FREQUENTLY ASKED QUESTIONS ABOUT COVID-19 VACCINES

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COVID-19 VACCINE APPROVAL

1. **How does WHO review the vaccines submitted for Emergency Use Listing (EUL) approval?**
   The World Health Organization (WHO) Technical Advisory Group for Emergency Use Listing (TAG-EUL) is an advisory committee of independent experts. The functions of this advisory group are to:
   - Review the assessment reports prepared by the WHO Product Evaluation Group (PEG) as part of the EUL assessment process, particularly the initial assessment and any updates based on additional information received. WHO may request additional information for its consideration.
   - Conduct a benefit-risk assessment for the potential use of these COVID-19 vaccines in response to the pandemic.
   - Provide a recommendation to WHO on whether the evaluated vaccine should be listed for emergency use under the EUL procedure, and under what conditions.
   - Advise on formulating conditions for listing, should the decision be positive. The conditions must include a detailed list of the manufacturer’s post-listing commitments.
   - Consider any emergency program needs, as applicable.

   More information:
   [https://extranet.who.int/pqweb/vaccines/TAG-EUL](https://extranet.who.int/pqweb/vaccines/TAG-EUL).

2. **Who authorizes which vaccines can be used in a country?**
   The National Regulatory Authority (NRA) of each country has the power to determine which vaccines are licensed for use in its territory. The State makes the final decision on immunization policies in the public system.

3. **What is the difference between vaccine “efficacy” and vaccine “effectiveness”?**
   Efficacy refers to the performance of a vaccine during clinical trials. This is the ideal performance, since the vaccine is tested in an experimental setting that can be more tightly controlled than everyday life.
   Effectiveness refers to the vaccine’s performance in the real world, after it has been released for consumer use. In this context, the vaccine is offered to a broader population, including those who may have health conditions or other factors that may affect how well the vaccine protects against disease. Therefore, effectiveness is a more realistic measure of a vaccine’s performance.

   More information:
   [https://www.who.int/influenza_vaccines_plan/resources/Session4_VEfficacy_VEffectiveness.PDF](https://www.who.int/influenza_vaccines_plan/resources/Session4_VEfficacy_VEffectiveness.PDF).

4. **Why has WHO yet to approve the Sputnik V vaccine, produced by the Gamaleya National Centre for Epidemiology and Microbiology?**
   WHO welcomes the signing by the Russian Direct Investment Fund of all the legal agreements necessary for evaluation under the WHO EUL procedure. We look forward
to receiving the full data set for analysis and for the continuation of the assessment process.
The applicant and the manufacturers also agreed to submit updated corrective and preventive actions (CAPAs) to address the original inspection observations.

The updating of this status depends on the producer complying with the requested requirements, the same as those requested of all producers that are part of the EUL. More information: https://www.who.int/news-room/news-updates.
5. Which COVID-19 vaccines has WHO authorized for emergency use?

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<tr>
<th>SAGE provisional recommendations</th>
<th>Producers of COVID-19 vaccines and names of vaccines</th>
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<td>Pfizer-BioNTech (BNT162b2)</td>
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<tr>
<td>Vaccine platform</td>
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<td>No. of doses</td>
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<td>Recommendation of additional doses</td>
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<td>SAGE provisional recommendations</td>
<td>Pfizer-BioNTech (BNT162b2)</td>
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<td>or booster doses of the vaccine</td>
<td>workers, older adults, immuno-compromised people: 4–6 months after the second dose</td>
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<tr>
<td>Recommendation to co-administer the COVID-19 vaccine with the flu vaccine</td>
<td>Yes</td>
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WHO Strategic Advisory Group of Experts on Immunization (SAGE)

*Because of limited experience with the Matrix-MTM adjuvant of the Novavax NVX-Co2373 vaccine in pregnancy, the benefit-risk assessment for this vaccine includes considering whether any other WHO EUL COVID-19 vaccine with a more established safety record in pregnancy is locally available.

More information:
COVID-19 VACCINES AGAINST SARS-COV-2 VARIANTS OF CONCERN

1. What are the definitions of SARS-COV-2 “variants of interest” and “variants of concern”?
   A variant of the SARS-CoV-2 virus is classified as of interest if: 1) it is circulating widely and 2) there is scientific evidence of mutations suspected of causing significant changes in the virus. A variant of interest becomes a variant of concern if it is known to spread more easily, cause more severe disease, escape the body's immune response, change clinical presentation, or decrease the effectiveness of known tools (e.g., public health measures, diagnostics, treatments, and vaccines).

2. Which SARS-COV-2 variants has WHO defined as variants of concern?
   To date, the World Health Organization (WHO) and Pan American Health Organization (PAHO) are monitoring five variants of concern:
   - Alpha (first identified in the United Kingdom)
   - Beta (first identified in South Africa)
   - Gamma (first identified in Brazil)
   - Delta (first identified in India)
   - Omicron (first identified in South Africa)
   Regardless of any circulating variants, all public health and social measures (proper use of masks, physical distancing, isolation of patients, quarantining contacts, and vaccination) are efficient and must be maintained.

3. What is known about the Delta variant?
   The Delta variant is a variant of concern classified by WHO on 11 May 2021. Delta spreads more easily than earlier strains of the virus and is responsible for more cases and deaths worldwide. All approved COVID-19 vaccines currently in use are safe and effective in preventing severe disease and death against the Delta variant.

4. What is known about the Omicron variant?
   The Omicron variant was first reported to WHO on 24 November 2021. The WHO Technical Advisory Group on the Evolution of the Virus classified it as a variant of concern on 26 November 2021. The decision was based mainly on information from South Africa, which showed that the variant had a large number of mutations and had caused a shift in COVID-19 epidemiological trends in the country. This large number of mutations can cause the virus to act differently than other variants that are circulating.
   The WHO Technical Advisory Group on the Evolution of the Virus will continue to monitor and evaluate data as they become available. At the moment, the data suggest:
• **Transmissibility:** The Omicron variant has a substantial growth advantage over the Delta variant, which it is rapidly replacing around the world. There is now important evidence that immune evasion contributes to the rapid spread of Omicron.

• **Severity:** Epidemiological trends continue to show a decoupling between incident cases, hospital admissions, and deaths when compared to the epidemic waves caused by previous variants. This is likely due to the lower intrinsic severity of the Omicron variant. It is also possible that the effectiveness of the vaccine is preserved more against severe disease than against infection. However, most countries are reporting high levels of hospitalizations and intensive care unit admissions because transmission levels are higher than ever before during the pandemic.

• **Diagnostic tests:** Omicron does not appear to affect the accuracy of rapid antigen detection diagnostic tests, or the commonly used polymerase chain reaction (PCR) tests. Specifically, no effects have been reported in the recommended reverse transcriptase polymerase chain reaction (RT-PCR) protocol (Charité Hospital, Berlin) or in the WHO Emergency Use Listing (EUL) trials. Moreover, no effect has been reported in the two recommended tests (the Abbott Panbio® COVID-19 Ag and the SD Biosensor). All WHO EUL trials are under review.

• **Therapeutics:** Therapeutic interventions for the management of patients with severe or critical COVID-19 associated with the Omicron variant (such as corticosteroids and interleukin-6 receptor blockers) are expected to maintain their efficacy. However, preliminary data from non-peer-reviewed publications suggest that the neutralization against Omicron of some of the monoclonal antibodies developed against SARS-CoV-2 may be altered.

• **Risk of reinfection:** Current evidence consistently shows a reduction in neutralization against Omicron in fully-vaccinated individuals or in those who have had a previous SARS-CoV-2 infection. In addition, some preliminary data suggest that the effectiveness of vaccines is significantly lower against infection and symptomatic disease by Omicron, compared to the Delta variant. The use of booster doses (homologous and heterologous) increases the efficacy of the vaccine.

• **Public health measures:** With the emergence of the Omicron variant, physical distancing, the use of well-fitting masks, indoor ventilation, hand hygiene, and the avoidance of crowds remain essential to reducing the transmission of SARS-CoV-2.

WHO supports urgent and comprehensive access to COVID-19 vaccines for priority populations around the world to provide protection against serious illness and death globally and, in the longer term, to mitigate the emergence and impact of new variants of concern by reducing the burden of infection.

More information:
https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states.
https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states.

5. **What impact do the new variants of the COVID-19 virus have on vaccines?**
The COVID-19 vaccines that are currently in development or have been approved are expected to provide at least some protection against new virus variants because these vaccines elicit an immune response involving a range of antibodies and cells. Therefore, changes or mutations in the virus do not lead to a complete loss of vaccine efficacy. If any of these vaccines prove to be less effective against one or more variants, it will be possible to change the composition of the vaccines to protect against these new variants.

While we are learning more, we need to do everything possible to stop the spread of the virus to prevent mutations that may reduce the efficacy of existing vaccines. Moreover, manufacturers and programs using their vaccines will need to adapt to the evolution of the virus. For example, vaccines may need to incorporate more than one strain when in development, booster shots may be required, and other vaccine changes may be needed. Trials must also be designed and continued to allow any changes in efficacy to be assessed and must be of sufficient scale and diversity to enable clear interpretation of results. Studies of the impact of vaccines as they are deployed are also necessary.


6. **What is the effectiveness of COVID-19 vaccines against each variant of concern?**

   COVID-19 vaccines granted emergency use listing (EUL) by WHO provide different levels of protection against infection, mild illness, severe illness, hospitalization, and death. Thousands of scientists around the world are conducting ongoing research to better understand the impact of new virus mutations and variants on the effectiveness of the different COVID-19 vaccines. Overall, COVID-19 vaccines are very effective in preventing severe illness, hospitalization, and death caused by all current variants of the virus. They are less effective at protecting against infection and mild disease than they were for earlier virus variants; however, for those who become ill after being vaccinated, symptoms are more likely to be mild.

   Remember that while the COVID-19 vaccines authorized by WHO are incredibly effective at reducing the risk of developing serious illness and death, no vaccine is completely effective. A small percentage of people will still become ill from COVID-19 even though they have been vaccinated. Currently there is limited information about the risk of vaccinated people passing the virus to others if they are infected. This makes it very important to continue to practice public health and social measures, even after being fully vaccinated.


7. **How can new COVID-19 variants be prevented from appearing?**

   It remains critical to curb the spread of the virus from its source. Measures that have been in place so far to reduce transmission—such as frequent handwashing, wearing a mask, physical distancing, and avoiding crowded or enclosed places—continue to help reduce the likelihood of new variants appearing because they make it difficult for the virus to be transmitted, giving it fewer opportunities to mutate.

   To protect people before they are exposed to the virus and to the risk posed by new variants, it will also be critical to step up the production and distribution of vaccines as quickly and widely as possible. Everywhere, vaccinating the highest-risk groups must be prioritized to increase protection against new variants as much as possible and to reduce the risk of transmission. To cope with the evolution of the pandemic, it is also more important than ever to ensure equitable
access to COVID-19 vaccines. The more people who are vaccinated, the more likely it is that the circulation of the virus will be reduced and, therefore, the risk of mutations appearing will be lower.

More information:

8. **Why is it important to get vaccinated even if there are new variants of the virus?**

Vaccines are a critical tool in the battle against COVID-19, and there are clear public health and lifesaving benefits to using the tools we already have. Vaccination should not be postponed just because of concern about new variants of the virus. Vaccination should continue even if the vaccines have lost some efficacy against some of the variants. It is crucial to continue using the available tools while continuing to improve them. We will only be safe when all of us are safe.

More information:

**COVID-19 VACCINE SAFETY**

1. **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 the World Health Organization (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 effectiveness. Unprecedented scientific collaborations have allowed COVID-19 vaccine research, development, and authorizations 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 confirm that they remain safe for all who receive them.

More information:

2. **How will we know if the vaccines are causing adverse effects?**

The effect of the COVID-19 vaccine varies from person to person, as it does for most vaccines. As more people get vaccinated, we may be able to determine patterns. This information continues to be collected, but for now, we cannot anticipate who may have side-effects. Persons who receive vaccines are encouraged to follow local guidance on observation periods immediately following vaccination and to alert their usual health providers if they experience any adverse effects or unexpected health incidents after vaccination. Monitoring reactions after vaccination is a standard practice in all national immunization programs, regardless of the vaccine being administered.

More information:
3. **Are there long-term adverse effects after COVID-19 vaccination?**
To date, clinical trials have been conducted and more than 10 billion doses of vaccine have been administered to people in every country in the world. Reports of serious long-term side effects (allergic reactions) have been rare. No long-term complications have been reported after vaccination with any COVID-19 vaccine that received Emergency Use Listing (EUL) approval from WHO.

4. **What are the latest updates on adverse effects?**
   
   For the mRNA vaccines produced by Pfizer and Moderna:
   - **Myocarditis**: Some data reviewed by the WHO Global Advisory Committee on Vaccine Safety (though not all) suggest that the incidence of myocarditis in young men after a second dose is higher for the Moderna vaccine than for the Pfizer mRNA vaccine, although the overall risk is small. Available data suggest that the immediate course of myocarditis and pericarditis following vaccination with both of these vaccines is generally mild and responds to treatment. Continuous monitoring is conducted to determine long-term outcomes. The different mRNA vaccines have a clear benefit in preventing hospitalization and death from COVID-19.

   For adenoviral vaccines produced by AstraZeneca and Janssen:
   - **Thrombosis with thrombocytopenia syndrome** (TTS): According to current data, one case of TTS has been reported for every 2 million doses of vaccine administered. The majority (69%) were reported in the United States of America, in people under 65 years of age (83%); of those affected, 55% were women and 45% were men. The average time until onset of the event was 16.5 days.
   - **Guillain-Barré syndrome** (GBS): According to current data, one case of GBS was reported for every 7 million to 8 million doses of vaccine administered. The majority of cases (64%) were reported in the United States of America. The median reported age was 53 years; of those affected, 64% were men and 36% were women. The average time until the start of the event was 36 days.
   - **Capillary leakage syndrome** (CLS): Very rare CLS events (0.21 per 1 million doses) have been reported, some in people with a history of CLS, and some with fatal outcomes. The average time until the start of the event was 1 day.

In countries with ongoing SARS-CoV-2 transmission, the benefit of vaccination in protecting against COVID-19 far outweighs the risks of TTS, GBS, and CLS.

More information:
[https://cdn.who.int/media/docs/default-source/immunization/sage/2022/january/evidence-review-on-paediatrics-data.pdf?sfvrsn=ffbaa9ff_7](https://cdn.who.int/media/docs/default-source/immunization/sage/2022/january/evidence-review-on-paediatrics-data.pdf?sfvrsn=ffbaa9ff_7)
5. **What about people who have had anaphylactic shock after the first dose of vaccine?**
   A history of anaphylaxis to any other vaccine or injectable treatment (i.e., vaccines or treatments administered intramuscularly, intravenously, or subcutaneously) is not a contraindication to vaccination.
   For such persons, a risk assessment should be conducted by a health professional. It is not known whether there is an increased risk of anaphylaxis, but advice on the potential risk of anaphylaxis and weighing the risks of vaccination against its benefits is necessary. These individuals should be kept under observation for 30 minutes after vaccination, in health care settings where anaphylaxis can be treated immediately.
   People with an immediate non-anaphylactic allergic reaction to the first dose (such as urticaria, angioedema, or respiratory symptoms without any other symptoms that occur within 4 hours of administration) should not receive additional doses, unless recommended after review by a health professional with specialist expertise. Subject to individual benefit-risk assessment, the vaccine could be provided under close medical supervision if it is the only available vaccine for persons at high risk of severe COVID-19. If a second dose is offered, the patient should be kept under close observation for 30 minutes after vaccination, in a healthcare setting where severe allergic reactions can be treated immediately.

6. **Is it safe to take antibiotics after getting vaccinated?**
   There is no known influence or interaction between antibiotics and COVID-19 vaccines. Patients who are prescribed antibiotics before or after vaccination should go ahead and take the full course. However, if they have a temperature above 38.5°C at the time of the vaccination appointment, vaccination should be rescheduled.

7. **Do COVID-19 vaccines have any impact on fertility?**
   There is no evidence suggesting that COVID-19 vaccines cause or have caused infertility. This has been shown in the clinical trial phases of vaccines already licensed for emergency use. Some women who participated in the trials became pregnant during that period. A vaccine suspected of affecting a person’s ability to conceive has never been nor will ever be approved.

8. **Can a dose of COVID-19 vaccine be administered at the same time as other vaccines?**
   Co-circulation of the SARS-CoV-2 virus and influenza viruses puts additional pressure on health systems. WHO recommends that influenza and COVID-19 vaccines be administered at the same time.
   For the administration of other vaccines, WHO continues to recommend a 14-day waiting period after receiving the COVID-19 vaccine.
COVID-19 VACCINES

1. **What is the definition of a “fully vaccinated” person?**
   The World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) considers a person to be “fully vaccinated” if they have received a series of primary vaccinations as defined in the vaccine-specific Emergency Use Listing (EUL), regardless of whether it is a two-dose schedule (for most WHO-approved vaccines) or a one-dose schedule (for the Janssen vaccine).
   For example, if the SAGE recommendation for a COVID-19 vaccine says the vaccine is to be administered in two doses, a person must receive two doses to be considered “fully vaccinated”. However, in some people, two doses are not enough to generate a sufficient immune response. Immunocompromised people and those 60 years of age or older who received two doses of the Sinovac or Sinopharm vaccine should be offered a third dose of vaccine to be considered “fully vaccinated”. For immunocompromised people, this additional dose should be given 1–3 months after the second dose. In people 60 years of age or older who received two doses of the Sinovac or Sinopharm vaccine, this additional dose should be given 4–6 months after the second dose.

   More information:

2. **Is it recommended to mix different brands of vaccines?**
   To complete a primary schedule, WHO recommends that a person receive two doses of the same vaccine. This is the safest and most efficient combination. If the supply of vaccines is limited, WHO suggests:
   - Countries administering inactivated vaccines (Sinovac, Sinopharm, Bharat) may consider administering a second dose of a vectored vaccine (AstraZeneca, Janssen) or an mRNA vaccine (Pfizer, Moderna).
   - Countries administering vectored vaccines (AstraZeneca, Janssen) may consider administering a second dose of an mRNA vaccine (Pfizer, Moderna).
   - Countries administering mRNA vaccines (Pfizer, Moderna) may consider administering a second dose of a vectored vaccine (AstraZeneca, Janssen).
   These recommendations are applicable to the primary vaccination series and booster doses.
   More information:

3. **Should people who already had COVID-19 be vaccinated?**
   Even those who have already had COVID-19 should get vaccinated when it is offered to them. This recommendation is valid for the primary series of vaccination, as well as for booster doses. WHO
does not recommend basing national vaccination policies on seroprevalence rates or individual pre-vaccination screening.

More information:

4. What is the WHO recommendation on vaccinating persons who are suspected of being infected with COVID-19?
Those with suspected COVID-19 symptoms should wait until they are out of isolation and fully recovered from their illness before being vaccinated.

More information:

5. Can a vaccinated person get sick?
All COVID-19 vaccines with EUL approval have high levels of efficacy, but none offer full protection. There will always be some people who do not develop protection as expected after COVID-19 vaccination. In addition to a vaccine’s specific characteristics, several factors—such as a person’s age, underlying health conditions, or previous exposure to SARS-CoV-2—may have an impact on a vaccine’s effectiveness. Remember that vaccination offers the maximum level of protection from 14 days after the administration of the last dose.

In the context of the Omicron variant of concern, current evidence consistently shows a reduction in protection against Omicron in individuals who have already received a series of primary vaccinations or in those who had a previous SARS-CoV-2 infection. In addition, the preliminary data suggest that the effectiveness of vaccines is significantly lower against infection and symptomatic disease by Omicron, compared to the Delta variant. The use of booster doses (homologous and heterologous) increases the efficacy of the vaccine.

However, we do not yet know how long immunity from different COVID-19 vaccines will last. That is one reason why it is essential to continue using all the public health measures that work, such as physical distancing, wearing masks, and handwashing.

More information:
https://healthalert.whofreebasics.org/sections/your-questions-answered/covid-19-vaccines-safety/?
https://www.who.int/publications/m/item/enhancing-readiness-for-omicron-(b.1.1.529)-technical-brief-and-priority-actions-for-member-states.

6. Why, if a country has reached high levels of vaccination coverage, are we still seeing high hospitalization and mortality rates?
At the beginning of the pandemic in March 2020, WHO, governments, and pharmaceutical manufacturers decided to design vaccines that could minimize the level of hospitalization and deaths, to reduce the overload of health services and save lives. To date, the design of these vaccines continues to protect people.

However, this design does not confer high protection against SARS-CoV-2 infection. That is why some vaccinated people can become infected with the virus and be asymptomatic or have very mild symptoms.
Since July 2021, the number of cases in some countries of the world has been fluctuating, but the number of deaths has remained consistently low. This phenomenon results from the effectiveness of COVID-19 vaccines in preventing deaths, although they are not highly effective in preventing infections. Infection can be avoided through public health and social measures, such as the correct use of masks, handwashing, and social distancing.

More information:

COVID-19 VACCINE IMMUNITY

1. Can someone still get COVID-19 after being vaccinated?
   Yes. The maximum level of protection from COVID-19 vaccines is not reached until 2 weeks after full vaccination. If vaccination is with a two-dose vaccine, this means that full immunity is not achieved until 2–4 weeks after the second dose. It is still possible to become infected and ill during this time.
   While COVID-19 vaccines are highly effective against serious illness, hospitalization and death, no vaccine is totally effective. As a result, some vaccinated people will get infected and may fall ill with COVID-19 in spite of having received a complete series of doses of the vaccine. With more infectious virus variants such as Delta and Omicron, more breakthrough infections and cases are being seen.
   Breakthrough infections can happen with every vaccine, and do not mean that the vaccine does not work. According to data from the US Centers for Disease Control Prevention (CDC), unvaccinated people are at a risk of death from COVID-19 that is 11 times higher than vaccinated people. People who get COVID-19 after being vaccinated are much more likely to experience only mild symptoms; efficacy against serious illness and death remains high. It is crucial for people to get vaccinated when it is their turn.
   Even once all doses of vaccine have been received, people must follow the same preventive measures to protect themselves. These include staying at least 1 meter away from others, wearing a well-fitted mask over nose and mouth when this is not possible, avoiding poorly ventilated places and settings, frequent handwashing, staying home if they feel unwell and getting tested if possible, and keeping informed about how much virus is circulating in the areas where they travel, live, and work.
   More information:

2. How long does immunization last with a primary vaccination series?
   For all COVID-19 vaccines with Emergency Use Listing (EUL) approval from the World Health Organization (WHO), exactly how long their protection lasts is still unknown. Current data indicate that most people are strongly protected against severe illness and death for at least 6 months.
   • Regarding the Delta variant of concern, all EUL-authorized COVID-19 vaccines maintain a high level of effectiveness in preventing severe illness, hospitalization, and death. Reduction in effectiveness over time is minimal. As to preventing infection and symptomatic disease, a moderate reduction in effectiveness over time has been reported for all COVID-19 vaccines.
• Regarding the Omicron variant of concern, preliminary data suggest that the effectiveness of COVID-19 vaccines in preventing hospitalization decreases over time. However, to date the studies available are few. More evidence is needed to measure the effectiveness of COVID-19 vaccines against the Omicron variant, and how long it lasts. Immunity may diminish faster in people who are older or who have underlying medical conditions, or who have a high level of exposure to the virus. For people to protect themselves it is crucial to get vaccinated and to continue practicing the other protective behaviors against COVID-19. More information:
  https://cdn.who.int/media/docs/default-source/immunization/sage/2022/january/evidence-review-on-booster-dose-data.pdf?sfvrsn=59a1ee2c_5.

3. What is WHO advice for what vaccinated people can safely do (such as gather in small groups without masks) compared to what non-vaccinated people should do?

Even after getting vaccinated, WHO recommends that people continue taking precautions to protect themselves, their family, and their friends. Vaccination protects people from serious illness and death from COVID-19. For the first 14 days after getting a vaccination, there is not a significant level of protection; it then increases gradually. With a single-dose vaccine, immunity is usually reached 2 weeks after vaccination. For two-dose vaccines, both doses are needed to achieve the highest level of immunity possible.

COVID-19 vaccines are highly effective, but a certain percentage of people will still get ill from COVID-19 after vaccination (this is known as a breakthrough infection). There is also still a chance that they could pass the virus on to others who are not vaccinated. Some people have not been vaccinated against COVID-19, cannot be administered the vaccine, or do not develop full immunity in response to COVID-19 vaccines because of having a weakened immune system. It is crucial for everyone to practice all the prevention behaviors to protect themselves and others. For these reasons, and while many of those in the community may not yet be vaccinated, maintaining other prevention measures is important, especially in communities where SARS CoV-2 circulation is significant. To protect themselves and others, and while efforts continue to curtail transmission of the virus and increase vaccination coverage, it is important for people to stay at least 1 meter away from others; wear a properly fitted mask over nose and mouth when this is not possible; avoid poorly ventilated places and settings; wash their hands frequently; stay home if they feel unwell and get tested; keep informed about how much virus is circulating in the areas where they travel, live, and work; and get vaccinated as soon as it is their turn. More information:

4. Does being vaccinated stop someone from infecting other people with COVID-19?

There is some evidence that being fully vaccinated can prevent infection with the COVID-19 virus. This means that being vaccinated is likely to help people protect others close to them by making it less likely that someone will pick up the virus and pass it on.

Even those who have received all their vaccine doses must follow the same prevention measures to protect other people: staying at least 1 meter away from others, wearing a well-fitted mask over nose and mouth, avoiding poorly ventilated places and settings, frequent handwashing,
staying home if feeling unwell and getting tested if possible, and keeping informed about how much virus is circulating in the areas where they travel, live, and work.

More information:

5. **Is immunity conferred by COVID-19 higher than the one conferred by the vaccine?**

There is not enough data to make a conclusive statement one way or another, but it can be said that COVID-19 vaccines have prevented disease as expected and are much safer than contracting the virus itself. Even people who did not have symptoms when they were infected can have ongoing health problems. Most infected people produce at least some antibodies and immune cells that can fight infection, but the magnitude of the immune response varies greatly. In people with mild disease, the immune protection that could prevent a second infection may disappear in a matter of months.

More information:

6. **If a person is vaccinated, can an antigen-based COVID-19 test return a positive result because of the vaccine?**

No, the COVID-19 vaccine will not cause a positive test result for a COVID-19 polymerase chain reaction (PCR) or antigen laboratory test. This is because these tests check for active disease and not whether an individual is immune. However, because the COVID-19 vaccine prompts an immune response, it may be possible to test positive on an antibody (serology) test that measures COVID-19 immunity in an individual.

More information:

7. **Is it better to get the vaccine now, or to wait for new vaccines designed to protect against variants of concern?**

It is important for everyone to get vaccinated as soon as possible when their turn comes, not to wait, and to get vaccinated with the first available vaccine, whatever it is, even if they have already had COVID-19. Approved COVID-19 vaccines provide a high degree of protection against getting seriously ill and dying from the disease, although no vaccine is completely protective.

More information:

**BOOSTER DOSES**

1. **What is the difference between additional doses and booster doses?**

The term “additional dose” refers to a dose that is necessary to complete the vaccination schedule, and that is the last dose in the primary series. This last dose is necessary in people whose immune system is weak and who did not benefit from the expected immunogenicity after the first two doses.
The term “booster dose” refers to doses of vaccine given after the primary series (one or two doses) that are necessary to increase immunity after the decrease in the initial immune response. More information:

2. What is the SAGE recommendation on additional doses?
The World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) does not recommend additional doses of COVID-19 vaccine in the general population. However, there are two population groups that may benefit from a three-dose primary vaccination series to support their immune system against COVID-19:

- Immunocompromised individuals may receive an additional dose of a COVID-19 vaccine, with an interval of 1–3 months between the second and third doses. Any EUL-authorized vaccine meets these requirements. Using the same product for all three doses is recommended.
- People 60 and older who received Sinopharm or Sinovac can receive a third dose of COVID-19 vaccine. Any vaccine with EUL approval can be given as a third dose. An interval of 3–6 months between the second and third doses is recommended.

More information:

3. If a person is vaccinated with the Janssen schedule (one dose), is it advisable to give them a booster dose?
A single dose of the Janssen vaccine is effective and facilitates rapidly increasing vaccine coverage, which in turn will reduce the burden on health care systems by preventing severe illness. A single dose may also be a preferred option for vaccinating hard-to-reach populations. As vaccine supplies or accessibility improve, countries should consider offering a second dose, starting with high-priority populations.

- WHO recommends a period between doses of 2–6 months.
- No major safety concerns have been identified regarding the use of the Janssen vaccine in heterologous schedules.

More information:

4. What does SAGE recommend regarding booster doses?
A booster dose is an additional dose given to people who have already completed a series of primary vaccinations but whose immune protection has fallen below an acceptable level. The booster dose enables the immune system to regain the level of protection against COVID-19 that it had lost over time. Booster doses should be offered based on the evidence showing that this improves protection against serious illness, hospitalization, and death. Moreover, by reducing the number of hospitalizations, booster doses help national health systems remain operational and not be overwhelmed.
WHO recommends that everyone receive the primary series of vaccines and a booster dose, starting with people at increased risk of illness and death from COVID-19 (i.e., health workers, people aged 60 and older, and immunocompromised people). The only group for which booster doses are not recommended is children under 12 years of age, as there is not enough information on the safety and effectiveness of boosters in this age group. People are recommended to follow national guidelines when deciding if and when to receive a booster dose. Recommendations may vary by age groups, by the interval between the primary series and the booster, and by previous COVID-19 vaccines received.

More information:
https://cdn.who.int/media/docs/default-source/immunization/sage/2022/january/evidence-review-on-booster-dose-data.pdf?sfvrsn=59a1ee2c_5.

5. How long does immune protection last with a primary series and a booster dose?
To date, there is little data available on the duration of effectiveness of COVID-19 vaccines once a booster dose is administered. Preliminary data suggest that:

• Faced with the Delta variant of concern, an increase in the effectiveness of all COVID-19 vaccines with Emergency Use Listing (EUL) approval has been found after the administration of a booster dose. After a 4-month follow-up, the reduction in effectiveness is minimal.
• As for the Omicron variant of concern, an increase in vaccine effectiveness has been observed after the administration of a booster dose. After a 3-month follow-up, there is evidence of a reduction in effectiveness.

More information:

6. How long should people who have been infected with COVID-19 wait to get a booster dose?
WHO has only published recommendations on the use of booster doses for the Pfizer vaccine. The third dose is recommended 4–6 months after the primary series. If a person develops COVID-19 between doses (primary series or booster dose), WHO recommends that they wait until the end of the acute phase of the disease to receive the next dose. Therefore, if a person receives two doses of the Pfizer vaccine, and then becomes infected with SARS-CoV-2, they can receive the booster dose immediately after recovering from the disease, as long as the interval of 4–6-months has elapsed. Alternatively, the person will need to wait for the end of this interval to receive the booster dose (just like everyone else).

More information:
VACCINATION IN POPULATION SUBGROUPS

1. **What are the priority groups according to the updated SAGE roadmap?**
   According to the updated roadmap of the World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE), these are the guidelines for priority use of COVID-19 vaccine doses (primary series and booster doses):
   - **Highest risk group**: health workers, older adults, and immunocompromised people.
   - **High-risk group**: adults with comorbidities, pregnant women, teachers and other essential workers, populations living in vulnerable situations and at high risk of COVID-19 infection and severe illness.
   - **Medium-risk group**: healthy adults, children and adolescents with comorbidities.
   - **Lowest risk group**: healthy children and adolescents.

2. **What is the recommendation for pregnant women? Should they be vaccinated against COVID-19?**
   Pregnant women are more vulnerable to respiratory infections (such as COVID-19) because their immune system is altered during pregnancy. If they become ill, they tend to develop more severe symptoms whose treatment may require longer hospitalization in intensive care units, a greater need for ventilatory assistance, and a higher chance of dying when compared to nonpregnant women of the same age and ethnicity.
   While there is less data available on the vaccination of pregnant women, evidence on the safety of COVID-19 vaccines during pregnancy has been growing, and no safety concerns have been identified. Especially in countries with high transmission, or if the woman’s job entails more risk of being exposed to COVID-19, the benefits of getting the vaccine outweigh potential risks. There is no risk of getting COVID-19 from the vaccine.
   WHO recommends that pregnant women receive all doses of COVID-19 vaccine as soon as possible to protect themselves. If national standards recommend a third dose of vaccine for pregnant women, it is advisable to administer it to them.
   More information:

3. **What is the recommendation for breastfeeding women? Should they be vaccinated against COVID-19?**
   Breastfeeding mothers should get vaccinated against COVID-19 as soon as it is their turn. None of the current COVID-19 vaccines have live virus in them. This means there is no risk of transmitting COVID-19 to babies through breast milk. In fact, the antibodies developed after vaccination may be transmitted through breast milk and help to protect the baby.
   More information:
4. **Can the COVID-19 vaccine be administered to immunocompromised people or people taking immunosuppressants?**

Immunocompromised people are at higher risk of severe COVID-19. Given that the vaccine is not a live virus, immunocompromised people who are part of a group recommended for vaccination may be vaccinated. Information and, where possible, counselling about vaccine safety and efficacy profiles in immunocompromised people should be provided to inform individual benefit-risk assessment.

In addition, multiple clinical trials and observational studies have shown that immunocompromised people often fail to generate an adequate response to a primary series of COVID-19 vaccine. While the number of studies available varies for different vaccines, this finding appears to be consistent across vaccine platforms and products. It is possible that the immune response to the vaccine may be reduced, which may alter its effectiveness.

Therefore, immunocompromised people are recommended to receive three doses of any COVID-19 with Emergency Use Listing (EUL) approval to be considered as “fully vaccinated”. The third dose should be given 1–3 months after the second dose.

More information:
- [https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials](https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials)

4. **Can the Pfizer vaccine be given to children younger than 5 years old?**

No vaccine with WHO approval is recommended for children under 5 years of age. To date, WHO and the Pan American Health Organization (PAHO) recommend that only the Pfizer vaccine be given to children between the ages of 5 and 11.

- The National Regulatory Authority (NRA) of each country has the power to authorize vaccines. However, it is important to note that the Pfizer vaccine approved for pediatric populations has a different formulation and dosage than the Pfizer vaccine licensed for adults.
- The Pfizer vaccine for use in children aged 5–11 includes the same mRNA and lipids, but different inactive ingredients compared to the vaccine for use in persons 12 years and older. The pediatric dose is 10 μg, whereas the adult dose is 30 μg. Moreover, it should be noted that in the reconstitution of the vaccine for use in children from 5–11 years old, a different volume of diluent to that of the formulation for adults is used.
- To date, no safety or efficacy data are available for use of the adult version of the vaccine in pediatric populations.

WHO recommends that countries consider using the Pfizer vaccine in children aged 5–17 years only when high vaccine coverage rates (primary series and booster) have been achieved in higher priority groups.

More information:
- [https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf](https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf)
- [https://www.cdc.gov/vaccines/covid-19/downloads/Pediatric-Planning-Guide.pdf](https://www.cdc.gov/vaccines/covid-19/downloads/Pediatric-Planning-Guide.pdf)
- [https://www.fda.gov/media/153717/download#:~:text=The%20vaccine%20includes%20the%20following,tromethamine%20hydrochloride%2C%20sucrose%2C%20and%20sodium.](https://www.fda.gov/media/153717/download#:~:text=The%20vaccine%20includes%20the%20following,tromethamine%20hydrochloride%2C%20sucrose%2C%20and%20sodium.)

5. **What is the WHO recommendation on the vaccination of children against COVID-19?**
Most children are at a low risk of serious disease. Vaccinating them would be primarily about reducing SARS-CoV-2 transmission, which can also be achieved through public health measures including staying at least 1 meter away from other people, wearing a properly fitted mask over the nose and mouth when appropriate for children, avoiding poorly ventilated places and settings, washing hands frequently, staying home if unwell and getting tested if possible, and keeping informed about how much virus is circulating in the areas where children travel, live, and go to school.

Hospitalizations and severe cases are more common among children with pre-existing conditions. However, due to the scale of ongoing SARS-CoV-2 transmission, the virus is infecting more people of all ages. And considering that vaccinated adults are well protected against serious illnesses, most hospitalizations are for unvaccinated people, including children who are not eligible to receive doses of the vaccine.

In January 2021, WHO approved the use of the Pfizer vaccine in people aged 5 years and older, with an adjustment in the recommended dose for children aged 5–11 years. The other vaccines that have received WHO Emergency Use Listing (EUL) are still authorized for people 18 years and older, except for the Moderna vaccine, which is approved for use in people 12 years and older.

Regarding children aged 5–17 years, WHO recommends that countries only offer vaccination (primary series and booster doses) to those with comorbidities, who are at highest risk of severe illness from COVID-19. WHO does not recommend that countries prioritize vaccination of children or adolescents without comorbidities, at least until the groups most at risk of infection and mortality have reached a high vaccination rate.

There is currently no evidence available regarding the use of booster doses in children 5–11 years of age.

More information:

COVID-19 VACCINE MANAGEMENT

1. Can doses of COVID-19 vaccine be used after their expiration date?
The World Health Organization (WHO) does not recommend the use of any type of vaccine (including COVID-19 vaccines) after its expiration date.
While the available scientific evidence does not report risks in terms of safety or effectiveness in the use of COVID-19 vaccines after their expiration date, the authorization for use after the expiration date should be specified for each vaccine and reviewed by the National Regulatory Agency of each country.

More information:

COVID-19 VACCINE DOCUMENTATION

1. Is there a WHO COVID-19 vaccination certificate?
At present, the World Health Organization (WHO) does not have an international certificate of vaccination or prophylaxis card for COVID-19 vaccines. WHO does not issue vaccination certificates to people immunized against COVID-19. The vaccination document issued by the health authorities of the country where a person was vaccinated is the only proof of COVID-19 vaccination currently available.

2. **What are WHO recommendations for governments regarding international travel?**

   International travelers must follow the national requirements of the countries to which they travel. Some countries are allowing fully vaccinated people to avoid quarantine and testing on arrival.

   However, even fully vaccinated travelers should maintain preventive measures, since no vaccine is completely effective, and following those measures helps people to protect themselves and others. These include keeping at least 1 meter away from others, wearing a well-fitting mask over nose and mouth, avoiding places and settings with poor ventilation, frequent handwashing, staying home if feeling unwell and getting tested if possible, and keeping informed about the amount of virus circulating in the areas where people live, work, and travel.

   WHO does not recommend that countries require proof of vaccination as the sole requirement for entering the country. This would not be fair, given that there are not enough vaccines for everyone, and that some countries have more access to vaccines than others.

   More information:

**THE PAHO REVOLVING FUND AND THE COVAX FACILITY**

1. **What is the PAHO Revolving Fund?**

   The Pan American Health Organization (PAHO) Revolving Fund for Access to Vaccines is a technical cooperation mechanism that supports PAHO Member States in planning their annual vaccine needs, consolidates forecasted vaccine demand, and leverages economies of scale to achieve lower prices and thus contribute to the sustainability of the National Immunization Programs. For more than 40 years, the Revolving Fund has facilitated access to high-quality life-saving vaccines and related products at the most affordable price for countries in the Region of the Americas. Currently, 42 Member States and 7 territories benefit from services offered by the Revolving Fund.

   More information:

2. **What is the COVAX Facility?**

   The COVID-19 Vaccine Global Access (COVAX) Facility is the vaccine pillar of the ACT Accelerator and the globally coordinated mechanism to provide equitable access, risk pooling, and affordable options for all participating countries. COVAX is co-led by Gavi, the Vaccine Alliance; the Coalition for Epidemic Preparedness Innovations (CEPI); and WHO. Gavi is the COVAX Facility administrator and, as such, is responsible for making investments across a broad portfolio of promising vaccine candidates and EUL-authorized vaccines being delivered to participating countries.

   More information:
   - [https://www.who.int/initiatives/act-accelerator/covax](https://www.who.int/initiatives/act-accelerator/covax)