Interim recommendations for use of the Moderna mRNA-1273 vaccine against COVID-19

Interim guidance

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World Health Organization

Background

This interim guidance has been developed on the basis of the advice issued by the Strategic Advisory Group of Experts on Immunization (SAGE) at its extraordinary meeting on 21 January 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 summarised in the Background document on the Moderna mRNA-1273 vaccine against COVID-19 (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 mRNA-1273 vaccine, manufactured by Moderna. The vaccine is also known as COVID-19 Vaccine Moderna. In the subsequent text the vaccine will be referred to as mRNA-1273.

On 30 April 2021, mRNA-1273 was granted WHO's Emergency Use Listing (EUL).

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.

Goal and strategy for the use of the Moderna mRNA-1273 vaccine against COVID-19

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 for effective and safe vaccines and to make them available at scale and equitably across all countries.

The mRNA-1273 has been shown to have an efficacy of 94.1%, based on a median follow-up of two months. High efficacy was maintained across all age groups (above 18 years), and was not affected by sex or ethnicity. The data reviewed by WHO at this time support the conclusion that the known and potential benefits of mRNA-1273 outweigh the known and potential risks. Trials in age groups below the age of 18 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 (7) and the WHO Values Framework (8) as guidance for their prioritization of target groups. When 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 at high risk 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 (7), taking into account national epidemiological data and other relevant considerations.

Intended use

Persons aged 18 years and above.

Administration

The recommended schedule is two doses (100 µg, 0.5 ml each) given intramuscularly into the deltoid muscle. An interval of 28 days between doses is recommended. If the second dose is inadvertently administered less than 28 days after the first, the dose does not need to be repeated. If administration of the second dose is inadvertently delayed it should be given as soon as possible thereafter, according to the manufacturer's instructions. It is currently recommended that individuals receive no more than two doses in total.

Considerations for deferring the second dose in settings with limited vaccine supply

WHO acknowledges that a number of countries face exceptional circumstances of vaccine supply constraints combined with a high disease burden. Some countries have therefore considered delaying the administration of the second dose to allow for a higher initial coverage. This is based on the observation that efficacy has been shown to be 91.9%, starting 14 days after the first dose, with a median follow-up time of 28 days. There appears to be protection against COVID-19 disease following one dose; however, there is insufficient information about longer-term protection beyond 28 days after a single dose, as most trial participants received two doses. Neutralizing antibody responses were modest after the first dose and increased substantially after the second dose.

Some countries have chosen an inter-dose interval of mRNA vaccines for up to 12 weeks. Based on post-introduction vaccine effectiveness studies from these countries to date, persistence of post dose 1 effectiveness up to 10 weeks has been observed.

Countries should take into account the following factors when considering deferral of the second dose beyond 3 to 6 weeks after the first dose: During an initial period of limited vaccine supply, prioritizing distribution of first doses of vaccine to as many highly vulnerable individuals as possible will avert more deaths than covering fewer such people with two doses - so long as the effectiveness of a single dose against COVID-19 mortality is at least half that of two

doses and does not wane below this level before receipt of the second dose. The optimal interval before offering second doses depends not only on vaccine effectiveness and waning but also on population vaccine coverage, supply projections, pre-existing naturally acquired immunity and country-specific vaccine prioritization plans (9-12). Furthermore, for settings with substantial circulation of variants of concern which have been shown to have reduced single doses effectiveness, the importance of providing the most vulnerable groups with 2 doses must be considered.

In conclusion, for countries that have not yet achieved high vaccine coverage rates in the high-priority groups who are experiencing a high incidence of COVID-19 cases combined with vaccine supply constraints, WHO recommends that such countries should focus on achieving a high first dose coverage in the high priority groups by extending the inter-dose interval up to 12 weeks.

Booster doses

There is currently no evidence on the need for a booster dose or booster doses of the vaccine after the current two-dose vaccine series is complete. Antibody persistence for up to 6 months after dose 2 has been documented (13). The need for and timing of homologous or adapted booster doses will be evaluated as further data accumulate.

Interchangeability with other vaccines

Heterologous (mix-and-match) studies are ongoing with regards to the interchangeability of this vaccine with other COVID-19 vaccine platforms. It is currently recommended that the same product should be used for both doses. If different COVID-19 vaccine products are administered in the two doses, no additional doses of either vaccine are recommended at this time. Recommendations may be updated as further information becomes available on interchangeability.

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, until 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. If anaphylaxis occurs after the first dose, a second dose of the vaccine should not be administered.

Precautions

A history of anaphylaxis to any other vaccine or injectable therapy (i.e. intramuscular, intravenous, or subcutaneous vaccines or therapies) is considered as a precaution but not a contraindication to vaccination. For such persons, a risk assessment should be conducted by a health professional with specialist expertise in allergic disorders. Such individuals may still receive vaccination. It remains uncertain if there is an increased risk of anaphylaxis, but they should be counselled about the potential risk of anaphylaxis and the risks should be weighed against the benefits of vaccination. Such persons should be observed for 30 minutes after vaccination in health care settings where anaphylaxis can be immediately treated.

In general, persons with an immediate non-anaphylactic allergic reaction to the first dose should not receive additional doses, unless recommended after review by a health professional with specialist expertise. For the purposes of this guidance, an immediate non-anaphylactic allergic reaction is defined as any signs or symptoms, such as urticaria, angioedema or respiratory symptoms without any other symptoms (cough, wheezing, stridor), that occur within 4 hours of administration. However, subject to individual risk–benefit assessment, mRNA-1273 could be provided under close medical supervision if it is the only available option for persons at high risk of severe COVID-19.

As a small number of anaphylactic reactions have also been reported in vaccinees without a history of anaphylaxis, WHO recommends that mRNA-1273 should be administered only in settings where anaphylaxis can be treated. Until more data and insights are available with regard to anaphylaxis after mRNA-1273 vaccination, all vaccinees should be observed for at least 15 minutes after vaccination.

Food, insect venom and contact allergies and allergic rhinitis, eczema and asthma are not considered a precaution. The vial stoppers are not made with natural rubber latex, and there is no contraindication or precaution to vaccination for persons with a latex allergy. In addition, as mRNA-1273 does not contain eggs or gelatine, there is no contraindication or precaution to vaccination for persons with allergies to any food substances.

A possible causal association with very rare cases of myocarditis in young men is currently being investigated.

Anyone with an acute febrile illness (body temperature over 38.5 ºC) should postpone vaccination until they are afebrile.

Vaccination of specific populations

Populations for which supportive data are available from phase 2/3 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 without an upper age limit. Post introduction vaccine effectiveness studies have shown high effectiveness and good safety profiles in this age group. Vaccination is recommended for older persons without an upper age limit.

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 in the phase 3 clinical trial included chronic lung disease, significant cardiac disease, severe obesity, diabetes, liver disease 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 in line with the WHO Prioritization Roadmap.

Populations for which limited or no data exist from the phase 3 clinical trial

Children and adolescents below the age of 18 years

Studies are underway to assess the immunogenicity and safety of mRNA-1273 in children and adolescents. At present, individuals below 18 years of age should not be routinely vaccinated with this vaccine.

Pregnant women

Evidence suggests that pregnant women (2nd and 3rd trimester) 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. Clinical trial data on safety and immunogenicity in pregnancy are not currently available. Post-introduction vaccine pharmacovigilance data thus far have not identified any acute safety problems, with a reactogenicity and adverse events profile similar to that reported in the absence of pregnancy. Based on previous experience with other vaccine use during pregnancy, the effectiveness of the mRNA-1273 in pregnant women is expected to be comparable to that observed for non-pregnant women in similar age groups. Data from small studies have demonstrated that COVID-19 mRNA vaccines are immunogenic in pregnant women and that vaccine-elicited antibodies are transported to infant cord blood and breast milk, suggesting possible neonatal as well as maternal protection (14, 15). As data from additional studies become available, recommendations will be updated accordingly.

In the interim, WHO recommends the use of mRNA-1273 in pregnant women when 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, the likely benefits of vaccination, and the current limitations of safety data. 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 mRNA-1273 is not a live virus vaccine and the mRNA does not enter the nucleus of the cell and is degraded quickly, 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 mRNA-1273 in lactating women as in other adults. WHO does not recommend discontinuing breastfeeding because of vaccination.

Persons living with HIV

Persons living with HIV may be at higher risk of severe COVID-19. Among the phase 3 clinical trial participants with well controlled HIV, there were no reported differences in safety signals. HIV-positive persons who are well controlled on highly active antiretroviral therapy and are part of a group recommended for vaccination can be vaccinated. Available data on administration of the vaccine are currently insufficient to allow assessment of vaccine efficacy or safety for persons living with HIV who are not well controlled on therapy. It is possible that the immune response to the vaccine may be reduced, which may alter its effectiveness. In the interim, given that the vaccine is not a live virus, persons living with HIV 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. 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. It is possible that the immune response to the vaccine may be reduced, which may alter its effectiveness. In the interim, given that the vaccine is not a live virus, 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 the vaccine 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 choose to delay vaccination until near the end of this 6-month period. However, emerging data indicate that symptomatic reinfection may occur in settings where variants of concern are circulating that are associated with markedly reduced vaccine effectiveness (for example Beta (B1.351)). In these settings earlier immunization after infection is advisable eg within 90 days. 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, including persons who are in-between doses, should not be vaccinated until after they have recovered from acute illness and the criteria for discontinuation of isolation have been met. The optimal minimum 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 (7), 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 enable equitable access to vaccines.

Other considerations

SARS-CoV-2 variants

SARS-CoV-2 viruses undergo evolution. Variants of concern may have higher transmissibility, disease severity, risk of reinfection, or a change in antigenic composition resulting in lower vaccine effectiveness. Preliminary data show some reduction in neutralization activity of mRNA-1273 against the Beta (B.1.351) variant, and less marked reduction against the other variants of concern (Gamma (P1), Alpha (B.1.1.7) and Epsilon (B.1.429) (16). The impact of variants of concern on vaccine effectiveness remains unknown to date, especially for the recently emerged Delta (B.1.617.2) variant.

These preliminary findings highlight the 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 mRNA that encodes 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 mRNA-1273, a test that specifically evaluates IgM or IgG to the nucleocapsid protein should be used. A positive nucleocapsid protein-based assay indicates prior infection. Antibody testing is not currently recommended to assess immunity to COVID-19 following mRNA-1273 vaccination.

Role of vaccines among other preventive measures

As there is not yet sufficient evidence of the extent of vaccine impact on transmission, non-pharmaceutical interventions must continue, including use of face masks, physical distancing, handwashing and other measures based on the epidemiology of SARS-CoV-2 and vaccine coverage rates. Government advice on non-pharmaceutical 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.

Countries' strategies related to COVID-19 control should be designed to facilitate children's participation in education and other aspects of social life (17).

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 mRNA vaccines, and efficacy and safety data derived from clinical trials and post-marketing studies, 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 mRNA-1273 is provided as a frozen suspension at –25 ºC to –15 ºC in a multidose vial containing 10 doses. The vaccine must be thawed prior to administration. After thawing, 10 doses (0.5 ml each) can be withdrawn from each vial. Vials can be stored refrigerated at 2–8 °C for up to 31 days prior to withdrawal of the first dose. After the first dose has been withdrawn, the vial should be held between 2 ºC and 25 °C and discarded after 6 hours.

When assessing the feasibility of deploying mRNA-1273, immunization programmes should consider the cold-chain requirements. Conditions must be met to avoid exposure of vials to sunlight and ultraviolet light.

Appropriate medical treatment to manage anaphylaxis must be immediately available for vaccinees. Hence, this vaccine should only be administered in settings with the necessary resources and trained health workers, and that allow for at least 15 minutes of post-vaccination observation.

When scheduling vaccination for occupational groups, e.g. health workers, consideration should be given to the reactogenicity profile of mRNA-1273 observed in clinical trials, occasionally leading to 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 (for example, how to ensure cold-chain storage and the need to be able to provide treatment for anaphylaxis).

Recommendations on addressing current knowledge gaps through further surveillance and research

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

- Safety surveillance and monitoring:
  - serious adverse events including myocarditis (18), thromboembolic events, thrombosis with thrombocytopenia syndrome (TTS), anaphylaxis and other serious allergic reactions, Bell`s palsy, and transverse myelitis
  - cases of multisystem inflammatory syndrome following vaccination, cases of COVID-19 following vaccination that result in hospitalization or death;
  - background rates of AESIs (including myocarditis, thromboembolic events and TTS), maternal and neonatal outcomes, and mortality in groups prioritized for vaccination.
- Vaccine effectiveness:
  - vaccine effectiveness in relation to time interval between the first and second dose;
  - vaccine effectiveness in relation to new virus variants;
  - vaccine effectiveness over time and whether protection can be prolonged by booster doses;
  - booster studies with heterologous 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 in pregnant and lactating women;
  - 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;
  - safety, immunogenicity, and impact of a delayed second dose, as currently implemented by certain countries;
  - interchangeability and “mix and match” studies within and across COVID-19 vaccine platforms;
  - stability of vaccine under alternative cold-chain distribution and storage conditions.
- 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.

Table of updates

Section	Rationale for update
Considerations for deferring the second dose in settings with limited vaccine supply	Post-introduction vaccine effectiveness studies in countries that have implemented an inter-dose interval longer than per emergency use authorization (up to 12 weeks) have shown a high public health impact. This observation combined with additional immunological data support that countries facing a high incidence of COVID-19 combined with severe vaccine supply constraints could consider delaying the second dose up to 12 weeks in order to achieve a higher first dose coverage in high priority populations.
Pregnant and lactating women	Text was updated and harmonized with the Recommendations for the Pfizer mRNA vaccine.
Role of vaccines among other preventive measures	The following statement was added: "Countries' strategies related to COVID-19 control should be designed to facilitate children's participation in education and other aspects of social life.".
SARS-CoV-2 variants	This section has been added to reflect the latest data with regards to the circulation of variants of concern and evidence on the impact on effectiveness of the vaccine.

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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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