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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/Effective: August 2015

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These STIKO vaccination recommendations were endorsed during the 79th and 81st STIKO meetings and are considered enacted upon their publication on 24 August 2015. This 2015 version replaces the previous STIKO vaccination recommendations published in August 2014 in Epidemiologisches Bulletin (Epid. Bull.) 34/2014 of the Robert Koch Institute (RKI). The scientific rationale for the modified STIKO recommendations will be available in Epid. Bull. 35/2015, 36/2015, and 37/2015 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 (http://www.rki.de/stiko-empfehlungen) on behalf of the Robert Koch Institute as of 8/2015. 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.

Preliminary remarks

Vaccinations are among the most effective and significant preventive medical measures. Modern vaccines are well tolerated, and serious long-term adverse events 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 and a consistent vaccination policy supported by all stakeholders, 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 specified and achievable goals of national and international health policy.

Compulsory vaccination does not exist in Germany. Vaccinations and other means of specific prophylaxis are "publicly recommended" by the health authorities of the Länder (federal states) and are based on STIKO recommendations according to § 20 (3) of the Protection Against Infection Act [Infektionsschutzgesetz (IfSG)]. Compensation in case of vaccination-induced injury caused by publicly recommended vaccinations is assured by the federal states.

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 insure 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, when appropriate, to complete immunisation schedules.

This week 34/2015

Recommendations of the Standing Committee on Vaccination (STIKO) at the Robert Koch Institute
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Overview of new or updated recommendations in 2015

- Routine pneumococcal vaccination in infants and toddlers using the 2+1 scheme (see immunisation schedule p. 329 and p. 339)
- Meningococcal serogroup B vaccination for persons at increased risk (see table 2, p. 334 and p. 338)
- Modification of the recommendation for yellow fever vaccination (see table 2, p. 331 and p. 340)
- Revision of the recommendation for passive immunisation with varicella-zoster-immunoglobulin (see table 3, p. 347)

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 card or issuing a vaccination certificate.

Immunisation plan (routine vaccinations)

The routine immunisation schedule for infants, children, adolescents and adults (Table 1) includes vaccinations against tetanus (T), diphtheria (D/d), pertussis (aP/ap), Haemophilus influenzae type b (Hib), poliomyelitis (IPV), hepatitis B (HB), pneumococci, rotavirus (RV), meningococcal C, measles, mumps, rubella (MMR), varicella, 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 occur between the day of the child's 5th birthday and the day before the 7th birthday. Vaccination should occur at the earliest recommended time. To keep the number of injections as low as possible, combination vaccines should preferably be used. 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. Regarding minimum intervals between two vaccinations and the possibility of co-administering vaccines, the Summary of Product Characteristics ("physician insert") for the respective vaccine 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 (usually 6 months) is not shortened. The specified vaccination intervals take into account the minimum intervals between vaccinations necessary to induce protection.

Vaccination cards should be checked and subsequent immunisations provided when indicated during the healthy-child visits that infants and children 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 threats faced 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 and 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).

Please note that catch-up vaccination against Hib should be administered only until the age of 5 years and vaccination against pneumococci only until the age of 2 years. Rotavirus vaccination must be completed by the ages of either 24 or 32 weeks depending of the brand of vaccine used.

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

Vaccine	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					
Pneumococcal [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 Human papilloma virus									G1[d]	G2[d]	N [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 This is the standard vaccination for girls aged 9–13 or 9–14 years, depending on the vaccine used, with 2 doses given 6 months apart. If given as catch-up vaccination and in completion of a vaccination series at ages > 13 years or > 14 years, respectively, or when the 1st and 2nd doses were administered < 6 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 polysaccharide vaccine.

Standard vaccinations for adults; indicated and booster vaccinations, and vaccinations for increased occupational risk or travel

To comply with the immunisation schedule for infants, children, adolescents and adults (see Table 1, p. 329) 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 and are therefore also listed. 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 "vaccination indications" are possible based on the existing market authorisation for a vaccine. These are not discussed further below, but they can be useful for an individual, depending on his or her individual health situation. It is the physician's responsibility to inform patients of these additional protective options. Therefore, 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 market authorisation valid for Germany or by the Summary of Product Characteristics for 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 injury due to vaccination pursuant to § 60 Infektionsschutzgesetz (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. 343); they are divided into the following categories:

S **Standard** vaccinations for general application (see also Table 1, p. 329, immunisation plan)

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

Table 2: Standard vaccinations for adults; indicated, and booster vaccinations

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 greater 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.
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.* 21/2015.
	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). Note seasonality: April–November **Particular risk areas in Germany** are currently: ▶ **Baden-Württemberg** ▶ **Bavaria** (with the exception of most of Swabia and the western part of 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, distirct 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)	
	T	Tick exposure in TBE risk areas outside Germany.	
Yellow fever	**R**	▶ Before staying in known 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. *Since the implementation of the current changes in the International Health Regulations (IHR), which state that a single dose of yellow fever vaccine is sufficient to confer life-long protective immunity and a booster dose every 10 years is no longer necessary, will take until July 2016, information on countries requiring yellow fever vaccination for entry (eg WHO: http://www.who.int/entity/ith/2015-ith-county-list.pdf?ua=1//; http://www.who.int/entity/ith/2015-ith-annex1.pdf?ua=1) should be considered until then (Web link contains a list of countries with the yellow fever vaccine requirements and the further need of a yellow fever booster dose).

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Yellow fever	O	▶ when working with contact to Yellow Fever Virus (eg in research institutions or research laboratories)	One-time vaccination in yellow fever immunisation facilities approved by health authorities.
***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 whose sexual behaviour entails a high risk of infection. ▶ 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	▶ Health care workers (including kitchen, laboratory, technical and cleaning services, ambulance services, psychiatric and welfare institutions, sheltered employment facilities, and asylum seekers' shelters), including trainees and students: at risk of contact to potentially infectious stools. ▶ Sewer system and wastewater workers in contact with sewage. ▶ Employment (including kitchen and cleaning) in children's day care centres, children's homes, 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.[a] 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.[a]	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).[b] 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).[c] 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 controversy 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.[2] 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.
	O	3. Persons who are at increased risk of occupational exposure, for example: Health care personnel at risk of exposure (including trainees, laboratory personnel, and cleaning personnel), 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).[a,b]	
	T	4. Travel-related indication: an individual risk assessment is required.	

[a] This list of groups of persons provides examples and is not intended to be a definitive list of indicated groups. In any case, an individual risk assessment is required (see *Epid. Bull.* 36/2013).[2]

[b] In the field of occupational health services, the recommendations of the ArbMedVV should be attended as well.

[c] 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.

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Human papilloma virus (HPV)			Please see p. 337
Influenza	**S**	Adults ≥ 60 years of age.	Yearly vaccination in autumn with a 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 a vaccine containing the current antigen combination recommended by the WHO.
		Children, adolescents and adults 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 nursing homes.	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). LAIV should be preferred in children aged 2 to 6 years.
	O/I	Persons at increased risk, e.g., medical personnel, persons in establishments dealing extensively with the public, as well as persons who may be possible sources of infection by caring for individuals at particular risk.	Yearly vaccination in autumn with a vaccine containing the current antigen combination recommended by WHO.
		Persons at increased risk by direct contact with poultry and wild birds.	Vaccination with the current seasonal human influenza vaccine does not offer direct protection against infection with the avian influenza virus. It can, however, prevent 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 full-scale 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.

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Measles	I		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 against serogroups A, C, W, Y and/or B, if licensed for the respective age group. For further details regarding implementation of meningococcal vaccination see p. 338
	I	During outbreaks or regional clusters upon recommendation by the local health authorities (see p. 348).	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 conjugate vaccine, if licensed for the respective age group (see p. 339).
	T	Before a pilgrimage (Hajj, Umrah).	Vaccination with a quadrivalent conjugate vaccine (serogroups A, C, W, Y), if licensed for the respective age group (see p. 339). Take note of entry regulations.
	T	Students before long-term stays in countries with recommended standard vaccination of adolescents or selective vaccination of students.	One-time vaccination with MMR vaccine.
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.[15]	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. 359.)
	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.	

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Pneumococcal diseases	**S**	Adults ≥ 60 years of age.	One-time vaccination with a polysaccharide vaccine.
	I	Children, adolescents and adults at increased health risk as a result of an underlying disease: 1. Congenital or acquired immunodeficiencies 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) 2. Chronic diseases, such as: ▶ Chronic diseases of the cardiovascular system, respiratory tract (e. g., asthma, emphysema, or COPD), liver, or kidney ▶ Metabolic diseases, e. g., diabetes mellitus ▶ Neurological diseases, e. g., cerebral palsy or seizure disorders 3. Anatomical and foreign-material associated risks for pneumococcal meningitis, such as: ▶ Cerebral spine fluid fistula ▶ Cochlea implant* *vaccination preferably before intervention	At-risk infants ≤ 4 years should receive a vaccination with the **pneumococcal conjugate vaccine** (the requisite number of doses depends on age – please see Table 7, p. 353); see the STIKO statement concerning indicated vaccinations of children at risk in *Epid. Bull.* 33/2010. From the age of 5 years, the 13-valent pneumococcal conjugate vaccine or the 23-valent polysaccharide vaccine can be used for vaccination. For the following indications the administration of one vaccination or, if necessary, several repeat vaccinations at intervals of 5 years (adults) or at minimum 3 years (children under 10 years of age) can be considered: 1. Congenital or acquired immunodeficiencies, including functional or anatomical asplenia (indication group 1, left column) 2. Chronic kidney diseases/nephrotic syndrome See the STIKO statement concerning pneumococcal vaccination with conjugate or polysaccharide vaccine for adults in *Epid. Bull.* 7/2012, p. 55–56.
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. 344	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.

(Table 2 continued)

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
Rubella	I	Women of childbearing age that are non-immunised or with an unclear vaccination status.[24] Women of childbearing age vaccinated once.[24]	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.
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 the currently available BCG vaccine is not recommended.	
Typhus	T	When travelling in endemic regions.	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. "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, especially in the fields of paediatrics, oncology, obstetrics and gynaecology, intensive care medicine, those involved in the care of immunodeficient persons, and new workers in community facilities for preschool-age children.	

Notes on routine vaccinations listed in the immunisation plan

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. 332), for example functional or anatomical asplenia.

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. 332) as well as *Epid. Bull.* 31/2007[3] and 36/2013[2].

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 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).

Human papilloma virus (HPV)

STIKO recommends routine vaccination against HPV (types 16 and 18) for all girls aged 9 to 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 to 13 years (Gardasil®) or 9 to 14 years (Cervarix®), with an administration interval of 6 months between the 2 doses. A 3rd dose is necessary for catch-up vaccinations at the age of > 13 years and > 14 years, respectively, or if the time intervals between the 1st and 2nd dose was < 6 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.

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)[4] and the assessment of vaccination (*Epid. Bull.* 32/2009)[5], will be published in *Epid. Bull.* 36/2014.[6]

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. 333). Annual vaccination is recommended even when the antigen composition of the vaccine is unchanged compared with the previous season.

Measles, Mumps, Rubella (MMR)
Vaccination against measles, mumps and rubella should be performed with a combination vaccine (MMR vaccine), usually at the age of 11 to 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 can 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. 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 5–6 months. This should be taken into consideration in the event of an indication for immunoglobulin administration (see also *Epid. Bull.* 16/2013).

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.[11]

Meningococcal B
A vaccine against serotype B meningococcal disease (Bexsero®) was licensed in Europe in January 2013 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 will be published in *Epid. Bull.* 36/2014.[23]

However, STIKO recommends vaccination against serogroup B meningococci (MenB) in addition to MenACWY vaccination for persons with certain underlying diseases. (see Tab. 2, p. 334). 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.[14]

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. 334).

Meningococcal ACWY
A meningococcal vaccination against serogroups ACWY is recommended for certain indications (see Table 2, p. 334 and Table 3, p 346). In Europe, tetravalent MenACWY conjugate vaccines are licensed from the age of one (Nimenrix®) and 2 years (Menveo®), according to the Summary of Product Characteristics (July 1, 2015). In the US, Menveo® is licensed for children aged 2 months or older. For protection against MenC disease, MenC conjugate vaccines can

be administered from the age of 2 months onwards. The majority of IMD cases in infants are due to serogroup B (about 37 cases annually from 2010 to 2014), followed by serogroup C (6 cases annually), while only 0 to 2 cases annually are due to serogroups A, W or Y.

If protection against MenACWY is indicated after the first birthday following MenC vaccination in the first year of life, a tetravalent conjugate vaccine should be administered.

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 children 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 (see *Epid. Bull.* 3/2006) and 9–17 years of age (see *Epid. Bull.* 17/2000). 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.

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. 334).

Pneumococcal

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 June 2015). A detailed justification of the pneumococcal vaccine recommendation can be found in *Epid. Bull.* 36/2015.

For persons ≥ 60 years of age, one-time vaccination against pneumococci with a pneumococcal polysaccharide vaccine is recommended as a standard vaccination. Repeat vaccinations at 5-year intervals should be performed only in certain indications (see Table 2, p. 335). The recommendations for the vaccination of persons at increased risk are outlined in Table 2 (p. 335). If additional vaccination with pneumococcal conjugate vaccine is considered after vaccination with pneumococcal polysaccharide vaccine, an interval of at least 2 months between the respective vaccine doses should be adhered to according to the Summary of Product Characteristics.

A STIKO comment on the use of pneumococcal conjugate vaccine for adults can be found in *Epid Bull.* 7/2012.

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. 335).

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 recommends 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.[25] 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.

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. 331 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.

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. Bul.* 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 two doses, in accordance with the Summary of Product Characteristics. The minimum interval between two doses of varicella or MMRV vaccine is 4 to 6 weeks (depending on the Summary of Product Characteristics provided by the manufacturer). Children and adolescents who have only been vaccinated once against varicella should receive a second dose of varicella or MMRV vaccine.

The background paper and detailed scientific rationale for the varicella vaccination recommendation was published in *Epid. Bull.* 32/2009[27], and an evaluation of the recent varicella vaccination strategy is found in *Epid. Bull.* 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 current regulation that a certificate of yellow fever vaccination is valid for a period of 10 years and a booster vaccination is necessary afterwards can be omitted. The change extending the validity of a certificate of vaccination against yellow fever from 10 years to lifelong will come into force from July 2016, so it may be possible that some countries still require a certificate not older than 10 years. Updates of current entry requirements can be found on the WHO web site: http://www.who.int/entity/ith/2015-ith-county-list.pdf?ua=1//; http://www.who.int/entity/ith/2015-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, (2) women who have been vaccinated during pregnancy, (3) HIV-infected people, (4) individuals who get yellow fever vaccination and MMR vaccination simultaneously.

The detailed scientific rationale for the adaption of the yellow fever vaccination recommendation can be found in *Epid. Bull.* 35/2015.

General information on immunisations

Obligation for risk/benefit communication prior to immunisation

Providing all relevant information is an important part of the vaccination service provided by the physician (see preliminary remark, p. 327). Before carrying out an immunisation, it is the physician's duty to inform the person being vaccinated or their parent or guardian about the disease to be prevented and the vaccination; the aim is to enable them to make an informed decision about receiving the vaccination. The information should include: information on the disease to be prevented and the benefit of the vaccination, the contraindications, the administration of the vaccination, the onset and duration of vaccination protection, behaviour after the vaccination, possible adverse events following vaccination (see *Epid. Bull.* 25/2007), and the necessity of and timeframes for follow-up and booster vaccinations.

Providing written information is recommended during official vaccination appointments. The opportunity for further discussion with the physician must also be given. **Information sheets** for vaccinations by physicians are available on the website of the STIKO (www.rki.de > Infektionsschutz > Informationsmaterialien in verschiedenen Sprachen) and they are sold by commercial providers. In addition, information sheets are available free of charge on the home page of the "Forum for vaccinating physicians" (www.forum-impfen.de) with a password.

The leaflets also contain a questionnaire appropriate to the respective vaccination on the state of health of the person being vaccinated and on previous immunisations. Should there be any uncertainty about the responses, a discussion with the person being vaccinated, or with their parents or guardians, is necessary in all cases. The leaflets contain an informed consent form. For minors, the consent of the parents or guardians must routinely be obtained. Adolescents can give their own consent if they possess the required ability to reason and make a decision; this is usually the case at 16 years of age. For individual vaccinations, verbal information is sufficient. A signature is also not required for consent. The information provided must be documented in the patient files by the physician administering the vaccine. If the information is based upon a relevant information sheet, the physician administering the vaccine should refer to this in his documentation. In this case, as well, the person being vaccinated or the guardian must be given the opportunity to ask direct questions.

To support physicians in patient counselling, the current STIKO vaccination schedule and informed consent forms for vaccination against measles, mumps, rubella and varicella have been translated into 15 different languages. These documents are published on the RKI website (www.rki.de/impfen).

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 person 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 person 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: they can be vaccinated according the specifications of the STIKO immunisation schedule independently of the kind of their feeding (breast milk, formula, or other kinds of 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.

Vaccination intervals

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 > Infektionsschutz > Impfen > Impfungen von A–Z > 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 children. 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 two vaccine administrations.
- In the case of immunisation with inactivated vaccines (inactivated pathogens, their antigen components, and toxoids) no minimum time interval between two 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.

Interval between vaccinations and operations

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.

Handling of vaccines and procedure during vaccination

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.

Documentation of the vaccination

The 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.

Adverse events following vaccinations

Local reactions such as reddening, swelling and pain in the region of the injection site or **general reactions** such as fever (≤ 39.5°C), head and joint pain, and feeling unwell, are generally observed within the first 72 hours following the vaccination. A mild "**vaccination illness**", for example with symptoms resembling those of measles or mumps (immunisation measles; a slight swelling of the parotid glands) and elevated temperatures can occur 1 to 4 weeks after MMR vaccination. Prophylactic administration of antipyretics may be considered for the period of potential febrile reactions to vaccination.

Severe adverse events following vaccinations are extremely rare. Illnesses with a different origin occurring at the same time as the vaccination can present as an adverse event; therefore an event exceeding the normal reaction to a vaccine must be subject to prompt differential diagnostic evaluation.

Procedure for adverse events following vaccination

Suspicion of damage to health exceeding the usual scale of a reaction to vaccination must immediately be reported to the health authority (reporting obligation pursuant to § 6 (1) no. 3 IfSG; request a report form from the health authority or via the internet at www.pei.de > Vigilanz > Übersicht Meldeformular). The Drug Commission of the German Medical Association must also be informed of adverse drug reactions (via internet at www.akdae > Arzneimittelsicherheit > Unerwünschte Arzneimittelwirkung). The manufacturer can also be informed. The immunological analysis (e. g., to exclude an immune deficiency) or microbiological analysis (e. g., for differential diagnostic exclusion of an intercurrent infection) relevant for diagnosing an adverse event following vaccination should be started without delay. Analysis material necessary for this, for example serum or stool samples, must be obtained. The vaccinated person or their parents or guardians must be informed about the legal requirements concerning care following vaccination-induced injury (§ 60 – § 64 IfSG). The application for care must be made to the responsible healthcare office.

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 § 20 d 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 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 the Public Health Service [Öffentlicher Gesundheitsdienst (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 downtime 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.

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 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 two vaccinations against rubella (MMR), and seronegative women who wish to conceive should be vaccinated twice against varicella.

- 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.

Information on post-exposure vaccinations and other measures of specific prophylaxis of communicable diseases

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

Vaccine	Indication	Notes on use
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:** 20 mg/kg/day (up to a maximum of 600 mg) in 1 single dose for 4 days **Adults:** 600 mg p. o. in 1 single dose for 4 days As administration of rifampicin is contraindicated in pregnant women, ceftriaxone can be used for prophylaxis instead, if necessary. 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:** 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. 348.
	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. 337.
Measles	People with unclear vaccination status, who have not been vaccinated, or who received only one vaccination during childhood after contact with measles cases.	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*

(Table 3 continued)

Vaccine	Indication	Notes on use
Measles	▶ at the age of 6 to 8 months: exceptionally after individual risk benefit consideration (Off-label-use)	One-time vaccination; a 2nd and 3rd vaccination should be given at the age of 11 to 14 and 15 to 23 months
	▶ at the age of von 9 to 10 months	One-time vaccination; the 2nd vaccination should be given at the beginning of the 2nd year of life.
	▶ 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. Passive immunisation with immunoglobulins can 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 where necessary. 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 5–6 months. This should be taken into consideration in the event of an indication for immunoglobulin administration (see also *Epid. Bull.* 29/2001, S. 223).
Meningococcal	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 secretions ▶ 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.[13]	**Chemoprophylaxis:** *Rifampicin:* **Newborn babies:** 10 mg/kg/day in 2 single doses p. o. for 2 days. **Infants, children and adolescents up to 60 kg:** 20 mg/kg/day in 2 single doses p. o. for 2 days (maximum single dose 600 mg). **Adolescents and adults from 60 kg:** 2 × 600 mg/day 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*: **From 2–12 years of age:** 125 mg i. m. **From 12 years of age:** 250 mg i. m. in 1 single dose Eradication rate: 97 % Because administration of rifampicin and gyrase inhibitors is contraindicated in pregnant women, ceftriaxone can be used as prophylaxis if necessary. 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.

(Table 3 continued)

Vaccine	Indication	Notes on use
Meningococcal		**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. 338) ▶ **For serogroups A, W or Y:** Vaccination with a quadrivalent conjugate vaccine, if licensed for the respective age group (see p. 338) ▶ **For serogroups B:** Vaccination with a MenB-vaccine, according to the Summary of Product Characteristics and if licensed for the respective age group (p. 338) See also updates in *Epid. Bull.* 33/2010 and *Epid. Bull.* 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. 350.	
Rabies	See Table 6, p. 351.	
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

Vaccinations for clustered occurrences or outbreaks of meningococcal diseases

- A **"meningococcal disease outbreak"** is defined as two or more cases of the same serogroup within 4 weeks in a children's facility, school class, playgroup, a community facility with a household-like character (for example, a hostel, boarding school, or barracks);

- A **"regionally clustered occurrence"** is defined as three or more cases of the same serogroup within 3 months

  – in a restricted age group of the population (e.g., adolescents) in one place, or

  – in a region with a resulting incidence ≥ 10/100,000 in the respective population.

As a supplement to antibiotic prophylaxis for close contact persons (see Table 3, p. 346, 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, Meningococcal ACWY infections, category P, p. 334).

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.

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.* 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 #2).

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

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).
– 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).[2]

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, p. 349).

- *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).
- 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 < 10 IU/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, two 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.

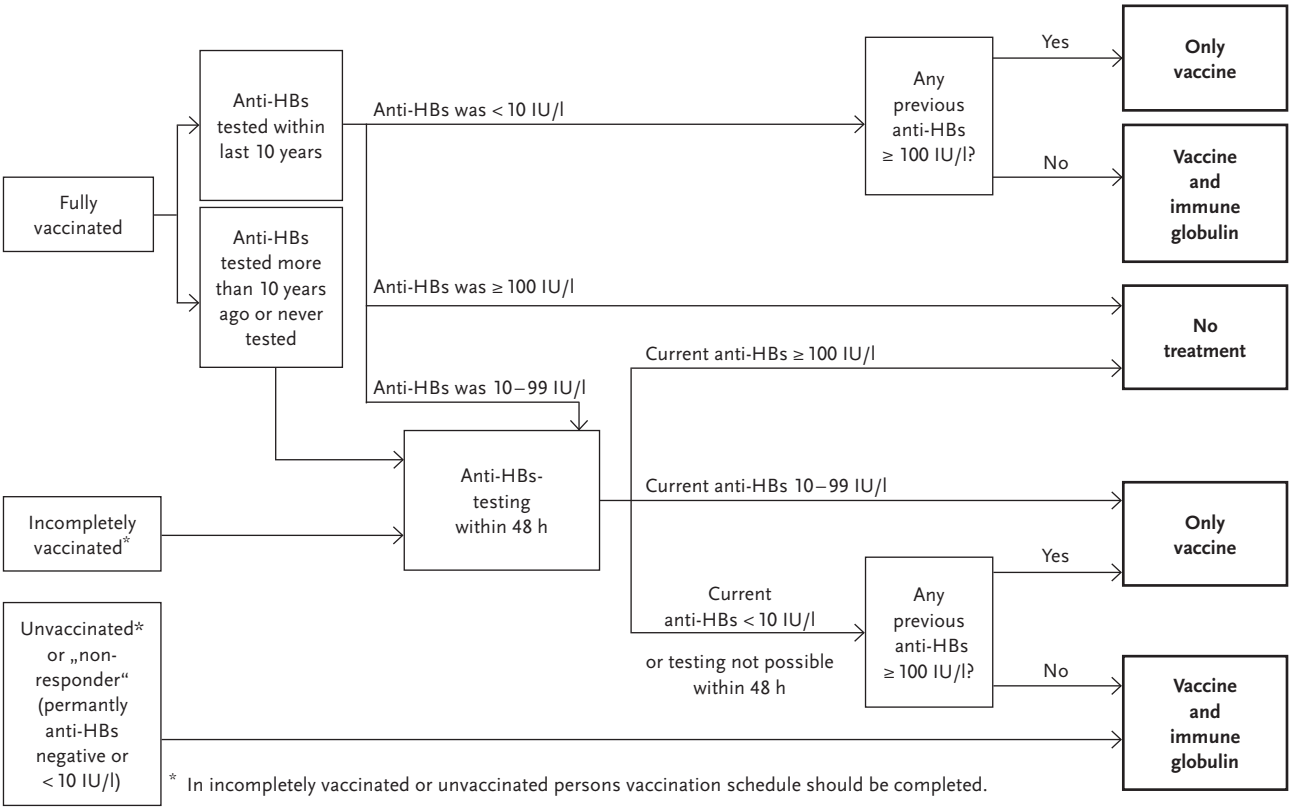

Figure 1: Procedure for the hepatitis B immunoprophylaxis (see detailed information, p. 348)

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

Post-exposure tetanus immunoprophylaxis in case of injury

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
0 to 1	Yes	No	Yes	Yes
2	Yes	No	Yes	No [4]
3 or more	No [5]	No	No [6]	No

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.334).

3 TIG = Tetanus immunoglobulin. Generally, 250 IU are administered but the dose can be increased to 500 IU; TIG is used simultaneously with a DTaP/Tdap vaccine.

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

5 Yes (1 dose), if more than 10 years have passed since the last vaccination.

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

Post-exposure rabies immunoprophylaxis

Detailed information on the epidemiology of rabies in Germany can be found in *Epid. Bull.* 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 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.
- Care must be taken to check tetanus vaccination documentation and if necessary to administer simultaneous tetanus immunoprophylaxis (see Table 5, p. 350).

Recommendations for catch-up vaccinations

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

Preliminary remarks

The present notes are based on the recommendations for routine vaccination of infants, children, adolescents and adults (Table 1, p. 329).

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 national and international immunisation technical advisory groups were considered.[1,2,8-13]

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.

Unvaccinated persons and persons with unclear vaccination status

An overview regarding recommended catch-up vaccinations and the corresponding vaccination schedule for different age groups is given in Table 7. 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 is the age at start of the catch-up series.

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 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, 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 number and timing of previously administered vaccinations, an individual immunisation schedule should be compiled. The number of vaccine doses needed to complete the interrupted primary immunisation series is, in principle, calculated based on the recommendations **for the age at which the vaccination series was started.** For vaccinations that are recommended only until a specific age, an interrupted primary immunisation series will not be continued if the vaccinee has in the meantime surpassed this specific age.

Literature: see p. 360

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

Unvaccinated persons: Apply the table using the patient's current age
Partly immunised persons: Apply table using the patient's age when first vaccinated with the respective antigen
C = Catch-up vaccination B = Booster vaccination P = Primary vaccination

Children < 12 months						
Vaccine	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		
Pneumococcal	C1		C2	C3		

Children aged 12 months to < 5 years					
Vaccine	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		
Pneumococcal [d]	C1	Vaccination interval ≥ 8 weeks	C2		
Meningococcal C	C1				
MMR [e]	C1	C2			
Varicella [e]	C1	C2			

Footnotes at the end of table 7

(Table 7 continued)

Children from 5 to < 11 years				
Vaccine	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	
Meningococcal C	C1			
MMR	C1	C2		
Varicella	C1	C2		

Children/adolescents from 11 to < 18 years					
Vaccine		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	
Meningococcal C		C1			
MMR		C1	C2		
Varicella		C1	C2		
HPV (Girls ≥ 9 years)	9–14	P1		P2	
	> 14	C1	C2	C3	
		At the age of 9–13 years or 9–14 years (depending on product), HPV primary immunisation (P) consists of 2 doses 6 months apart. For catch-up vaccinations (C) and completion of vaccination series at age > 13 years and > 14 years, respectively, 3 doses are necessary (note Summary of Product Characteristics).			

Footnotes at the end of table 7

(Table 7 continued)

Adults over 18 years				
Vaccine	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 [h]	C1	C2		
Varicella for serone-gative women who wish to conceive	C1	C2		

According to the Recommendations of Routine Vaccinations (Effective: August 2015)

Hib = *Haemophilus influenzae* type b MMR = Measles, mumps, rubella HPV = Human papilloma virus

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

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 routine vaccination after the age of 24 months; accordingly, there is no need for catch-up vaccination.

e) Starting at the age of 11 months.

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.

h) 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.

Example

A 2.5-year-old child received one dose each of the hexavalent vaccine DTaP-IPV-Hib-HepB and the pneumococcal vaccine at 2 and 3 months; after this point, no further vaccinations were given.

The completion of this primary immunisation is carried out according to the information for "Children aged < 12 months" (= age at first administered vaccination) in Table 7. Two more vaccinations are required against tetanus, diphtheria, pertussis, poliomyelitis and hepatitis B, separated by an interval of at least 6 months. One additional dose of a Hib-containing vaccine would be sufficient for protection against Haemophilus influenza 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).

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 plans. 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.

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.

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 routine vaccinations. Exceptions are verifying vaccination success in patients with immunodeficiency (see STIKO notes in *Epid. Bull.* 39/2005), and confirming protection against hepatitis B among persons with an elevated exposure risk. Serological testing is also recommended to confirm protection against varicella among women who wish to conceive and who have unclear anamnesis of varicella.

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 '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 antigen.[5]

For primary immunisation against *Haemophilus influenzae* type b, a single vaccine dose is sufficient after the age of 12 months. However, the common pentavalent or hexavalent vaccines DTaP-IPV-HiB[-HepB] can be used if practical for completing the remaining vaccinations. Negative consequences from the surplus Hib component in the vaccine are not expected.

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 inevitable to administer combination vaccines (for example, for catch-up of 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 2nd birthday) and the restriction of licensed vaccine administration to certain age groups.

The hexavalent vaccine Infanrix hexa® (DTaP-IPV-HiB-HepB) and the pentavalent vaccine Infanrix®-IPV+Hib (DTaP-IPV-Hib) can be given until the age of 36 months (the 3rd birthday) according to the Summary of Product Characteristics. The hexavalent vaccine Hexyon® (DTaP-IPV-Hib-HepB) is licensed for use until the age of 24 months (the 2nd birthday). Following the specifications of the Summary of Product Characteristics, the pentavalent vaccine Pentavac® (DTaP-IPV-Hib) should not be used in children from the age of 6 years. 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).

Vaccinations against tetanus, diphtheria, poliomyelitis and pertussis from the age of 5–6 years

Starting with the age of 5–6 years, vaccines with reduced antigen content (d instead of D and ap instead of aP) should be used for vaccinations against diphtheria and pertussis. The corresponding combination vaccines with reduced diphtheria and pertussis antigen content (Tdap, Td-IPV, and Tdap-IPV) are primarily intended for booster vaccinations. The licensure is based on evidence of efficacy and safety for the indication "booster vaccination".

Td vaccines and monovalent polio vaccines (IPV) are licensed for the vaccination of previously unvaccinated individuals. Because the Td and Tdap vaccines and the respective Td-IPV and Tdap-IPV vaccines from the same manufacturer are identical regarding antigen content of tetanus, diphtheria, and polio, it seems immunologically plausible that Tdap and Tdap-IPV vaccines are also suitable for this group of persons.

Several national immunisation technical advisory groups (from Switzerland, France, the United States, and Canada)[2,8-10] as well as various experts[11-13] recommend without restrictions the use of Tdap and Tdap-IPV combination vaccines for primary immunisation in this age group.

Currently, data on the use of Tdap and Tdap-IPV vaccines in previously unvaccinated persons in this age group are only available for a few vaccine products (see footnote below). It is assumed that this application is covered by the licensure. However, because it cannot be completely excluded that the use of ap-containing vaccines is legally considered an "off-label use", STIKO recommends informing the patient and documenting this information as a precaution.

Protection against pertussis can currently be achieved with a single dose of a combination vaccine including the pertussis component in older children and adults, because these vaccinees are generally not immunologically naïve against pertussis given the current prevalence of *Bordetella pertussis*. A study showed that one vaccination dose induced an immunological response in more than 90 percent of vaccinated individuals aged 11 years and older.[14] Equivalent information can also be found in the Summary of Product Characteristics for the respective vaccines.

"Off-label use"

Off-label use denotes the prescription of a licensed drug product outside of the use for which licensure had been applied and approved by national regulatory authorities and the European Medicine Agency (EMA), including differences in scope of application (indication), 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 and 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 information have to be documented comprehensively in the patient's file.[15-18]

Age-dependent recommendations for conducting catch-up vaccinations

Age < 12 months

Missing DTaP-IPV-HepB-Hib and pneumococcal conjugate vaccine doses should be administered. Three vaccine doses should be given with intermediary intervals of 1 month, and a 4th dose ≥ 6 months after the 3rd dose to complete a primary immunisation series.

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 and 32 weeks, respectively. Additional vaccinations are carried out according to the general STIKO immunisation plan.

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[1] This currently only applies to Boosterix® and Boosterix Polio® (as of July 2013).
A randomized study examined the immunogenicity and tolerance of Boosterix® (Tdap) and Boosterix Polio® (Tdap-IPV) in comparison to Td vaccine among adults of > 40 years of age that had not received a diphtheria or tetanus toxoid-containing vaccine in the previous 20 years.[6] Irrespectively of the type of vaccine used, 99–100 % of the subjects developed protecting antibody titres against diphtheria after 3 doses (0–1–6 months). One hundred percent developed protecting antibody titres against tetanus after just 2 vaccine doses. These findings also applied to subjects who stated that they had never been vaccinated against tetanus or diphtheria and/or who had no detectable antibody titres at the beginning of the vaccination series. Just 1 dose of Tdap or Tdap-IPV induced an immune response against pertussis in 95 % of subjects, without a significant increase after further vaccine doses. All vaccines showed comparably good tolerance profiles.[6] A similar study also showed comparable immunogenicity and tolerance among adolescents and adults aged 15–93 years that only received 1 dose of the abovementioned vaccines.[7]

Age 12 months to < 5 years

Missing DTaP-IPV-HepB-Hib vaccine doses should be administered. To complete a primary immunisation series, 2 doses should be administered with intermediary intervals of at least 1 month followed by a 3rd dose ≥ 6 months after the previous dose. 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 years, pneumococcal vaccination is only recommended for children with an increased health risk (see specific indication vaccination). In addition, 2 MMR and varicella vaccinations must be given separated by an interval of 4–6 weeks, and 1 conjugate vaccination against meningococcal C.

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. 357). 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 vaccination against meningococcal C.

Girls at the age of 9 to 13 and 14 years, respectively (product-dependent), should receive two HPV vaccinations following the immunisation scheme reported in the 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.[14] 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. 357).

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 13 or 14 years (product-dependent) 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 at the age of > 13 and > 14 years, respectively, 3 doses are necessary (note the Summary of Product Characteristics).

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 doses of a Td or Td-IPV combination vaccine* (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. 357).[9] 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 one-time vaccination against pneumococci and yearly vaccination against seasonal influenza as routine vaccinations.

See p. 359 for references and Table 8 regarding the section "Recommendations for catch-up vaccinations".

Table 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	3rd birthday (36 months)
	Pentavac®	2 months	6th birthday (72 months)[c]
DTaP-IPV-HepB-Hib	Infanrix hexa®	2 months	3rd birthday (36 months)
	Hexyon®	6 weeks	2nd birthday (24 months)
Td	Td-Immun®, Td-Impfstoff ®, Td-pur®	5th birthday (60 months)	no age limit
	Td-Rix®	6th birthday (72 months)	no age limit
Tdap	Boostrix®, Covaxis®, TdaP-IMMUN®	4th birthday (48 months)	no age limit
Tdap-IPV	Boostrix Polio®	4th birthday (48 months)	no age limit
	Repevax®	3rd birthday (36 months)	no age limit
Td-IPV	Revaxis®	5th birthday (60 months)	no age limit
IPV	IPV-Mérieux®	2 months	no age limit
MMR	M-M-RVaxPro®	(9 –) 12 months[b]	no age limit
	Priorix®	9 months	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

a See also Summary of Product Characteristics (as of July 2015).

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, mumps, and rubella (p.338).

c Limitation by age not mentioned explicitly anymore in the Summary of Product Characteristics as of July 2015.

References for the section on catch-up vaccinations

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List of STIKO recommendations and scientific background papers

Cholera:

1. Änderung der Empfehlungen zur Impfung gegen Cholera; publiziert im *Epid. Bull.* 31/2010 http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2010/Ausgaben/31_10.pdf?__blob=publicationFile)

Hepatitis B:

2. Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen Hepatitis B; publiziert im *Epid. Bull.* 36/37/2013 (http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2013/Ausgaben/36_37_13.pdf?__blob=publicationFile)
3. Hinweise zur Notwendigkeit der Wiederimpfung 10 Jahre nach erfolgter Grundimmunisierung gegen Hepatitis B (HB) im Säuglings- bzw. Kindesalter, publiziert im *Epid. Bull.* 31/2007 (http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2007/Ausgabenlinks/31_07.pdf?__blob=publicationFile)

HPV:

4. Impfung gegen humane Papillomaviren (HPV) für Mädchen von 12 bis 17 Jahren – Empfehlung und Begründung; publiziert im *Epid. Bull.* 12/2007 (http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2007/Ausschnitte/HPV_STIKO_12_07.pdf?__blob=publicationFile)
5. Impfung gegen HPV – Aktuelle Bewertung der STIKO; publiziert im *Epid. Bull.* 32/2009 (http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2009/Ausgaben/32_09.pdf?__blob=publicationFile)
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Seasonal influenza:

7. Wissenschaftliche Begründung für die Änderung der Empfehlung zur Impfung gegen Influenza; publiziert im *Epid. Bull.* 36/37/2013(http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2013/Ausgaben/36_37_13.pdf?__blob=publicationFile)
8. Änderung der Empfehlungen zur Impfung gegen Influenza; Empfehlung zur Impfung von Schwangeren, publiziert im *Epid. Bull.* 31/2010 (http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2010/Ausgaben/31_10.pdf?__blob=publicationFile)
9. Begründung der STIKO für die Influenza-Impfung bei Patienten mit Multipler Sklerose (MS) mit durch Infektionen getriggerten Schüben; publiziertim *Epid. Bull.* 32/2004 (http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2004/Ausgabenlinks/32_04.pdf?__blob=publicationFile)
10. Wirksamkeit und Sicherheit der Influenza-Impfung fur Patienten mit chronischen Lungenerkrankungen (online verfugbar unter: http://www.rki.de/DE/Content/Kommissionen/STIKO/Empfehlungen/Begruendung/influenza_cl.pdf?__blob=publicationFile)

Measles:

11. Änderung der Empfehlung zur Impfung gegen Masern, publiziert im *Epid. Bull.* 32/2010 http://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2010/Ausgaben/32_10.pdf?__blob=publicationFile)

Meningococcal C:

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National immunisation plan available in 15 languages: www.stiko.de/en

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