive mothers or of mothers with unknown HBsAg status (regardless of birth weight).	See comments on the vaccination schedule, p. 344.
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 von 9 to 10 months;	Vaccination with MMR(V)** vaccine preferably within 3 days after exposition; according to the number of vaccine doses or the time of administration please consider the following age-specific recommendations. ** MMR(V) = MMR with or without co-administration of VZV vaccine ▶ 1st vaccination; a 2nd and 3rd vaccination should be given at the age of 11 to 14 and 15 to 23 months. ▶ 1st vaccination; the 2nd vaccination should be given at the beginning of the 2nd year of life.

(Table 3 continued)

Vaccination against	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Measles (continued)	▶ at the age of 11 months to 17 years;	▶ People with unclear vaccination status or who have not been vaccinated vaccination with 2 doses administered at least 4 weeks apart; People who have received only one vaccination receive 1 more vaccination.
	▶ at the age of 18 years or more, born after 1970.	▶ People who have not been vaccinated, with unclear vaccination status, or who have been given only one vaccination during childhood receive 1 more vaccination.
	Unprotected people for whom vaccine is contraindicated and who have a high risk of complications after exposition to measles: ▶ Infants aged < 6 months of age ▶ susceptible pregnant women ▶ immunodeficient individuals	Passive immunisation with immunoglobulins (off label-use) can be considered up to 6 days after exposition: 1 x 400 mg/kg body weight i. v. Infants between 6 to 8 months of age can receive immunoglobulins after individual risk-benefit consideration alternatively to the 1st vaccination. 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, S. (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 2/2017).
Meningococci	Chemoprophylaxis is recommended for persons in close contact with a patient with invasive meningococcal infection (all serogroups). This includes: ▶ All household contact members ▶ Persons in contact with a patient's oropharyngeal sec-retions ▶ Contact persons in children's establishments with children under 6 years of age (only in the affected group in cases where the groups are well separated) ▶ Persons in close contact in community facilities with a household-like character (for example, boarding schools, hostels and barracks) Chemoprophylaxis is indicated if close contact with the index patient took place in the 7 days preceding the onset of illness. Chemoprophylaxis should take place as soon as possible after diagnosis of the index patient; however, it is useful up to 10 days after the last exposure. In addition to chemoprophylaxis, meningococcal vaccination of unvaccinated household contacts or close contacts of a household-like character is recommended 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 contact.	**Chemoprophylaxis:** *Rifampicin:* **Newborn babies:** 2 x 5 mg/kg body weight p. o. for 2 days. **Infants, children and adolescents up to 60 kg:** 2 x 10 mg/kg body weight (max. ED 600 mg) p. o. for 2 days **Adolescents and adults from 60 kg:** 2 × 600 mg p. o. for 2 days. Eradication rate: 72–90 % Or: *Ciprofloxacin:* From 18 years of age: 1 × 500 mg p. o. Eradication rate: 90–95 % Where applicable, *Ceftriaxone:* **Up to 12 years of age:** 1 x 125 mg i. m. **From 12 years of age:** 1 x 250 mg i. m. Eradication rate: 97 % Because administration of rifampicin and gyrase inhibitors is contraindicated in pregnant women, ceftriaxone can be used as prophylaxis if necessary (1 x 250 mg i. m.). The index patient with an invasive meningococcal infection should also receive rifampicin after completion of therapy, unless he or she received intravenous treatment with a third-generation cephalosporin. **Post-exposure vaccination:** ▶ **For serogroup C:** Vaccination with a conjugate vaccine from 2 months of age, according to the Summary of Product Characteristics (see p. 346) ▶ **For serogroups A, W or Y:** Vaccination with a quadrivalent conjugate vaccine, if licensed for the respective age group (see p. 347) ▶ **For serogroup B:** Vaccination with a MenB-vaccine, according to the Summary of Product Characteristics and if licensed for the respective age group (p. 346)

(Table 3 continued)

Vaccination against	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Meningococci (continued)		See also updates in *Epid. Bull.* 33/2010 and *Epid. Bull.* 31/2012 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issues 33/2010 and 31/2012.
Mumps	Non-immunised persons, persons immunised once during childhood, and persons with an unclear immune status in contact with mumps cases, if possible within 3 days after exposure.	One-time vaccination with an MMR vaccine.
Pertussis	Persons without vaccination protection in close contact in a family, shared accommodation, or a community facility.	Chemoprophylaxis with a macrolide is recommended (see also RKI-Ratgeber für Ärzte "Pertussis" ["Pertussis Guide"] at www.rki.de > Infektionskrankheiten A–Z > Pertussis).
Poliomyelitis	All contact persons of a poliomyelitis case regardless of their vaccination status. A secondary case is a cause for ring vaccinations.	Immediate post-exposure vaccination with IPV. Immediate extensive investigations and stipulation of measures by the health authorities. Ring vaccinations with IPV and stipulation of further measures by decree of health authorities.
Tetanus	See Table 5, p. 362.	
Rabies	See Table 6, p. 363.	
Varicella	1. In non-immunised persons with no history of varicella and in contact with persons at increased risk.	Post-exposure vaccination within 5 days of exposure* or within 3 days following commencement of the rash in the index case. Independent of these measures, contact with persons at risk (for example, those listed in point 2) should be avoided at all costs.
	2. Persons at increased risk of varicella complications, including: ▶ Non-immunised pregnant women with no history of varicella; ▶ Immunocompromised patients with uncertain or absent varicella immunity; ▶ Newborn babies whose mothers became ill with varicella between 5 days preceding and 2 days following 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 immunoglobulin (VZIG) as soon as possible within 3 to 10 days at maximum following exposure*. VZIG can prevent or markedly alleviate the outbreak of disease. Please follow the Summary of Product Characteristics for the administration and dosing of VZIG! Post-exposure prophylaxis with VZIG might be accomplished by use of antivirals. * Exposure is defined as: ▶ 1 hour or longer with an infectious person in a room ▶ Face to face contact ▶ Household contact

5.2 Vaccinations for clustered occurrences or outbreaks of meningococcal diseases

- A "**meningococcal disease outbreak**" is defined as 2 or more cases of the same serogroup within 4 weeks in a children's facility, school class, playgroup, a community facility with a household-like character (for example, a hostel, boarding school, or barracks);
- A "**regionally clustered occurrence**" is defined as 3 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 ≥ 10/100,000 in the respective population.

As a supplement to antibiotic prophylaxis for close contact persons (see Table 3, p. 358 f., as well as the recommendations of the German Society of Paediatric Infectiology [Deutsche Gesellschaft für Pädiatrische Infektiologie (DGPI)], of the National Reference Centre for Meningococci, and the Ratgeber für Ärzte [Guide for Physicians] of the RKI), the responsible health authorities can additionally recommend vaccination prophylaxis if the clustered occurrence or the outbreak was caused by a strain preventable by vaccination. Vaccination prophylaxis 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 in the event of an outbreak.

In the case of a regionally clustered occurrence, the decision of the responsible health authorities must be made considering the epidemiological and temporal correlations of the diseases, their age distribution, the level of public concern, and the feasibility of the measures.

Authorised vaccines corresponding to the meningococcus serogroup causing the outbreak can be used for vaccination (see notes on use in Table 2 and, p. 346).

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

5.3 Post-exposure hepatitis B immunoprophylaxis after exposure to HBV-containing material

Prompt prophylaxis is required in case of exposure to 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 present a risk of infection. Any such event (for example, during patient care, the patient hereby called the "index patient") should be reported as an occupational accident by the employee (hereby called the "exposed person"). The HBsAg status of the index patient and the HBV vaccination status of the exposed person should be determined.

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

1. **If the index patient is HBsAg negative:** further measures in regard to hepatitis B are superfluous(see *). If the exposed person is not vaccinated or vaccination is incomplete, primary immunisation should be started and completed, respectively.
2. **If the index patient is HBsAg positive:** further measures depend on the vaccination status of the exposed person and are explained below.
3. **If the HBsAg status of the index patient is unknown:** the HBsAg level of the index patient 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 is simply not possible (e. g., injury due to a hollow needle in a trash bag), the index patient is classified as HBsAg positive, and further measures depend on the vaccination status of the exposed person (see **).

The proceedings described in the following are additionally depicted in a flow chart (see Figure 1, p. 361).

For exposed persons with complete vaccination the following applies:

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 4, p. 362).
  – Anti-HBs was <10 IU/l: Blood withdrawal (testing for HBsAg, anti-HBc, and anti-HBs), succeeded by immediate simultaneous administration of HB vaccine and

HB immunoglobulin (without waiting for the test results).**

Exception: If at a prior point in time, i.e. 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 longer than 10 years ago or never (or if testing result is unknown): Immediate testing of the current anti-HBs level. Further action depends on the test result (see Table 4).

For exposed persons with incomplete vaccination, the following applies:

- Immediate testing of the current anti-HBs level. Further action depends on the test result (see Table 4, p. 362).
- Administration of missing vaccinations (where applicable, a shortened vaccination schedule can be used; see Summary of Product Characteristics).

For unvaccinated exposed persons and known "non-responders" (individuals with permanent anti-HBs < 10IU/l) the following applies:

- 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 persons, 2 additional vaccine doses (after the initial dose) should be given according to the standard vaccination schedule in order to achieve a complete primary immunisation. Antibody response following HB vaccination is not affected by simultaneous administration of immunoglobulin.

* Very rarely, HBs-Ag negative persons can be infectious. From a cost-benefit point of view, routine testing for HBV-DNA of all index patients is not practicable.
** An isolated positive result of an anti-HBc test necessitates further diagnostic clarification. However, required vaccination should not be delayed.

Figure 1: Procedure for the hepatitis B immunoprophylaxis (see detailed information, p. 360)

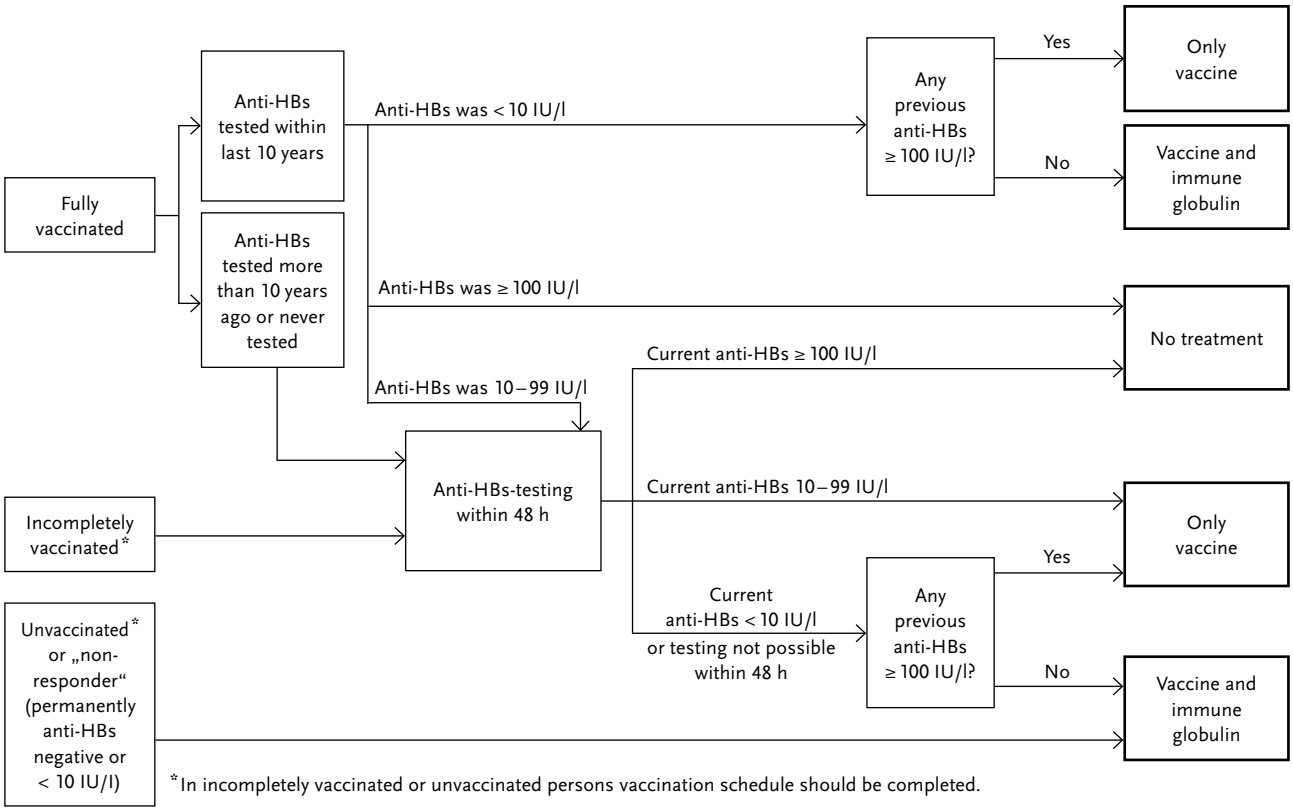

Table 4: Hepatitis B immunoprophylaxis after exposure depending on the current anti-HBs level
(see also flow chart, Figure 1)

Current anti-HBs level		Required administration of	
		HB vaccine	HB immunoglobulin
≥ 100 IU/l		No	No
10–99 IU/l		Yes	No
< 10 IU/l, or not determinable within 48 hours	and anti-HBs was ≥100 IE/l at a prior point in time	Yes	No
	and anti-HBs was never ≥100 IE/l, or is unknown	Yes	Yes

5.4 Post-exposure tetanus immunoprophylaxis in case of injury

Even trivial injuries can be entry ports for tetanus bacteria or spores. In the event of an injury, the treating physician should verify the current tetanus vaccination status. Tetanus immunoprophylaxis must be carried out immediately. Missed primary immunisation vaccinations must be reinstated in accordance with the recommendations given for primary immunisation.

Table 5: Tetanus immunoprophylaxis in case of injury

Previous history of tetanus immunisation (# of tetanus vaccine doses received)	Clean, negligible wounds		All other wounds [1]	
	DTaP/Tdap [2]	TIG [3]	DTaP/Tdap [2]	TIG [3]
Unknown	Yes	No	Yes	Yes
1	Yes	No	Yes	Yes
2	Yes	No	Yes	No [4]
3 or more	No [6]	No	No [5]	No [6]

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). Further indications include:

- Severe burns and frostbite
- Tissue necrosis
- Septic miscarriages

2 Children under 6 years old receive a combination vaccine with DTaP, while older children receive Tdap (that is, a tetanus and diphtheria vaccine with a reduced diphtheria toxoid content and reduced acellular pertussis component). Adults also receive Tdap if they have not yet received a Tdap vaccine as adults (≥18 years of age) or if there is a current indication for pertussis vaccination (see Table 2, p. 342).

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 dose can be increased to 500 IU in cases of infected wounds (that do not receive adequate surgical treatment within 24 hours); deep or contaminated wounds with tissue damage and reduced oxygen supply as well as foreign body penetration (e.g. bites, stab or bullet wounds); severe burns and frostbite, tissue necrosis and septic abortions.

4 Yes if the injury dates back longer than 24 hours.

5 Yes (1 dose), if more than 5 years have passed since the last vaccination.

6 Yes (1 dose), if ≥10 years have passed since the last vaccination.

5.5 Post-exposure rabies immunoprophylaxis

Detailed information on the epidemiology of rabies in Germany can be found in *Epid. Bull.* 8/2011 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 8/2011).

Table 6: Post-exposure rabies immunoprophylaxis

Level of exposure	Type of exposure from a wild animal, pet, or bat with suspected or confirmed rabies	Type of exposure from a rabies vaccine bait	Immunoprophylaxis* (Note the Summary of Product Characteristics)
I	Touching/feeding of animals; licking of intact skin.	Touching of vaccine baits with intact skin.	No vaccination.
II	Superficial scratches or abrasions without bleeding; Licking or nibbling of broken skin.	Contact with the vaccination fluid of a damaged vaccine bait with broken skin	Protective rabies vaccination.
III	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.	Contamination of mucous membranes and fresh skin injuries with the vaccination fluid of a damaged vaccine bait.	Protective rabies vaccination and a single administration of rabies immunoglobulin (20 IU/kg body weight) simultaneously with the 1st dose.

* Individual vaccinations and administration of rabies immunoglobulin must be carefully documented.

Notes on post-exposure rabies immunoprophylaxis

- Potentially contaminated body sites and all wounds must be cleaned immediately and generously with soap or detergent, rinsed thoroughly with water, and treated with 70% alcohol or an iodine preparation; this also applies to contamination with vaccination liquid from vaccine bait. When possible, wounds should not undergo primary suturing.
- With exposure level II, a rabies vaccine is used for active immunisation according to the Summary of Products Characteristics.
- With exposure level III, in addition to active immunisation, passive immunisation with rabies immunoglobulin (20 IE/kg body weight) is initiated. **As much rabies immunoglobulin as possible** is instilled in and around the wound, and the remaining amount is administered intramuscularly.
- If an indicated administration of rabies immunoglobulin was not administered at first vaccination, it can still be given until 7 days after the first dose of rabies vaccine.
- If a person 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 either incomplete vaccination or vaccination with vaccines not authorised in the EU, full immunoprophylaxis is carried out in accordance with Table 6.
- If indicated, immunoprophylaxis must be carried out immediately; there should be no delay while waiting for clarification of a suspected infection in the biting 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 of the incubation period, which can last be between < 10 days and > 1 year, a post-exposition prophylaxis is in case of a reasonable suspicion still useful for weeks to months after exposure.
- Care must be taken to check tetanus vaccination documentation and if necessary to administer simultaneous tetanus immunoprophylaxis (see Table 5, p. 362).

6. Recommendations for catch-up vaccinations

For children, adolescents and adults with incomplete or unknown vaccination status

6.1 Preliminary remarks

The present notes are based on the recommendations for vaccination of infants, children, adolescents and adults (see immunisation schedule, p. 336).

These notes are intended to guide physicians in deciding which vaccinations are required for unvaccinated, delayed, or incompletely vaccinated individuals to achieve the recommended vaccination protection according to age. Evidence supporting this guidance is often limited, as studies of high methodological quality examining vaccine effectiveness under irregular immunisation schedules are often not available. The recommendations given here are therefore mainly based on the long-term experience and expertise of STIKO members.

In addition, expert opinions and the recommendations of other international immunisation technical advisory groups were considered.[1,2,6-11] Bibliographic details for the following references are listed at the end of the chapter on "recommendations for catch-up vaccinations".

Every physician consultation of children, adolescents and adults should be used to check the individual's vaccination status and to prompt catch-up of missing vaccinations.

6.2 Unvaccinated persons and persons with unclear vaccination status

An overview regarding recommended catch-up vaccinations and the corresponding immunisation schedule for different age groups is given in Table 7 (see p. 367–371). Age groups were chosen to incorporate age-related particularities in vaccination recommendations and application notes according to the Summary of Product Characteristics of licensed vaccines. The relevant age for the required vaccinations is **the age at start of the catch-up series**.

6.3 Partly immunised persons

For partly immunised children, adolescents, and adults, all documented vaccinations up to the present are counted, if 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). Given this prerequisite, 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 repeated. A booster vaccination that has not been administered according to schedule can also be administered at a later point in time.

In considering the current **age** and number and timing of previously administered vaccines, an individual immunisation schedule should be compiled. If children aged between 12 months and < 5 years are vaccinated, who had already received vaccinations at the age of < 12 months, it must be ensured that a 3-dose immunization schedule is only possible with a distance of at least 2 or 6 months to the previous 1st and 2nd dose respectively. Therefore, children who have already received (i) 2 or (i) 3 doses in a 1-month interval still need (i) 2 doses or (ii) 1 dose to complete the primary vaccination. It is explicitly pointed out that the STIKO only recommend a 3-dose schedule for the vaccination of children > 12 months (see chapter 6.10).

For vaccinations that are recommended only until a specific age (pneumococcal for infants/children, Hib, rotavirus), an interrupted primary immunisation series will not be continued if the vaccinee has in the meantime surpassed this specific age.

An incomplete HPV vaccination series, however, should be completed even after the age of 18 (clarify who will bear the cost).

Literature: see p. 373
Table 8: see p. 372

6.4 Procedure in the case of missing immunisation documentation

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

Missing vaccination cards is a frequent problem in daily life among migrant children, adolescents, and adults. A summary of up to date vaccination recommendations according to country of origin can be found on the webpages of the WHO (http://apps.who.int/immunization_monitoring/globalsummary/schedules) and ECDC (http://vaccine-schedule.ecdc.europa.eu/Pages/Scheduler.aspx) listing all national immunisation schedules. In principle, however, according to STIKO recommendations, all vaccinations that are not documented should be administered under the assumption that they are missing.

In case of an unknown vaccination status, including missing or incomplete documentation of vaccinations, it should be assumed in the interest of the individual to be protected that the respective 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 might be justifiable in individual cases.

6.5 Anamnestic information regarding varicella

Varicella (chicken pox) is an exception regarding the reliability of anamnestic information. Studies show that such information showing a previous history of varicella with typical clinical manifestations is of high validity.[3] A varicella vaccination is not required after an anamnestic response indicating 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.[4] 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 for serological testing

Serological testing to determine the need for catch-up vaccinations based on antibody titres only makes sense in exceptional cases, because the test methods used in clinical laboratories often do not have a sufficient sensitivity and specificity. For some vaccine-preventable diseases (e. g., pertussis), no reliable serological correlate exists that would be suitable as a surrogate marker for the presence of immunity. Moreover, antibody titre levels do not allow drawing conclusions regarding potential cellular immunity. In principle, routine antibody testing is not appropriate before or after vaccinations. Exceptions are verifying vaccination success in patients with immunodeficiency (see STIKO notes in *Epid. Bull.* 39/2005, (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 39/2005), and confirming protection against hepatitis B among persons with an elevated exposure risk (see Table 2, p. 338). 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 Are "too many" vaccinations dangerous?

In general, there is no elevated risk of side effects resulting from excess vaccine doses. To limit necessary injections, it is therefore possible to use combination vaccines even if not all antigens/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'). The self-limiting reaction most likely occurs after 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.[5]

6.8 Choice of vaccines

Combination vaccines are to be preferred over monovalent vaccines if in consequence the number of injections can be reduced, the vaccination goal can be reached at an earlier date, and vaccination acceptance can be increased. There are at present no monovalent vaccines in Germany available against certain diseases (childhood diphtheria, measles, mumps, rubella, and pertussis); in these cases it is unavoidable to administer combination vaccines (for example, to catch-up a missing mumps or rubella vaccination with an MMR vaccine). Individual immunisation schedules are often necessary owing to age-dependent changes of vaccination indications (for example, vaccination for *Haemophilus influenzae* type b until the 5th birthday, and pneumococci until the 2*nd* birthday) and the restriction of licensed vaccine administration to certain age groups.

According to the current Summary of Product Characteristics, the hexavalent vaccines Infanrix hexa® (DTaP-IPV-HiB-HepB), Vaxelis® and Hexyon® can be used for basic immunisation and booster vaccinations for infants and small children; a concrete age limit is not given. According to the Paul Ehrlich Institute in its function as national regulatory authority, in this context there is no binding definition of the term "small child". According to the current Summary of Product Characteristics, the pentavalent vaccines Infanrix®-IPV+Hib (DTaP-IPV-Hib) and Pentavac® are suitable from the age of 2 months; an upper age limit is not given (see Table 8, p. 372). For basic immunisation against *Haemophilus influenzae*, Type b, a single dose of vaccine from 12 months is sufficient. Nonetheless, the usual pentavalent or hexavalent vaccines DTaP-IPV-Hib(-HepB) can continue to be administered if this is necessary to complete the other vaccinations. Negative effects due to excess Hib vaccine doses are not to be expected

Alternatively, missing vaccinations can be completed with the tetravalent 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, differently dosed vaccines 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 5–6 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 vaccinee is usually not immunologically naïve against pertussis given the current prevalence of Bordetella pertussis. A study showed that one vaccine dose induced an immunological response in more than 90% of vaccinated individuals aged 11 years and older.[2] Equivalent information can also be found in the Summary of Product Characteristics for the respective vaccines.

Starting at the age of 5 to 6, 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®, with the exception of Td-Immun®) 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® [currently not on the market], TdaP-Immun®), **Tdap-IPV:** (Boostrix-Polio®, Repevax®)) are mainly intended for booster vaccinations.

According to PEI, the term "primary immunisation" merely refers to the 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, PEI determined that the above-mentioned ap-containing vaccines 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 the vaccines given below is covered by licensing in the respective age groups:

1. TdaP-IMMUN® (Tdap)) vaccine for the primary immunisation of individuals from the age of 4;
2. Boostrix® (Tdap), Boostrix-Polio® (Tdap-IPV), Covaxis® (Tdap) und Repevax® (Tdap-IPV) vaccines for primary immunisation from the age of ≥ 12 years.

Only when these vaccines are used outside the respective age groups, information about an off-label use should be provided (see p. 350 for off-label use), and this should also be documented in writing.

For booster vaccinations, all the vaccines named can be used without restrictions for the age stated in the respective 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 (www.rki.de > Infektionsschutz > *Epidemiologisches Bulletin* > issue 4/2016).

6.10 Age-dependent recommendations for conducting catch-up vaccinations

Table 7: Recommended catch-up vaccinations among children, adolescents and adults with missing primary immunisation (P)

Apply the table using the patient's current age

C = Catch-up vaccination
B = Booster vaccination
P = Primary vaccination
Hib = *Haemophilus influenzae* type b
MMR = Measles, mumps, rubella
HPV = Human papilloma virus

Tab. 7A: Children < 12 months

Vaccination against	Minimum interval in months after previous vaccination dose				Age in years	
	0	1	1	6	5–8	9–17
Tetanus	C1	C2	C3	C4	B1	B2
Diphtheria (D)	C1	C2	C3	C4	B1	B2
Pertussis (aP)	C1	C2	C3	C4	B1	B2
Hib	C1	C2[a]	C3	C4		
Poliomyelitis	C1	C2[a]	C3	C4		B1
Hepatitis B	C1	C2[a]	C3	C4		
Pneumococcus	C1		C2	C3		

[a] This dose can be omitted when using a monovalent vaccine.

Age <12 months

Missing DTaP-IPV-HepB-Hib and pneumococcal conjugate vaccine doses should be administered (see p. 366 and Table 8, p. 372). To complete primary immunization against DTaP-IPV-Hib-HepB, 3 vaccine doses should be given at 1 month intervals and a 4th dose after an interval of ≥ 6 months since the previous vaccination. For full protection against pneumococcal disease 2 primary vaccine doses with a minimum interval of 2 months in between are required, which should be followed by a 3rd dose (booster) with a minimum interval of 6 months after the second dose.

There is only a short time slot for catch-up of the rotavirus immunisation series, because administration of the 1st 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 to the used vaccine brand (see Summary of Product Characteristics). The vaccination series must be completed by the age of 24 (Rotarix®) and 32 (RotaTeq®) weeks, respectively.

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

Tab. 7B: Children aged 12 months to < 5 years

Vaccination against	Minimum interval in months after previous vaccination dose			Age in years	
	0	1	6	5–17	
Tetanus	C1	C2	C3	B1[b]	B2[b]
Diphtheria (D)	C1	C2	C3	B1[b]	B2[b]
Pertussis (aP)	C1	C2	C3	B1[b]	B2[b]
Hib	C1				
Poliomyelitis	C1	C2	C3		B1[c]
Hepatitis B	C1	C2	C3		
Pneumococcus[d]	C1	Vaccination interval ≥ 8 weeks	C2		
Meningococcus C	C1				
MMR[e]	C1	C2			
Varicella[e]	C1	C2			

[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 9–17 years.
[d] The pneumococcal vaccination is not recommended as a standard vaccination after the age of 24 months; accordingly, there is no need for catch-up vaccination.
[e] Starting at the age of 11 months.

Age 12 months to < 5 years

Missing DTaP-IPV-HepB-Hib vaccine doses can be administered (see p. 366 and Table 8, p. 372). For a complete primary immunisation, 2 vaccine doses should be given at an interval of at least 1 month, plus a 3rd vaccination after an interval of ≥ 6 months since the previous vaccination. Booster vaccinations are given at the age of 5-6 years (at earliest 2 years after the 3rd dose) and at the age of 9–17 years. 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, a pneumococcal vaccination is only recommended for children in a risk category (indication vaccination). Furthermore, 2 MMR and varicella vaccinations should be given at intervals of 4–6 weeks as well as a meningococcal C conjugate vaccination. Due to 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, preference should be given to separate MMR and V vaccines for the first dose in children aged < 5 years. For the 2nd vaccination against MMR and V, either the MMRV combination vaccine or separate MMR and V vaccines can be used.

Example

A 2.5-year old child recieved 2 doses of the hexavalent vacine DTaP-IPV-Hib-HepB at 2 and 3 months and 2 doses of the pneumococal vaccine at 2 and 4 months, after this point, no further vaccinations were given.

The completition of this primary immunization is carried out according to the information for "Children aged 12 months to < 5 years" (current age) in Table 7B. From previously administered doses of the hexavalent vaccine only one dose is counted, because for a 3-dose schedule the distance of the previously administered doses was too short. Therefore two additional doses of the hexavalent vaccine at least 6 months apart are required. One additional dose of a Hib-containing vaccine would be sufficient for protection against *Haemophilus influenzae* type b, as only 1 dose is needed after the age of 12 months. However, both vaccinations can be carried out with a hexavalent vaccine to keep the number of injections to a minimum. The additional dose of Hib is not likely to pose an increased risk of side effects.

The missing vaccinations against MMR, varicella, and meningococcal C have to be administered according to the information for “Children aged from 12 months to < 5 years” (because at this time the child is unvaccinated against these diseases). The primary immunisation against pneumococci will not be initiated because this vaccination is not recommended after the age of 24 months (except for children with certain underlying diseases, in which case 2 additional doses would be required at an interval of at least 8 weeks).

Tab. 7C: Children aged 5 to < 11 years

Vaccination against	Minimum interval in months after previous vaccination dose			Age in years
	0	1	6	10–17
Tetanus	C1	C2	C3	B1[f]
Diphtheria (d)	C1	C2	C3	B1[f]
Pertussis (ap)[g]	C1	C2	C3	B1[f]
Poliomyelitis	C1	C2	C3	B1
Hepatitis B	C1	C2	C3	
Meningococcus C	C1			
MMR	C1	C2		
Varicella	C1	C2		
HPV (Girls) from the age of 9 years	P1		P2	

f Depending on the age at completion of the primary immunisation, 2 booster vaccinations may be appropriate before adulthood; the interval between P and B1 and between B1 and B2 is 5 – 10 years.

g As there is no monovalent pertussis vaccine available in Germany, only Tdap or Tdap-IPV combination vaccines can be used.

Age 5 to <11 years

Missing polio vaccinations and DTaP or Tdap vaccine doses should be administered using vaccines with an antigen content appropriate for age. Until the 6th birthday, according to the Summary of Product Characteristics it is possible to administer the tetravalent vaccine Infanrix® (DTaP) and simultaneously inject an IPV vaccination against polio (requiring 2 or 3 doses depending on the manufacturer; see Summary of Product Characteristics) 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. If applicable, the combination vaccines Tdap or Tdap-IPV can be used (3 doses at intervals 0–1–6 months; see p. 366 and Tab. 8, p. 372). Depending on age upon completion of the primary immunisation series, it might be appropriate for this age group to receive 1 or 2 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 3 vaccinations (0–1–6 months). In addition, 2 MMR and varicella vaccinations are given at an interval of 4 to 6 weeks and one conjugate vaccine against meningococcal C.

Girls at the age of 9–14 years, should receive 2 HPV vaccinations at least 5 months apart. (Note the Summary of Product Characteristics.)

Tab. 7D: Children/adolescents from 11 to < 18 years

Vaccination against		Minimum interval in months after previous vaccination dose			Vaccination interval
		0	1	6	5–10 years
Tetanus		C1	C2	C3	B1
Diphtheria (d)		C1	C2	C3	B1
Pertussis (ap)[g]		C1			B1
Poliomyelitis		C1	C2	C3	B1
Hepatitis B		C1	C2	C3	
Meningococcus C		C1			
MMR		C1	C2		
Varicella		C1	C2		
HPV [h] (Girls)	9–14 years	P1		P2	
	> 14 years	C1	C2	C3	

[g] As there is no monovalent pertussis vaccine available in Germany, only Tdap or Tdap-IPV combination vaccines can be used.

[h] At the age of 9–14 years HPV primary immunisation (P) consists of 2 doses 5 months apart. For catch-up vaccinations (C) and completion of vaccination series at age > 14 years, 3 doses are necessary (note Summary of Product Characteristics).

Age 11 to <18 years

In case of a missing vaccination against pertussis, protection can be achieved with 1 dose of a Tdap or Tdap-IPV vaccine.[12] If primary immunisation against tetanus, diphtheria and poliomyelitis is also indicated, the first of the required 3 vaccinations (0–1–6 months) should be conducted with a Tdap or Tdap-IPV vaccine (see p. 366 and Table 8, p. 372).

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 3 vaccine doses (0–1–6 months) using the vaccine licensed for the respective age. In addition, 2 MMR and varicella vaccinations are to be given at an interval of 4 to 6 weeks, and one conjugate vaccination against meningococcal C.

Girls under the ages of 14 years should receive a 2-dose HPV vaccination according to the vaccination scheme described in the Summary of Product Characteristics. Catch-up vaccinations should be offered to older girls and young women until the age of 17 years. For catch-up vaccinations when the primary vaccination was administered at the age of > 14 years, 3 doses are necessary (note the Summary of Product Characteristics).

Tab. 7E: Adults over 18 years

Vaccination against	Minimum interval in months after previous vaccination dose			Vaccination interval
	0	1	6	Every 10 years
Tetanus	C1	C2	C3	B
Diphtheria (d)	C1	C2	C3	B
Pertussis (ap)[g]	C1			B1 (one-time)
Poliomyelitis	C1	C2	C3	B1 (one-time)
Measles for persons born after 1970	C1			
Rubella for women in childbearing age[i]	C1	C2		
Varicella for seronegative women who wish to conceive	C1	C2		
Pneumococcal for adults ≥ 60 years of age	C1			Repeat immunisation only per individual indication, see Table 2, p. 342 (after 6 years at the earliest)

[g] As there is no monovalent pertussis vaccine available in Germany, only Tdap or Tdap-IPV combination vaccines can be used.

[i] Unvaccinated women or women without documented vaccinations are administered 2 doses, while one-time vaccinated women are administered 1 dose. In absence of a monovalent rubella vaccine, an MMR vaccine can be used

Catch-up vaccinations in adulthood

Adults should receive all vaccinations recommended for their respective age group, including catch-up vaccinations for tetanus, diphtheria, pertussis and poliomyelitis if necessary. Unvaccinated persons or persons with unknown vaccination status can receive 3 vaccination doses of a Td or Td-IPV combination vaccine (see p. 366) (0–1–6 months). To achieve a protection against pertussis, the first vaccination should be given as a Tdap or Tdap-IPV combination vaccine* (see p. 366 and Tab. 8, p. 372).[7] Td booster vaccinations should be administered in all cases 10 years after the previous vaccination. For the first booster, a Tdap combination vaccine should be used once.

Persons born after 1970 of ≥ 18 years of age should receive a one-time measles-virus containing vaccine, preferably an MMR vaccine. Women of childbearing age should be given 2 rubella vaccinations with an MMR vaccine. Varicella vaccination (2 doses at an interval of 4–6 weeks) is recommended for seronegative women planning pregnancy.

From the age of 60 years, STIKO recommends a vaccination against pneumococcal disease with a polysaccharide vaccine (PPSV23) and yearly vaccination against seasonal influenza as standard vaccinations. A repeat vaccination against pneumococci should be given no sooner than 6 years later and should be determined on a case-by-case basis (see p. 347 and Table 2, p. 341).

Tabelle 8: Brand names and indicated age groups of vaccines available in Germany mentioned in the text
(list does not claim to be exhaustive)

Antigen	Brand name	Minimum age [a]	Maximum age [a]
DTaP	Infanrix®	2 months	6th birthday (72 months)
DTaP-IPV-Hib	Infanrix-IPV + Hib®	2 months	No information
	Pentavac®	2 months	No information
DTaP-IPV-HepB-Hib	Infanrix hexa®	No information	Including small children [c]
	Hexyon®	6 weeks	Including small children [c]
	Vaxelis®	6 weeks	Including small children [c]
Td	Td-pur®	5th birthday (60 months) [f]	no age limit
	Td-Immun®	5th birthday (60 months)	no age limit
	Td-Mérieux®	5th birthday (60 months) [f]	no age limit
Tdap	Boostrix®	4th birthday (48 months) [d]	no age limit
	Covaxis® (currently not on the market)	4th birthday (48 months) [d]	no age limit
	TdaP-IMMUN®	4th birthday (48 months) [e]	no age limit
Tdap-IPV	Boostrix Polio®	4th birthday (48 months) [d]	no age limit
	Repevax®	3rd birthday (36 months) [d]	no age limit
Td-IPV	Revaxis®	5th birthday (60 months)	no age limit
IPV	IPV-Mérieux®	2 months [f]	no age limit
MMR	M-M-RVaxPro®	(9–) 12 months [b]	no age limit
	Priorix®	9 months	no age limit
	ProQuad®	(9–) 12 months [b]	no age limit
MMR-V	Priorix-Tetra®	(9–) 11 months [b]	13th birthday
Varicella	Varivax®	(9–) 12 months	no age limit
	Varilrix®	(9–) 11 months	no age limit
Meningococcal C	Menjugate® 10 Mikrogramm	2 months	no age limit
	NeisVac-C®	2 months	no age limit
HPV	Cervarix®	9 years	No information
	Gardasil® 9	9 years	No information
Pneumococcal	Pneumovax® 23	2 years	no age limit
	Prevenar 13®	2 months	no age limit
	Synflorix®	6 weeks	5th birthday

a See also Summary of Product Characteristics (as of August 2017).

b If immunisation protection is considered necessary at an earlier point in time, vaccination can be given starting at the age of 9 months; see recommendations for measles (p. 345).

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

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

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

f Also licensed for primary and first-time immunisation.

6.11. References for the section on catch-up vaccinations

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7. List of STIKO recommendations and scientific background papers

Cholera:

1. Änderung der Empfehlungen zur Impfung gegen Cholera; (www.rki.de/epidbull issue 31/2010)

Yellow Fever:

2. Wissenschaftliche Begründung zur Änderung der Gelbfieber-Impfempfehlung aufgrund der Änderungen in den Regelungen der Internationalen Gesundheitsvorschriften zu Gelbfieber (ww.rki.de/epidbull issue 35/2015)

Hepatitis B:

3. Wissenschaftliche Begründung für die Anpassung der Empfehlungen zur Impfung gegen Hepatitis A und B, publiziert im *Epid. Bull.* 35/2017 (www.rki.de/epidbull issue 35/2017)
4. Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen Hepatitis B (www.rki.de/epidbull issue 36/37/2013)
5. Hinweise zur Notwendigkeit der Wiederimpfung 10 Jahre nach erfolgter Grundimmunisierung gegen Hepatitis B (HB) im Säuglings- bzw. Kindesalter (www.rki.de/epidbull issue 31/2007)

Herpes zoster:

6. Wissenschaftliche Begründung zur Entscheidung die Herpes zoster Lebendimpfung nicht als Standardimpfung zu empfehlen; publiziert im *Epid. Bull.* 36/2017 (www.rki.de/epidbull Ausgabe 36/2017)

HPV:

7. Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen humane Papillomviren (www.rki.de/epidbull issue 35/2014)
8. Impfung gegen HPV – Aktuelle Bewertung der STIKO (www.rki.de/epidbull issue 32/2009)
9. Impfung gegen humane Papillomaviren (HPV) für Mädchen von 12 bis 17 Jahren – Empfehlung und Begründung (www.rki.de/epidbull issue 12/2007)

Seasonal Influenza:

10. Wissenschaftliche Begründung für die Anpassung der Empfehlung zur Anwendung von Influenzaimpfstoffen bei Kindern und Jugendlichen im Alter von 2 – 17 Jahren, publiziert im *Epid. Bull.* 35/2017 (www.rki.de/epidbull Ausgabe 35/2017)
11. Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen Influenza (www.rki.de/epidbull issue 36/37/2013)
12. Änderung der Empfehlungen zur Impfung gegen Influenza; Empfehlung zur Impfung von Schwangeren (www.rki.de/epidbull issue 31/2010)
13. Begründung der STIKO für die Influenza-Impfung bei Patienten mit Multipler Sklerose (MS) mit durch Infektionen getriggerten Schüben (www.rki.de/epidbull issue 32/2004)
14. Wirksamkeit und Sicherheit der Influenza-Impfung für Patienten mit chronischen Lungenerkrankungen (online verfügbar unter: www.rki.de > Kommissionen > STIKO > Empfehlung der STIKO > Begründung > Influenza)

Measles:

15. Änderung der Empfehlung zur Impfung gegen Masern (www.rki.de/epidbull issue 32/2010)

Meningococcal:

16. Aktualisierung der Meningokokken-Impfempfehlung: Indikationsimpfung – Postexpositionelle Impfung – Berufliche Indikation; (www.rki.de/epidbull issue 37/2015)
17. Änderung der Empfehlungen zur Indikationsimpfung gegen Meningokokken (www.rki.de/epidbull issue 32/2012)
18. Änderung der Empfehlungen zur Impfung gegen Meningokokken; (www.rki.de/epidbull issue 32/2010)
19. Empfehlung und Begründung einer postexpositionellen Meningokokken-Impfung (www.rki.de/epidbull issue 31/2009)
20. 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 (www.rki.de/epidbull issue 31/2006)

Mumps:

21. Änderung der Empfehlung zur Impfung gegen Mumps; (www.rki.de/epidbull issue 31/2012)

Pertussis:

22. Zusätzliche Pertussis-Impfung im Erwachsenenalter als Tdap-Kombinationsimpfung bei der nächsten fälligen Td-Impfung – Empfehlung und Begründung (www.rki.de/epidbull issue 31/2009)
23. Klinische Studien mit azellulären Pertussiskomponenten-Impfstoffen bei Erwachsenen (www.rki.de/epidbull issue 31/2009)
24. Erweiterung der beruflichen Indikationen für eine Pertussis-Impfung; / (www.rki.de/epidbull issue 31/2009)
25. Begründung für die STIKO-Empfehlung einer Pertussis-Auffrischimpfung im Vorschulalter (www.rki.de/epidbull issue 3/2006)

Pneumococcal:

26. Wissenschaftliche Begründung zur Aktualisierung der Empfehlung zur Indikationsimpfung gegen Pneumokokken für Kinder und Erwachsene; (www.rki.de/epidbull issue 37/2016)
27. Wissenschaftliche Begründung zur Aktualisierung der Pneumokokken-Impfempfehlung bei Senioren (Standardimpfung ab 60 Jahren); (www.rki.de/epidbull issue 36/2016)
28. Wissenschaftliche Begründung zur Änderung der Pneumokokken-Impfempfehlung für Säuglinge (www.rki.de/epidbull issue 36/2015)
29. Wissenschaftliche Begründung für die Änderung der Empfehlung zur Indikationsimpfung gegen Pneumokokken (www.rki.de/epidbull issue 36/2014)
30. Begründungen zur allgemeinen Empfehlung der Impfung gegen Pneumokokken im Säuglings- und Kindesalter – Pneumokokken-Impfung mit 7-valentem Konjugatimpfstoff für Kinder unter 2 Jahren; (www.rki.de/epidbull issue 31/2006)
31. Zur Impfung gegen Pneumokokken-Krankheiten; (www.rki.de/epidbull issue 31/2005)
32. Begründung der STIKO-Empfehlung zur Pneumokokken-Impfung; (www.rki.de/epidbull issue 28/2001)

Rubella:

33. Änderung der Empfehlungen zur Impfung gegen Röteln; (www.rki.de/epidbull issue 31/2010)

Rotavirus:

34. Empfehlung und wissenschaftliche Begründung der Empfehlung zur Rotavirus-Standardimpfung von Säuglingen (www.rki.de/epidbull issue 35/2013)

Rabies:

35. Änderung der Empfehlungen zur Impfung gegen Tollwut; (www.rki.de/epidbull issue 31/2010)

Varicella:

36. Wissenschaftliche Begründung für die Änderung der Empfehlung zur passiven Immunisierung mit Varizella-Zoster-Immunglobulin (VZIG); (www.rki.de/epidbull Ausgabe 35/2015)
37. Impfung gegen Varizellen im Kindesalter: Empfehlung einer zweiten Varizellenimpfung (www.rki.de/epidbull issue 32/2009)
38. Begründung der STIKO für eine allgemeine Varizellenimpfung; (www.rki.de/epidbull issue 49/2004)

National immunisation schedule available in 20 languages: www.stiko.de/en

Disclaimer

This document is a translation of the original Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute (www.rki.de/stiko-empfehlungen) on behalf of the Robert Koch Institute as of 8/2017 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.

Notes

Ständige Impfkommission (STIKO) am Robert Koch-Institut

Vorsitzender:
Prof. Dr. Thomas Mertens, Abteilung Virologie, Universitätsklinikum Ulm

Stellvertretende Vorsitzende:
Prof. Dr. Eva Hummers-Pradier, Institut für Allgemeinmedizin, Universitätsmedizin Göttingen

Mitglieder der STIKO:
Siehe www.stiko.de/Mitgliedschaft

Geschäftsstelle der STIKO:
Robert Koch-Institut | Abteilung für Infektionsepidemiologie | Fachgebiet Impfprävention
Seestraße 10 | 13353 Berlin

Das Fachgebiet Impfprävention am Robert Koch-Institut bietet telefonische Auskunft bei Fragen zur Umsetzung der STIKO-Empfehlungen an (nur für impfende Ärzte!).
Es wird keine reisemedizinische Impfberatung angeboten.
Tel.: 030. 18 754 – 35 39, Montag von 9.30 – 11.30 Uhr und Donnerstag von 12.00 – 14.00 Uhr

Bezugsmöglichkeiten der Empfehlungen der Ständigen Impfkommission (STIKO) am Robert Koch-Institut (*Epid. Bull.* 34/2017)

Einzelexemplare können beim RKI zu folgenden Bedingungen angefordert werden:

- **kostenfrei bis zu 2 Exemplare nach Einsenden eines adressierten und mit 1,45 Euro frankierten Rückumschlages für das Format A4,**
- mehr als 2 Exemplare nach Bestellung (schriftl.) gegen Rechnung zum Stückpreis von 0,50 €.

Wir bitten, zur Bestellung folgende Adresse zu verwenden:
Robert Koch-Institut
Kennwort „STIKO-Empfehlungen“
Nordufer 20
13353 Berlin

Die Impfempfehlungen der STIKO sind auch im **Internet** abrufbar unter **www.stiko.de**, in englischer Sprache unter **www.stiko.de/en**.

Bei Verbreitung dieser Ankündigung wird gebeten, die Bezugsbedingungen korrekt wiederzugeben. Falls ein Nachdruck in anderen Zeitschriften gewünscht ist, wird gebeten, die Redaktion des *Epidemiologischen Bulletins* zu kontaktieren.

Weitere Informationsmaterialien

- **RKI-Ratgeber für Ärzte zu einzelnen Infektionskrankheiten**
  www.rki.de/ratgeber
- **Fremdsprachige Informationsmaterialien zu Impfungen**
  www.rki.de/impfen > Informationsmaterialien in verschiedenen Sprachen
  - **Impfkalender in 20 Sprachen**
  - **Glossar medizinischer Begriffe zum Thema Impfen in 15 Sprachen**
  - **Aufklärungsbögen und Einverständniserklärungen in deutscher Sprache**
  - **Informationen zu Kinderlähmung (engl., franz., arab.)**
  - **Aufklärungsinformationen zu folgenden Impfungen in 19 Sprachen:**
    - **Hepatitis-A-Impfung**
    - **Hepatitis-B-Impfung**
    - **Influenza-Impfung**
    - **Influenza-Impfung mit dem Lebendimpfstoff (nasal)**
    - **MMR-Impfung**
    - **Pneumokokken-Impfung**
    - **Rotavirus-Impfung**
    - **TdaP-IPV-Impfung**
    - **6-fach-Impfung (DTaP-IPV-Hib-HepB)**
    - **Varizellen-Impfung**
- **Praxis-Plakat zur Aufklärung über das schmerzreduzierte Impfen „Wie helfen Sie Ihrem Kind beim Impfen?“** kann über den Bestellservice des BVKJ (www.bvkj-shop.de/infomaterial/plakate.html) bezogen werden.
- **Ein Merkblatt für Ärzte mit Hinweisen zum schmerzreduzierten Impfen im Praxisalltag s**teht unter www.rki.de/schmerzreduziertes-impfen zum Download zur Verfügung
- **Laienverständliche Informationsmaterialien**
  der Bundeszentrale für gesundheitliche Aufklärung (BZgA) zum Thema Impfen (teilweise fremdsprachig): www.impfen-info.de/infomaterial

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Herausgeber
Robert Koch-Institut
Nordufer 20, 13353 Berlin
Tel.: 030. 18 754 – 0
E-Mail: EpiBull@rki.de

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Redaktion
► Dr. med. Jamela Seedat (v. i. S. d. P.)
Tel.: 030. 18 754 – 23 24
E-Mail: SeedatJ@rki.de
Dr. rer. nat. Astrid Milde-Busch (Vertretung)

► Redaktionsassistenz: Francesca Smolinski
Tel.: 030. 18 754 – 24 55
E-Mail: SmolinskiF@rki.de
Claudia Paape, Judith Petschelt (Vertretung)

Das Epidemiologische Bulletin
gewährleistet im Rahmen des infektionsepidemiologischen Netzwerks einen raschen Informationsaustausch zwischen den verschiedenen Akteuren – den Ärzten in Praxen, Kliniken, Laboratorien, Beratungsstellen und Einrichtungen des öffentlichen Gesundheitsdienstes sowie den medizinischen Fachgesellschaften, Nationalen Referenzzentren und den Stätten der Forschung und Lehre – und dient damit der Optimierung der Prävention. Herausgeber und Redaktion erbitten eine aktive Unterstützung durch die Übermittlung allgemein interessierender Mitteilungen, Analysen und Fallberichte. Das Einverständnis mit einer redaktionellen Überarbeitung wird vorausgesetzt.

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Die Ausgaben ab 1996 stehen im **Internet** zur Verfügung: www.rki.de/epidbull

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