Statement of the Standing Commission on Vaccination (STIKO) at the Robert Koch Institute

Decision on the implementation of the COVID-19 vaccination into the general recommendations of the STIKO 2023

STIKO recommendation on COVID-19 vaccination

Since the beginning of the vaccination campaign in winter 2020/2021, the primary goal of the STIKO's Coronavirus Disease 2019 (COVID-19) vaccination recommendations has been the prevention of severe outcomes (COVID-19-related hospitalizations and deaths) and long-term consequences of COVID-19, as well as the protection of medical and nursing staff against infections with Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). With the shift from the pandemic to the endemic phase, the STIKO discussed the transition from the previous recommendations to a more permanent COVID-19 vaccination recommendation. The following updated recommendation has been integrated into the vaccination calendar of the general STIKO recommendations.

In spring 2023 – in the fourth year since the beginning of the COVID-19 pandemic – a substantial part of the population in Germany has a pronounced baseline immunity against SARS-CoV-2. It was estimated that at least half of the population has been infected at least once with SARS-CoV-2 and more than 95% of the population has been exposed to SARS-CoV-2 antigens through vaccination and/or infection. According to many scientific studies, the so-called hybrid immunity, the combination of vaccination and infection, provides a strong and long-lasting protection against severe courses of disease after SARS-CoV-2 infections for at least 12 months.

The Omicron variant of SARS-CoV-2, which began circulating in late 2022, and its dominantly remaining sublineages have led to very high infection rates due to their easier transmissibility compared to previous SARS-CoV-2 variants. However, the majority of Omicron infections are mild or even asymptomatic due to its reduced pathogenicity compared to previous virus variants.

In general, people aged 60 years and older are at greater risk of severe illness or death from COVID-19 after an infection with SARS-CoV-2. Furthermore, the risk of developing a severe illness increases steadily with increasing age. COVID-19 is a threat at all ages to immunocompromised people, those with certain underlying medical conditions, and individuals in long-term care facilities.

Despite the tremendous advances in understanding the epidemiology, pathogenesis and immune control of SARS-CoV-2 infections, as well as the efficacy/effectiveness and safety of COVID-19 vaccines, some research areas are still inconclusive. For example, it is not possible to predict how viral variants will evolve, whether new immune escape variants will emerge, or whether more virulent variants will emerge. There is also a lack of data on the duration of immune protection after variant-adapted vaccination or the acquisition of hybrid immunity. Adjustments to the vaccination recommendation will therefore be made by the STIKO, as necessary.

Considering the currently available data on disease burden, risk factors for severe COVID-19 disease and long-term consequences of COVID-19, data on effectiveness and duration of protection of hybrid immunity, and data on effectiveness and safety of variant-adapted bivalent mRNA vaccines, the

STIKO issues the following recommendations for future COVID-19 vaccinations. The COVID-19 vaccination recommendation is now part of the general recommendations of the STIKO 2023 (Epidemiological Bulletin 04/2023; updated online version). This recommendation replaces the 25th update of the COVID-19 vaccination recommendation, which is no longer valid.

Baseline immunity to SARS-CoV-2 should be achieved in all persons aged ≥ 18 years. At least 3 contacts with the SARS-CoV-2 antigen (vaccination or infection) are required to achieve basic immunity. According to the STIKO, at least 2 out of 3 antigen contacts should be achieved by vaccination in order to build up the optimal basic immunity. Missing antigen contacts should be completed with European Union (EU)-licensed COVID-19 vaccines and in accordance with the recommendations of the STIKO. Serological testing for infection prior to vaccination is not required.

For the COVID-19 immunization a minimum interval of 3 weeks between the first and second vaccine dose (G1 and G2) and a minimum interval of 6 months between the second and third vaccine dose (G2 and A1) should be maintained to achieve basic immunity. In general, an infection should only be counted as an event for the targeted 3 antigen contacts if the interval to the previous vaccination is at least 3 months. On the other hand, a primary vaccination should be administered at least 3 months after an infection.

Persons aged ≥ 60 years, persons aged 6 months or older with an underlying disease associated with an increased risk of severe COVID-19, persons of any age with an increased occupational risk of infection in health care and nursing settings with direct patient or resident contact, as well as family members and close contacts of individuals in whom a protective immune response is unlikely to be achieved by COVID-19 vaccination should receive further booster doses in the future, usually at least 12 months after the last known antigen exposure (see **Table A, Table B**). If the last known antigen exposure was at least 12 months ago, the booster should preferably be given in autumn.

No further boosters are currently recommended for healthy adults aged < 60 years and pregnant women.

For infants, (young) children, and adolescents without underlying diseases, no primary or booster COVID-19 vaccination is currently recommended due to the meanwhile predominantly mild course of disease and very low incidence of hospitalization.

Persons reaching a certain age with an indication for achieving baseline immunity or further booster doses, with a new onset of an underlying disease or with a new occupational exposure should be vaccinated according to the recommendations above.

Underlying diseases with an increased risk of severe COVID-19 may include

- Chronic respiratory diseases (e.g. chronic obstructive pulmonary disease [COPD])
- Chronic cardiovascular, liver and kidney diseases
- Diabetes mellitus and other metabolic disorders
- Obesity
- Central nervous system (CNS) disorders, such as chronic neurological diseases, dementia or mental retardation, psychiatric diseases or cerebrovascular diseases
- Trisomy 21

- Congenital or acquired immunodeficiency (e.g. human immunodeficiency virus (HIV) infection, chronic inflammatory diseases under relevant immunosuppressive therapy, post-organ transplantation)
- Active neoplastic diseases

Immunocompromised people with a relevant suppression of the immune response (e.g. after organ or stem cell transplantation, hemodialysis patients) may require additional vaccine doses at least 4 weeks apart to achieve baseline immunity. At least 4 weeks after receiving a vaccine dose, the immune response to the vaccination can be monitored serologically by quantitative determination of specific antibodies against the SARS-CoV-2 spike protein. If an insufficient immune response is achieved despite repeated vaccination, the dose may be increased (e.g. doubled) as an off-label use or a vaccine based on a different technology can be administered. It may be necessary to shorten the recommended minimum 12-month interval between booster doses in immunocompromised individuals to maintain a protective immune response.

Table C lists the COVID-19 vaccines, which are currently licensed in Germany, as well as recommended by the STIKO for primary and booster vaccination. In addition, two other COVID-19 vaccines (Vidprevtyn Beta; Bimervax) have marketing authorisation in the EU. Due to the limited data available, the STIKO has not yet been able to make a final assessment of these vaccines. The STIKO will evaluate the safety and efficacy/effectiveness of these vaccines as further results from clinical trials and post-marketing surveillance data become available.

Table A: Vaccination table for COVID-19-Immunization

Indication	Primary vaccination + 1st booster	Additional booster doses
	To achieve baseline SARS-CoV-2 immunity: 3 antigen exposures (vaccination and/or infection), including at least 2 vaccinations.	usually at an interval of ≥ 12 months [1] since the last known exposure to antigen; preferably in autumn [2]
≥ 60 years	**Yes** EU-licensed mRNA-, vector- or protein-based vaccine according to the recommendations of the STIKO (**Table C**)	**Yes**[5] EU-licensed variant-adapted vaccine according to the STIKO recommendations should be used preferentially. (**Table C**)[3, 6]
Residents in long-term care facilities	**Yes** EU-licensed mRNA-, vector-, protein-based or inactivated whole virus vaccine according to the recommendations of the STIKO (**Table C**)[3]	
Medical and nursing staff who have direct contact with patients or residents, and family members and close contacts of immunocompromised persons.	**Yes** EU-licensed mRNA-, vector-, protein-based or inactivated whole virus vaccine according to the recommendations of the STIKO (**Table C**)[3]	
Age ≥ 6 months with underlying diseases (including immunodeficiency)	**Yes**[4] EU-licensed mRNA-, vector-, protein-based or inactivated whole virus vaccine according to the recommendations of the STIKO (**Table C**)[3, 6]	
18-59 years without underlying medical conditions	**Yes** EU-licensed mRNA-, vector-, protein-based or inactivated whole virus vaccine according to the recommendations of the STIKO (**Table C**)[3]	**No**
Pregnant women without underlying medical conditions	**Yes** EU-licensed mRNA-vaccine Comirnaty according to the recommendations of the STIKO (**Table C**)[3]	
< 18 years without underlying medical conditions	**No**	

[1] Current data suggest that protection against severe disease lasts at least 12 months. Data on long-term protection are not yet available.

[2] Seasonal influenza and pneumococcal vaccines could also be administered on the same day in autumn, if indicated.

[3] Usually Spikevax should not be used in people < 30 years and pregnant women.

[4] In persons with a significant impairment of the immune response, further vaccine doses may be required at least 4 weeks apart, according to the assessment of the treating physician. (Antibody controls should be performed if necessary).

[5] In persons with a significant impairment of the immune response, it may be necessary to shorten the regularly recommended minimum interval of 12 months.

[6] For booster vaccination, a vaccine licensed for primary immunization in this age group may be used off-label if necessary.

Table B: Recommendations on standard vaccinations for adults, indication-based vaccinations and boosters for all age groups

Vaccination against	Category	Indication	Notes on use (Note package leaflet/Summary of Product Characteristics)
COVID-19 (Coronavirus Disease 2019)	**S**	All persons aged 18-59 years with incomplete baseline immunity (≥ 3 antigen contacts, of which at least 2 vaccinations)	Vaccination with a COVID-19 vaccine licensed for primary or booster vaccination and recommended by STIKO until the number of ≥ 3 SARS-CoV-2 antigen contacts required for basic immunity is reached. - Pregnant women of all ages should not receive missing doses before the 2nd trimester.
	S	Adults ≥ 60 years of age	Vaccination with an age-specific COVID-19 vaccine licensed for primary or booster vaccination and recommended by STIKO until the number of ≥ 3 SARS-CoV-2 antigen contacts required for basic immunity is reached. Booster vaccination with a licensed, STIKO-recommended, age-appropriate COVID-19 vaccine; usually at least 12 months after the last antigen exposure (vaccination or infection); preferably in autumn. *** * CAVE: for for children aged 6 months to 4 years a booster vaccine is not yet licensed. For booster vaccination, a vaccine licensed for primary immunization in this age group may be used off-label if necessary. ** In persons with a significant impairment of the immune response additional doses or a shorter vaccination interval (≥ 4 weeks) might be necessary. *** If vaccination is administered in autumn, seasonal influenza and pneumococcal vaccines could be administered on the same day, if indicated.
	I	Residents in long-term care facilities	
	I	People from 6 months of age* with an increased risk of severe COVID-19 disease because of underlying diseases, for example: ▸ Chronic respiratory diseases (e.g. chronic obstructive pulmonary disease [COPD]) ▸ Chronic cardiovascular, liver and kidney diseases ▸ Diabetes mellitus and other metabolic disorders ▸ Obesity ▸ Central nervous system (CNS) disorders, such as chronic neurological diseases, dementia or mental retardation, psychiatric diseases or cerebrovascular diseases ▸ Trisomy 21 ▸ Congenital or acquired immunodeficiency (e.g. human immunodeficiency virus (HIV) infection, chronic inflammatory diseases under relevant immunosuppressive therapy, post-organ transplantation) ▸ Active neoplastic diseases**	
	I	Family members and close contacts of individuals unlikely to develop a protective immune response when vaccinated with COVID-19 vaccines	
	B	Persons of any age with an increased occupational risk of infection in healthcare and nursing settings with direct patient or resident contact	

Table C1: Information on the COVID-19 vaccines licensed in Germany and currently recommended by the STIKO for primary vaccination (PV) or booster vaccination (BV) (as of 20.04.2023)

Brand name (manufacturer)	Vaccine type	Age group	Dosage for primary vaccination	EU-authorization for primary vaccination	EU-authorization for booster vaccination	Dosage for booster vaccination	Special features
Comirnaty (BioNTech/Pfizer)	mRNA	6 mon. – 4 years	3 µg	yes (3)	no	-	STIKO recommends vaccination in these age groups only in the case of underlying diseases or weakened immune systems. Variant-adapted vaccines are preferably recommended for booster vaccination. Also recommended for occupational vaccination of adolescents.
		5 – 11 years	10 µg	yes (2)	yes	10 µg	
		≥ 12-17 years	30 µg	yes (2)	yes	30 µg	
		≥ 18 years	30 µg	yes (2)	yes	30 µg	Variant-adapted vaccines are preferably recommended for booster vaccination.
Comirnaty Original/ Omicron BA.4/5	bivalent mRNA	5 – 11 years	–	no	yes	5 µg/5 µg	STIKO recommends vaccination in these age groups only in the case of underlying diseases or weakened immune systems. Variant-adapted vaccines are preferably recommended for booster vaccination. Also recommended for occupational vaccination of adolescents.
Comirnaty Original/ Omicron BA.1; Comirnaty Original/ Omicron BA.4/5	bivalent mRNA	≥ 12-17 years	–	no	yes	15 µg/15 µg	
		≥ 18 years	–	no	yes	15 µg/15 µg	
Spikevax (Moderna)	mRNA	6 mon. – 5 years	25 µg	yes (2)	no	–	Spikevax products: Not recommended in those < 30 years of age due to increased risk of peri-/myocarditis.
		6 – 11 years	50 µg	yes (2)	yes	25 µg	
		12 -17 years	100 µg	yes (2)	yes	50 µg	
		≥ 18 years	100 µg	yes (2)	yes	50 µg	
Spikevax bivalent Original/Omicron BA.1	bivalent mRNA	6 – 11 years	-	no	yes	12.5 µg/12.5 µg	
Spikevax bivalent Original/Omicron BA.1, Spikevax bivalent Original/Omicron BA.4/5	bivalent mRNA	12 - 17 years	–	no	yes	25 µg/25 µg	
		≥ 18 years	–	no	yes	25 µg/25 µg	
Vaxzevria (AstraZeneca)	vector-based	≥ 18 years	≥ 2.5 x10^8 IE	yes (2)	yes[1]	≥ 2.5 x10^8 IE	Limitation: only persons aged ≥ 60 years due to rare thromboembolic events.
JCOVDEN (Janssen Cilag International)	vector-based	≥ 60 years	≥ 8.92 $\log_{10}$ IE	yes (1)	yes[1]	–	See footnote 2
Nuvaxovid (Novavax)	protein-based	12 – 17 years	5 µg	yes (2)	no	–	See footnote 3
		≥ 18 years	5 µg	yes (2)	yes	5 µg	
Valneva (Valneva)	Inactivated whole virus vaccine	18 – 50 years	33 Antigenic units	yes (2)	Yes[1]	33 Antigenic units	See footnote 4

[1] Vaxzevria, JCOVDEN and Valneva are approved for booster vaccination in the EU, an evaluation by the STIKO is still pending.

[2] JCOVDEN: Optimization with an additional dose of either an mRNA-based vaccine or Nuvaxovid is recommended due to insufficient efficacy after a single dose. Age restriction to ≥ 60 years due to rare thromboembolic events. Approved for booster vaccination only for persons who have completed the primary vaccination series with an mRNA- or adenoviral vector-based COVID-19 vaccine.

[3] Nuvaxovid: Not currently recommended for pregnant or breastfeeding women due to lack of data on the efficacy and the safety of the new adjuvant. Vaccines may be an option in individual cases (e.g. if there is a product-specific medical or other contraindication to mRNA vaccines). Rare adverse events: Peri-/myocarditis.

[4] Valneva: Approved for booster vaccination only for persons who have completed the primary vaccination series with Valneva or with an adenoviral vector-based COVID-19 vaccine. Not currently recommended for pregnant or breastfeeding women due to lack of data on the safety and efficacy, vaccines may be an option in individual cases (e.g. if there is a product-specific medical or other contraindication to mRNA vaccines.