

Interim recommendations for the use of the Janssen Ad26.COV2.S (COVID-19) vaccine

Interim guidance

First issued 17 March 2021

Updated 15 June 2021



Background

This interim guidance has been developed on the basis of the advice issued by the Strategic Advisory Group of Experts (SAGE) on Immunization at its extraordinary meeting on 15 March 2021 (1) and updated during its extraordinary meeting on 27 May 2021 (2).

Declarations of interests were collected from all external contributors and assessed for any conflicts of interest. Summaries of the reported interests can be found on the [SAGE meeting website](#) and [SAGE Working Group website](#).

The guidance is based on the evidence summarized in the background document on the Janssen Ad26.COV2.S (COVID-19) vaccine (3) and the background paper on COVID-19 disease and vaccines (4).

Annexes which include GRADE and evidence-to-recommendations (ETR) tables have also been updated to reflect the updated recommendations.

All referenced documents are available on the SAGE COVID-19 webpage: <https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials>.

These interim recommendations refer to the Ad26.COV2.S vaccine, manufactured by Janssen (Johnson and Johnson). The vaccine is also known as the Johnson & Johnson's/Janssen COVID-19 Vaccine. In the subsequent text the vaccine will be referred to as Ad26.COV2.S.

Methods

SAGE applies the principles of evidence-based medicine and has set in place a thorough methodological process for issuing and updating recommendations (5). A detailed description of the methodological processes as they apply to COVID-19 vaccines can be found in the SAGE evidence framework for COVID-19 vaccines (6). This framework contains guidance on considering data emerging from clinical trials in relation to the issuance of vaccine-specific evidence-based recommendations.

General goal and strategy for the use of the Janssen Ad26.COV2.S (COVID-19) vaccine

The COVID-19 pandemic has caused significant morbidity and mortality throughout the world, as well as major social, educational and economic disruptions. There is an urgent global need to develop effective and safe vaccines and to make them available at scale and equitably across all countries.

The Ad26.COV2.S vaccine against COVID-19 is a recombinant, replication-incompetent adenovirus serotype 26 (Ad26) vector encoding a full-length and stabilized SARS-CoV-2 spike protein. This vaccine does not contain adjuvants, preservatives, materials of animal origin, or fetal tissue. A single dose of Ad26.COV2.S has an efficacy of 66.9% (95% confidence interval (CI): 59.0,73.4) against symptomatic SARS-CoV-2 infection, 76.7% (95% CI: 54.6, 89.1) against severe COVID-19 disease after 14 days, and 85.4%

(95% CI: 54.2, 96.9) after day 28¹ (8). Vaccine efficacy against hospitalisations was 93.1% (95% CI: 72.7, 99.2) after 14 days and 100.0% (95% CI: 74.3, 100.0) after 28 days. There were no COVID-19 related deaths in the active groups versus six COVID-19 related deaths in the placebo group. Efficacy was maintained in Brazil and South Africa, where most COVID-19 cases were caused the P2 lineage and B.1.351 variant, respectively. Furthermore, vaccine efficacies were maintained across genders, age and ethnicities. At the time of analysis, the median follow-up was 58 days, with 55% of participants having had 2 months and more of follow-up. More detailed data on the efficacy and safety of this vaccine can be found in the background document on the Janssen Ad26.COV2.S (COVID-19) vaccine (3).

These data reviewed by WHO support the conclusion that the known and potential benefits of Ad26.COV2.S outweigh the known and potential risks. As sufficient vaccine supply will not be immediately available to immunize all who could benefit from it, countries are recommended to use the WHO Prioritization Roadmap (9) and the WHO Values Framework (10) as guidance for their prioritization of target groups. As long as vaccine supplies are very limited (stage I in the WHO Prioritization Roadmap), in settings with community transmission, the Roadmap recommends that priority be given initially to health workers and older people with and without comorbidities. As more vaccine becomes available, additional priority groups should be vaccinated as outlined in the WHO Prioritization Roadmap (9), taking into account national epidemiological data, vaccine-specific characteristics as outlined in product information approved by regulatory authorities, and other relevant considerations.

Intended use

Persons aged 18 years and above.

Administration

The recommended schedule is one dose (0.5 ml) given intramuscularly into the deltoid muscle.

Booster doses

Evidence currently supports the use of a single dose. The need for, and timing of, additional doses is currently being studied in clinical trials.

Co-administration with other vaccines

There should be a minimum interval of 14 days between administration of this vaccine and any other vaccine against other conditions. This recommendation may be amended as data on co-administration with other vaccines become available.

Contraindications

A history of anaphylaxis to any component of the vaccine is a contraindication to vaccination.

Precautions

No severe allergic reactions or anaphylaxis caused by Ad26.COV2.S have been recorded in the context of clinical trials. Very rare severe allergic reactions and one confirmed case of anaphylaxis have been recorded in a large open label study in South Africa, where 500 000 health care workers have been vaccinated with Ad26.COV2.S. As for all vaccines Ad26.COV2.S should be given under health care supervision, with the appropriate medical treatment available in case of allergic reactions. As for any other vaccine, an observation period of 15 min after vaccination should be ensured.

A very rare syndrome of blood clotting combined with low platelet counts has been reported about 3 to 15 days following vaccination with Ad26.COV2.S, described as Thrombosis with Thrombocytopenia Syndrome (TTS) (12). TTS typically involves thrombosis in unusual locations, including cerebral venous sinuses, portal vein, splenic vein and other rare venous and arterial thrombosis, but can also occur in more common locations, causing deep vein thrombosis and pulmonary embolism. A causal relationship between the vaccine and TTS is considered plausible although the biological mechanism for this syndrome is still being investigated. The clinical

¹ The case definitions used were developed by Janssen and differ slightly from WHO standard definitions of COVID-19 disease severity which can be found in: COVID-19 clinical management: living guidance, 25 January 2021. Geneva: World Health Organization; 2021 (<https://apps.who.int/iris/handle/10665/338882>).

course of TTS shares features with autoimmune heparin-induced thrombocytopenia and is frequently associated with positive testing for anti-platelet factor (PF) 4-antibodies. However, TTS after vaccination is independent of previous exposure to heparin. Most of the TTS cases following Ad26.COV2.S vaccination were reported from the United States (US), the country that was the first to introduce Ad26.COV2.S. As of 7 May 2021, 28 cases of TTS were reported out of 8 million doses of Ad26.COV2.S administered in the US. Cases of TTS have occurred with a median onset of symptoms of 9 days (range 3 to 15 days) after vaccination; most cases were in females ages 18 through 59 years; and three have been fatal. No cases occurred above the age of 60. The reporting rate among women 30-39 years of age is 12.4 cases per one million persons vaccinated; among women aged 40-49 years 9.4 cases per one million vaccinated. Specific risk factors for TTS following Ad26.COV2.S vaccination are still under investigation. An estimation of the risk outside the US needs further data collection and analysis.

In countries with ongoing SARS-CoV-2 transmission, the benefit of vaccination in protecting against COVID-19 far outweighs the risks. However, benefit-risk assessments for subgroups (e.g. younger vs. older individuals) may differ from country to country, and countries should consider their epidemiological situation, individual and population-level risks, availability of other vaccines, and alternate options for risk mitigation. The benefit risk ratio is greatest in older age groups as the risk of severe COVID-19 disease outcomes increases with age.

Early identification of TTS is important in order to initiate appropriate treatment. Patients who are diagnosed with thrombocytopenia (low blood platelets) within 30 days of vaccination should be actively investigated for signs of thrombosis (formation of blood clots in the vessels) (13); and patients who present with thrombosis within 30 days of vaccination should be evaluated for thrombocytopenia. Clinicians should also be aware that although heparin is used to treat blood clots in general, administration of heparin in TTS may exacerbate the syndrome due to the presence of PF4 antibodies, and alternative treatments such as immunoglobulins and non-heparin anticoagulants should be considered.

Vaccination of specific populations

Populations for which supportive data are available from immunogenicity and clinical trials

Older people

The risk of severe COVID-19 and death increases steeply with age. Data from the phase 3 trial indicate that the efficacy and safety of the vaccine are comparable across all age groups (above the age of 18). Vaccination is recommended for older persons.

Persons with comorbidities

Certain comorbidities have been identified as increasing the risk of severe COVID-19 disease and death. The phase 3 clinical trial demonstrated that the vaccine has similar safety and efficacy profiles in persons with various underlying medical conditions, including those that place them at increased risk for severe COVID-19. The comorbidities studied in the phase 3 clinical trial included hypertension, chronic lung disease, significant cardiac disease, obesity, diabetes, and human immunodeficiency virus (HIV) infection. Vaccination is recommended for persons with such comorbidities that have been identified as increasing the risk of severe COVID-19.

Populations for which limited or no data exist from the clinical trials

Children and adolescents below the age of 18 years

For most children and adolescents the disease profile is less severe. There are currently no efficacy or safety data for children or adolescents below the age of 18 years. Until such data are available, vaccination of individuals below 18 years of age is not routinely recommended.

Pregnant women

Evidence suggests that pregnant women with COVID-19 are at higher risk of developing severe disease compared to non-pregnant women of reproductive age. COVID-19 in pregnancy has also been associated with an increased risk of preterm birth and of neonates requiring neonatal intensive care. Pregnant women who are older (age 35 years and above), or have high body mass index, or have an existing comorbidity such as diabetes or hypertension are at particular risk of serious outcomes from COVID-19.

Completed developmental and reproductive toxicology (DART) studies in animals have not shown harmful effects of the vaccine in pregnancy. Ad26.COV2.S is a replication-defective vaccine. While available data on Ad26.COV2.S vaccination of pregnant women are insufficient to assess vaccine efficacy or vaccine-associated risks in pregnancy, studies in pregnant women are planned in the coming months. Based on previous experience with other vaccine use during pregnancy, the effectiveness of Ad26.COV2.S in pregnant women is expected to be comparable to that observed for non-pregnant women in similar age groups. Of note, compared to non-pregnant women, pregnancy is associated with higher rates of thrombosis, thrombocytopenia, and haemorrhage; however, it is currently not known whether pregnancy is associated with a higher risk of TTS. As data become available, recommendations on vaccination will be updated accordingly.

In the interim, WHO recommends the use of Ad26.COV2.S in pregnant women only if the benefits of vaccination to the pregnant woman outweigh the potential risks. To help pregnant women make this assessment, they should be provided with information about the risks of COVID-19 in pregnancy (including, for example, that some pregnant women are at increased risk of infection or have co-morbidities that add to their risk of severe disease), the likely benefits of vaccination in the local epidemiologic context, and the current limitations of the 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.

Lactating women

Breastfeeding offers substantial health benefits to lactating women and their breastfed children. Vaccine effectiveness is expected to be similar in lactating women as in other adults. Data are not available on the potential benefits or risks of the vaccine to breastfed children. However, as Ad26.COV2.S is not a live virus vaccine, it is biologically and clinically unlikely to pose a risk to the breastfeeding child. On the basis of these considerations, WHO recommends the use of Ad26.COV2.S in lactating women as in other adults. WHO does not recommend discontinuing breastfeeding because of vaccination.

Persons living with HIV

Persons living with human immunodeficiency virus (HIV) may be at higher risk of severe COVID-19. Persons with well-controlled HIV were included in the trials and no safety concern was observed. Data on administration of the vaccine are currently insufficient to allow assessment of vaccine efficacy for persons living with HIV. It is possible that the immune response to the vaccine may be reduced, which may lower its clinical effectiveness. In the interim, given that the vaccine is nonreplicating, persons living with HIV who are part of a group recommended for vaccination may be vaccinated. Information and, where possible, counselling should be provided to inform individual benefit–risk assessment. It is not necessary to test for HIV infection prior to vaccine administration.

Immunocompromised persons

Immunocompromised persons are at higher risk of severe COVID-19. Available data are currently insufficient to assess vaccine efficacy or vaccine-associated risks in severely immunocompromised persons, including those receiving immunosuppressant therapy. It is possible that the immune response to the vaccine may be reduced, which may lower its clinical effectiveness. In the interim, given that the vaccine is nonreplicating, immunocompromised persons 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 persons should be provided to inform individual benefit–risk assessment.

Persons who have previously had SARS-CoV-2 infection

Vaccination should be offered regardless of a person's history of symptomatic or asymptomatic SARS-CoV-2 infection. Viral or serological testing for prior infection is not recommended for the purpose of decision-making about vaccination. Data from the pooled analyses indicate that Ad26.COV2.S is safe in people with evidence of prior SARS-CoV-2 infection. Within 6 months after an initial natural infection, available data show that symptomatic reinfection is uncommon. Given limited vaccine supply, persons with PCR-confirmed SARS-CoV-2 infection in the preceding 6 months may therefore delay vaccination until near the end of this period. However, emerging data indicate that symptomatic reinfection may occur in settings where variants with evidence of

markedly reduced neutralization activity are circulating. In these settings earlier immunisation after infection may be advisable. When more data on duration of immunity after natural infection become available, the length of this time period may be revised.

Persons with current acute COVID-19

Persons with acute PCR-confirmed COVID-19 should not be vaccinated until after they have recovered from acute illness and the criteria for discontinuation of isolation have been met. The optimal interval between a natural infection and vaccination is not yet known.

Persons who previously received passive antibody therapy for COVID-19

Currently there are no data on the safety or efficacy of vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Hence, as a precautionary measure, vaccination should be deferred for at least 90 days to avoid interference of the antibody treatment with vaccine-induced immune responses.

Special settings

Persons in settings such as refugee and detention camps, prisons, slums, and other settings with high population densities, where physical distancing is not implementable, should be prioritized for vaccination as outlined in the WHO Prioritization Roadmap (4), taking into account national epidemiological data, vaccine supply and other relevant considerations.

As noted in the WHO Prioritization Roadmap, national programmes should give special consideration to groups that are disproportionately affected by COVID-19 or that face health inequities as a result of social or structural inequities. Such groups should be identified, barriers to vaccination should be addressed, and programmes should be developed to allow equitable access to vaccines.

In the current period of very limited vaccine supply, preferential vaccination of international travellers would counter the principle of equity. WHO currently recommends that travellers should only be vaccinated if they are part of a high-risk group or in epidemiological settings identified in the WHO Prioritization Roadmap (9). As vaccine supply increases, these recommendations will be revisited.

Other considerations

SARS-CoV-2 variants

SARS-CoV-2 viruses undergo evolution. Some new virus variants may be associated with higher transmissibility, disease severity, risk of reinfection, or a change in antigenic composition resulting in lower vaccine effectiveness.

In the US, where newly emerging variants of concern were not predominant at the time of the vaccine trial, vaccine efficacy for moderate to severe/critical COVID-19 was 72.0% (58.2, 81.7), and efficacy for severe/critical COVID-19 was 85.9% (-9.4, 99.7) (8). In South Africa, despite the fact that the 20H/501Y.V2 variant (B.1.351 lineage) was the predominant strain, similar efficacies were observed as in the US: efficacy for moderate to severe/critical COVID-19 was 64.0% (95% CI: 41.2, 78.7) and efficacy for severe/critical COVID-19 was 81.7% (95% CI: 46.2, 95.4). In Brazil, where a variant from the P.2 lineage was the predominant strain, vaccine efficacy for moderate to severe/critical COVID-19 was 68.1% (95% CI: 7.8, 99.7) and for severe/critical COVID-19 87.6% (95% CI: 48.8, 80.7). There are no data as yet with regards to the newly emerged B.1.617.

WHO currently recommends the use of Ad26.COV2.S according to the Prioritization Roadmap (9) even if variants are present in a country. Countries should conduct a benefit-risk assessment according to the local epidemiological situation including the extent of circulating virus variants. There is an urgent need for a coordinated approach for surveillance and evaluation of variants and their potential impact on vaccine effectiveness. WHO will continue to monitor the situation; as new data become available, recommendations will be updated accordingly.

SARS-CoV-2 tests

Prior receipt of the vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests for diagnosis of acute/current SARS-CoV-2 infection. However, it is important to note that currently available antibody tests for SARS-CoV-2 assess

levels of IgM and/or IgG to the spike or the nucleocapsid protein. The vaccine contains the spike protein; thus, a positive test for spike protein IgM or IgG could indicate either prior infection or prior vaccination. To evaluate for evidence of prior infection in an individual who has received the Ad26.COV2.S, a test that specifically evaluates IgM or IgG to the nucleocapsid protein should be used. A positive nucleocapsid protein-based assay indicates prior infection, while a negative nucleocapsid protein-based assay is expected after vaccination (unless a natural infection has occurred). Antibody testing is not currently recommended to assess immunity to COVID-19 following Ad26.COV2.S.

Role of vaccines among other preventive measures

As there is not yet sufficient evidence of an effect of the vaccine on transmission, nonpharmaceutical interventions must continue, including use of face masks, physical distancing, handwashing and other measures as appropriate in particular settings, depending on the COVID-19 epidemiology, vaccine coverage rates and potential risks of emerging variants. Government advice on nonpharmaceutical interventions should continue to be followed by vaccinated individuals, as well as those who have not yet been vaccinated. This advice will be updated as information on the impact of vaccination on virus transmission and indirect protection in the community is assessed.

Community engagement, effective communication, and legitimacy

Community engagement and effective communication (including risk communication) are essential to the success of COVID-19 vaccination programmes. Prioritization decisions should be made through transparent processes that are based on shared values, the best available scientific evidence, and appropriate representation and input by affected parties. Furthermore, communication about the mechanism of action of vector-based vaccines, and efficacy and safety data derived from clinical trials and post-marketing studies, as well as background mortality, maternal and neonatal outcomes and rates of adverse events of special interest (AESI) in groups prioritized for vaccination, needs to be strengthened. Strategies should include: (i) culturally acceptable and linguistically accessible communications regarding COVID-19 vaccination made freely available; (ii) active community engagement and involvement of community opinion leaders and trusted voices to improve awareness and understanding of such communications; and (iii) inclusion of diverse and affected stakeholder opinions in decision-making. Such efforts are especially important in subpopulations who may be unfamiliar with or distrustful of health care systems and immunization.

Vaccination logistics

The vaccine is provided to countries at -20°C with a shelf life of 24 months in a multi-dose vial containing 5 doses (0.5ml each). The vaccine can be stored at 2°C to 8°C for 3 months within the 24 months of shelf life. Once thawed the vaccine should not be re-frozen. The vials should be protected from light. After the first dose has been withdrawn, the vial should be held between at 2°C to 8°C for not longer than 6 hours in compliance with the WHO Multidose open vial policy.

Any remaining doses in an opened vial must be discarded after 6 hours or at the end of the immunization session, whichever comes first.

When scheduling vaccination for occupational groups, e.g., health workers, consideration should be given to the reactogenicity profile of Ad26.COV2.S observed in clinical trials, which may occasionally necessitate time off work in the 24–48 hours following vaccination.

In considering the programme implications of implementing these recommendations, particular attention should be given to equity, including the feasibility, acceptability, and effectiveness of the programme in resource-constrained settings.

Recommendations on addressing current knowledge gaps through further research

WHO recommends the following post-authorization monitoring activities and research.

- Safety surveillance and monitoring:
 - serious adverse events such as myocarditis, thrombosis with thrombocytopenia syndrome (TTS), anaphylaxis and other serious allergic reactions
 - cases of multisystem inflammatory syndrome following vaccination, cases of COVID-19 following vaccination that result in hospitalization or death;
 - background rates of AESIs (including thromboembolic events, cerebral venous sinus thrombosis, and thrombosis with thrombocytopenia syndrome), maternal and neonatal outcomes, and mortality in groups prioritized for vaccination.
 - Incidence of TTS by WHO region, age and sex
- Vaccine effectiveness:
 - vaccine effectiveness in relation to new virus variants;
 - vaccine effectiveness over time and whether protection can be prolonged by booster doses;
 - booster studies with a second dose, heterologous or variant-adjusted vaccines;
 - studies to investigate whether this vaccine reduces SARS-CoV-2 transmission and viral shedding;
 - assessment and reporting of breakthrough infections and virus sequence information; head-to-head studies with other vaccines on extent and duration of immunity using standardized neutralization, T-cell and mucosal immunity assays;
 - vaccine effectiveness against Post-COVID-19 conditions
- Subpopulations:
 - prospective studies on the safety this vaccine in pregnant and lactating women;
 - immunogenicity and safety of vaccination in persons below the age of 18 years;
 - safety data on vaccination in immunocompromised persons, including persons living with HIV and persons with autoimmune disease.
- Vaccination logistics
 - immunogenicity and safety studies of co-administration with other vaccines, including influenza and pneumococcal vaccines, to adults and older persons;
 - interchangeability and “mix and match” studies for boosters within and across COVID-19 vaccine platforms;
- Virus variants
 - global surveillance of virus evolution and the impact of virus variants on vaccine effectiveness to support update of vaccines;
 - Modelling to determine the trade-offs for the use of vaccines with reduced effectiveness against emergent variants;
 - Booster studies with updated vaccine formulations.

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Table of updates

Section	Rationale for update
Precautions	Post-introduction safety surveillance showed that a very rare syndrome of blood clotting combined with low platelet counts (thrombosis with thrombocytopenia syndrome) has emerged. The section under Precautions was therefore updated to reflect this safety signal.
Pregnancy	Compared to non-pregnant women, pregnancy is associated with higher rates of thrombosis, thrombocytopenia, and haemorrhage; however, it is currently not known whether pregnancy is associated with a higher risk of TTS. As data become available, recommendations on vaccination will be updated accordingly. In the interim, WHO recommends the use of Ad26.COV2.S in pregnant women only if the benefits of vaccination to the pregnant woman outweigh the potential risks.

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WHO continues to monitor the situation closely for any changes that may affect this interim guidance. Should any factors change, WHO will issue a further update. Otherwise, this interim guidance document will expire 2 years after the date of publication.

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