CLINICAL TOOLKIT FOR COVID19 VACCINATION

PharMerica

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PURPOSE OF THIS GUIDE

The COVID-19 pandemic has introduced the need for expedited vaccine development and distribution, spearheaded by Operation Warp Speed (OWS), a government-led partnership between the public and private sector. The accelerated nature of this immunization initiative will place timely, current and accurate information at a premium, as LTCF healthcare providers operate under ever changing circumstances.

The purpose of this guide is threefold:

1. ***Elevate LTC Healthcare Provider knowledgeability*** around Emergency Use Authorized COVID-19 vaccine(s) by providing this consolidated resource of reliable information detailing CDC guidance on vaccinating LTC residents, FDA-sourced vaccine-product-specific information from the respective products' EUA Fact sheets, and CMS comments on regulatory aspects of this novel immunization initiative.

2. ***Equip LTC Healthcare Providers with answers to frequently arising questions*** and the tools to make strong recommendations to concerned residents. The Q&A / FAQ materials have been designed to help facility staff assuage resident concerns and overcome vaccine hesitancy.

3. ***Provide LTC Healthcare Providers with educational materials*** for community display, as we endeavor to improve public vaccine acceptance.

In order to satisfy the need for up-to-date information, content considered prone to change will be dated and links provided for users to easily access the dynamic source material versus a static guide.

This information is for general educational purposes only. Please discuss individual patient conditions with the appropriate healthcare providers prior to administration of any vaccine or pharmaceutical and refer to the product's Full Emergency Use Authorization (EUA) Prescribing Information for comprehensive prescribing information of any vaccine or pharmaceutical listed.

Acknowledgements

The majority of the information provided here is available publicly through various government websites that are referenced throughout this guide. Primarily, the Centers for Disease Control and Prevention (CDC), the Advisory Committee on Immunization Practices (ACIP), the Department of the U.S. Health and Human Service Department (HHS), and the Centers for Medicaid and Medicare Services (CMS) were instrumental in our information gathering. The nature of drug information is that it is constantly evolving because of ongoing research and clinical experience and is often subject to interpretation. While great care has been taken to ensure the accuracy of the information presented, the reader is advised that the authors, editors, reviewers, contributors and publishers cannot be responsible for the continued currency of the information. All readers are advised that decisions regarding drug therapy and treatment must be based on the independent judgment of treating clinicians, changing drug information (e.g., as reflected in literature and manufacturer's most current product information), and changing medical practices. The editors are not responsible for any inaccuracy of quotations or for any false or misleading implication that may arise due to the text or formulas as used or due to the quotation of revisions no longer official. PharMerica Corporation does not represent or warrant the accuracy of the information provided in this manual and nothing in this manual is intended to replace the treatment by an established clinician. No official support or endorsement by any federal or state agency or pharmaceutical company is intended or inferred.

CMS REQUIREMENTS & CDC RECOMMENDATIONS

"What Does CMS Say?"

Current as of 1-8-21 –
check www.cms.gov/medicare/covid-19/ to ensure you are accessing the most current information

Will there be quality reporting metrics associated with COVID-19 vaccines?

CMS will support efforts to encourage COVID-19 vaccination through its quality and value based incentive programs. CMS is partnering with the CDC to develop quality measures to reflect both patient and personnel vaccination measures to be used in appropriate programs such as ursing Homes and dialysis facilities.

In addition, as a reminder, CMS offers credit in the provider MIPS program for participation in COVID-19 clinical trials and clinical registries, offering points for Improvement Activities.

Related Resources

- CMS COVID-19 webpage
- CMS COVID-19 FAQs
- CMS COVID-19 toolkits
- CDC COVID-19 website

CMS REQUIREMENTS & CDC RECOMMENDATIONS

"What Does the CDC Say?"

Current as of 1-8-21 —
check https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/LTCF-residents.html
to ensure you are accessing the most current information

Importance of COVID-19 Vaccination for Residents of LTCFs
Based on recommendations from the Advisory Committee on Immunization Practices (ACIP), an independent panel of medical and public health experts, CDC recommends residents of long-term care facilities be included among those offered the first supply of COVID-19 vaccines.

Vaccinating LTCF residents will save lives
Making sure LTCF residents can receive COVID-19 vaccination as soon as vaccines are available will help save the lives of those who are most at risk of dying from COVID-19. According to ACIP's recommendations, long-term care facility residents include adults who reside in facilities that provide a range of services, including medical and personal care, to persons who are unable to live independently. The communal nature of LTCFs and the population served (generally older adults often with underlying medical conditions) puts facility residents at increased risk of infection and severe illness from COVID-19. By November 6, 2020, approximately 569,000–616,000 COVID-19 cases and 91,500 deaths were reported among LTCF residents and staff members in the United States, accounting for 39% of deaths nationwide.

Benefits of vaccination believed to outweigh possible risks
All COVID-19 vaccines were tested in clinical trials involving tens of thousands of people to make sure they meet safety standards and protect adults of different races, ethnicities, and ages, including adults over the age of 65. There were no serious safety concerns. The most common side effects were pain at the injection site and signs and symptoms like fever and chills. After a review of all the available information, ***ACIP and CDC agreed the lifesaving benefits of COVID-19 vaccination for LTCF residents outweigh the risks of possible side effects.***

The safety of COVID-19 vaccines is a top priority
To help make important unapproved medical products, including vaccines, available quickly during the COVID-19 pandemic, the US Food and Drug Administration (FDA) can use what is known as an Emergency Use Authorization (EUA) . Before any vaccine can be authorized for use under an EUA, FDA must determine that the vaccine's benefits outweigh possible risks.

Once people begin receiving COVID-19 vaccinations, CDC and FDA will monitor vaccine safety closely. The United States will use existing robust systems and data sources to conduct ongoing safety monitoring. An additional layer of safety monitoring has also been added that allows CDC and FDA to evaluate COVID-19 vaccine safety almost immediately. Learn more about COVID-19 vaccine safety monitoring.

For LTCFs in particular, CDC will work with pharmacies and other partners to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS). Facility staff and residents' families are encouraged to also report any adverse events immediately.

CMS REQUIREMENTS & CDC RECOMMENDATIONS

"What Does the CDC Say?" | Continued

CDC will work with pharmacies and other partners to provide communication materials to help LTCFs educate residents and their families about the vaccine, answer their questions about vaccine safety and other issues, and prepare them for vaccination clinics. For some COVID-19 vaccines, two shots are needed to provide the best protection, and the shots are given several weeks apart. Each recipient or caregiver will receive a vaccination record card to ensure they receive the correct vaccine for the second dose.

Risks and benefits will be explained to everyone offered a COVID-19 vaccination
Explaining the risks and benefits of any treatments to a patient in a way that they understand is the standard of care. In LTCFs, consent or assent for vaccination should be obtained from residents (or the person appointed to make medical decisions on their behalf) and documented in the resident's chart per standard practice.

Pharmacy partners that are administering COVID-19 vaccine at LTCFs as part of the Federal Pharmacy Partnership for Long-term Care Program may require verbal, email, or written consent from recipients before vaccination. This is at the discretion of the pharmacy. LTCF administrators can request pharmacy partners obtain consent from residents' families in advance when they are serving as medical proxies.

Pharmacy partners will also work directly with LTCFs to ensure staff and residents who receive the vaccine also receive an EUA fact sheet before vaccination. The EUA fact sheet explains the risks and benefits of the COVID-19 vaccine they are receiving and what to expect. ***Each LTCF resident's medical chart must note that this information was provided to the resident.*** If a resident is unable to make medical decisions due to decreased mental capacity or illness, the EUA fact sheet will be provided to the person appointed to make medical decisions on their behalf (the medical proxy or power of attorney).

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Current as of 1-8-21 —
check https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
to ensure you are accessing the most current information

Authorized age groups

Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

Administration

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 ml each): three weeks (21 days) apart
- Moderna (100 µg, 0.5 ml): one month (28 days) apart

Persons should not be scheduled to receive the second dose earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. Doses inadvertently administered earlier than the grace period do not need to be repeated. There is no maximum interval between the first and second doses for either vaccine. Therefore, if the second dose is administered >3 weeks after the first Pfizer-BioNTech vaccine dose or >1 month after the first Moderna vaccine dose, there is no need to restart the series. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Interchangeability with other COVID-19 vaccine products

Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated; ACIP does not state a product preference. However, these mRNA COVID-19 vaccines are not interchangeable with each other or with other COVID-19 vaccine products. The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product. However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. Recommendations may be updated as further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.

Coadministration with other vaccines

Given the lack of data on the safety and efficacy of mRNA COVID-19 vaccines administered simultaneously with other vaccines, the vaccine series should routinely be administered alone, with a minimum interval of 14 days before or after administration with any other vaccine. However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration (e.g., tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to mRNA COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to/upon admission or onboarding). If mRNA COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine.

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Booster doses
The need for and timing of booster doses for mRNA COVID-19 vaccines has not been established. No additional doses beyond the two-dose primary series are recommended at this time.

Vaccination of persons with SARS-CoV-2 infection/exposure

Persons with a current or prior history of SARS-CoV-2 infection
Data from clinical trials indicate that mRNA COVID-19 vaccines are safe in persons with evidence of a prior SARS-CoV-2 infection. Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection solely for the purposes of vaccine decision-making is not recommended.

Vaccination of persons with known current SARS-CoV-2 infection should be deferred until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. This recommendation applies to persons who develop SARS-CoV-2 infection before receiving any vaccine doses as well as those who develop SARS-CoV-2 infection after the first dose but before receipt of the second dose. While there is otherwise no recommended minimum interval between infection and vaccination, current evidence suggests that reinfection is uncommon in the 90 days after initial infection. Thus, persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

For vaccinated persons who subsequently develop COVID-19, prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration) or timing of such treatments.

Persons who previously received passive antibody therapy for COVID-19
Currently, there are no data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment. Based on the estimated half-life of such therapies as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, vaccination should be deferred for at least 90 days, as a precautionary measure until additional information becomes available, to avoid potential interference of the antibody therapy with vaccine-induced immune responses. This recommendation applies to persons who receive passive antibody therapy before receiving any vaccine doses as well as those who receive passive antibody therapy after the first dose but before the second dose, in which case the second dose should be deferred for at least 90 days following receipt of the antibody therapy.

For persons receiving antibody therapies not specific to COVID-19 treatment (e.g., intravenous immunoglobulin, RhoGAM), administration of mRNA COVID-19 vaccines either simultaneously with or at any interval before or after receipt of an antibody-containing product is unlikely to substantially impair development of a protective antibody response. Thus, there is no recommended minimum interval between other antibody therapies (i.e., those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination.

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Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Vaccinating persons with a known SARS-CoV-2 exposure or during COVID-19 outbreaks
mRNA vaccines are not currently recommended for outbreak management or for post-exposure prophylaxis, which is vaccination to prevent the development of SARS-CoV-2 infection in a person with a specific known exposure. Because the median incubation period of SARS-CoV-2 is 4 to 5 days, it is unlikely that the first dose of COVID-19 vaccine would provide an adequate immune response within the incubation period for effective post-exposure prophylaxis. Thus, vaccination is unlikely to be effective in preventing disease following an exposure.

Persons in the community or outpatient setting who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended to avoid potentially exposing healthcare personnel and other persons to SARS-CoV-2 during the vaccination visit.

Residents with a known COVID-19 exposure living in congregate healthcare settings (e.g., long-term care facilities), where exposure and transmission of SARS-CoV-2 can occur repeatedly for long periods of time, may be vaccinated. In these settings, healthcare personnel are already in close contact with residents (e.g., entering patient rooms for evaluation and treatment). Vaccinators should employ appropriate infection prevention and control procedures.

Residents of other congregate settings (e.g., correctional and detention facilities, homeless shelters) with a known COVID-19 exposure may also be vaccinated, in order to avoid delays and missed opportunities for vaccination given the increased risk for outbreaks in these settings. However, where feasible, precautions should be taken to limit mixing exposed individuals with other residents or staff (except those essential for the provision of vaccination services, who should employ appropriate infection and control procedures).

Persons residing in congregate settings (healthcare and non-healthcare) who have had an exposure and are awaiting results of SARS-CoV-2 testing may be vaccinated if the person does not have symptoms consistent with COVID-19.

In situations where facility-wide testing is being conducted to identify SARS-CoV-2 infections, facilities should attempt to complete facility-wide testing within a period that allows for test results to be received prior to vaccination in order to isolate those patients with SARS-CoV-2 infection. However, it is not necessary to wait for test results if this would create delays in vaccination. In such situations, persons without symptoms consistent with COVID-19 may be vaccinated. Although not contraindicated, vaccination may be deferred pending outcome of testing in persons with symptoms consistent with COVID-19. Viral testing for acute SARS-CoV-2 infection solely for the purposes of vaccine decision-making is not recommended.

Vaccination of persons with underlying medical conditions

mRNA COVID-19 vaccines may be administered to persons with underlying medical conditions who have no contraindications to vaccination (see 'contraindications' section below). Clinical trials demonstrated similar safety and efficacy profiles in persons with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities. Information on groups with specific underlying medical conditions is included below.

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Immunocompromised persons
Persons with HIV infection or other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19. Data are not currently available to establish vaccine safety and efficacy in these groups. Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data remain limited. Immunocompromised individuals may still receive COVID-19 vaccination if they have no contraindications to vaccination. However, they should be counseled about the unknown vaccine safety profile and effectiveness in immunocompromised populations, as well as the potential for reduced immune responses and the need to continue to follow all current guidance to protect themselves against COVID-19 (see below). Antibody testing is not recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination.

Persons with autoimmune conditions
No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials. No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo. Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

Persons with a history of Guillain-Barré syndrome
To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials. With few exceptions, ACIP's general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination. Persons with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Persons with a history of Bell's palsy
Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials. However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination. Post-authorization safety surveillance will be important to further assess any possible causal association. In the absence of such evidence, persons with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination. Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS.
Vaccination of pregnant or lactating people.

Vaccination of pregnant or lactating people

Pregnant people
Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness, including illness resulting in intensive care admission, mechanical ventilation, or death. Additionally, they might be at an increased risk of adverse pregnancy outcomes, such as preterm birth.

There are currently few data on the safety of COVID-19 vaccines, including mRNA vaccines, in pregnant people. Limited data are currently available from animal developmental and reproductive toxicity studies. No safety concerns were

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demonstrated in rats that received Moderna COVID-19 vaccine prior to or during gestation in terms of female reproduction, fetal/embryonal development, or postnatal development. Studies in pregnant people are planned and the vaccine manufacturers are following outcomes in people in the clinical trials who became pregnant. mRNA vaccines are not live vaccines. The mRNA in the vaccine is degraded quickly by normal cellular processes and does not enter the nucleus of the cell. Based on current knowledge, experts believe that mRNA vaccines are unlikely to pose a risk to the pregnant person or the fetus. However, the potential risks of mRNA vaccines to the pregnant person and the fetus are unknown because these vaccines have not been studied in pregnant people.

If pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated. A conversation between the patient and their clinical team may assist with decisions regarding the use of a mRNA COVID-19 vaccine, though a conversation with a healthcare provider is not required prior to vaccination. When making a decision, pregnant people and their healthcare providers should consider the level of COVID-19 community transmission, the patient's personal risk of contracting COVID-19, the risks of COVID-19 to the patient and potential risks to the fetus, the efficacy of the vaccine, the side effects of the vaccine, and the lack of data about the vaccine during pregnancy.

Side effects can occur with COVID-19 vaccine use in pregnant people, similar to those expected among non-pregnant people. Pregnant people who experience fever following vaccination may be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes. Acetaminophen may be offered as an option for pregnant people experiencing other post-vaccination symptoms as well.

There is no recommendation for routine pregnancy testing before receipt of a COVID-19 vaccine. Those who are trying to become pregnant do not need to avoid pregnancy after mRNA COVID-19 vaccination.

Lactating people

There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA COVID-19 vaccines on the breastfed infant or milk production/excretion. mRNA vaccines are not thought to be a risk to the breastfeeding infant. A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated.

Vaccination of children and adolescents

Adolescents aged 16–17 years are included among persons eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different than those observed in persons 18 years of age and older.

Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine, with appropriate assent. Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

Children and adolescents younger than 18 years of age are not authorized to receive the Moderna COVID-19 vaccine at this time.

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Patient counseling

Vaccine efficacy
Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine (Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]; Moderna: 94.1% [95% CI: 89.3%, 96.8%]). Limited data are currently available regarding the efficacy of a single dose. Patients should be counseled on the importance of completing the two-dose series (of the same vaccine product) to optimize protection.

Reactogenicity
Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Depending on vaccine product (Pfizer vs. Moderna), age group, and vaccine dose, approximately 80–89% of vaccinated persons develop at least one local symptom and 55–83% develop at least one systemic symptom following vaccination.

Most systemic post-vaccination symptoms are mild to moderate in severity, occur within the first three days of vaccination, and resolve within 1–3 days of onset. These symptoms are more frequent and severe following the second dose and among younger persons compared to older persons (i.e., >55 or ≥65 years [for Pfizer-BioNTech or Moderna vaccines, respectively]). Unless persons develop a contraindication to vaccination (see below), they should be encouraged to complete the series even if they develop local or systemic symptoms following the first dose to optimize protection against COVID-19.

Hypersensitivity-related adverse events were observed in 0.63% of Pfizer-BioNTech and 1.5% of Moderna COVID-19 vaccine clinical trial participants who received the vaccine, compared to 0.51% and 1.1%, respectively, in the placebo groups. Anaphylaxis following vaccination was not observed in the Pfizer-BioNTech or Moderna COVID-19 vaccine clinical trials. However, anaphylactic reactions have been reported following receipt of the Pfizer-BioNTech COVID-19 vaccine during vaccination outside of clinical trials.

Antipyretic or analgesic medications (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken for the treatment of post-vaccination local or systemic symptoms, if medically appropriate. However, routine prophylactic administration of these medications for the purpose of preventing post-vaccination symptoms is not currently recommended, as information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

Infection prevention and control considerations are available for healthcare personnel and long-term care facility residents (e.g., populations included in phase 1a of vaccine allocation) with systemic signs and symptoms following COVID-19 vaccination. Considerations may be updated as additional information becomes available or additional groups are prioritized for vaccine allocation.

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Public health recommendations for vaccinated persons
Given the currently limited information on how much the mRNA COVID-19 vaccines may reduce transmission in the general population and how long protection lasts, vaccinated persons should continue to follow all current guidance to protect themselves and others. This includes wearing a mask, staying at least 6 feet away from others, avoiding crowds, washing hands often, following CDC travel guidance, following quarantine guidance after an exposure to someone with COVID-19, and following any applicable workplace or school guidance, including guidance related to personal protective equipment use or SARS-CoV-2 testing.

Contraindications and Precautions

Contraindications
CDC considers a history of the following to be a contraindication to vaccination with both the Pfizer-BioNTech and Moderna COVID-19 vaccines:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components
- Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or any of its components (including polyethylene glycol [PEG])*
- Immediate allergic reaction of any severity to polysorbate (due to potential cross-reactive hypersensitivity with the vaccine ingredient PEG)*

* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available). See Appendix B for more information on ingredients included in mRNA COVID-19 vaccines.

Persons with an immediate allergic reaction to the first dose of an mRNA COVID-19 vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines. Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects (which are not contraindications to receiving the second vaccine dose) (Appendix C).

Healthcare personnel or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project for a complex COVID-19 vaccine safety question about an individual patient residing in the United States not readily addressed by CDC guidance.

Precautions
CDC considers a history of any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate) as a precaution but not a contraindication to vaccination for both the Pfizer-BioNTech and Moderna COVID-19 vaccines.

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These persons should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. Deferral of vaccination and/or consultation with an allergist-immunologist may be considered until further information on the risk of anaphylaxis is available. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination in these individuals:

- Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago
- Note: Vaccination is recommended for persons with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, persons with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis.

Neither contraindications nor precautions to vaccination
Allergic reactions (including severe allergic reactions) not related to vaccines, injectable therapies, components of mRNA COVID-19 vaccines (including PEG), or polysorbates, such as food, pet, venom, or environmental allergies, or allergies to oral medications (including the oral equivalents of injectable medications) are not a contraindication or precaution to vaccination with either mRNA COVID-19 vaccine. The vial stoppers of these mRNA vaccines 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 the mRNA COVID-19 vaccines do not contain eggs or gelatin, persons with allergies to these substances do not have a contraindication or precaution to vaccination.

Observation periods following vaccination (for persons without contraindications to mRNA COVID-19 vaccines)
CDC recommends an observation period following vaccination with mRNA COVID-19 vaccines. Persons with a history of an immediate allergic reaction of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause should be observed for 30 minutes. All other persons should be observed for 15 minutes.

Management of anaphylaxis after mRNA COVID-19 vaccination
Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine. Administration of antihistamines to COVID-19 vaccine recipients prior to vaccination to prevent allergic reactions is not recommended. Antihistamines do not prevent anaphylaxis, and their use may mask cutaneous symptoms, which could lead to a delay in the diagnosis and management of anaphylaxis.

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Risk assessment for mRNA COVID-19 vaccination

When assessing a person's history of allergic reaction to a vaccine or injectable therapy, it can sometimes be challenging to determine whether the reaction was truly severe. The following considerations can be used to help the provider conduct a risk assessment for mRNA COVID-19 vaccination:

- Type of reaction and symptoms (e.g., whether symptoms were generalized and consistent with anaphylaxis)
- For a reaction to a medication, whether the medication was administered by injection or another route
- Whether the reaction required use of epinephrine (EpiPen®, etc.) or resulted in advanced medical care, (e.g., emergency room visit, hospitalization)
- How long ago the reaction occurred and whether the same vaccine or medication was subsequently administered without symptoms
- Whether the patient has been evaluated by an allergist-immunologist and the diagnosis has been confirmed

Persons who are determined to have had a severe allergic reaction (e.g., anaphylaxis) to an mRNA COVID-19 vaccine should not receive a second dose. For those determined to have had a severe allergic reaction to another vaccine or injectable medication, considerations for the administration of an mRNA COVID-19 vaccine might include:

- Risk of exposure to SARS-CoV-2 (e.g., because of residence in a congregate setting such as a long-term care facility, occupation)
- Risk of severe disease or death due to COVID-19 (e.g., because of age, underlying medical conditions)
- The unknown risk of anaphylaxis (including fatal anaphylaxis) following mRNA COVID-19 vaccination in a person with a history of anaphylaxis to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where advanced medical care is immediately available for anaphylaxis
- Risk of adverse events after anaphylaxis treatment with epinephrine (older adults with hypertension and atherosclerotic heart disease may be at increased risk for cardiac adverse events following anaphylaxis treatment with epinephrine
- Whether the patient has previously been infected with SARS-CoV-2 and, if so, how long ago
- *Note: Vaccination is recommended for persons with a history of COVID-19; however, because reinfection is uncommon in the 90 days following infection, persons with a history of anaphylaxis to another vaccine or injectable therapy and recent COVID-19 may choose to defer vaccination until further information is known about the risk of anaphylaxis following vaccination.*

Management of allergic reactions

Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine. Vaccine providers should observe patients with a history of anaphylaxis (due to any cause) for 30 minutes after vaccination. All other persons should be observed for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions. Further information on preparing for the potential management of anaphylaxis at COVID-19 vaccination sites has been published.

See ***Appendix B*** for additional information on the triage and management of persons presenting for mRNA COVID-19 vaccination.

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Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Reporting of vaccine adverse events

Adverse events that occur in a recipient following mRNA COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the Food and Drug Administration to report the following that occur after mRNA COVID-19 vaccination under Emergency Use Authorization:

- Vaccine administration errors
- Serious adverse events
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Reporting is encouraged for any other clinically significant adverse event even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.govexternal or by calling 1-800-822-7967.

In addition, CDC has developed a new, voluntary smartphone-based tool, v-safe. This tool uses text messaging and web surveys to provide near real-time health check-ins after patients receive COVID-19 vaccination. Reports to v-safe indicating a medically significant health impact, including pregnancy, are followed up by the CDC/v-safe call center to collect additional information to complete a VAERS report, if appropriate.

Interpreting SARS-CoV-2 test results in vaccinated persons

Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests (nucleic acid amplification or antigen tests). Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to one of two viral proteins: spike or nucleocapsid. Because both the Pfizer-BioNTech and Moderna COVID-19 vaccines contain mRNA that encodes the spike protein, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination. To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used. Antibody testing is not currently recommended to assess for immunity to COVID-19 following mRNA COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person.

Interpretation of tuberculosis test results in vaccinated persons

Inactive vaccines do not interfere with tuberculosis (TB) test results. There is no immunologic reason to believe either a Tuberculin Skin Test (TST) (administered by intradermal placement of 0.1 cc of purified protein derivative) or blood draw for interferon gamma release assay (IGRA) would affect the safety or effectiveness of mRNA COVID-19 vaccines. We have no data to inform the impact of the COVID-19 mRNA vaccines on either TB test for infection (i.e., TST or IGRA).

For healthcare personnel or patients who require baseline TB testing (at onboarding or entry into facilities) at the same time they are to receive an mRNA COVID-19 vaccine:

- Perform TB symptom screening on all healthcare personnel or patients.
- If utilizing the IGRA, draw blood for interferon gamma release assay prior to COVID-19 vaccination.

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

- If utilizing the TST, place prior to COVID-19 vaccination.
- If vaccination has been given and testing needs to be performed, defer TST or IGRA until 4 weeks after COVID-19 vaccine 2-dose completion.
- All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

For healthcare personnel who require testing for other reasons:

- Perform TB symptom screening on all healthcare personnel
- Test for infection should be done before or at the same time as the administration of COVID-19 vaccination. If this is not possible, prioritization of test for TB infection needs to be weighed with the importance of receiving COVID-19 vaccination based on potential COVID-19 exposures and TB risk factors.
- Healthcare personnel with high-risk conditions for TB progression should be fully evaluated as soon as possible.
- Healthcare personnel without high-risk conditions for TB progression should proceed with contact tracing (i.e., symptom screening, chest radiograph or other imaging, specimen for microbiologic evaluation) but delay test for TB infection (TST or IGRA) if prioritized for receiving COVID-19 vaccination.
- All potential recipients of COVID-19 vaccination should weigh the risks and benefits of delaying TST/IGRA with their providers.

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Appendix A: Ingredients included in Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines

For both Pfizer-BioNTech and Moderna COVID-19 vaccines, severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine is a contraindication to vaccination. The following is a list of ingredients for the Pfizer-BioNTech and Moderna COVID-19 vaccines, as reported in the prescribing information for each vaccine.

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
mRNA	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	Cholesterol	Cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102 (Proprietary to Moderna)
Salts, sugars, buffers	Potassium chloride	Tromethamine
	Monobasic potassium phosphate	Tromethamine hydrochloride
	Sodium chloride	Acetic acid
	Dibasic sodium phosphate dihydrate	Sodium acetate
	Sucrose	Sucrose

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Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Appendix B: Triage of persons presenting for mRNA COVID-19 vaccination

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	**CONDITIONS** • Immunocompromising conditions • Pregnancy • Lactation **ACTIONS** • Additional information provided* • 15 minute observation period	**CONDITIONS** • Moderate/severe acute illness **ACTIONS** • Risk assessment • Potential deferral of vaccination • 15 minute observation period if vaccinated	**CONDITIONS** • None **ACTIONS** • N/A
ALLERGIES	**ALLERGIES** • History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including mRNA COVID-19 vaccines*) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of an mRNA COVID-19 vaccine* **ACTIONS** • Do not vaccinate

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized

Appendix C: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following mRNA COVID-19 vaccination

In patients who develop post-vaccination symptoms, determining the etiology (including allergic reaction, vasovagal reaction, or vaccine side effects) is important to determine whether a person can receive additional doses of mRNA COVID-19 vaccines. The following table of signs and symptoms is meant to serve as a resource but may not be exhaustive, and patients may not have all signs or symptoms. Providers should use their clinical judgement when assessing patients to determine the diagnosis and management.

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes after vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site: lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable: If accompanied by may have elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable: may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendations			
Recommended to receive 2nd dose of mRNA COVID-19 vaccine?	No	Yes`	Yes

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Post Vaccine Considerations for Residents

Current as of 1-8-21 —
check https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html
to ensure you are accessing the most current information

Infection prevention and control considerations for residents of LTCFs with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed by long-term care facilities to appropriately evaluate and manage post-vaccination signs and symptoms among their residents. The approach described in this document is intended to balance:

- The risk of unnecessary testing and implementation of Transmission-Based Precautions for residents with only post-vaccination signs and symptoms with that of
- Inadvertently allowing residents with infectious COVID-19 or another transmissible infectious disease to expose others in the facility.

While this guidance is intended for long-term care facilities, it could also be applied to patients in other healthcare settings. These considerations are based on the current understanding of signs and symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine accumulates.

Overview
Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination. Preliminary data from mRNA COVID-19 vaccine trials indicate that most systemic post-vaccination signs and symptoms are mild to moderate in severity, occur within the first three days of vaccination (the day of vaccination and following two days, with most occurring the day after vaccination), resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (>55 years). Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are not consistent with post-vaccination symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.

Note: The following signs and symptoms, alone, are not consistent with SARS-CoV-2 infection and should be managed per usual protocols for vaccine-related side effects:

- immediate hypersensitivity reactions (e.g., urticaria, anaphylaxis)
- local symptoms (e.g., pain, swelling, or redness at injection site)

Routine infection prevention and control practices:
Healthcare personnel at long-term care facilities should follow the recommended infection prevention and control practices described in the Preparing for COVID-19 in Nursing Homes and the Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic. These recommendations, which emphasize close monitoring of residents of long-term care facilities for symptoms of COVID-19, universal source control, physical distancing (when possible), hand hygiene, and optimizing engineering controls, are intended to protect healthcare personnel and residents from exposures to SARS-CoV-2. Use of personal protective equipment (PPE), including universal use of a facemask and eye protection for healthcare personnel in areas experiencing moderate to substantial community transmission who are caring for residents not suspected to have SARS-CoV-2 infection, is also recommended. (Continued)

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Post Vaccine Considerations for Residents | Continued

Because information is currently lacking on vaccine effectiveness in the general population; the resultant reduction in disease, severity, or transmission; or the duration of protection, residents and healthcare personnel should continue to follow all current infection prevention and control recommendations to protect themselves and others from SARS-CoV-2 infection, regardless of their vaccination status.

Suggested approaches to evaluating and managing systemic new onset post-vaccination signs and symptoms for residents in long-term care facilities.

The approaches described in the Table below apply to residents who have received COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1).

Note: Facilities that are conducting outbreak testing for SARS-CoV-2 transmission, or evaluating residents who have had prolonged close contact with someone with SARS-CoV-2 infection in the previous 14 days, should care for residents following all recommended infection control practices including placement in Transmission-Based Precautions with use of all recommended personal protective equipment, and performing appropriate testing.

All symptomatic residents should be assessed; the approaches suggested in the table below should be tailored to fit the clinical and epidemiologic characteristics of the specific case.

In any situation, positive viral (nucleic acid or antigen) tests for SARS-CoV-2, if performed, should not be attributed to the COVID-19 vaccine, as vaccination does not influence the results of these tests.

CMS REQUIREMENTS & CDC RECOMMENDATIONS

Post Vaccine Considerations for Residents | Continued

Signs and Symptoms	Suggested approach	Additional notes
Signs and symptoms unlikely to be from COVID-19 vaccination: Presence of ANY systemic signs and symptoms consistent with SARS-CoV-2 (e.g., cough, shortness of breath, rhinorrhea, sore throat, loss of taste or smell) or another infectious etiology (e.g., influenza) that are not typical for post-vaccination signs and symptoms	*Evaluate for possible infectious etiologies,* including testing for SARS-CoV-2 and/or other pathogens, as appropriate. Pending evaluation, these residents should be placed in a single person room (if available) and cared for by healthcare personnel wearing all PPE recommended for residents with suspected or confirmed SARS-CoV-2 infection. They should not be cohorted with residents with confirmed SARS-CoV-2 infection unless they are also confirmed to have SARS-CoV-2 infection through testing. Criteria for when Transmission-Based Precautions may be discontinued depend on the results of the evaluation.	If performed, a negative SARS-CoV-2 antigen test in a resident who has signs and symptoms that are not typical for post-vaccination signs and symptoms should be confirmed by SARS-CoV-2 nucleic acid amplification test (NAAT). Further information on testing is available here: https://www.cdc.gov/coronavirus/2019-nCoV/lab/index.html
Signs and symptoms that may be from either COVID-19 vaccination, SARS-CoV-2 infection, or another infection: Presence of ANY systemic signs and symptoms (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) that are consistent with post-vaccination signs and symptoms, SARS-CoV-2 infection, or another infectious etiology (e.g., influenza). Fever in long-term care settings is defined as a single measured temperature of 100.0oF (37.8oC) or higher or repeated temperatures of 99.0oF (37.2oC).	*Evaluate the resident.* These residents should be restricted to their current room (except for medically necessary procedures) and closely monitored until: • Fever (if present) resolves and • Symptoms improve Healthcare personnel caring for these residents should, ideally, wear all PPE recommended for residents with suspected or confirmed SARS-CoV-2 infection while evaluating the cause of these symptoms. Strategies to optimize PPE supply are available here: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html If the resident's symptoms resolve within 2 days, precautions can be discontinued. Fever, if present, should have resolved for at least 24 hours before discontinuing precautions. Viral testing for SARS-CoV-2 should be considered for residents if their symptoms are not improving or persist for longer than 2 days. Residents residing in facilities with active transmission, or who have had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days, should be tested for SARS-CoV-2 infection.	If SARS-CoV-2 antigen testing is used to evaluate a symptomatic resident, a negative antigen test in a resident who has symptoms that are limited only to those observed following COVID-19 vaccination (i.e., do not have cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell) may not require confirmatory SARS-CoV-2 NAAT. However, confirmatory SARS-CoV-2 NAAT testing should be conducted if there is active transmission in the facility, if the resident has had prolonged close contact with someone with SARS-CoV-2 infection in the prior 14 days, or if symptoms persist for longer than 2 days. Additional information is available here: https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html

COVID-19 Vaccine EUA Fact Sheets

Vaccine EUA Fact Sheets are the gold standard for accessing vaccine prescribing information promulgated directly by the FDA. In lieu of Vaccine Information Sheets (VIS) customarily produced for FDA-approved vaccines, these EUA Fact Sheets provide summary information for the vaccine products while their status remains unapproved but solely authorized for emergency use.

EUAs are designed both for Providers and for Recipients/Caregivers. The former provides detailed product specific information geared towards healthcare professionals, including a "Long Version" that constitutes the Full EUA Prescribing Information.

The Recipients/Caregivers oriented EUA provides a high level overview of key vaccine considerations constructed to provide easily comprehendible information, such that the usual recipient may have informed consent prior to receiving the vaccination,

The Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Vaccination Providers
may be directly accessed HERE or by entering this URL into your web browser's address bar:
https://www.fda.gov/media/144413/download

The Moderna COVID-19 Vaccine EUA Fact Sheet for Vaccination Providers
may be directly accessed HERE or by entering this URL into your web browser's address bar:
https://www.fda.gov/media/144637/download

In the following section PharMerica has provided a high level comparison of these 2 Emergency Use Authorized COVID-19 vaccine formulations.

Both the ***Pfizer-BioNTech*** and ***Moderna COVID-19 Vaccine EUA Fact Sheets for Recipients and Caregivers*** are included thereafter.

Brief Summary of Both mRNA Vaccines Currently Authorized:

	PFIZER	MODERNA
EUA Date	12/11/2020	12/18/2020
Age	≥ 16 years	≥ 18 years
Primary Endpoint - Overall Efficacy	95% effective 7 days after second dose	94.5% effective 14 days after second dose
Primary Endpoint - Subgroup Efficacy	Similar efficacy point estimates across age groups, genders, racial and ethnic groups, and participants with medical comorbidities associated with high risk of severe COVID-19	
Regimen	Two doses 21 days apart (second dose can be given as early as 17 days)	Two doses 28 days apart (second dose can be given as early as 24 days)
Volume	0.3mL	0.5mL
Coadministration with other vaccines	• A minimum interval of 14 days before or after administration with any other vaccines • If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine	
Adverse Reactions	Reactogenic local and system reactions were generally found to be more severe following the second dose in all age groups, and more frequent in younger participants (<55 y/o for Pfizer, <65 y/o for Moderna)	
Persons with current or prior history of COVID-19 infection	The vaccines are safe for individuals who have previously had COVID-19. Persons with current COVID-19 infection should wait until they have recovered and are out of the quarantine period.	

COVID-19 Vaccine EUA Fact Sheets: *Pfizer-BioNTech COVID-19 Vaccine*

FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 16 YEARS OF AGE AND OLDER

You are being offered the Pfizer-BioNTech COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Pfizer-BioNTech COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Pfizer-BioNTech COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Pfizer-BioNTech COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Pfizer-BioNTech COVID-19 Vaccine.

The Pfizer-BioNTech COVID-19 Vaccine is administered as a 2-dose series, 3 weeks apart, into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please see www.cvdvaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE?

WHAT IS COVID-19?
COVID-19 disease is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

COVID-19 Vaccine EUA Fact Sheets: *Pfizer-BioNTech COVID-19 Vaccine*

The FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 in individuals 16 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE PFIZER-BIONTECH COVID-19 VACCINE?
Tell the vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE PFIZER-BIONTECH COVID-19 VACCINE?
FDA has authorized the emergency use of the Pfizer-BioNTech COVID-19 Vaccine in individuals 16 years of age and older.

WHO SHOULD NOT GET THE PFIZER-BIONTECH COVID-19 VACCINE?
You should not get the Pfizer-BioNTech COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE PFIZER-BIONTECH COVID-19 VACCINE?
The Pfizer BioNTech COVID-19 Vaccine includes the following ingredients: mRNA, lipids ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2 [(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-Distearoyl-sn-glycero-3-phosphocholine, and cholesterol), potassium chloride, monobasic potassium phosphate, sodium chloride, dibasic sodium phosphate dihydrate, and sucrose.

HOW IS THE PFIZER-BIONTECH COVID-19 VACCINE GIVEN?
The Pfizer-BioNTech COVID-19 Vaccine will be given to you as an injection into the muscle.

The Pfizer-BioNTech COVID-19 Vaccine vaccination series is 2 doses given 3 weeks apart.

If you receive one dose of the Pfizer-BioNTech COVID-19 Vaccine, you should receive a second dose of this same vaccine 3 weeks later to complete the vaccination series.

COVID-19 Vaccine EUA Fact Sheets: *Pfizer-BioNTech COVID-19 Vaccine*

HAS THE PFIZER-BIONTECH COVID-19 VACCINE BEEN USED BEFORE?
The Pfizer-BioNTech COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 20,000 individuals 16 years of age and older have received at least 1 dose of the Pfizer-BioNTech COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
In an ongoing clinical trial, the Pfizer-BioNTech COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 3 weeks apart. The duration of protection against COVID-19 is currently unknown.

WHAT ARE THE RISKS OF THE PFIZER-BIONTECH COVID-19 VACCINE?
Side effects that have been reported with the Pfizer-BioNTech COVID-19 Vaccine include:

- injection site pain
- tiredness
- headache
- muscle pain
- chills
- joint pain
- fever
- injection site swelling
- injection site redness
- nausea
- feeling unwell
- swollen lymph nodes (lymphadenopathy)

There is a remote chance that the Pfizer-BioNTech COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Pfizer-BioNTech COVID-19 Vaccine. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Pfizer-BioNTech COVID-19 Vaccine. Serious and unexpected side effects may occur. Pfizer-BioNTech COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

COVID-19 Vaccine EUA Fact Sheets: *Pfizer-BioNTech COVID-19 Vaccine*

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Pfizer-BioNTech COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to Pfizer Inc. at the contact information provided below.

Website	Fax number	Telephone number
www.pfizersafetyreporting.com	1-866-635-8337	1-800-438-1985

WHAT IF I DECIDE NOT TO GET THE PFIZER-BIONTECH COVID-19 VACCINE?
It is your choice to receive or not receive the Pfizer-BioNTech COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES PFIZER-BIONTECH COVID-19 VACCINE?
Currently, there is no approved alternative vaccine available for prevention of COVID-19. FDA may allow the emergency use of other vaccines to prevent COVID-19.

CAN I RECEIVE THE PFIZER-BIONTECH COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Pfizer-BioNTech COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE PFIZER-BIONTECH COVID-19 VACCINE GIVE ME COVID-19?
No. The Pfizer-BioNTech COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you get your first dose, you will get a vaccination card to show you when to return for your second dose of Pfizer-BioNTech COVID-19 Vaccine. Remember to bring your card when you return.

COVID-19 Vaccine EUA Fact Sheets: *Pfizer-BioNTech COVID-19 Vaccine*

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Global website	Telephone number
www.cvdvaccine.com	1-877-829-2619 (1-877-VAX-CO19)

HOW CAN I LEARN MORE?

- Ask the vaccination provider.
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html.
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.
- Contact your local or state public health department.

WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs visit: https://www.cdc.gov/vaccines/programs/iis/about.html.

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Pfizer-BioNTech COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Pfizer-BioNTech COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19

COVID-19 Vaccine EUA Fact Sheets: *Pfizer-BioNTech COVID-19 Vaccine*

pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the Pfizer-BioNTech COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Manufactured by
Pfizer Inc., New York, NY 10017

BIONTECH
Manufactured for
BioNTech Manufacturing GmbH
An der Goldgrube 12
55131 Mainz, Germany

LAB-1451-0.7

Revised: December 2020

Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.

Barcode Date: 12/2020

COVID-19 Vaccine EUA Fact Sheets: *Moderna COVID-19 Vaccine*

FACT SHEET FOR RECIPIENTS AND CAREGIVERS
EMERGENCY USE AUTHORIZATION (EUA) OF THE MODERNA COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Moderna COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of the Moderna COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Moderna COVID-19 Vaccine is a vaccine and may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Moderna COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Moderna COVID-19 Vaccine.

The Moderna COVID-19 Vaccine is administered as a 2-dose series, 1 month apart, into the muscle.

The Moderna COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.modernatx.com/covid19vaccine-eua.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?
COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE MODERNA COVID-19 VACCINE?
The Moderna COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Moderna COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

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WHAT SHOULD YOU MENTION TO YOUR VACCINATION PROVIDER BEFORE YOU GET THE MODERNA COVID-19 VACCINE?

Tell your vaccination provider about all of your medical conditions, including if you:

- have any allergies
- have a fever
- have a bleeding disorder or are on a blood thinner
- are immunocompromised or are on a medicine that affects your immune system
- are pregnant or plan to become pregnant
- are breastfeeding
- have received another COVID-19 vaccine

WHO SHOULD GET THE MODERNA COVID-19 VACCINE?

FDA has authorized the emergency use of the Moderna COVID-19 Vaccine in individuals 18 years of age and older.

WHO SHOULD NOT GET THE MODERNA COVID-19 VACCINE?

You should not get the Moderna COVID-19 Vaccine if you:

- had a severe allergic reaction after a previous dose of this vaccine
- had a severe allergic reaction to any ingredient of this vaccine

WHAT ARE THE INGREDIENTS IN THE MODERNA COVID-19 VACCINE?

The Moderna COVID-19 Vaccine contains the following ingredients: messenger ribonucleic acid (mRNA), lipids (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), tromethamine, tromethamine hydrochloride, acetic acid, sodium acetate, and sucrose.

HOW IS THE MODERNA COVID-19 VACCINE GIVEN?

The Moderna COVID-19 Vaccine will be given to you as an injection into the muscle.

The Moderna COVID-19 Vaccine vaccination series is 2 doses given 1 month apart.

If you receive one dose of the Moderna COVID-19 Vaccine, you should receive a second dose of the same vaccine 1 month later to complete the vaccination series.

HAS THE MODERNA COVID-19 VACCINE BEEN USED BEFORE?

The Moderna COVID-19 Vaccine is an unapproved vaccine. In clinical trials, approximately 15,400 individuals 18 years of age and older have received at least 1 dose of the Moderna COVID-19 Vaccine.

WHAT ARE THE BENEFITS OF THE MODERNA COVID-19 VACCINE?

In an ongoing clinical trial, the Moderna COVID-19 Vaccine has been shown to prevent COVID-19 following 2 doses given 1 month apart. The duration of protection against COVID-19 is currently unknown.

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WHAT ARE THE RISKS OF THE MODERNA COVID-19 VACCINE?
Side effects that have been reported with the Moderna COVID-19 Vaccine include:

- Injection site reactions: pain, tenderness and swelling of the lymph nodes in the same arm of the injection, swelling (hardness), and redness
- General side effects: fatigue, headache, muscle pain, joint pain, chills, nausea and vomiting, and fever

There is a remote chance that the Moderna COVID-19 Vaccine could cause a severe allergic reaction. A severe allergic reaction would usually occur within a few minutes to one hour after getting a dose of the Moderna COVID-19 Vaccine. For this reason, your vaccination provider may ask you to stay at the place where you received your vaccine for monitoring after vaccination. Signs of a severe allergic reaction can include:

- Difficulty breathing
- Swelling of your face and throat
- A fast heartbeat
- A bad rash all over your body
- Dizziness and weakness

These may not be all the possible side effects of the Moderna COVID-19 Vaccine. Serious and unexpected side effects may occur. The Moderna COVID-19 Vaccine is still being studied in clinical trials.

WHAT SHOULD I DO ABOUT SIDE EFFECTS?
If you experience a severe allergic reaction, call 9-1-1, or go to the nearest hospital.

Call the vaccination provider or your healthcare provider if you have any side effects that bother you or do not go away.

Report vaccine side effects to **FDA/CDC Vaccine Adverse Event Reporting System (VAERS)**. The VAERS toll-free number is 1-800-822-7967 or report online to https://vaers.hhs.gov/reportevent.html. Please include "Moderna COVID-19 Vaccine EUA" in the first line of box #18 of the report form.

In addition, you can report side effects to ModernaTX, Inc. at 1-866-MODERNA (1-866-663-3762).

You may also be given an option to enroll in **v-safe. V-safe** is a new voluntary smartphone-based tool that uses text messaging and web surveys to check in with people who have been vaccinated to identify potential side effects after COVID-19 vaccination. **V-safe** asks questions that help CDC monitor the safety of COVID-19 vaccines. **V-safe** also provides second-dose reminders if needed and live telephone follow-up by CDC if participants report a significant health impact following COVID-19 vaccination. For more information on how to sign up, visit: www.cdc.gov/vsafe.

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WHAT IF I DECIDE NOT TO GET THE MODERNA COVID-19 VACCINE?
It is your choice to receive or not receive the Moderna COVID-19 Vaccine. Should you decide not to receive it, it will not change your standard medical care.

ARE OTHER CHOICES AVAILABLE FOR PREVENTING COVID-19 BESIDES MODERNA COVID-19 VACCINE?
Currently, there is no FDA-approved alternative vaccine available for prevention of COVID-19. Other vaccines to prevent COVID-19 may be available under Emergency Use Authorization.

CAN I RECEIVE THE MODERNA COVID-19 VACCINE WITH OTHER VACCINES?
There is no information on the use of the Moderna COVID-19 Vaccine with other vaccines.

WHAT IF I AM PREGNANT OR BREASTFEEDING?
If you are pregnant or breastfeeding, discuss your options with your healthcare provider.

WILL THE MODERNA COVID-19 VACCINE GIVE ME COVID-19?
No. The Moderna COVID-19 Vaccine does not contain SARS-CoV-2 and cannot give you COVID-19.

KEEP YOUR VACCINATION CARD
When you receive your first dose, you will get a vaccination card to show you when to return for your second dose of the Moderna COVID-19 Vaccine. Remember to bring your card when you return.

ADDITIONAL INFORMATION
If you have questions, visit the website or call the telephone number provided below.

To access the most recent Fact Sheets, please scan the QR code provided below.

Moderna COVID-19 Vaccine website	Telephone number
www.modernatx.com/covid19vaccine-eua	1-866-MODERNA (1-866-663-3762)

HOW CAN I LEARN MORE?

- Ask the vaccination provider
- Visit CDC at https://www.cdc.gov/coronavirus/2019-ncov/index.html
- Visit FDA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization
- Contact your state or local public health department

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WHERE WILL MY VACCINATION INFORMATION BE RECORDED?
The vaccination provider may include your vaccination information in your state/local jurisdiction's Immunization Information System (IIS) or other designated system. This will ensure that you receive the same vaccine when you return for the second dose. For more information about IISs, visit: https://www.cdc.gov/vaccines/programs/iis/about.html

WHAT IS THE COUNTERMEASURES INJURY COMPENSATION PROGRAM?
The Countermeasures Injury Compensation Program (CICP) is a federal program that may help pay for costs of medical care and other specific expenses of certain people who have been seriously injured by certain medicines or vaccines, including this vaccine. Generally, a claim must be submitted to the CICP within one (1) year from the date of receiving the vaccine. To learn more about this program, visit www.hrsa.gov/cicp/ or call 1-855-266-2427.

WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?
The United States FDA has made the Moderna COVID-19 Vaccine available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Services (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

The Moderna COVID-19 Vaccine has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of the scientific evidence available showing that the product may be effective to prevent COVID-19 during the COVID-19 pandemic and that the known and potential benefits of the product outweigh the known and potential risks of the product. All of these criteria must be met to allow for the product to be used during the COVID-19 pandemic.

The EUA for the Moderna COVID-19 Vaccine is in effect for the duration of the COVID-19 EUA declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

Patent(s): www.modernatx.com/patents
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Scan to capture that this Fact Sheet was provided to vaccine recipient for the electronic medical records/immunization information systems.
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Questions and Answers about the COVID-19 Vaccine for PALTC Staff, Patients, Residents and Family Members

December 1, 2020

1. **How is a vaccine developed and tested?**
   - Approval of a vaccine for use in people involves multiple phases with different goals for assessing effectiveness and safety in different populations. There are a total of 4 phases and the vaccine must meet very intense safety criteria before completing each phase. Once a vaccine is approved for use after phase 3, it has been tested in tens of thousands of people and if no significant harmful side effects are noted, it is considered safe for use. Phase 4 involves continued monitoring and gathering of safety data. This type of clinical trial has been used for decades to approve medications and vaccines.

2. **What are the Food and Drug Administration (FDA) requirements for the safety and efficacy of a COVID-19 vaccine?**
   - FDA requires 50% efficacy of a COVID-19 vaccine (the COVID-19 vaccines from Pfizer and Moderna are showing 94-95% efficacy in preventing COVID-19 disease during this trial phase). Many other companies are working on a vaccine and we expect that others will be approved by the FDA.
   - FDA requires 8 weeks of safety data on the COVID-19 vaccine.

3. **How will we know it is safe?**
   - Safety is the most important requirement for the vaccine and is assessed in trials by independent experts.
   - Most adverse side effects occur within 6 weeks of vaccine administration, and the FDA has required 8 weeks of safety monitoring so it can track any side effects.
   - FDA advises a minimum of 3,000 participants to assess safety. The current phase 3 trials have 30,000 to 50,000 participants. This really demonstrates how safety is a top priority for the FDA and the medical community.

4. **Who else will be evaluating this vaccine to ensure it is safe and effective?**
   - There are 2 advisory committees: (1) The Vaccine and Related Biological Products Advisory Committee (VRBPAC) that advises the FDA; (2) The Advisory Committee on Immunization Practices (ACIP) that advises the CDC.
   - These advisory boards are independent. Their job is to monitor vaccines to ensure safety regardless of money, politics, etc.
   - The people on these committees are experts from academic institutions and they are vetted to avoid a conflict of interest. Experts who may have a conflict of interest are not put on these committees.
   - The committees will evaluate the vaccine data for safety and efficacy, and also help to determine how it will be distributed.

Questions and Answers about the COVID-19 Vaccine for PALTC Staff, Patients, Residents and Family Members

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5. **What are the types of potential vaccines that may be approved?**
   - Messenger RNA (mRNA) vaccines are a new type of vaccine undergoing clinical trials (*see question #6 below for more information on this*). There are also other types vaccines being studied that are similar to vaccines we have used for other diseases. **None of these can give you COVID-19!** The goal is to give your body the tools it needs to fight COVID-19 effectively and/or prevent you from getting it at all.
   - Also, **none of the proposed vaccines contain live or killed viral particles**, even though some other effective vaccines for other diseases have (*see question #6 below for more information on how these new vaccines work).*
   - Most of the vaccines that are currently being tested will require 2 doses to be effective, given about 3-4 weeks apart.
   - This is to make sure your body has enough antibodies to fight COVID-19. Getting 2 doses within 3-4 weeks has been shown to be safe and there are other vaccines we have been using for years that require multiple doses without causing harm.

6. **How does an mRNA vaccine work?**
   - According to the Centers for Disease Control (CDC) website, mRNA vaccines contain material from the SARS-CoV-2 virus that causes COVID-19. This material gives our cells instructions for how to make a harmless protein that is unique to the virus. This protein cannot build a virus or cause infection. After our cells make copies of the protein, they destroy the genetic material from the vaccine. Our bodies recognize that the protein should not be there and build antibodies that will remember how to fight the virus that causes COVID-19 if we are infected in the future.
   - While mRNA technology is new in vaccine development, this technology is being successfully used in cancer treatments.
   - For more information, visit the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines/how-they-work.html

7. **What is an Emergency Use Authorization (EUA) and if the vaccine is approved for an EUA, what does that mean?**
   - An EUA is based on the need to use a vaccine quickly to save lives during an urgent health crisis.
   - You may be anxious about the speed with which a vaccine has been approved. While the EUA is a shorter process, no steps are skipped in the safety evaluation process.
   - This approval can still take weeks and the FDA will re-evaluate the numbers and data to ensure that the calculations are correct.
   - The FDA will assess if the vaccine's known and potential benefits outweigh the known and potential risks.
   - Both advisory boards (VRBPAC and ACIP) will also review all the data and information.

8. **How long will the vaccine protect us?**
   - It is likely that we will not know the answer to that question when a vaccine is released. That will take more research.

Questions and Answers about the COVID-19 Vaccine for PALTC Staff, Patients, Residents and Family Members

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- This vaccine may be like the annual flu vaccine, where we may need to have vaccine shots for COVID-19 on a regular basis. More research is needed to know this and it also depends on whether and how much the virus changes over the coming months to years.

9. When will we be protected after we get the vaccine?

- Even when people receive the vaccine they will not be immediately protected and will need to continue wearing masks, social distancing and practicing frequent hand hygiene.
- Some vaccines will require 2 shots, with a few weeks between each shot, and protection will usually occur about 2 weeks after the second shot.
- While no vaccine is 100% effective, some of the vaccines proposed are anticipated to be more than 90% effective. This will greatly reduce your risk of getting sick with COVID-19 and spreading COVID-19 to your loved ones.

10. After I have had the second dose of the vaccine and it is 2 weeks after my second shot, do I still have to wear a mask?

- Yes. Even though you have received your vaccine, most of the people around you have not. We know the vaccine prevents disease in the vaccinated person, but it still may be possible to transmit the disease to others, until the vaccine is in widespread use.
- Wearing a mask, social distancing, and practicing hand hygiene protects those who have not been vaccinated, especially our residents in long-term care.

11. What if I had COVID-19 or I took a test that showed I have antibodies? Should I get the vaccine?

- Yes, even if you have had COVID-19, it is safe to get the vaccine and this can add additional protection without causing any harm.
- If you have had a test that shows you have COVID-19 antibodies, you should still get the vaccine. It is safe and can increase your protection from future COVID-19 infections.

12. What are some of the possible side effects of the COVID-19 vaccine? Will the vaccine make me sick?

- The vaccines currently being tested in clinical trials can cause short-term discomfort (such as headache, muscle pains, fatigue, chills, fever, and pain at injection site) in a percentage of the people who receive them. This is the effect of your body developing immunity. Clinical trial participants reported that the discomfort went away after a day, sometimes sooner. When you receive the second dose of the vaccine, the discomfort can be more pronounced. This is a normal reaction, so be prepared.
- If you experience discomfort after the first dose of the vaccine, it is very important that you still receive the second dose a few weeks later for the vaccine to be effective.
- **This does not mean that the vaccine has given you COVID-19**. Rather, this means that the vaccine is causing your body's immune system to react and create antibodies to fight off the virus. **In other words, if you feel some discomfort, then the vaccine is doing its job!**
- In some cases, a person may **already** be infected with COVID-19 when they get the vaccine but are asymptomatic or pre-symptomatic. If they later have symptoms of COVID-19 or test positive for it, it **does not** mean they got COVID-19 from the vaccine.

Questions and Answers about the COVID-19 Vaccine for PALTC Staff, Patients, Residents and Family Members

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13. **We should expect that vaccine recommendations will change as additional vaccines are approved.**
    - At first, we may have one vaccine, then hopefully two or three. As different vaccines become available, some may be found to be better for different populations and different circumstances.
    - Just like our knowledge about the virus itself changes over time, so will the recommendations about vaccines.

14. **What can I be doing now while we wait for a vaccine to be approved and distributed?**
    - It is important to know about the process of how a vaccine is approved so you can ask questions.
    - Listen to the VRBPAC and ACIP committees' discussions as they are all public. Check the websites for updates:
      - VRBPAC meetings: https://www.fda.gov/advisory-committees/vaccines-and-related-biological-products-advisory-committee/2020-meeting-materials-vaccines-and-related-biological-products-advisory-committee
      - Here's a link to the recorded meeting from October 22, 2020: https://www.youtube.com/watch?v=1XTiLgrUpkg
      - ACIP meetings: https://www.cdc.gov/vaccines/acip/meetings/index.html
    - **Ask your medical director or provider about the vaccine** and have them share information and answer questions. You can talk to them about how they are planning to make their decision to get the COVID-19 vaccine.
    - It will be important to get your information from reliable sources, such as the CDC (www.cdc.gov), the Immunization Action Coalition (https://www.immunize.org), your facility's medical director, and other providers so you can get accurate information. **Social media is full of misinformation and opinions based on that misinformation, so be careful to look to reputable sources (such as those affiliated with academic institutions or non-profit professional organizations like AMDA) for information.**
    - Look for specific data on potential COVID-19 vaccines and listen to/read the scientists' evaluations of the data.

15. **Is the flu vaccine also safe and effective?**
    - **Yes!** The flu vaccine is a good example of how vaccines can help prevent disease and be safe.
    - It is more important this year than ever to get your flu shot so you can decrease your risk of getting the flu (you can get both the flu and COVID-19 at the same time), and reduce the spread of flu to others. This will also decrease the burden on healthcare staff who are caring for those with COVID-19.

16. **Who will be able to get the vaccine in a nursing home?**
    - CDC is recommending that nursing home residents and staff be among the first to get the vaccine. Long-term care staff will often be able to get vaccinated before the residents to decrease the risk of exposing the residents to COVID-19. Long-term care staff will include anyone who works in a nursing home, such as those who work in environmental services, not just those who perform direct patient care. This also includes staff who visit the nursing home, including doctors, physician assistants, nurse practitioners, medical directors, lab technicians and consultants.

Questions and Answers about the COVID-19 Vaccine for PALTC Staff, Patients, Residents and Family Members

December 1, 2020

Now is the time to understand the process, ask questions and get accurate information!

Additional Resources from the CDC:

CDC: About COVID-19 vaccines. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/about-vaccines.html

CDC: Provider Resources for COVID-19 Vaccine Conversations with Patients and Answering Patients' Questions. https://www.cdc.gov/vaccines/hcp/covid-conversations/ https://www.cdc.gov/vaccines/hcp/covid-conversations/answering-questions.html

CDC: Understanding the Pharmacy Partnership for Long-Term Care Program and Frequently Asked Questions. https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships.html https://www.cdc.gov/vaccines/covid-19/long-term-care/pharmacy-partnerships-faqs.html

CDPH: COVID-19 Vaccine Planning Questions and Answers. https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/COVID-19-Vaccine-Planning-Questions-and-Answers.aspx

Approved by the AMDA Executive Committee
December 1, 2020

FAQ'S AND Q&A'S

Answering Your Questions About the New COVID-19 Vaccines

Do clinical trial results show whether vaccines are effective?

Yes. Clinical trials provide data and information about how well a vaccine prevents an infectious disease and about how safe it is. The Food and Drug Administration (FDA) evaluates these data, along with information from the manufacturer, to assess the safety and effectiveness of a vaccine. FDA then decides whether to approve a vaccine or authorize it for emergency use in the United States.

After a vaccine is either approved or authorized for emergency use by FDA, more assessments are done before a vaccine is recommended for public use. The goal of these assessments is to understand more about the protection a vaccine provides under real-world conditions, outside of clinical trials.

After COVID-19 vaccines are approved or authorized for emergency use by FDA and recommended for public use, CDC will further assess their effectiveness. These real-world assessments will compare groups of people who do and don't get vaccinated and people who do and don't get COVID-19 to find out how well COVID-19 vaccines are working to protect people.

Why would the effectiveness of vaccines be different after the clinical trials?

Many factors can affect a vaccine's effectiveness in real-world situations. These factors can include things such as how a vaccine is transported and stored or even how patients are vaccinated. Vaccine effectiveness can also be affected by differences in the underlying medical conditions of people vaccinated as compared to those vaccinated in the clinical trials.

Assessments of vaccine effectiveness can also provide important information about how well a vaccine is working in groups of people who were not included or were not well represented in clinical trials.

How will experts evaluate the COVID-19 vaccines in real-world conditions?

Experts are working on many types of real-world studies to determine vaccine effectiveness, and each uses a different method:

- **Case-control studies** will include cases (people who have the virus that causes COVID-19) and controls (people who do not have the virus that causes COVID-19). People who agree to participate in a case-control study will provide information on whether they received a COVID-19 vaccine or not. Experts will look to see if the cases were less likely to have received the vaccine than controls, which would show that the vaccine is working.
- **A test-negative design study** will enroll people who are seeking medical care for symptoms that could be due to COVID-19. In this special type of case-control study, experts will compare the COVID-19 vaccination status of those who test positive (meaning they have COVID-19) to those who test negative (meaning they do not have COVID-19).

CDC

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www.cdc.gov/coronavirus/vaccines

FAQ'S AND Q&A'S

CDC | NCIRD | Answering Your Questions About the New COVID-19 Vaccines

- **Cohort studies** will follow people who have and haven't had a COVID-19 vaccine for several months to see if getting vaccinated protects them from getting the disease. This can be done in real time (prospectively) or by looking back in time (retrospectively) using data that were already collected, such as information in participants' medical records.
- **Screening method assessments** look at vaccination status among a group of cases (for example, cases detected through ongoing COVID-19 surveillance) and compares those cases with vaccination coverage among the overall population where those cases come from (for example people from the same state). By comparing coverage between these two groups, researchers can get an early estimate of whether a vaccine is working as expected.
- **Ecologic analysis assessments** look at groups of people – such as those in different geographic locations or at different times – to find out how many were vaccinated and how many were diagnosed with COVID-19. These analyses may be hard to interpret because the number of COVID-19 illnesses has changed rapidly over time and in different places.

CDC will use several methods because they can all contribute different information about how the vaccine is working.

Will assessments determine if the vaccines protect people from severe COVID-19 illness?

Yes. Severe illness from COVID-19 is defined as needing care in a hospital or intensive care unit (ICU), needing to be on a ventilator, or dying due to COVID-19.

- Experts will assess how well COVID-19 vaccines protect people against severe illness using case-control studies among hospitalized patients.
- Experts also will use cohort studies of electronic health records to see if people hospitalized with COVID-19 received the vaccine or not.

Will assessments determine if the vaccines protect people against mild illness?

Yes. CDC will use case-control studies to assess how well COVID-19 vaccines protect people against less severe forms of COVID-19 – for example, people with COVID-19 who need to visit a doctor but don't need to be hospitalized.

Will assessments determine if the vaccines protect people who are ill with no symptoms at all?

Yes. Some people can be infected with or "carry" the virus that causes COVID-19, but they don't feel sick or have any symptoms. Experts call this asymptomatic infection. It is important to know whether COVID-19 vaccines can help lower the number of people who have asymptomatic infection. People with asymptomatic infection can unknowingly spread the virus to others.

A special type of cohort study will find out how effective the vaccine is when people are asymptomatic. People who agree to participate will be tested for COVID-19 every week whether they have symptoms or not. Experts will then compare the proportion of people with infection who were vaccinated to the proportion of people with infection who were not vaccinated.

Who will be included in the real-world vaccine assessments?

CDC is working to make sure real-world vaccine assessments include diverse groups of people including the following:

Healthcare personnel and essential workers

Experts will rapidly assess vaccine effectiveness among healthcare personnel working in hospitals, long term care/skilled nursing facilities, or nursing homes in selected sites across the United States. These assessments will show how well COVID-19 vaccines protect healthcare personnel from getting sick or having severe illness. Assessments among healthcare personnel and essential workers will also inform how well COVID-19 vaccines protect them against getting infected, regardless of whether they have symptoms or not.

Older adults and those living in nursing homes

The risk for severe illness from COVID-19 increases with age, so making sure these vaccines protect older adults is critical. People living in nursing homes and long-term care facilities are at especially high risk of getting COVID-19 and severe disease. The Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) will

use CMS Medicare billing data to assess COVID-19 vaccine effectiveness among older adults, including those living in nursing homes and long-term care facilities. These data will include information about whether people received a COVID-19 vaccine, whether they got sick with COVID-19, and if they needed hospital care. This information will help inform how well the vaccine works in preventing COVID-19 and severe illness among older adults.

Experts will also use data from CDC and CMS to conduct a case-control assessment. Experts will identify older adults hospitalized for COVID-19 and older adults hospitalized for other reasons. They will then compare how many cases and controls received a COVID-19 vaccine to estimate vaccine effectiveness.

People with underlying medical conditions
To better understand how well COVID-19 vaccines protect people with underlying medical conditions who may be at increased risk for severe illness. Experts are working to make sure various real-world vaccine assessments will include adults with heart conditions, obesity, and diabetes. The real-world vaccine effectiveness assessments will also collect information about other underlying medical conditions. This information will be used to better understand how well COVID-19 vaccines protect people with underlying medical conditions.

People in racial and ethnic minority groups
Long-standing systemic health and social inequities have put many people from racial and ethnic minority groups at increased risk of getting sick and dying from COVID-19. CDC is working to ensure that real-world assessments of vaccine effectiveness include diverse populations, such as people from racial and ethnic minority groups disproportionately affected by COVID-19.

CDC also is working with the Indian Health Service (IHS), tribal nations, and other partners to ensure that these real-world assessments include American Indian and Alaska Native populations who have been disproportionately affected by COVID-19. This is important to ensure that COVID-19 vaccines can help achieve health equity, so everyone has a fair opportunity to be as healthy as possible.

These vaccines were produced so quickly. How do we know they are safe?

It is the U.S. vaccine safety system's job to make sure that all vaccines are as safe as possible. Safety has been a top priority while federal partners have worked to make COVID-19 vaccines available for use in the United States.

The new COVID-19 vaccines have been evaluated in tens of thousands of individuals, who volunteered to be vaccinated and to participate in clinical trials. The information from these clinical trials allowed the U.S. Food and Drug Administration (FDA) to determine the safety and effectiveness of the vaccines. These clinical trials were conducted according to rigorous standards set forth by FDA.

FDA has determined that the newly authorized COVID-19 vaccines meet its safety and effectiveness standards. Therefore, FDA has made these vaccines available for use in the United States under what is known as an Emergency Use Authorization.

Will CDC continue to watch for problems with these new vaccines?

Yes. Even though no safety issues arose during the clinical trials, CDC and other federal partners will continue to monitor the new vaccines for serious side effects (known as adverse events) using many vaccine safety monitoring systems.

This continued monitoring can pick up on side effects that may not have been seen in clinical trials. If an unexpected side effect with the new COVID-19 vaccines is seen, experts can quickly study it further to determine if it is a true safety concern. Monitoring vaccine safety is critical to help ensure that the benefits of the COVID-19 vaccines continue to outweigh the risks for people who are vaccinated.

The current vaccine safety system is strong and robust, with the capacity to monitor COVID-19 vaccine safety effectively. Existing data systems can rapidly detect if a vaccine has any possible safety problems. These systems are being scaled up to fully meet the needs of the nation. Additional systems and data sources are also being developed to further enhance safety monitoring capabilities.

CDC | NCIRD | Answering Your Questions About the New COVID-19 Vaccines

New vaccine safety monitoring systems and information sources

The following systems and information sources add another layer of safety monitoring, giving CDC and FDA the ability to evaluate COVID-19 vaccine safety in real time and make sure COVID-19 vaccines are as safe as possible:

- **CDC: V-SAFE** — A new smartphone-based, after-vaccination health checker for people who receive COVID-19 vaccines. V-SAFE will use text messaging and web surveys from CDC to check in with vaccine recipients for health problems following COVID-19 vaccination. The system also will provide telephone follow up to anyone who reports medically significant (important) adverse events.
- **CDC: National Healthcare Safety Network (NHSN)** — An acute care and long-term care facility monitoring system with reporting to the Vaccine Adverse Event Reporting System or VAERS
- **FDA: Other large insurer/payer databases** — A system of administrative and claims-based data for surveillance and research

Existing Safety Monitoring Systems

The safety of vaccines is monitored all the time with multiple approaches. As people get vaccinated, CDC, FDA, and other federal partners will use the following existing, robust systems and data sources to conduct ongoing safety monitoring in the following groups:

General public

- **CDC and FDA: Vaccine Adverse Event Reporting System (VAERS)** — The national system that collects reports from healthcare professionals, vaccine manufacturers, and the public of adverse events that happen after vaccination; reports of adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns are followed up with specific studies
- **CDC: Vaccine Safety Datalink (VSD)** — A network of 9 integrated healthcare organizations across the United States that conducts active surveillance and research; the system is also used to help determine whether possible side effects identified using VAERS are actually related to vaccination
- **CDC: Clinical Immunization Safety Assessment (CISA) Project** — A collaboration between CDC and 7 medical research centers to provide expert consultation on individual cases and conduct clinical research studies about vaccine safety
- **FDA and the Centers for Medicare and Medicaid Services: Medicare data** — A claims-based system for active surveillance and research
- **FDA: Biologics Effectiveness and Safety System (BEST)** — A system of electronic health record, administrative, and claims-based data for active surveillance and research
- **FDA: Sentinel Initiative** — A system of electronic health record, administrative, and claims-based data for active surveillance and research

Members of the military

- **Department of Defense (DOD): DOD VAERS data** — Adverse event reporting to VAERS for the DOD populations
- **DOD: Vaccine Adverse Event Clinical System (VAECS)** — A system for case tracking and evaluation of adverse events following immunization in DOD and DOD-affiliated populations
- **DOD: DOD Electronic Health Record and Defense Medical Surveillance System** — A system of electronic health record and administrative data for active surveillance and research

Veterans

- **Department of Veterans Affairs (VA): VA Adverse Drug Event Reporting System (VA ADERS)** — A national reporting system for adverse events following receipt of drugs and immunizations
- **VA Electronic Health Record and Active Surveillance System** — A system of electronic health record and administrative data for active surveillance and research

Tribal nations

- **Indian Health Service (IHS): IHS VAERS data** — Spontaneous adverse event reporting to VAERS for populations served by IHS and Tribal facilities

FAQ'S AND Q&A'S

Myth Vs. Fact

MYTH

The COVID-19 vaccine is not safe because it was rapidly developed and tested

Many pharmaceutical companies invested significant resources into quickly developing a vaccine for COVID-19. Due to these significant resources, they were able to combine steps, to meet all safety protocols and adequate testing.

FACT

FACT

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again. This is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this.

I already had COVID-19 and recovered, so I don't need to get a COVID-19 vaccine when it's available

MYTH

MYTH

There is high risk for severe side effects of the COVID-19 vaccines

There are short-term mild or moderate vaccine reactions, similar to other vaccines, that resolve without complication or injury. The early phase studies of the vaccine show that it is safe.

FACT

FACT

It may take time for everyone who wants a COVID-19 vaccination to get one. While the vaccine may prevent you from getting sick, it is unknown at this time if you can still carry and transmit the virus to others. It is important to continue with precautions such as mask-wearing and physical distancing.

I won't need to wear a mask after I get the COVID-19 vaccine.

MYTH

MYTH

The COVID-19 vaccine will alter my DNA

The first COVID-19 vaccines to reach the market are messenger RNA (mRNA) vaccines. According to the CDC, mRNA vaccines work by instructing cells in the body how to make a protein that triggers an immune response. Injecting mRNA into your body will not interact or do anything to the DNA of your cells. Human cells break down and get rid of the mRNA soon after they have finished using the instructions.

FACT

FACT

COVID-19 vaccines will not give you COVID-19. None of the COVID-19 vaccines currently in development in the United States use the live virus that causes COVID-19. The goal for the vaccine is to teach our immune systems how to recognize and fight the virus that causes COVID-19. Sometimes these vaccines will provide mild symptoms, such as fever, but these are normal and are a sign that the body is building immunity.

The COVID 19 vaccine gives you COVID 19

MYTH

FAQ'S AND Q&A'S

Fast Facts — *What LTCF's Want to Know*

Q. ***Why Should I get vaccinated?***

A: Getting vaccinated protects yourself, your family and those that are around you. It helps stop the spread in the community and keeps those around you safe.

Q. ***What if I am not able to sign the COVID 19 Consent Form?***

A: Walgreens has shared that facilities/communities should follow standard procedures and that they would accept verbal consent

Q. ***Will residents and staff be charged for vaccine?***

A: No, the vaccine and administration during the public health emergency are free to anyone who receives it.

Q. ***Is getting the vaccine safe?***

A: Yes – The FDA analysis of the vaccine's safety and effectiveness on people aged 16 and older found "no specific safety concerns" that would preclude the vaccine's use.

Q. ***Do I need a vaccine if I have had COVID-19?***

A: It is recommended that all individuals should receive the COVID 19 vaccine unless the person currently has COVID-19 infection.

Q. ***Do I have to get the vaccine?***

A: No, the COVID 19 vaccine is not required. The CDC does highly recommend getting the COVID 19 vaccine once it is available.

Q. ***Do I still need to wear a mask after receiving the COVID 19 vaccine?***

A: Yes, It is important to continue with precautions such as mask-wearing and physical distancing until those precautions are lifted by the CDC.

Q. ***Will I have symptoms after getting the vaccine?***

A: Individuals may experience mild symptoms, such as a headache or fever, but these generally only last 1-2 days. These symptoms are a sign that your immune system is doing exactly what is it supposed to do. ***Note: Some potential side effects may mimic symptoms.***

Q. ***Could I still get COVID 19 if I took the vaccine?***

A: It is possible that you may still become infected with Coronavirus after taking the COVID 19 vaccine. Though the rate of efficacy of the COVID 19 vaccines is high.

Q. ***What if I do not get the second dose in time?***

A: There is a grace period of 4 days for the second dose being given earlier (on Days 17-21). If more than 21 days have elapsed since the first dose, the second dose should be given at the earliest opportunity; the series does not need to be repeated.

Q. ***What if I get COVID 19 between vaccine doses?***

A: The second dose should also be deferred if a person contracts COVID until the person has recovered from the acute illness (if the person had symptoms) and criteria have been met for them to discontinue isolation. The series does not need to be repeated

Q. ***Will getting the COVID 19 vaccine give me COVID 19?***

A: A person will not get COVID 19 as a result of the COVID 19 vaccine.

Q. ***Can I switch my COVID 19 vaccine between doses?***

A: People should complete the series with the same product. It is not interchangeable with other vaccines currently under review.

Q. ***Can I get other vaccines at the same time as getting the COVID 19 vaccine?***

A: No, you cannot get other vaccines at the same time as getting the COVID 19 vaccine, and you should not receive the COVID 19 vaccine within 14 days of another vaccine.

Understanding Common Symptoms

Common symptoms that can occur following the COVID 19 vaccination:

- Fever, fatigue, headache, chills, myalgia (muscle pain), and arthralgia (joint pain) are the most commonly reported symptoms
- These tend to be rated mild to moderate in severity
- The symptoms typically occur within the first three days of vaccination (the day of vaccination and following two days, with most occurring the day after vaccination)
- They generally resolve within 1-2 days of onset
- Symptoms occur more frequently and severely following the second dose
- Symptoms were noted more frequently among younger persons compared to those who are older (>55 years)

Symptoms not consistent with post-COVID 19 vaccination:

- Cough, shortness of breath, rhinorrhea (runny nose), sore throat, or loss of taste or smell (may be symptoms of COVID-19 or another infection)

Signs and symptoms, alone, not consistent with SARS-CoV-2 infection:

- Immediate hypersensitivity reactions (e.g., urticaria, anaphylaxis)
- Local symptoms (e.g., pain, swelling, or redness at injection site)

NOTE: these should be managed per usual protocols for vaccine-related side effects

Continued Infection Prevention and Control Practices

Healthcare personnel at LTCs should follow recommended infection prevention and control practices such as:

- Close monitoring of residents for symptoms of COVID-19
- Universal source control
- Physical distancing (when possible)
- Hand hygiene
- Optimizing engineering controls
- Use of personal protective equipment (PPE)
    - o Facemask and eye protection

Because information is quickly changing on vaccine effectiveness; the reduction in disease, severity, or transmission; the duration of protection, residents and healthcare personnel should continue to follow all current infection prevention and control recommendations to protect themselves and others from the COVID-19 infection, regardless of their vaccination status.

Proposed tactics to evaluating and managing new onset post-vaccination symptoms

Symptoms	Proposed Tactic
Symptoms **NOT** consistent with post-COVID 19 vaccination but symptoms consistent with COVID 19 or another Infection	Evaluate for possible infections, including testing for COVID 19 or other pathogens. Pending evaluation, these residents should be quarantined to a single room and cared for by healthcare personnel following PPE guidelines. If results are negative, resident may return to normal activity
Symptoms **THAT ARE** consistent with post-COVID 19 vaccination Fever defined in LTC: single measured temperature of 100.0°F (37.8°C) or higher or repeated temperatures of 99.0°F (37.2°C)	Evaluate the resident. Resident should be restricted to current room and closely monitored (unless medical attention is necessary) until: • *Fever resolves and* • *Symptoms improve* Healthcare personnel should wear PPE. If residents symptoms resolve within 2 days, precautions can be discontinued. Fever should be resolved for at least 24 hours before discontinuing precautions. COVID 19 testing should be considered if symptoms do not begin to improve in 2 days. Residents that are COVID 19 positive or who have been in prolonged close contact with a COVID 19 positive person with the previous 14 days should be tested for COVID 19.

The tactics outlined in the Table above apply to residents who have received the COVID-19 vaccination in the prior 3 days (including day of vaccination, which is considered day 1).

NOTE: Facilities that are conducting outbreak testing for COVID-19 transmission, or evaluating residents who have had prolonged close contact someone with the COVID-19 infection in the previous 14 days, should care for residents following all recommended infection control practices including placement in Transmission-Based Precautions with use of all recommended personal protective equipment,and performing appropriate testing.

All symptomatic residents should be assessed; the tactics suggested in the table above should be tailored to fit the clinical and epidemiologic characteristics of the specific case.

In any situation, positive tests for COVID-19, if performed, should not be attributed to the COVID-19 vaccine, as vaccination does not influence the results of these tests.

These factors are based on the current understanding of symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine unfolds.

Stay up to date by visiting the PharMerica COVID-19 webpage: pharmerica.com/covid19

COMMUNICATING WITH RESIDENTS

Making a Strong Recommendation for COVID-19 Vaccination

Engaging in Effective COVID-19 Vaccine Conversations

The following techniques and resources provide support for discussing vaccination with patients before COVID-19 vaccines are widely available in the United States. Whether you have these discussions with your patients during an in-person office visit, through messages on your patient portal, or at a telemedicine appointment, your strong vaccine recommendation is the most important part of the conversation.

1 ***Start from a Place of Empathy and Understanding***

The pandemic has been stressful for many people. The first step is to acknowledge the disruption COVID-19 has caused in all our lives, providing an opportunity to recognize common concerns that can be addressed by a vaccine.

2 ***Assume Patients Will Want to Be Vaccinated but May Not Know When to Expect It***

Consider providing the following general information to patients about the timeline for COVID-19 vaccines:

- Limited COVID-19 vaccine doses may be available in 2020.
- It is anticipated that vaccine supply will increase substantially in 2021.
- The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. However, not everyone will be able to get vaccinated right away.

It is understandable how concerning it could be for your patients if they cannot be vaccinated right away. Encourage them to continue taking steps to protect themselves from COVID-19 and let them know how you plan to share updates about vaccine availability.

3 ***Give Your Strong Recommendation***

Let your patients know you plan to recommend COVID-19 vaccination for them. Patients consistently rank healthcare providers as their most trusted source for vaccine information. In this unique position, you are able to provide a strong recommendation that is critical for vaccine acceptance. Share the importance of COVID-19 vaccines to protect patients' health, as well as the health of those around them, or talk about your personal plans to get a COVID-19 vaccine.

Example:

"I strongly recommend you get a COVID-19 vaccine once it is widely available..."
"...This shot is especially important for you because of your [job/underlying health condition]."
"...I believe in this vaccine so strongly that I plan to get it as soon as it is available."

Making a Strong Recommendation for COVID-19 Vaccination | Continued

4 ***Listen to and Respond to Patient Questions***

If a patient has concerns or questions, this doesn't necessarily mean they won't accept a COVID-19 vaccine. Sometimes patients simply want your answers to their questions.

Your willingness to listen to their concerns will play a major role in building trust in you and your recommendation. Make it clear that you understand they have questions, and you want to answer them, so they feel confident in choosing to get vaccinated.

Seek to understand your patients' concerns and provide information they need in a way they can understand it. Explore some of the vaccine questions patients ask about most and find tips for how to answer their questions: Answering Patient's Questions.

5 ***Wrapping up the Conversation***

Once you've answered their questions, let your patients know that you are open to continuing the conversation. Encourage your patients to take at least one action, such as:

- Scheduling another appointment, or
- Reading the additional information you provide them about COVID-19 vaccination.

Because these vaccines are new, your patients' comfort level with when to get vaccinated will vary. Continue to remind them about the importance of getting a COVID-19 vaccine during future routine visits.

COMMUNICATING WITH RESIDENTS

Answering Patients' Questions

Some patients won't have questions about coronavirus disease 2019 (COVID-19) vaccination when you give your strong recommendation and use language that assumes patients will get vaccinated when doses are widely available. If a patient questions your recommendation about COVID-19 vaccination, this does not necessarily mean they will not accept a COVID-19 vaccine. This is a new vaccine, and some questions are to be expected. Your patients consider you their most trusted source of information when it comes to vaccines, and sometimes they simply want your answers to their questions.

Questions about Vaccine Safety and the Speed of Vaccine Development

The federal government, under the umbrella of Operation Warp Speed, has been working since the start of the pandemic to make a COVID-19 vaccine available as soon as possible. This accelerated timeline is unprecedented and has raised concerns for some people that safety may be sacrificed in favor of speed. However, as with all vaccines, safety is a top priority.

Patients may ask: How do we really know if COVID-19 vaccines are safe? To respond, you can explain how:

- The Food and Drug Administration (FDA) carefully reviews all safety data from clinical trials and authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
- The Advisory Committee on Immunization Practices (ACIP) reviews all safety data before recommending any COVID-19 vaccine for use. Learn how ACIP makes vaccine recommendations.
- FDA and CDC will continue to monitor the safety of COVID-19 vaccines, to make sure even very rare side effects are identified

Example:
COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offers protection to people of different ages, races, and ethnicities, as well as those with different medical conditions.

Questions about Whether It Is Better to Get Natural Immunity Rather than Immunity from Vaccines

Because some people with COVID-19 can have very mild symptoms, some may see natural infection as preferable to receiving a new vaccine. Others may be concerned that getting a COVID-19 vaccine could make a later illness worse. Help your patients understand the risks and benefits so they can be confident choosing to get vaccinated.

Patients may ask: Is the vaccine that helpful? I heard getting COVID-19 gives you better and longer immunity than the protection a vaccine can give. Can it actually make my illness worse if I do end up getting COVID-19?
To respond, you can:

- Explain the potential serious risk COVID-19 infection poses to them and their loved ones if they get the illness or spread it to others. Remind them of the potential for long-term health issues after recovery from COVID-19 disease
- Explain that scientists are still learning more about the virus that causes COVID-19. And it is not known whether getting COVID-19 disease will protect everyone against getting it again, or, if it does, how long that protection might last.
- Describe how the vaccine was tested in large clinical trials and what is currently known about its safety and effectiveness.

COMMUNICATING WITH RESIDENTS

Answering Patients' Questions | Continued

Be transparent that the vaccine is not a perfect fix. Patients will still need to practice other precautions like wearing a mask, social distancing, handwashing and other hygiene measures until public health officials say otherwise.

Example:
"Both this disease and the vaccine are new. We don't know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people. If you get COVID-19, you also risk giving it to loved ones who may get very sick. Getting a COVID-19 vaccine is a safer choice."

Understanding and Explaining mRNA COVID-19 Vaccines

This page provides vaccine information for healthcare professionals and vaccine providers and tips for explaining mRNA vaccines to patients and answering questions about how mRNA vaccines work, their safety profile, and common misconceptions.

Key Points to Share with Your Patients

In addition to the following key messages, you can refer your patients with questions to CDC's COVID-19 mRNA vaccine webpage.

- Like all vaccines, COVID-19 mRNA vaccines have been rigorously tested for safety before being authorized for use in the United States.
- mRNA technology is new, but not unknown. They have been studied for more than a decade.
- mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person.
- mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA.

A New Approach to Vaccines

mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response and build immunity to SARS-CoV-2, the virus that causes COVID-19. In contrast, most vaccines use weakened or inactivated versions or components of the disease-causing pathogen to stimulate the body's immune response to create antibodies.

Mechanism for Action

mRNA vaccines have strands of genetic material called mRNA inside a special coating. That coating protects the mRNA from enzymes in the body that would otherwise break it down. It also helps the mRNA enter the muscle cells near the vaccination site.

mRNA can most easily be described as instructions for the cell on how to make a piece of the "spike protein" that is unique to SARS-CoV-2. Since only part of the protein is made, it does not do any harm to the person vaccinated but it is antigenic.

After the piece of the spike protein is made, the cell breaks down the mRNA strand and disposes of them using enzymes in the cell. It is important to note that the mRNA strand never enters the cell's nucleus or affects genetic material. This information helps counter misinformation about how mRNA vaccines alter or modify someone's genetic makeup.

Once displayed on the cell surface, the protein or antigen causes the immune system to begin producing antibodies and activating T-cells to fight off what it thinks is an infection. These antibodies are specific to the SARS-CoV-2 virus, which means the immune system is primed to protect against future infection.

Understanding and Explaining mRNA COVID-19 Vaccines | Continued

COVID-19 mRNA Vaccines Will Be Rigorously Evaluated for Safety

COVID-19 mRNA vaccines will go through the same rigorous safety assessment as all vaccines before they are authorized or approved for use in the United States by the Food and Drug Administration. This includes large clinical trials and data review by a safety monitoring board.

Often patients are concerned about live vaccines. mRNA vaccines are not live vaccines and do not use an infectious element, so they carry no risk of causing disease in the person vaccinated.

mRNA Vaccines Are New, But Not Unknown

There are currently no licensed mRNA vaccines in the United States. However, researchers have been studying them for decades.

Early stage clinical trials using mRNA vaccines have been carried out for influenza, Zika, rabies, and cytomegalovirus (CMV). Challenges encountered in these early trials included the instability of free RNA in the body, unintended inflammatory outcomes, and modest immune responses. Recent technological advancements in RNA biology and chemistry, as well as delivery systems, have mitigated these challenges and improved their stability, safety, and effectiveness.

Beyond vaccines, numerous preclinical and clinical studies have used mRNA to encode cancer antigens to stimulate immune responses targeted at clearing or reducing malignant tumors.

Benefits of mRNA Vaccines

mRNA vaccines have several benefits compared to other types of vaccines including use of a non-infectious element, shorter manufacturing times, and potential for targeting of multiple diseases. mRNA vaccines can be developed in a laboratory using a DNA template and readily available materials. This means the process can be standardized and scaled up, making vaccine development faster than traditional methods. In addition, DNA and RNA vaccines typically can be moved most rapidly into the clinic for initial testing. In the future, mRNA vaccine technology may allow for one vaccine to target multiple diseases

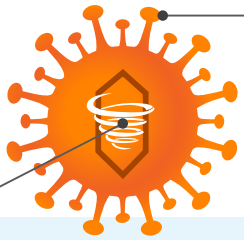
WHAT ARE RNA VACCINES
and how do they work?

PharMerica®

What are RNA vaccines?

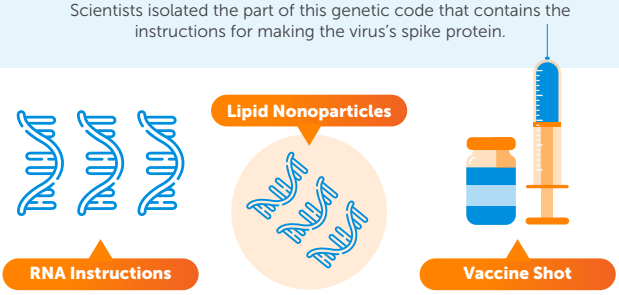
SARS-CoV-2

Viral RNA
The virus's genetic material. Contains instructions for making proteins.

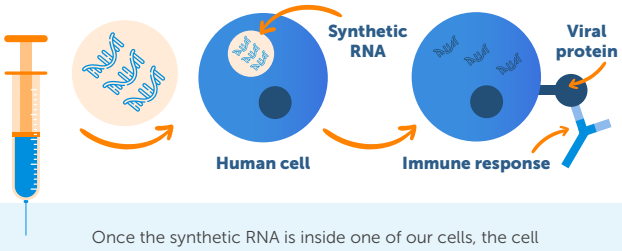


Spike protein
Protein which helps the virus penetrate cells and initiates an infection.

The genetic code of the SARS-CoV-2 virus is made up of RNA. Scientists isolated the part of this genetic code that contains the instructions for making the virus's spike protein.



Synthetic RNA which codes for the virus spike protein is packed in lipid nonparticles (very small fat droplets). This stops our bodies' enzymes breaking it down and helps our cells take it in.



Once the synthetic RNA is inside one of our cells, the cell follows the RNA instructions to produce the virus spike protein. It's production then triggers an immune response in our bodies.

RNA Vaccines: Benefits and Challenges

Vaccine Production

RNA is easy to make in a lab, so RNA vaccines can be developed quicker than other vaccines.

Safety of the Vaccines

RNA can't cause infection and is broken down by normal processes in our cells. An RNA vaccine hasn't been licensed for use in humans before but they've been under development for several years for other viruses, including influenza, HIV, and Zika.

Storage and Transport

Some RNA vaccines must be stored at low temperatures to remain stable, which makes storage and transport more challenging.

RNA Vaccines for COVID-19

Several proposed vaccines for COVID-19 are RNA vaccines.

mRNA vaccines: Moderna • Pfizer & BioNTech • CureVac

Getting 'Back to Normal' Is Going to Take **All of Our Tools**

If we use all the tools we have, we stand the best chance of getting our families, communities, schools, and workplaces "back to normal" sooner:

Get vaccinated.

Wear a mask.

Stay 6 feet from others, and avoid crowds.

Wash hands often.

www.cdc.gov/coronavirus/vaccines

12/09/20

Three Reasons Why You Were Given Top Priority to Be Vaccinated Against COVID-19

1. You are on the front lines and risk being exposed to people with COVID-19 each day on the job.

2. Protecting you also helps protect your patients and your family, especially those who may be at higher risk for severe illness from COVID-19.

3. You matter. And you play an essential role in keeping your community healthy.

Lead the way!

Encourage your coworkers, patients, family and friends to get vaccinated.

www.cdc.gov/coronavirus/vaccines

12/09/20

HELP US ALL BE VACCINATION READY

PROTECT YOURSELF!

- ***FDA-authorized COVID-19 vaccines*** have demonstrated effectiveness in preventing COVID-19 development in those vaccinated.

PROTECT OTHERS!

- ***Herd immunity happens when a virus can't spread*** because it keeps encountering people who are protected against infection.
- ***Vaccination will build this immunity*** without people having to experience sickness.
- ***Our nation's most vulnerable residents,*** including young children and elders, are counting on us.

DO IT SAFELY!

- ***FDA-authorized COVID-19 vaccinations have been rigorously tested*** in large, well designed studies, following the same multi-phase process as every other vaccine.
- ***Data from these studies*** have been made available for public review to offer transparency.
- Prior to earning approval for Emergency Use Authorization, authorized vaccines withstood FDA scrutiny by meeting ***all quality, safety, and efficacy standards.***

STOP THE PANDEMIC!

- ***COVID-19 vaccination will be an important tool*** to help stop the pandemic.
- ***Wearing masks and social distancing*** help reduce your chance of being exposed to the virus or spreading it to others, but these measures are not enough to stop the pandemic.
- ***Vaccination is our strongest countermeasure*** to overcome the Public Health Emergency.
- ***The United States has done this before,*** with diseases that include: Smallpox, Polio, Diphtheria, and Rubella.

PharMerica | Contact your PharMerica Account Manager for any additional needs
To learn more visit: pharmerica.com/covid19