

- Vaccination / Virus

## COVID 19 AND VACCINE SAFETY

(WORLD HEALTH ORGANIZATION)

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How do we know that COVID-19 vaccines are safe?

There are strict protections in place to help ensure the safety of all COVID-19 vaccines. Before receiving validation from WHO and national regulatory agencies, COVID-19 vaccines must undergo rigorous testing in clinical trials to prove that they meet internationally agreed benchmarks for safety and efficacy.

Unprecedented scientific collaborations have allowed COVID-19 vaccine research, development, and authorisations to be completed in record time – to meet the urgent need for these vaccines while maintaining high safety standards. As with all vaccines, WHO and regulatory authorities will continuously monitor the use of COVID-19 vaccines to identify

and respond to any safety issues that might arise, and through that process to assure they remain safe for use around the world.

What are the side effects of COVID-19 vaccines?

Like any vaccine, COVID-19 vaccines can cause mild, short term side effects, such as a low-grade fever or pain or redness at the injection site. Most reactions to vaccines are mild and go away within a few days on their own. More serious or long-lasting side effects to vaccines are possible but extremely rare. Vaccines are continually monitored for as long as they are in use, to detect rare adverse events and implement approaches to limit their occurrence.

Reported side effects to COVID-19 vaccines have mostly been mild to moderate and short-lasting. They include: fever, fatigue, headache, muscle pain, chills, diarrhoea, and pain at the injection site. The chances of any of these side effects following vaccination differ according to the specific COVID-19 vaccine.

In most cases, these can be managed with rest, plenty of non-alcoholic liquids, and paracetamol/acetaminophen for the typical side effects. Contact your care provider if the tenderness (pain) where you got the injection increases after 24 hours, or the side effects do not go away within a couple days. If you have difficulty breathing, chest pain, confusion, loss of speech or mobility, call a healthcare provider immediately.

What happens if an adverse event is reported?

As with any vaccine, it is essential to closely monitor the safety and effectiveness of COVID-19 vaccines that are used in immunization programmes. If a health problem is reported following vaccination, a thorough investigation should take place by the public health programme in the country.

It is rare to find that health problems occurring following receipt of a vaccine are actually caused by the vaccine itself. Health problems following vaccination are most often found to be coincidental and entirely unrelated to vaccination. Sometimes they are related to how the vaccine has been stored, transported, or administered. Errors related to the delivery of the vaccine can be prevented by better training health workers and strengthening supply chains.

In the very rare cases where an adverse reaction is suspected to be related to the vaccine itself, the vaccine may be suspended from use while the situation is assessed. Further investigations will take place to determine what exactly caused the event, and corrective measures will be put in place. WHO works with vaccine manufacturers, health officials, researchers, and other partners to monitor any safety concerns and potential side effects on an ongoing basis.

Under what circumstances should a COVID-19 vaccine be recalled?

Vaccine recalls or withdrawals due to safety issues are rare. Recalls are usually initiated voluntarily by a vaccine manufacturer before any adverse events are reported. For example, ongoing monitoring of vaccine production may show that an irregularity has caused a batch of vaccines to lose their strength. In this case, people who have received a vaccine from that batch may need to be vaccinated again to ensure they are protected.

How will WHO inform the public about suspected or confirmed adverse events related to COVID-19 vaccines?

Suspected safety events officially reported to WHO go through a series of rapid verification steps involving an independent panel of experts. WHO shares the results of these evaluations on its website.

WHO also coordinates with local, regional, and national health officials to investigate vaccine safety concerns and advise on next steps. Information is also made available through the <https://www.vaccinesafetynet.org/>, a publicly available network of digital international resources on vaccine safety that have been approved by WHO.

Is it possible that someone vaccinated against COVID-19 will still get infected?

While COVID-19 vaccines have high levels of efficacy, especially against hospitalisation and severe disease, no vaccine is 100 per cent protective. As a result, there will be some small percentage of vaccinated people who fall ill with COVID-19 in spite of being vaccinated.

In addition to a vaccine's specific characteristics, several factors such as a person's age, their underlying health conditions, previous COVID-19 disease, current exposure to SARS-CoV-2, or the circulation of virus variants may have an impact on a vaccine's effectiveness.

We do not yet

know how long immunity from different COVID-19 vaccines will last. That is one reason why, even as COVID-19 vaccines are being rolled out, we must continue using all public health measures that work to decrease exposure risk, such as physical distancing, masks, and handwashing.

For the first 14 days after getting vaccinated, you do not have significant levels of protection as the protection increases gradually. For a single dose vaccine, protection is generally considered to occur by two weeks after vaccination. For two-dose vaccines, both doses are needed to achieve the highest level of immunity possible.

While a COVID-19 vaccine is most effective against serious illness and death, we are still learning about their ability to protect you from getting infected and passing the virus on to others. To help keep yourself and others safe, and while vaccination rolling out in your community, continue to maintain at least a one metre distance from others, cover a cough or sneeze in your elbow, clean your hands frequently and wear a mask, particularly in enclosed, crowded or poorly ventilated spaces. Always follow guidance from local authorities based on the situation and risk where you live.

Who should be excluded from receiving COVID-19 vaccines?

Medical professionals can best advise individuals on whether or not you should receive a COVID-19 vaccine. There are very few conditions that would exclude someone from being vaccinated. Based on available evidence, people with a history of severe allergic reactions to any ingredients of the COVID-19 vaccine should generally be excluded from COVID-19 vaccination in order to avoid possible adverse effects.

If you are currently sick or experiencing symptoms of COVID-19, you can get vaccinated once your primary symptoms have resolved.

In addition to the general recommendations above, each vaccine may have specific considerations for specific populations and health conditions.

Is it safe for pregnant women, those planning to become pregnant, and breastfeeding mothers to receive COVID-19 vaccines?

In the interim, WHO recommends that for pregnant women the use of the COVID-19 vaccine be considered on the basis of a benefit versus risk assessment. To help pregnant women make this assessment, they should be provided with information about the risks of COVID-19 in pregnancy, the likely benefits of vaccination in the local epidemiological context, and the current limitations of safety data in pregnant women. WHO does not recommend pregnancy testing prior to vaccination. WHO does not recommend delaying pregnancy or terminating pregnancy because of vaccination.

Vaccination with any of the vaccine products that have been assessed by the WHO Strategic Advisory Group of Experts on Immunization can be offered to breastfeeding women. WHO does not recommend discontinuation of breastfeeding after vaccination. More evidence will continue to be sought in order to further inform WHO's policy recommendations on this subject.

Should women who are on their periods take the COVID-19 vaccine?

Women can receive a vaccine at any point in their menstrual cycle.

Are mRNA vaccines safe? If they're based on new technology, how can we be sure?

The COVID-19 mRNA vaccine technology has been rigorously assessed for safety, and clinical trials have shown that mRNA vaccines produce an immune response that has high efficacy against disease. mRNA vaccine technology has been studied for several decades, including in the contexts of Zika, rabies, and influenza vaccines. mRNA vaccines are not live virus vaccines and do not interfere with human DNA.

How will WHO ensure vaccine safety monitoring and response when COVID-19 vaccines are used?

Vaccine safety monitoring is ensured at the national, regional, and global level. As is standard practice in all national immunisation programmes, WHO supports the set up of safety monitoring systems for COVID-19 vaccines in every country. After a COVID-19 vaccine is introduced in a country, WHO works with vaccine manufacturers, health officials and other partners to monitor for any safety concerns on an ongoing basis. Specific safety concerns that may arise are evaluated by WHO and an independent group of experts (the Global Advisory Committee on Vaccine Safety, or GACVS) in conjunction with the relevant national authorities.