Fact sheet: COVID-19 vaccination with mRNA vaccines

Why does vaccination for COVID-19 make sense?

- In most cases, the progression of an infection with SARS-CoV-2 is mild and without complications. However, older people, and people with chronic diseases in particular are at a significantly higher risk of suffering a severe case of the disease with complications, like admissions to hospital and deaths.
- Younger people without chronic diseases can also suffer severe cases with complications, albeit much more rarely than older people.
- An infection can result in health impairments that last for a long time, even for younger people.
- There is a risk that health care will be overloaded due to the large number of severe cases of the disease, meaning that care can no longer be fully guaranteed for members of the public.
- Measures to manage the SARS-CoV-2 pandemic are severely restricting the social and economic life of individuals and the whole community. The fewer people contract the disease, the more quickly everyday life can return to normal.
- The available mRNA vaccine technologies have been tested for years and have already been administered to billions of people. mRNA vaccines have demonstrated a very good efficacy and safety profile in clinical trials and observational studies. Vaccination is much safer for individuals than an infection and its potentially severe consequences.
- This leads to a major reduction in the number of severe cases and deaths, and thus to a reduction in admissions to hospital.
- Current data indicate that transmission of the virus can be reduced for a certain time by full vaccination.

Target groups

According to the vaccination strategy and vaccination recommendations formulated by the Federal Vaccination Commission (EKIF/CFV) and the Federal Office of Public Health (FOPH/BAG), vaccination against Covid-19 is recommended for all adults (from age 16). This recommendation applies in particular to persons at increased risk of severe disease (vulnerable persons) and their close contacts. Vaccination is also recommended for adolescents aged 12 to 15 years, especially those with chronic diseases. See the separate fact sheet for children for the vaccination recommendations for children from 5 to 11. According to the vaccination strategy, the following target groups have been defined:

1. Vulnerable persons:

People aged 65 and over, as well as adults under 65 with chronic diseases (from the age of 16). These include specific forms of:
- Arterial hypertension
- Cardiovascular diseases
- Diabetes mellitus
- Lung and respiratory diseases (including COPD and pulmonary fibrosis)
- Congenital or acquired immunodeficiency and immunosuppressive therapy (including cancers)
- Cancer
- Obesity (BMI ≥ 35 kg/m²)
- Renal insufficiency
- Liver cirrhosis

and furthermore, people from the age of 16 years with Trisomy 21.

2. Personnel with patient contact and personnel caring for vulnerable persons

3. Close contacts of vulnerable persons (household members or caring family members from the age of 16 years), in particular persons with immunodeficiency

4. People aged 16 to 64 in community facilities with an elevated risk of infection and outbreak

5. All other people aged 16 to 64 years

6. Young people between 12 and 15 years

7. Children 5-11 years whose parents/guardians wish this

For children under 5 years of age: There are no data available for the use of the vaccine in this age group. Therefore, vaccination is not yet recommended. The vaccine (initial immunisation or booster vaccination, depending on the situation) is recommended for all pregnant women from the second trimester, especially to women with certain types of chronic diseases. Women who are planning to become pregnant should also be vaccinated against COVID-19. Vaccination is also possible in principle in the 1st trimester and can be carried out at the request of the pregnant woman. Vaccination with an mRNA vaccine is also recommended for breastfeeding mothers. The increasing evidence on the safety and efficacy of COVID-19 vaccination with an mRNA vaccine during pregnancy confirms that the benefits of vaccination outweigh the risks. No written consent or medical certificate is required.

Contraindications and indications after clarification of a reservation

Possible contraindications, which must be assessed by a medical specialist, are:
- Anaphylaxis or general allergic reaction to vaccine ingredients, known or probable immediate-type sensitisation to polyethylene glycol (PEG), tromethamine (trometamol, TRIS), severe anaphylaxis (grade III/IV) with unclear or unresolved trigger, idiopathic anaphylaxis as well as anaphylaxis after the first dose of vaccine. In the latter case, the vaccination series can be completed with the Janssen-Cilag vector vaccine after a consultation with a specialist in allergy and clinical immunology.
- Myocarditis/pericarditis after 1st vaccination dose: until additional safety data are available, it is generally recommended to postpone the 2nd dose. However, the 2nd dose may be considered after consultation with a specialist and with a personal risk-benefit analysis.

For further specification of relative or absolute contraindications of allergic or non-allergic nature, see the vaccination recommendation for mRNA vaccines section 2.3.1, section 10.5 and appendix 2.

People aged under 30 should preferably receive Comirnaty® (due to the observed very small increased risk of myocarditis/pericarditis following vaccination with Spikevax® in this age group, see section “known side-effects”). This also includes people who have already received Spikevax®.

1 Capacity to consent: For adolescents aged 12 years and over who consult without a legal representative, the capacity to consent must be assessed on an individual basis.
3 Categories of persons at high risk and here www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - English documents
4 Here the indication for vaccination must be assessed by the attending specialist, carefully weighing up the risks and benefits.
5 www.swissmedinfo.ch (in German, French)
6 Vaccination recommendation for mRNA vaccines against COVID-19 and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen (only available in German and French).
For people with immunodeficiency: These people are at high risk of severe cases of the disease and the indication for vaccination should be determined generously in accordance with the vaccination recommendations by the attending specialist. The efficacy for these people might possibly be reduced (see vaccination scheme).

You will find more specific information on precautionary measures and vaccinating people with immunodeficiency and with known acute severe allergies in the vaccination recommendation9.

For pregnant women in the 1st trimester: The vaccination can be carried out at the woman’s request.

Vaccines6

The mRNA vaccines are so-called messenger ribonucleic acid (mRNA) vaccines manufactured by Pfizer/BioNTech and Moderna. This type of vaccine has been in testing in research for ten years already.

The vaccines contain lab produced messenger RNA (mRNA) with the information for the SARS-CoV-2 virus's spike protein. After vaccination, some cells produce the viral spike protein (antigen). This provokes the immune system into an immune response involving the formation of antibodies and cellular defences against SARS-CoV-2. The mRNA remains in the cytoplasm, is not transported into the cell nucleus, and accordingly cannot affect the human genetic material. The mRNA and the proteins produced are quickly broken down again.

Efficacy

According to clinical trials and observational studies, the mRNA vaccines offer a very high degree of protection from COVID-19 for adults of around 94% (95% CI 89%-98%) (variants of 2020 and Alpha), and also from severe cases (all known variants incl. Delta). Very good protection has also been demonstrated for older people. For young people aged 12 to 15 years, the protective effect was also very high (100%, 95 CI 29%-100%). Data show a slight to moderate decrease in protection against severe illness from 5 months after initial immunisation in people aged 65 years and over, although this significant decrease has thus far not been observed for Spikevax® in this age group. According to current knowledge, the approved mRNA vaccines guarantee good protection for at least 6 months against severe illness in people aged under 65 years, regardless of the currently known virus variants. New evidence in this regard will be closely monitored. Protection against infection and mild disease decreases a few months (4-7 months) after initial immunisation across all age groups, from >90% after initial immunisation to around 50-60%.

Initial studies estimate that the transmission risk if people are infected after full vaccination is significantly lower than in unvaccinated people. This protection appears to significantly decrease a few months after two doses of vaccine (data from Comirnaty®).

Note on data situation regarding Omicron variant:

Various studies indicate that the risk of infection among fully vaccinated and recovered people is high. One study shows that the protection from symptomatic infection with Omicron 2–9 weeks after the second dose of Comirnaty® decreases from 88% (95 CI 65.9–95.8%) to 35% (95 CI 9.7–52%) at 15 weeks. The same study shows that a booster vaccination at least 2 weeks later can increase protection against symptomatic infection with Omicron to 75.5% (95 CI 56.1–86.3%). Long-term protection against infection with the Omicron variant after a booster vaccination cannot yet be assessed owing to the short tracing period. While it has not been possible to assess the efficacy against hospitalisation and severe cases of the disease so far, it is likely to be significantly higher than the efficacy against symptomatic infection.

Known side-effects

According to the results of the clinical trials, the vaccines are well tolerated. However, they can be associated with mild to moderate side effects that disappear within a few days. The side effect profile of adolescents aged 12 to 15 years is similar to that in young adults, according to currently available data. The most common side-effects are the kind of local reactions that also occur with other vaccinations. The most frequent side-effect6 include pain at the injection site (>80%), fatigue (>60%) and headache (>50%). Chills, aching muscles and joints (20–60%), and fever and swelling at the injection site (around 10%) may also occur. In the Spikevax® (Moderna), there have also been very frequent reports of nausea/vomiting (>20 %), lymphadenopathy (20–40%) and redness at the injection site (10-30%). According to reports, increased side effects were observed following the second vaccine dose. Older people display fewer side-effects. Delayed local inflammatory reactions were observed around one week after the vaccination and usually manifest themselves as a well-defined area of red, swollen skin on the injected arm, in some cases accompanied by pain and/or itching (“COVID Arm”). These reactions improve without further measures after a few days. Such an event is not a contraindication to a second vaccine dose.

Severe allergic reactions to a vaccine ingredient (in particular polyethylene glycol (PEG) and tromethamine/trometamol (TRIS)) are very rare and mostly occur immediately after the vaccination. The first signs of a severe reaction, such as shortness of breath, drop in blood pressure or severe reactions at the injection site mostly occur within minutes.

The risk of rare extraordinary or serious side-effects cannot currently be ruled out. Such side-effects occur within months of the vaccination. However, experience shows that the risk of this is very low. The institutions in charge observe possible signs closely. Other health problems may continue to arise, sometimes also in direct temporal relation to a vaccination. This does not mean, however, that this is necessarily a result of the vaccination.

Very rare cases of myocarditis and pericarditis have been reported. The cases occurred mainly within two weeks of vaccination, more frequently after the second vaccination, more often in young men and were mostly of mild severity. Pharmaceutical vigilance data show that these were observed more frequently in persons under 30 years of age after vaccination with Spikevax® than after vaccination with Comirnaty® (13 versus 6/100,000 vaccine doses). These are very rare side-effects and the risk of myocarditis and pericarditis is significantly higher in connection with a confirmed infection. The benefit of being vaccinated against COVID-19 significantly outweighs the potential risks in people under 30.

The risk of other severe side-effect from the vaccination is according to the actual evidence much smaller than the risk of a complication of COVID-19, the disease from which the vaccination protects. A doctor, pharmacist or vaccination centre should be notified of any serious and unexpected side-effects. These notifications are recorded in Swissmedic’s vigilance system9. If necessary action will be taken on this basis.

Vaccination Schedule

Initial immunisation6

Initial immunisation comprises 2 injections into the deltoid muscle at an interval of 28 days or one vaccine dose in combination with a confirmed COVID infection at an interval of at least 4 weeks. Both vaccinations should be with the same vaccine. The anticipated vaccine immune protection occurs around 1–2 weeks after initial immunisation. People under 30 should preferably receive the Comirnaty® vaccine.

Note on initial immunisation:

Initial immunisation is considered complete (i) after the second vaccine dose, (ii) after one vaccine dose following confirmed SARS-CoV-2 infection (PCR/antigen test/anti-spike or anti-nucleocapsid IgG)10 or (iii) after confirmed SARS-CoV-2 infection (PCR/antigen test or anti-nucleocapsid IgG) after the first vaccine dose. In principle a minimum interval of 4 weeks applies (exception: anti-nucleocapsid IgG after first injection: no minimum interval necessary).

As vaccination after infection can increase protection effectively, particularly against new variants, vaccination within 3 months of infection is recommended. However, there is no upper time limit for vaccination with one dose after infection.

Persons with severe immunodeficiency are an exception and should receive 2 vaccine doses, even in the case of a confirmed infection. For persons with severe immunodeficiency (e.g. with severe immunosuppressive treatments in transplantation, autoimmune diseases or malignant neoplasms) a 3rd dose is recommended from 4 weeks after

References:

1. mRNA is basically also produced by the human body itself, and serves as a readable template for the production of endogenous proteins. Afterwards the mRNA is broken down again. The vaccine provides another template of this sort which is then broken down again via the normal processes.


4. www.swissmedicinfo.ch


7. www.swissmedicinfo.ch


the 2nd dose for initial immunisation. The ideal time for administering the 3rd dose should be discussed with the attending specialist (see chapter 3.3 recommendation of vaccination6).

Serological testing is not generally recommended and should not be performed explicitly to determine the vaccination schedule. Serological testing is recommended following initial immunisation (third dose) for persons with severe immunodeficiency (vaccination recommendation, section 3.3).

Booster11:
The booster vaccination is recommended as follows;

1. As a priority due to the decrease in protection against severe disease and hospitalisation:
   - Persons aged 65 and over and then persons whose last dose was ≥ 6 months ago.
2. To improve direct and indirect protection against frequently mild but in rare cases serious disease in order to ease pressure on the health system and to help contain the pandemic by reducing circulation of the virus:
   - Everyone aged 16 to 64, in particular:
     - Vulnerable persons with chronic diseases that put them at the highest risk (in accordance with Table 2 of the recommendation for mRNA vaccines)
     - Healthcare workers with direct patient contact and carers of vulnerable persons.

Like the initial immunisation, the booster is also recommended for pregnant women from the 2nd trimester and women who are breastfeeding, even though the data in this area are still limited.

A booster is recommended for these groups from 4 months after complete initial immunisation. If a confirmed SARS-CoV-2 infection occurs within 4 months after completion of immunisation, a booster vaccination is recommended 4 months after this infection.

Caution: A confirmed infection more than 4 months after initial immunisation counts as a booster, and no booster vaccination is necessary. In individual cases, a booster vaccination may be recommended for people at particular risk and particularly exposed people (e.g., healthcare workers) if this infection occurred more than 4 months ago11.

Severely immunodeficient people aged 16 and older are recommended a booster vaccination off label from 4 months after administration of 3 mRNA vaccine doses for initial immunisation. The booster should be with the same mRNA vaccine where possible.

In the case of Spikevax®, the booster is recommended at a reduced dose of 50 µg. People under 30 should preferably receive Comirnaty® for their booster. For people between 12 and 7, a booster with Spikevax® is only authorised for vulnerable persons.

People who have received a dose of COVID-19 Vaccine Janssen®, at least 4 months ago are recommended to have an off-label booster vaccination with a dose of an mRNA vaccine (provided an mRNA vaccine is not contraindicated and is not rejected for other reasons).

Caution: no more than 4 vaccine doses in total are currently recommended.

People who have been given initial immunisation with a vaccine that is not authorised in Switzerland are recommended to have a booster vaccination with an mRNA vaccine at the earliest 4 months after the last dose. See also appendix 3 of the vaccination recommendation6 and the tabular overview15.

Off-label use
The duty to inform must be complied with. The usual liability rules3 apply.

The vaccination should be postponed in the event of acute febrile illness.

Care after the vaccination

Given that all vaccinations entail the risk of allergic reaction, a doctor or qualified pharmacist should be available to be brought in if required. The necessary precautions to treat an anaphylactic reaction must be taken. The person vaccinated should remain on site for at least 15 minutes after the vaccination and be instructed in possible adverse vaccination events and the procedure if they occur. This especially applies when people with known severe allergic reactions are vaccinated. If the first vaccination went without a problem, the observation time after the second vaccination can be reduced to 5 minutes.

Vaccinated persons should be advised to watch for signs of myocarditis and pericarditis, such as shortness of breath, palpitations and chest pain, and to seek medical attention immediately if such signs appear.

The generally recommended hygiene and behavioural measures (masks, distancing, hand hygiene) must continue to be observed before, during and also after the vaccination, with the exception of private meetings between fully vaccinated persons (waiver of mask and distance possible) as well as events with a certificate (according to the organiser’s instructions). There is no minimal interval to other vaccinations.

Availability of vaccine

Responsibility for organising vaccinations for COVID-19 lies with the cantonal departments of health. They will provide information on how and where people can be vaccinated. The vaccination is free of charge.

You will find further information at
- www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen
- www.infovac.ch
- www.foph-coronavirus.ch/vaccination

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1 Booster vaccination recommendation for mRNA vaccines and at www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - Covid-19-impfung (only available in German and French)

2 Tabular overview of COVID-19 vaccines not authorised in Switzerland and www.bag.admin.ch/covid-19-dokumente-gesundheitsfachpersonen - COVID-19 vaccination (only available in German and French)

3 If the professional responsible bases their choice of vaccine on the FOPH vaccination recommendations, they can prove that they have observed the recognised rules of medical and pharmaceutical science and have thus complied with the due diligence rules under the Therapeutic Products Act. If the professional responsible also complies with the duties of care arising from the treatment contract (including the duty to inform, explain and document), they cannot usually be held liable (see also FOPH Bulletin 2015; 13:217, only available in German).