Announcement from the German Standing Committee on Vaccination (STIKO) at the Robert Koch Institute

Decision of the STIKO for the recommendation of the COVID-19 vaccination and the corresponding scientific rationale (2nd update)

STIKO-recommendation for the COVID-19-vaccination

The German Standing Committee on Vaccination recommends the vaccination against COVID-19. For the vaccination one of the two licensed mRNA-vaccines (Comirnaty from BioNTech/Pfizer, COVID-19 vaccine from Moderna) or the licensed viral vector vaccine (COVID-19 Vaccine AstraZeneca) should be used. A vaccination series that has already started should be completed with the same product. The two mRNA vaccines are considered to be equivalent in regard to safety and efficacy. Due to the currently available data, the COVID-19 vaccine from AstraZeneca is only recommended for the age group 18-64 years; there is not yet sufficient data available to evaluate the vaccine efficacy for the age of 65 years and older. Apart from this limitation, this vaccine is also considered suitable for individual protection and to fight the pandemic. Direct comparative studies between the different vaccines are missing.

Due to the limited availability of vaccines, the vaccination should initially only be offered to groups of persons who have a particularly high risk of severe or fatal courses of a COVID-19 disease or who are either particularly exposed at work or who have close contact with vulnerable groups of persons. Since there are differences in terms of the level of risk and the vaccination goals aimed at, the STIKO recommends a step-by-step approach (**prioritisation recommendation**). The AstraZeneca vaccine (in contrast to the mRNA vaccines) should only be offered to persons who are 18-64 years old in the respective steps. In the **1st step**, the following groups of persons should be vaccinated:

- Residents of retirement and nursing homes
- Persons at the age of ≥80 years
- Personnel with a particularly high risk of exposure in medical facilities (e.g. in emergency rooms, in the medical care of COVID-19 patients)
- Personnel in medical facilities in close contact with vulnerable groups (e.g. in oncology or transplant medicine)
- Nursing personnel in outpatient and inpatient care for the elderly
- Other workers in retirement and nursing homes with contact to the residents

Within step 1, the ≥80-year-olds and residents of nursing homes are particularly at risk and should be vaccinated at the beginning of the vaccination campaign, despite being difficult to reach.

With a steadily increasing but still limited vaccine availability, person groups of the 2nd step should be vaccinated, followed by persons in the subsequent step. The point in time one can switch from one step to the next should be decided locally and depends on the availability of the vaccines. New evidence on the risk groups will be continuously evaluated.

The present STIKO recommendation consists of a general vaccination recommendation and a recommendation for prioritisation. **The prioritisation recommendation is only valid until sufficient vaccine is available.** In the medium run, the goal is to offer every resident in Germany equitable access to a vaccine against COVID-19.

Table 1: Step-by-step plan and vaccination indication groups to prioritise COVID-19 vaccination in Germany

Step	Person groups
1	• Residents of retirement and nursing homes • Persons at the age of ≥80 years • Personnel with a particularly high risk of exposure in medical facilities° • Personnel in medical facilities in close contact with vulnerable groups° • Nursing personnel in outpatient and inpatient care for the elderly • Other workers in retirement and nursing homes with contact to the residents
2	• Persons at the age of ≥75-79 years • Personnel with a high risk of exposure in medical facilities° • Persons in institutions with dementia or mental disabilities • Those working in the outpatient or inpatient care of persons with dementia or mental disabilities • Persons with Down syndrome (trisomy 21)
3	• Persons at the age of ≥70-74 years • Persons with underlying diseases at high risk (after organ transplantation, active malignant hematological diseases, advanced solid cancers that are not in remission, as well as malignant diseases under current systemic therapy (except exclusively anti-hormonal monotherapy), interstitial lung diseases, psychiatric disorders (bipolar disorder, schizophrenia and severe depression), dementia, diabetes mellitus with an HbA1c ≥ 58 mmol/mol or ≥ 7.5%, COPD and other lung diseases of similar severity, obesity (BMI> 30kg/m2), chronic liver diseases including liver cirrhosis, chronic kidney disease) • Residents and workers in communal accommodation • Close contact persons of pregnant women • Close contact persons or caregivers of persons at high risk • Personnel with a moderate risk of exposure in medical facilities° and in positions that are particularly relevant for the maintenance of the hospital infrastructure • Sub-areas of the Public Health Service (Öffentlicher Gesundheitsdienst, ÖGD)
4	• Persons at the age of ≥65-69 years • Persons with underlying diseases at increased risk (diabetes mellitus with HbA1c <58 mmol/mol or <7.5%, arrhythmia/atrial fibrillation, coronary artery disease, heart failure, HIV infection, autoimmune diseases, malignancies in treatment-free remission, arterial hypertension, rheumatological diseases, bronchial asthma, chronic inflammatory bowel diseases, cerebrovascular diseases/apoplexy and other chronic neurological diseases) and their closest contact persons • Personnel with a low risk of exposure in medical facilities° • Teachers • Educators • Persons with precarious working and/or living conditions
5	• Persons at the age of ≥60-64 years • Personnel in key positions in the state and federal governments • Retail workers • Employees to maintain public safety with an increased risk of exposure • Critical infrastructure occupational groups
6	• All other persons at the age of <60 years

°For the classification of personnel in medical facilities see Table 2 below

Three vaccines are currently licensed in the European Union for vaccination against COVID-19. These are two mRNA vaccines (Comirnaty from BioNTech/Pfizer and COVID-19-Vaccine Moderna from Moderna) and a viral vector vaccine (COVID-19 Vaccine Astra-Zeneca from AstraZeneca). For a complete vaccination series, two intramuscular (IM) vaccine doses are required. In regard to the licensing STIKO recommends for the mRNA-vaccines (Comirnaty und COVID-19-Vaccine-Moderna) an interval of 3 or 4 weeks, respectively to 6 weeks between the two vaccine doses and for the viral vector vaccine (COVID-19 Vaccine AstraZeneca) an interval of 9 to 12 weeks.

As further vaccines are licensed and available in Germany or new relevant findings with an influence on this recommendation become known, the STIKO will update its COVID-19 vaccination

recommendation and, if necessary, adapt indications for particular groups. Each update will be published in the epidemiological bulletin and will be announced on the RKI webpage.

Notes on practical implementation:

- The federal states or the bodies commissioned by them are responsible for implementing the recommendation.
- In the prioritization of the COVID-19 vaccination recommendation of the STIKO, not all clinical conditions or vaccination indications could be named explicitly. It is the responsibility of the persons in the federal states who are responsible for the vaccinations prioritization to assign individuals, who are not explicitly named, to the respective prioritization category. This concerns e.g. individuals with rare, severe pre-existing conditions, for which there is not yet sufficient scientific evidence available regarding the course of COVID-19, but for whom an increased risk must be assumed. This also applies to individuals who cannot be vaccinated later or can not be vaccinated later with the same benefit of efficacy (e. g. with an imminent chemotherapy). In addition, decisions are possible on a case-by-case basis if professional activities or life circumstances are accompanied with an understandable inevitable very high risk of infection. This opening clause must not be abused to carry out an unjustified vaccination and in the consequence withhold a vaccination from individuals who are at higher risk.
- COVID-19 vaccination requires that the person to be vaccinated or the responsible legal guardian has been informed carefully. The STIKO refers to chapter 4.1 of the STIKO vaccination recommendations 2020/2021 (Epid. Bull. 34/2020).
- When vaccinating, the instructions in the Summary of Product Characteristics for the corresponding vaccine are to be observed.
- In very old individuals or individuals with progressive diseases that result in a poor general condition, individual vaccination ability must be assessed. Within those groups, it should be individually medically assessed whether vaccination can be recommended.
- There are currently no data available on the use of COVID-19 vaccines during pregnancy or lactation. The STIKO does not currently recommend general vaccination during pregnancy. Nevertheless, accidental vaccination during pregnancy is not an indication for abortion. Pregnant women with pre-existing conditions and a resulting high risk for severe COVID-19 could be offered a vaccination, after a risk-benefit risk assessment, and after detailed information in individual cases. The STIKO deems it unlikely that vaccination of the mother during breastfeeding poses a risk to the infant.
- For other scheduled vaccinations, a minimum interval of 14 days before the start and after the completion of the vaccination series should be complied with (emergency vaccinations are excluded).
- The vaccination must be administered strictly intramuscularly (IM) and in no case it should be administered intradermally, subcutaneously or intravascularly. In patients on anticoagulation medication, the vaccination should also be administered IM with a very fine injection cannula followed by firm compression of the puncture site for at least 2 minutes.
- According to the data available as of today, there is no evidence that the vaccination poses a risk after an unnoticed SARS-CoV-2 infection. Accordingly, there is no necessity to exclude the presence of an acute asymptomatic or undetected SARS-CoV-2 infection by laboratory testing before administering a COVID-19 vaccination.

- Because of the assumed immunity after infection, to avoid excessive vaccine reactions and in view of the current shortage of vaccines, in the opinion of the STIKO individuals who formerly suffered from COVID-19 should get vaccinated about 6 months after recovery. When a laboratory test (positive PCR) confirmed SARS-CoV-2 infection occurs after the first vaccine dose, the second vaccine dose should also be administered only about 6 months after recovery or diagnosis, respectively.
- The administration of the second vaccine dose should be done within the time period covered by the registration studies (mRNA vaccines: 3 or 4, respectively to 6 weeks; AstraZeneca vaccine: 9 to 12 weeks). Even if the minimum interval between the 1st and 2nd vaccine dose has been exceeded, the vaccination series can be continued and does not have to be restarted. A vaccination series that has already started must be completed with the same product.
- A minimum follow-up period of 15 minutes after the COVID-19 vaccination is recommended. As a precaution, longer follow-up periods of 15-30 minutes should be met with certain risk persons, e.g. in persons with anticoagulant, anaphylactic or severe reactions to vaccinations in the medical history. Important for these decisions is the information provided by the person himself/herself and the medical impression of the state of health.
- It is currently not known whether, after exposure to SARS-CoV-2, a post-exposure vaccination can favourably influence the course of the infection or prevent the disease.
- The data available to date do not allow a conclusive assessment of the effectiveness of the COVID-19 mRNA and the viral vector vaccines in terms of preventing or reducing transmission. Until new data on the protection of the vaccination against transmission are available, the generally recommended protective measures (adherence to distance and hygiene rules) must therefore still be met after vaccination.
- After the approval of Comirnaty, individual serious allergic adverse reactions have occurred. According to the current data, a generally increased risk of serious adverse effects for persons with previously known allergic diseases is not assumed when vaccinating with mRNA vaccines, provided that there is no allergy to an ingredient (e.g. PEG) of the respective vaccine. For further information, please refer to „Empfehlung zur Coronaimpfung für Allergikerinnen und Allergiker“ des Paul-Ehrlich-Instituts (PEI) verwiesen: https://www.pei.de/SharedDocs/Downloads/DE/newsroom/mitteilungen/201223-stellungnahme-empfehlung-allergiker.pdf?__blob=publicationFile&v=6
- The established notifications systems should be used for reports on vaccination reactions and complications going beyond the usual level (see Chapter 4.9 "Vaccination complications and their reporting" in the STIKO vaccination recommendations 2020/2021; reporting form from PEI: https://www.pei.de/DE/arzneimittelsicherheit/pharmakovigilanz/meldeformulare-online-meldung/meldeformulare-online-meldung-node.html). Regular reports from PEI on safety of COVID-19 vaccines are available under the following link: https://www.pei.de/ DE / newsroom / dossier / coronavirus / drug safety. Html

Table 2: Examples of personnel in medical facilities by area of activity and their priority for a COVID-19 vaccination

Personnel in medical facilities	Examples for areas of activity/person groups	Step
With a particularly high risk of exposure	Emergency rooms; medical care for COVID-19 patients; emergency medical services; Employees from areas in which aerosol-generating activities are carried out on COVID-19 patients, e.g. in- and extubation, bronchoscopy, laryngoscopy	**1**
With close contact to vulnerable groups	Care facilities for the elderly; Facilities that care for severely immunocompromised/oncological/transplant patients; Palliative medicine; mobile vaccination teams	**1**
With a high risk of exposure	Infectious disease wards; general practitioner and paediatric practices; emergency services of the Association of Statutory Health Insurance Physicians; Transport of emergency patients; clinics or practices for ENT, eye, dentistry (close contacts, documented cases of infection among medical personnel); personnel in centres where smears are carried out; medical personnel of the public health service with patient contact	**2**
With a moderate risk of exposure	Other medical personnel in outpatient and inpatient care with patient contact or contact to pregnant women, blood donation personnel, cleaning personnel in clinics and practices, personnel in static vaccination centres	**3**
In positions that are relevant for the maintenance of the hospital infrastructure, public health service	Persons working in IT or hospital or medical technology; personnel of the public health service without patient contact	**3**
With a low risk of exposure	Personnel who do not care for patients with (suspected) infectious diseases and who do not carry out any aerosol-generating activities; Laboratory personnel	**4**