Moderna COVID-19 Vaccine Frequently Asked Questions

On December 18, 2020, the U.S. Food and Drug Administration issued an emergency use authorization (EUA (/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization)) for the second vaccine for the prevention of coronavirus disease 2019 (COVID-19 (/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19)) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The emergency use authorization allows Moderna COVID-19 Vaccine (/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine) to be distributed in the U.S for use in individuals 18 years of age and older.

Q: What data did the FDA review when deciding to authorize Moderna COVID-19 Vaccine for emergency use?

A: Moderna COVID-19 Vaccine is authorized to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older.

The FDA evaluated and analyzed (/media/144673/download) the safety and effectiveness data from clinical trials conducted in tens of thousands of study participants and manufacturing information submitted by ModernaTX, Inc. The FDA has determined that the totality of the available data provides clear evidence that Moderna COVID-19 Vaccine may be effective in preventing COVID-19. The data also show that that the known and potential benefits outweigh the known and potential risks of the vaccine's use in millions of people 18 years of age and older, including healthy individuals.

Q: How well does Moderna COVID-19 Vaccine prevent COVID-19?

A: The data to support the EUA include an analysis (/media/144673/download) of 28,207 participants in the ongoing randomized, placebo-controlled U.S. study who did not have evidence of SARS-CoV-2 infection prior to the first dose of vaccine. Among these participants, 14,134 received the vaccine and 14,073 received placebo. The vaccine was 94.1% effective in preventing COVID-19 disease among these clinical trial participants with 11 cases of COVID-19 in the vaccine group and 185 cases in the placebo group. At the time of the analysis of these 196 COVID-19 cases, 0 in the vaccine group and 30 in the placebo

group were classified as severe. One severe case in the vaccine group was identified after the analysis (and not included among the 196 cases) and was awaiting confirmation at the time the FDA review was conducted.

Q: Did clinical trial participation include members of racial or ethnic groups at greater risk from COVID-19?

A: Yes. Overall, 20.5% of participants identified themselves as Hispanic or Latino, 10.2% as African American or Black, 4.6% as Asian, 0.8% as American Indian or Alaska Native, 0.2% as Native Hawaiian or other Pacific Islander, 2.1% identified their race as other, and 2.1% as multiracial. The demographic characteristics were similar among participants who received Moderna COVID-19 Vaccine and those who received placebo.

Q: Can pregnant or breastfeeding women receive Moderna COVID-19 Vaccine?

A: While there have been no specific studies in these groups, there is no contraindication to receipt of the vaccine for pregnant or breastfeeding women. Pregnant or breastfeeding women should discuss their options with their healthcare providers.

Q: What safety information did FDA evaluate to authorize Moderna COVID-19 Vaccine for emergency use?

A: The available safety data (/media/144673/download) to support the EUA include an analysis of 30,351 participants enrolled in an ongoing randomized, placebo-controlled study conducted in the U.S. These participants, 15,185 of whom received the vaccine and 15,166 of whom received saline placebo, were followed for a median of more than two months after receiving the second dose.

The most commonly reported side effects were pain at the injection site, tiredness, headache, muscle pain, chills, joint pain, nausea and vomiting, swollen lymph nodes in the same arm of the injection and fever. Side effects typically started within two days of vaccination and resolved two or three days later.

Of note, more people experienced these side effects after the second dose than after the first dose, so it is important for vaccination providers and recipients to expect that there may be some side effects after either dose, but even more so after the second dose.

Q: Is information available about allergic reactions?

A: An FDA analysis of the safety database for hypersensitivity-related adverse events demonstrated a numerical imbalance across study groups, with 1.5% of vaccine recipients and 1.1% of placebo recipients reporting this type of event. There were no anaphylactic or severe hypersensitivity reactions reported following vaccination with Moderna COVID-19 Vaccine.

However, the Fact Sheet for Healthcare Providers Administering Vaccine (/media/144637/download) and the Prescribing Information include the following information, which is also included in the Pfizer-BioNTech COVID-19 Vaccine Fact Sheet for Healthcare Providers Administering Vaccine and Prescribing Information:

CONTRAINDICATION
Do not administer the Moderna COVID-19 Vaccine to individuals with a known history of a severe allergic reaction (e.g., anaphylaxis) to a previous dose of the Moderna COVID-19 Vaccine or any component of the Moderna COVID-19 Vaccine (see Full EUA Prescribing Information).

WARNINGS
Appropriate medical treatment to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the Moderna COVID-19 Vaccine.

This information is also consistent with the Prescribing Information for all vaccines intended to prevent infectious diseases.

The Fact Sheet for Healthcare Providers Administering Vaccine and the Prescribing Information direct the reader to the Centers for Disease Control and Prevention's guidelines (https://www.cdc.gov/vaccines/covid-19/) for monitoring for, and management of, allergic reactions following vaccination.

Q: Is information available about serious adverse events?

A: Serious adverse events were reported by 1.0% (147) of participants who received Moderna COVID-19 Vaccine and 1.0% (153) of participants who received placebo. These represented common medical events that occur in the general population at similar frequency.

Among Moderna COVID-19 Vaccine recipients, there were two serious adverse events of facial swelling that were likely related to vaccination, and also potentially related to these participants having previously received facial injections of dermal fillers (gel-like substances used for cosmetic purposes). There was one report of Bell's palsy that was serious which occurred 32 days following receipt of vaccine. The information currently available is insufficient to determine a causal relationship with the vaccine. In addition, one Moderna COVID-19 Vaccine recipient reported a serious adverse event of difficult-to-control nausea and vomiting that occurred 1 day after vaccination. Although this vaccine recipient had a history of previous episodes of difficult-to-control nausea and vomiting, FDA considers the post-vaccination episode as likely related to vaccination.

There were no other notable patterns or imbalances by age, race, ethnicity, or medical comorbidities, for specific categories of serious adverse events that would suggest a causal relationship to Moderna COVID-19 Vaccine.

Q: Are vaccine providers required to report side effects?

A: Providers administering Moderna COVID-19 Vaccine must report to the Vaccine Adverse Event Reporting System (VAERS) (https://vaers.hhs.gov/index.html) and are encouraged to report to Moderna TX Inc. the following information associated with the vaccine of which they become aware:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome (MIS) in adults
- Cases of COVID-19 that result in hospitalization or death

Q: How will additional safety monitoring be conducted?

A: ModernaTX Inc. has submitted a pharmacovigilance plan to FDA to monitor the safety of Moderna COVID-19 Vaccine. The pharmacovigilance plan includes a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plan also includes other activities aimed at monitoring the safety of the vaccine and ensuring that any safety concerns are identified and evaluated in a timely manner.

Responsibility for additional post-authorization vaccine safety monitoring will be shared primarily by FDA and the U.S. Centers for Disease Control and Prevention, along with other agencies involved in healthcare delivery. Post-authorization safety monitoring during the

COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. There will be multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government has a well-established post-authorization/post-approval vaccine safety monitoring infrastructure that will be scaled up to meet the needs of a large-scale COVID-19 vaccination program. The U.S. government – in partnership with health systems, academic centers, and private sector partners – will use multiple existing vaccine safety monitoring systems to monitor COVID-19 vaccines in the post-authorization/approval period. Some of these systems are the Vaccine Adverse Event Reporting System (VAERS) (https://vaers.hhs.gov/index.html), the Vaccine Safety Datalink (VSD) (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html), the Biologics Effectiveness and Safety (BEST) Initiative (https://www.bestinitiative.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer), and Medicare claims data.

Q: Can people who have already had COVID-19 get the vaccine?

A: Only 2.2% of participants had evidence of prior infection at study enrollment. While relatively few confirmed COVID-19 cases occurred overall among participants with evidence of infection prior to vaccination, limited data suggest that previously infected individuals can be at risk of COVID-19 (i.e., reinfection) and may benefit from vaccination. Furthermore, available data suggest that the safety profile of the vaccine in previously infected individuals is just as favorable as in previously uninfected individuals.

Q: How will additional data on the effectiveness of the vaccine be obtained?

A: Additional data on vaccine effectiveness will be generated from further follow-up of participants in clinical studies already underway before the EUA was issued, plus studies conducted by the manufacturer or by the U.S. government evaluating effectiveness of the vaccine as used under the EUA.

Q: Are the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine interchangeable?

A: No. There are no data available on the interchangeability of Moderna COVID-19 Vaccine with other COVID-19 vaccines, including Pfizer-BioNTech COVID-19 Vaccine. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of

Moderna COVID-19 Vaccine to complete the vaccination series.

Individuals who have received one dose of Pfizer-BioNTech COVID-19 Vaccine should receive a second dose of Pfizer-BioNTech COVID-19 Vaccine to complete the vaccination series.

Q: Is it possible to obtain an 11th dose from the multi-dose vial of the Moderna COVID-19 vaccine?

A: In some cases, providers may be able to obtain an 11th dose from a Moderna vaccine vial, and this may be used if it is truly a full dose. Whether an 11th dose is obtainable depends, in part, on the type of syringes and needles used to withdraw doses from the vials. Because the vaccine does not contain preservative, it is critical to note that if the amount of vaccine remaining in the vial cannot provide a full dose, discard the vial and content. Do not pool excess vaccine from multiple vials to create one dose.