COVID-19 Vaccine
Healthcare Provider Frequently Asked Questions
September 7, 2021

New/Updated Information is highlighted in yellow.

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General Vaccine Information

Who is the CDC and what is their role with the COVID-19 vaccine?
The Centers for Disease Control and Prevention (CDC) is the national public health institute in the United States under the Department of Health and Human Services. The CDC’s overall responsibility is to address health and safety.

The CDC is focused on vaccine planning, working closely with health departments and partners as vaccines become available. The CDC does not have a role in developing COVID-19 vaccines. Learn more about the vaccine planning process by visiting https://www.cdc.gov/coronavirus/2019-ncov/vaccines/8-things.html.

What is New Jersey doing to plan for the COVID-19 vaccine?
The New Jersey Department of Health collaborated with health care partners and immunization stakeholders to develop the New Jersey COVID-19 Vaccination Plan. This plan encompasses suggested priority groups for vaccination, logistics of vaccine storage and handling, healthcare provider recruitment, tracking and reporting of immunizations, etc. The plan is available at https://www.state.nj.us/health/cd/topics/covid2019_vaccination.shtml
The Department will continue to update the plan as we receive new information and federal guidance.

Is a COVID-19 vaccine necessary?
COVID-19 can be a minor illness in some or lead to severe disease or even death in previously healthy people. This means, everyone should take the virus seriously — if not for themselves, then for those around them.

Many treatments and medications are being studied, but there is no cure. Prevention is key. Vaccination is an important step in helping to prevent this illness and its potentially devastating consequences.

What vaccines are approved or authorized for use?
The FDA approved the Pfizer-BioNTech COVID-19 vaccine, which will now be marketed as Comirnaty (koe-mir’-na-tee), for the prevention of COVID-19 disease in those 16 years of age and older. The vaccine will continue to be available under emergency use authorization (EUA) for those 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

The following vaccines are available as an EUA in the United States:

- Moderna: two-dose series for those 18 and older
- Janssen’s Johnson & Johnson (hereon referred to as J&J): one-dose vaccine for those 18 and older.
Since the FDA already approved Comirnaty, what was the purpose of the Advisory Committee on Immunization Practices (ACIP) recommendation?

FDA approves licenses for vaccines, but ACIP makes recommendations for the use of those FDA-licensed vaccines. This recommendation comes after thoroughly evaluating all available data, ranging from disease burden, public health impact, a risk-benefit analysis and more. ACIP recommendations are what providers use to decide which vaccines should be administered to which individuals.

For more information about the ACIP, visit https://www.cdc.gov/vaccines/acip/committee/index.html.

When did Pfizer become available to those 12 through 15?

On May 12, 2021, CDC Director, Rochelle P. Walensky, adopted the CDC’s Advisory Committee on Immunization Practices’ (ACIP) recommendation of the Pfizer-BioNTech COVID-19 vaccine use in 12- through 15-year-old adolescents. CDC now recommends that this vaccine be used among this population, and providers may begin vaccinating them right away.


Why should children receive the COVID-19 vaccine?

COVID-19 vaccination can help protect children from getting COVID-19. While fewer children have been sick with COVID-19 compared to adults, children can be infected with the virus that causes COVID-19, can get sick from COVID-19, and can spread the virus that causes COVID-19 to others. Children, like adults, who have COVID-19 but have no symptoms (“asymptomatic”) can still spread the virus to others. Vaccination is now recommended for everyone 12 years and older. Currently, the Pfizer-BioNTech COVID-19 Vaccine is the only one available to children 12 years and older.

For more information, visit https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w.

How much will a vaccine reduce the risk of COVID-19 and its complications?

According to the FDA, the Moderna vaccine has 94.1% efficacy at preventing symptomatic cases. The Pfizer vaccine has 95% efficacy. J&J’s one-dose vaccine has a 72% efficacy rate in the U.S. clinical trial sites. Additionally, the J&J vaccine was approximately 77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination.

Recent studies that have looked at how COVID-19 vaccines work in real-world conditions (vaccine effectiveness studies) have shown that these vaccines are working well. While COVID-19 vaccines are working well, some people who are fully vaccinated against COVID-19 will still get sick, because no vaccines are 100% effective. These are called vaccine breakthrough cases. However, there are some data to suggest that vaccination may make symptoms less severe in

How many COVID-19 vaccines are under development?
Multiple COVID-19 vaccines are under development. There are currently more than 50 COVID-19 vaccine candidates in trials. For additional information, please see the WHO website at https://www.who.int/emergencies/diseases/novel-coronavirus-2019/covid-19-vaccines?gclid=EAIaIQobChMIroXC2uvD7AIIVNgilCRC3pCg1tEAAYAiAAEgJi7_D_BwE.

Are more people now eligible for vaccination?
Everyone 12 or older who lives, works, or studies in New Jersey is now eligible for a COVID-19 vaccine.

PLEASE NOTE: 12 to 17-year-olds must have the consent of a parent or legal guardian to be vaccinated, and can only receive the Pfizer vaccine at this time under the FDA’s Emergency Use Authorization. Persons less than 18 years of age should be sure to schedule appointments at a site that has Pfizer vaccine. Both Moderna and J&J are authorized for persons 18 years of age and older.

How can I get vaccinated?
There are multiple ways to get an appointment including:
  1. Use the NJ Vaccine Appointment Finder to find vaccination locations near you with available appointments.
  2. Attend a pop-up or mobile vaccination event in your community.
  3. Register with the NJ Vaccine Scheduling System to be notified when an appointment is available to you at vaccine locations that use the State's Vaccine Scheduling System. If you need assistance registering with the NJVSS, please call 855-568-0545.
  4. Seniors 65+ can call the senior-specific hotline at 856-249-7007 from 8am to 8pm to schedule dedicated vaccine appointments
  5. Veterans, their spouses, and their caregivers may be eligible for vaccines through the VA. Learn more here.

Note: Please verify requirements with a vaccination site before visiting or making an appointment. Some require proof of residency within a specific county or municipality. In addition, 12 to 17-year-olds must have the consent of a parent or legal guardian to be vaccinated, and can only receive the Pfizer vaccine at this time under the FDA’s Emergency Use Authorization.

I have some patients who are homebound. Will they be able to receive the COVID-19 vaccine?
A person who is homebound or their healthcare provider/caregiver may request an in-home vaccination appointment by completing a form at covid19.nj.gov/homeboundvax (English) or covid19.nj.gov/homeboundvax-es (Spanish).
For assistance completing the form by phone, please call the **NJ COVID-19 Vaccine Call Center at 1-855-568-0545**.

**Can you tell me more about the NJVSS? Is my information private?**
The NJVSS is a secure online website developed by the NJ Department of Health for public health purposes. The NJVSS is a system that allows you to sign-up to make a COVID-19 vaccine appointment.

You will be asked to provide personal information (name, address, gender, race, and email), medical screening and occupation information. This helps to determine your eligibility for the vaccine or more importantly, which phase best fits you! NJVSS will send you e-mail reminders about your appointment and reminders about getting the 2nd dose. The NJVSS also lets you make an appointment at a vaccination location most convenient for you.
The information collected on the NJVSS is used for public health purposes only AND to ensure that same person returns for the 2nd dose of the same vaccine. For more information, visit [https://covid19.nj.gov/pages/vaccine](https://covid19.nj.gov/pages/vaccine) and [https://covidvaccine.nj.gov/](https://covidvaccine.nj.gov/).

**Some of my patients used the NJVSS to receive the vaccine at my facility. Who do I contact for technical assistance with using NJVSS?**
Providers should email [NJVaxReporting@doh.nj.gov](mailto:NJVaxReporting@doh.nj.gov) for any issues or questions relating to NJVSS.

**I have patients who lost their COVID-19 vaccination card or need additional proof of vaccination. What advice can you give them?**
Patients may be able to get another copy of their COVID-19 vaccine card at the site where they were vaccinated; however, not all sites provide this service and some locations have closed. Alternatively, you can print your patient’s official immunization record for them. Please include the COVID-19 vaccine lot number for the patient. The official record will list all vaccines that your patient has received and the dates of administration.

Another option is for individuals to download the Docket mobile app (COVID-19 vaccines only) or submit a request to NJIIS. For specific instructions, visit [https://njiis.nj.gov/core/web/index.html#/requestImmunizationRecord](https://njiis.nj.gov/core/web/index.html#/requestImmunizationRecord).

**How many shots of COVID vaccine will be needed?**
Both Pfizer and Moderna require two shots. These vaccines are not interchangeable meaning you need to receive **two doses** of the **same** vaccine.

The J&J vaccine is only one dose.

**Are booster doses needed after you are fully vaccinated?**
A person is considered fully vaccinated ≥2 weeks after a 2-dose mRNA COVID-19 vaccine series or ≥2 weeks after a single dose of Janssen’s Johnson and Johnson COVID-19 Vaccine. The need
for and timing of a COVID-19 booster dose has not been established, and no booster doses are recommended at this time.

This guidance may be updated as more information becomes available.

Where can my patients find information on public transportation to vaccine locations?
Through the Department’s VAXRIDE initiative, NJ TRANSIT supports New Jerseyans in their efforts to get vaccinated against COVID-19. Visit https://www.njtransit.com/vaxride to find vaccination sites that are conveniently served by NJ TRANSIT bus, train and light rail routes.

In addition, NJ 211 is offering free rides to and from vaccination sites in partnership with United Way Worldwide and Lyft. Rides are available wherever Lyft operates in New Jersey and is available to everyone including those with collapsible wheelchairs and walkers. To request a free ride, call 211 or text 898-211, or visit 211 to learn more.

Can I be protected by just receiving one dose of the COVID-19 vaccine?
J&J’s one-dose vaccine has a 72% efficacy rate in the U.S. clinical trial sites. Additionally, the vaccine was approximately 77% effective in preventing severe/critical COVID-19 occurring at least 14 days after vaccination and 85% effective in preventing severe/critical COVID-19 occurring at least 28 days after vaccination. For more information, visit https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/janssen-covid-19-vaccine-frequently-asked-questions.

Both Pfizer and Moderna require two shots. A recent study showed under real-world conditions, mRNA vaccine effectiveness of full immunization (≥14 days after second dose) was 90% effective against SARS-CoV-2 infections regardless of symptom status; vaccine effectiveness of partial immunization (≥14 days after first dose but before second dose) was 80%. You must receive two doses in order to get the best protection against COVID-19. For more information, visit https://www.cdc.gov/mmwr/volumes/70/wr/mm7013e3.htm.

Ask your healthcare provider about tools (like V-safe) that can send you automated reminders about getting your first and second shots at the appropriate time. For more information about V-safe visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

Where can I schedule my second appointment?
Residents can get their second dose at any vaccine location and do not need to return to the site where they received their first dose. Use the Vaccine Appointment Finder to make an appointment for your second dose at any vaccination location. There is currently widespread vaccine availability across the United States.

What if my appointment for the second dose is longer than the recommended time between doses (i.e., 21 days for Pfizer: 28 days for Moderna)?
As always, it is recommended to follow the guidance by vaccine manufacturers and the CDC; however, this guidance should not be so rigid that it creates barriers to vaccination. Therefore,
COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose.

Is this a “live” virus vaccine?
None of the early vaccines (those by Moderna, Pfizer, AstraZeneca, or J&J) are live weakened versions (similar, for example, to the measles, mumps, rubella, or varicella (chickenpox) vaccines). Moderna’s and Pfizer’s are mRNA vaccines, and AstraZeneca’s and J&J’s are non-replicating vectored vaccines. You can learn more about the different types of vaccines being tested in the response to “What types of COVID-19 vaccines are being tested?”, visit https://www.chop.edu/centers-programs/vaccine-education-center/making-vaccines/prevent-covid.

Can COVID-19 vaccines change the DNA of a person?
COVID-19 mRNA vaccines (Pfizer and Moderna) teach our cells how to make a protein that triggers an immune response. The COVID-19 viral vector vaccine (J&J) uses a modified version of a different virus (the vector) to deliver important instructions to our cells. Neither affects nor interacts with our DNA in any way.

Vaccine Approval/Safety Concerns

What is Comirnaty? Why did the name change?
Comirnaty is the new name for the Pfizer-BioNTech COVID-19 vaccine. Once a drug or other intervention receives FDA approval the manufacturer typically gives it a brand name, and Comirnaty is the brand name that Pfizer has chosen for its COVID-19 vaccine. It is the exact same vaccine as the one that was first authorized for use in December 2020, which we have come to know as the COVID-19 Pfizer vaccine, with the same high degree of safety and effectiveness.

What is the difference between emergency use authorization and full approval?
In an emergency when lives are at risk, like a pandemic, it may not be possible to have all the evidence that the FDA would usually have before approving a vaccine or drug. If there’s evidence that strongly suggests that patients have benefited from a treatment, the agency can issue an EUA to make it available. For the COVID-19 vaccines, FDA required two months of safety and efficacy data before the EUA was granted. That included clinical trials with tens of thousands of people and rigorous testing and review, and all the vaccines continue to be closely monitored. Compared to emergency use authorization, FDA approval of vaccines requires even more data on safety, manufacturing, and effectiveness over longer periods of time and includes real-world data.

Why is the Pfizer COVID-19 vaccine not yet approved for individuals ages 12-15?
Pfizer’s application for FDA approval was for use in individuals age 16 and older. The FDA issued the EUA for the Pfizer COVID-19 vaccine in December 2020, at which time this vaccine was authorized for use in individuals age 16 and older. In May 2021, based on extensive effectiveness and safety data in clinical trials of adolescents, the EUA was expanded to include
those 12 through 15 years old. Pfizer plans to request full approval for this age group once it has collected and analyzed six months of safety data from clinical trial participants. The EUA remains in place for individuals ages 12 through 15, and the CDC continues to recommend that all adolescents and adults age 12 and older get a COVID-19 vaccine.

What about the Moderna and Johnson & Johnson vaccines? If Pfizer is only one with full approval, does that mean I shouldn’t get one of the other vaccines?
For most people, getting the first available COVID vaccine is the best thing you can do to safeguard your health.

The Moderna and Johnson & Johnson vaccines will continue to be safely administered through emergency use authorization as the FDA reviews data about their real-world use. The Pfizer COVID-19 vaccine was the first vaccine to receive emergency authorization, which is why it is the first to have enough data to receive full approval. It does not mean anything about the safety and effectiveness of either the Moderna or Johnson & Johnson vaccine. Moderna has also submitted an application for full approval of its COVID-19 vaccine, and the FDA is currently reviewing that data.

Can I offer my patients who do not have certain kinds of immunocompromise their booster early?
No. Off label use of the COMIRNATY/Pfizer-BioNTech COVID-19 Vaccine is not authorized at this time. The Administration is preparing systems and logistics to be able to offer COVID-19 booster shots to fully vaccinated adults this fall. The regulatory and clinical details of this booster plan are contingent on FDA conducting an independent evaluation and determination of the safety and effectiveness of a third dose of the mRNA vaccines (Pfizer and Moderna) and CDC’s Advisory Committee on Immunization Practices (ACIP) issuing recommendations based on a thorough review of the evidence when those recommendations are adopted by the CDC Director.

An additional dose for individuals beyond those with certain conditions associated with immunocompromise would be an off-label use at this time. Administration of the product off label may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims. Individuals who receive a third dose may not be eligible for compensation after a possible adverse event. Such use also would be in violation of the CDC COVID-19 Vaccination Program provider agreement and therefore may not be reimbursable, and may impact the ability of a provider to remain in the CDC Program, in addition to other potential sanctions. Administration fees for off-label doses may not be reimbursed by payers.

Can I offer the vaccine to patients under 12 years of age as part of "off-label" use?
No. At this time, clinical trials in this age group are still ongoing and no product has been authorized or approved for this age group yet. Children under age 12 likely will require a different dose of the vaccine than older individuals, and the safety and effectiveness of Pfizer-BioNTech’s product COMIRNATY (COVID 19 Vaccine, mRNA) in children under 12 remains yet to be determined. Pfizer has stated publicly that it plans to submit a request to amend the EUA to
include children 5 through 11 years of age by the end of September, following the completion of their clinical trial.

Further, any off-label use of the COMIRNATY/Pfizer-BioNTech COVID-19 Vaccine, including administration of the vaccine in children under 12, is not authorized at this time. Administration of the off-label product may not be covered under the PREP Act or the PREP Act declaration; therefore, providers may not have immunity from claims. Individuals who receive a third dose may not be eligible for compensation after a possible adverse event. Such use would be in violation of the CDC COVID-19 Vaccination Program provider agreement and therefore may not be reimbursable, and may impact the ability of a provider to remain in the CDC Program, in addition to other potential sanctions. Administration fees for off-label doses may not be reimbursed by payers.

What is an Emergency Use Authorization (EUA)?
Emergency Use Authorization is the legal authority of the FDA to authorize emergency use of an investigational medical product (e.g., vaccines prior to licensure, drugs prior to approval) or an unapproved use of an approved medical product to diagnose, treat, or prevent a serious or life-threatening disease. According to the FDA, an EUA is used to help make medical products available as quickly as possible by allowing unapproved medical products to reach patients in need when there are no adequate, FDA-approved and available alternatives. The known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, must outweigh the known and potential risks of the product to grant an EUA.

The term "EUA" can refer to either the legal authority itself or to the regulatory status of a medical product, such as COVID-19 vaccine – for example, one could say "FDA issued an EUA" or "an EUA is in place". Learn more about the EUA process by visiting [https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization](https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization) and watching the following video, [https://www.youtube.com/watch?v=iGkwaESsGBQ](https://www.youtube.com/watch?v=iGkwaESsGBQ).

Will there be a package insert or Vaccine Information Statement (VIS) along with an EUA? When FDA authorizes emergency use of a medical product such as an anticipated COVID-19 vaccine, an EUA Fact Sheet for Healthcare Providers (in place of a package insert typical of a licensed vaccine) and an EUA Fact Sheet for Recipients (akin to product information for patients or a CDC-provided VIS for a licensed vaccine) must be provided to the healthcare providers prescribing and/or administering the authorized medical product. The healthcare providers, in turn, provide the EUA Fact Sheet for Recipients to vaccine recipients or their guardians. These fact sheets are available at [https://www.state.nj.us/health/cd/topics/covid2019_vaccination.shtml](https://www.state.nj.us/health/cd/topics/covid2019_vaccination.shtml)

What is the difference between the EUA Fact Sheet for Recipients and the Vaccine Information Statement (VIS)? When FDA authorizes a vaccine for use under an EUA, providers and public health entities
involved in vaccine administration are legally required to provide the FDA-authorized EUA Fact Sheet for Recipients to individuals receiving vaccine or their guardians, similar to VIS’s that are also required by law for certain licensed vaccines. The EUA Fact Sheet for Recipients, like the VIS, explains the benefits and risks associated with the vaccine. But unlike a VIS, the EUA fact sheet also provides vaccine product-specific information, including the vaccine’s authorized use, dose/dose-series, and known information or experience with the vaccine from clinical trials that support issuance of the EUA by FDA.

Providers can provide the EUA Fact Sheet for Recipients (or VIS if/when the COVID-19 vaccine is licensed) in a variety of ways, including hard copy, online, video, or other electronic means of dissemination.

What safety monitoring is in place for these vaccines?
For COVID-19 vaccines, CDC and federal partners will use a toolbox of existing and new monitoring systems for COVID-19 vaccine safety.

- CDC will rely on existing systems that monitor the safety of vaccines every day, the Vaccine Adverse Event Reporting System (VAERS), the Vaccine Safety Datalink (VSD), and the Clinical Immunization Safety Assessment (CISA) Project.
- CDC has also developed a new, voluntary smartphone-based tool, v-safe, that uses text messaging and web surveys to provide personalized health check-ins after patients receive a COVID-19 vaccination.
- CDC has also expanded its collaboration with the Advisory Committee on Immunization Practices (ACIP) to include a special ACIP COVID-19 Vaccine Safety Technical Sub-Group to review available vaccine safety data.


What is the difference between VAERS and V-safe?
VAERS is the reporting mechanism for any adverse events. Specifically related to COVID-19 vaccination, providers will be required to report:

- Vaccine administration errors (whether associated with an adverse event or not)
- Serious adverse events
- Multisystem inflammatory syndrome
- Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine

Anyone can submit a report to VAERS, including patients, family members, healthcare providers, vaccine manufacturers and the general public. VAERS cannot determine if a vaccine caused an adverse event, but can determine if further investigation is needed. Additional information is available at the VAERS website, [https://vaers.hhs.gov/index.html](https://vaers.hhs.gov/index.html).

V-safe is an optional smartphone-based tool that anyone who has received a vaccination can register for. At the time of vaccination, everyone receiving a vaccine will be given information
about signing up for v-safe. Anyone reporting a clinically important even during any v-safe health check will receive a phone call from the VAERS (Vaccine Adverse Event Reporting System) hotline, and if applicable, a VAERS report will be taken during that call. V-safe also will collect information on pregnancy status and enables follow-up on pregnant women. For more information, please visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq.html.

What are some of the vaccine side effects?
The most common side effects are injection site pain, fatigue, headache, muscle pain, and joint pain. Some people in the clinical trials have reported fever. Side effects are more common after the second dose; younger adults, who have more robust immune systems, reported more side effects than older adults.

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. For more information, visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html.

What are the contraindications for (reasons for not receiving) COVID-19 vaccination?
A severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of the vaccine is a contraindication for receiving any of the COVID-19 vaccines.

People 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. CDC has provided a chart to assist in the evaluation of immediate reactions to vaccination: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-D. In addition, the CDC developed a quick reference guide available at https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf.

How can we distinguish side effects of the vaccine from COVID-19 illness?
Since systemic post-vaccination signs and symptoms might be challenging to distinguish from signs and symptoms of COVID-19 or other infectious diseases, healthcare personnel (HCP) with postvaccination signs and symptoms could be mistakenly considered infectious and restricted from work unnecessarily. This might have negative consequences for HCP, patients, and long-term care facility residents. Therefore, to minimize the confusion and avoid unnecessary work restrictions, the CDC developed the workplace prevention strategies.

How can I sign up for a clinical trial?

Should people who are pregnant or breastfeeding receive the COVID-19 vaccine?
Yes! COVID-19 vaccination is recommended for all people aged 12 years and older, including people who are pregnant, breastfeeding, trying to get pregnant now, or might become
pregnant in the future. Pregnant and recently pregnant people are more likely to get severely ill with COVID-19 compared with non-pregnant people. Getting a COVID-19 vaccine can protect you from severe illness from COVID-19. For more information, visit https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

Encourage pregnant people who choose to be vaccinated to enroll in v-safe, a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. A v-safe pregnancy registry has been established to follow outcomes among pregnant people who are vaccinated.

Learn more about vaccination of pregnant or lactating people and clinical considerations for COVID-19 vaccine.

Can being around someone who received COVID-19 vaccine affect my menstrual cycle?
The menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine. Individuals who have received a COVID-19 vaccine cannot shed or release any of the vaccine components. In addition, none of the vaccines authorized for use in the United States contain a live virus so it is not possible to shed it.

Many things can affect menstrual cycles, including stress, changes in monthly schedule, problems with sleep, and changes in diet or exercise. Infections may also affect menstrual cycles.

Why should children receive the COVID-19 vaccine?
COVID-19 vaccination can help protect children from getting COVID-19. Although fewer children have been sick with COVID-19 compared to adults, children can be infected with the virus that causes COVID-19, can get sick from COVID-19, and can spread the virus that causes COVID-19 to others. Getting your child vaccinated helps to protect your child and your family. Vaccination is now recommended for everyone 12 years and older. Currently, the Pfizer-BioNTech COVID-19 Vaccine is the only one available to children 12 years and older.

For more information, visit https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e1.htm?s_cid=mm7020e1_w and https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html.

Can you take acetaminophen and/or antihistamines before receiving mRNA COVID-19 vaccination to reduce pain and/or allergic reactions?
Medications to reduce fever and pain (e.g., acetaminophen, non-steroidal anti-inflammatory drugs) may be taken to treat post-vaccination local or systemic symptoms, if medically appropriate. However, routine administration of such medications before vaccination is not currently recommended because information on the impact of such use on mRNA COVID-19 vaccine-induced antibody responses is not available at this time.

Can the COVID-19 vaccine affect mammography screenings?
Vaccines can lead to temporary swelling in the lymph nodes and this could make results of the mammogram difficult to interpret. Such findings would lead to follow-up exams to rule out possible cancer. This can cause undo anxiety for people who may just be experiencing a temporary side effect from the vaccine.

According to some experts, such as the Society of Breast Imaging, people should either schedule the breast screening before getting the shot or wait at least four weeks after getting the second dose of vaccine to get your mammogram. However, they don't want anyone to delay care if there is any kind of concern. For more information visit, https://www.sbi-online.org/ and https://www.sbi-online.org/Portals/1/End-the-Confusion-Materials/recommendations-for-women-taking-covid-vaccine_landscape.pdf.

Use your clinical expertise to determine the best actions for your patients.

Is compensation for an injury resulting from an EUA COVID-19 vaccine available through the National Vaccine Injury Compensation Program (VICP)?
No. The EUA COVID-19 vaccines are not part of the VICP. The EUA COVID-19 vaccines are part of a similar program called the Countermeasures Injury Compensation Program (CICP). For more information, visit this web page: www.hrsa.gov/cicp.

Are there reports of myocarditis after receiving mRNA vaccines (Pfizer/BioNTech and Moderna)?
Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults. There has not been a similar reporting pattern observed after receipt of the Janssen COVID-19 Vaccine (Johnson & Johnson).

In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older.

Healthcare providers should:
- Consider myocarditis and pericarditis in adolescents or young adults with acute chest pain, shortness of breath, or palpitations. In this younger population, coronary events are less likely to be a source of these symptoms.
- Ask about prior COVID-19 vaccination if you identify these symptoms, as well as relevant other medical, travel, and social history.
- Report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS.

FDA updated the EUA Fact Sheets for mRNA COVID-19 vaccines to explain the rare risk of myocarditis and what to do if symptoms develop. CDC’s updated clinical considerations on myocarditis offer practical guidance for patients with a history of myocarditis or pericarditis and for those who develop symptoms after vaccination.
CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older given the greater risk of other serious complications related to COVID-19, such as hospitalization, multisystem inflammatory syndrome in children (MIS-C), or death. For more information, please visit https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.

**Have there been reports of Guillain-Barré syndrome among recipients of the J&J vaccine?**

Per the CDC, there have been 100 preliminary reports of GBS following vaccination with the Janssen vaccine in the Vaccine Adverse Event Reporting System (VAERS) after 12.8 million doses of Janssen COVID-19 vaccine administered. Of these reports, 95 were serious and required hospitalization. The majority of cases have occurred in males aged 50 years and older about two weeks after vaccination, mostly within six weeks. The vast majority of patients have recovered, although one fatality has been reported.

On July 12th, the FDA updated the Janssen COVID-19 vaccine Emergency Use Authorization (EUA) Fact Sheets to include a warning about the rare risk of GBS and symptoms for which to seek immediate care. These symptoms include weakness or tingling sensations, especially in the legs or arms, that's worsening and spreading to other parts of the body: difficulty walking, difficulty with facial movements, including speaking, chewing or swallowing, double vision or inability to move eyes, or difficulty with bladder control or bowel function. All cases of GBS after COVID-19 vaccination should be reported promptly to VAERS.

The CDC continues to advise that everyone 12 years of age and older receive a COVID-19 vaccine. The risk of severe adverse events after any COVID-19 vaccination remains rare, far lower than adverse health outcomes associated with contracting COVID-19.


**Why was production of J&J vaccine paused?**

Out of an abundance of caution and following the guidance of the U.S. Centers for Disease Control and Prevention (CDC) and the U. S. Food and Drug Administration (FDA), the New Jersey Department of Health (NJDOH) paused the administration of the J&J vaccine across all vaccination sites in the state from April 13 to April 23, 2021.

The CDC and the FDA reviewed the data involving six reported cases—among nearly 7 million doses administered in the U.S.—in women between the ages of 18 and 48 who received the J&J vaccine. Symptoms occurred 6 to 13 days after vaccination. In these cases, a type of blood clot called cerebral venous sinus thrombosis was seen in combination with low levels of blood platelets. Both the CDC and FDA have said that these adverse events are extremely rare. According to the FDA and CDC, individuals who have received the vaccine and develop abdominal pain, leg pain, shortness of breath, severe headache, or other unusual symptoms within three weeks after vaccination should contact their health care provider.
On April 23, 2021, the NJDOH notified vaccine Points of Dispensing (PODS) that updated FDA fact sheets for patients and providers will be provided and that they may resume administration of the one-dose vaccine. The decision came after the ACIP met to review data involving the cases of individuals who received the J&J vaccine and had adverse reactions.

The extended pause was meant to give scientists time to collect more data before deciding whether to resume use of the J&J doses to combat COVID-19.

CDC published an update in Morbidity and Mortality Weekly Report early next week related to the Advisory Committee on Immunization Practices (ACIP) recommendation and is updating relevant clinical materials and guidance.

Who is at risk for the blood clotting disorder associated with the J&J vaccine?
The likelihood of the blood clotting disorder resulting from the J&J vaccine is extremely rare. The risk varies by age and gender. There have been fewer than 1 case per million for men and for women who are 50 years or older. The risk is estimated to be about 7 cases per million for women age 18 to 49.

Should I tell my patients to wait to get vaccinated until they can get either Pfizer or Moderna?
Encourage patients to receive the vaccine that is available to them. However, women younger than 50 years old should be made aware of a rare risk of blood clots with low platelets following vaccination with J&J vaccine and the availability of other COVID-19 vaccines where this risk has not been observed. Read the CDC/FDA statement.

For most people, getting the first COVID vaccine is the best thing you can do to safeguard your health. Your odds of contracting a possibly life-threatening case of COVID-19 are much higher than your odds of serious side effects from the vaccine. The risk of blood clots from COVID illness is 165,000 per million cases.

More than 90% of the vaccine supply in the United States is the Pfizer of Moderna vaccine. However, for some settings the Johnson & Johnson vaccine may be the one that is available. And some people prefer the option of a single-dose vaccine.

Will ordering of J&J vaccine resume?
Yes, now that the CDC lifted the pause, ordering of the J&J vaccine has resumed. As a COVID-19 Vaccination Provider with Janssen (Johnson & Johnson) vaccine, please continue to follow state operational requirements for claiming your shipments and following all storage and handling guidelines.

What actions should healthcare take regarding this issue?
Healthcare providers should maintain acute clinical awareness of symptoms that might represent serious thrombotic events or thrombocytopenia in patients who have recently received the J&J/Janssen COVID-19 Vaccine, including:

- severe headache,
- backache,
- new neurologic symptoms,
- severe abdominal pain,
- shortness of breath,
- leg swelling,
- petechiae, or
- new or easy bruising.

Treatment of this specific type of blood clot is different from the treatment that might typically be administered. Usually, an anticoagulant drug called heparin is used to treat blood clots. In this setting, administration of heparin may be dangerous, and alternative treatments need to be given. Read the official CDC health alert, *Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine*, which includes details about how to handle a patient that presents with thrombosis or thrombocytopenia. Report adverse events to the [Vaccine Adverse Event Reporting System](https://www.vaers.hhs.gov/).

Remind patients that this potential safety issue was caught early, and this pause reflects the federal government’s commitment to transparency as CDC and FDA review these data. COVID-19 vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history.

**COVID-19 Vaccine Enrollment**

**How can I become a COVID-19 provider?**

The New Jersey Department of Health (NJDOH) began accepting new COVID-19 Vaccination Program Provider Agreement applications through NJIIS on Tuesday, June 1, 2021. Please visit [https://njiis.nj.gov/core/web/index.html#/newFacilityEnrollment](https://njiis.nj.gov/core/web/index.html#/newFacilityEnrollment) for specific information on joining the COVID-19 vaccination program.

**I heard vaccines have to be entered into NJIIS? What is NJIIS?**

The New Jersey Immunization Information System (NJIIS), operating since 1997, is the statewide immunization information system (IIS) serving as the official repository of immunizations administered to individuals in the state of New Jersey. NJIIS is a free, confidential, population-based online system that collects and consolidates immunization information to provide an accurate immunization assessment for individuals in the state of New Jersey, as well as assists communities in assessing their immunization coverage and identifying pockets of need. For more information on NJIIS, please visit [https://njiis.nj.gov/core/web/index.html#/home](https://njiis.nj.gov/core/web/index.html#/home).

**Why do I need to register with NJIIS?**
In order to receive and administer COVID-19 vaccines, you will be required to register with NJIIS by completing the NJIIS COVID-19 Facility Enrollment form available at https://njiis.nj.gov/covid/web/index.html#/newFacilityEnrollment. This form is for facilities and providers that are new to NJIIS and would like to administer COVID-19 vaccines.

**What if I am already an NJIIS provider?**

Current NJIIS facilities that wish to receive and administer COVID-19 vaccine DO NOT need to complete the COVID-19 Facility Enrollment form, but will need to complete the COVID-19 vaccine enrollment application which includes the CDC COVID-19 Provider Agreement that is available electronically through NJIIS. When you log into NJIIS, the COVID-19 Vaccine Enrollment will be on the landing page. For instructions on completing the provider agreement, please visit https://njiis.nj.gov/docs/covid/COVID-19%20Provider%20Agreement%20Completion%20Guide.pdf.

- If your facility is already enrolled in NJIIS but needs to create additional users in NJIIS that have not yet been trained but will play a role in your COVID-19 vaccination response, please refer to the User Enrollment Guide available at https://njiis.nj.gov/docs/covid/COVID-19%20User%20Enrollment%20Guide.pdf.

**Will a COVID-19 provider agreement be required?**

Yes, the CDC’s provider agreement form will need to be completed in order for a provider to order the COVID-19 vaccine. For instructions on completing the provider agreement, please visit https://njiis.nj.gov/docs/covid/COVID-19%20Provider%20Agreement%20Completion%20Guide.pdf https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html.

In addition, all providers interested in administering COVID-19 vaccine will be required to take the COVID-19 On-Demand Training/Tutorial. This tutorial will give an overview of how to utilize NJIIS, review inventory, add patients, run reports, order COVID-19 vaccine and a summary of requirements for providers administering COVID-19 vaccine.

Please note that COVID-19 vaccine ordering through NJIIS is not currently available. The VFC program will message out instructions once COVID-19 vaccine ordering through NJIIS becomes available.

**Where can I go for additional assistance?**

The New Jersey Department of Health (NJDOH) is pleased to announce the NJ Vaccine Call Center (855-568-0545) is now available for COVID-19 healthcare providers. Hours of operation are 8 a.m. to 8 p.m. seven days a week. The system is now using an interactive voice response (IVR) to help providers with basic information and resources. Live agents are also available to provide technical assistance on vaccine storage and handling, use of the New Jersey
Immunization Information System (NJIISS)—the statewide registry, and COVID-19 vaccine information.

New Jersey healthcare providers who are enrolled with the NJ COVID-19 vaccination program but are not receiving or administering the COVID-19 vaccines, can call the CDC Clinician On-Call center at 800-CDC-INFO (800-232-4636) if they have clinical questions regarding the COVID-19 vaccines. CDC clinicians are standing by to answer COVID-19 questions from healthcare personnel on a wide range of topics, such as diagnostic challenges, clinical management, and infection prevention and control.

**I am a registered nurse and would like to volunteer to vaccinate others. Can you provide information on where one can volunteer?**

At the current time, the NJDOH is accepting COVID-19 Enrollment Information Applications from NJIISS providers or facilities to administer COVID-19 vaccines. Applicants will be required to complete a 1-hour tutorial prior to application. Additionally, any resident can sign-up to volunteer to help with New Jersey’s COVID-19 response effort in their communities at [https://helpnjnow.communityos.org/](https://helpnjnow.communityos.org/).

**Who will pay for COVID-19 vaccine? Can it be ordered privately?**

COVID-19 vaccine will be distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. The COVID-19 vaccine cannot be ordered privately at this time.

**Will providers be able to charge patients for Comirnaty or the other COVID-19 vaccines?**

There are no out-of-pocket costs for patients associated with receiving the COVID-19 vaccine. Organizations must administer COVID-19 vaccine regardless of the vaccine recipient’s insurance status or ability to pay. Organizations may not seek any reimbursement, including through balance billing, from the vaccine recipient.

As providers receive the COVID-19 vaccine at no cost, they will not be able to charge for the vaccine.

Providers may bill insurance or other programs for a COVID-19 vaccine administration fee of $40.00 per dose for doses administered on or after 3/15/2021 ([https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies](https://www.cms.gov/medicare/medicare-part-b-drug-average-sales-price/covid-19-vaccines-and-monoclonal-antibodies)). For insured patients, providers may bill private insurance, Medicaid, or Medicare. For uninsured patients, providers may receive reimbursement through the federal uninsured fund managed by the Health Resources and Services Administration (HRSA).

**Can providers bill insurance plans or other programs for an office visit when administering COVID-19 vaccine?**

Yes, providers can bill insurance plans or other programs for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient’s plan.
Has there been a change with the NJIIS opt-in process?
Yes, Governor Murphy signed Executive Order (EO 207) to change NJIIS from an opt-in to an opt-out system. If someone chooses to receive the COVID-19 vaccine, their doses will be automatically entered into NJIIS. This does NOT require or mandate anyone to receive the COVID-19 vaccine. For more information, please visit https://www.state.nj.us/health/cd/documents/topics/NCOV/njiis_executive.pdf.
Providers are required to enter all administered COVID-19 doses into NJIIS.

Although Governor Murphy signed legislation on June 4, 2021, to terminate the COVID-19 Public Health Emergency, the Administration can retain the tools necessary to manage the ongoing threat posed by the pandemic. There are 14 executive orders including EO207, that will remain in place through January 1, 2022, though they can be modified or rescinded prior to that date by the Governor. For further information, please visit https://www.nj.gov/governor/news/news/562021/approved/20210604b.shtml.

Do I have to manually enter data?
NJIIS has four ways to send data to NJIIS. Manual data entry, HL7 interface, Upload Excel file, and NJVSS.
Data may be entered manually. Once a staff member has completed the COVID-19 training, they will be able to log into NJIIS, with their username and password, to manually enter COVID-19 doses into NJIIS. If you have an Electronic Health Record (EHR) and wish to establish an interface with NJIIS, please complete the Interface Enrollment Request Form. NJIIS can receive immunization data directly from a provider’s office EHR system via HL7 version 2.5.1 standard messaging protocol. The time it takes to establish an interface will vary based on issues with data submissions, errors in formatting of the messages.

The Excel reporting format is available as an intermediate step while setting up an interface. Excel upload is only for COVID-19 doses. If you would like a excel upload please complete the interface enrollment form. This form can be found on the NJIIS page under the interface enrollment section.

Can awardees use cooperative agreement funds to purchase PPE for staff conducting in-person VFC and IQIP site visits?
Yes. Funds from 317 and PPHF would be the easiest funds to use. Awardees may also reach out to Preparedness and/or Strategic National Stockpile to determine if funds/equipment are available through alternative channels.
**Vaccine Storage and Handling**

**Will there be different storage and handling requirements for COVID-19 vaccine?**
Yes, there are different storage requirements for each of the COVID-19 vaccines. CDC has recently revised the COVID-19 Addendum to the Vaccine Storage and Handling Toolkit available at https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html.

In addition, CDC is developing educational and training materials for health care providers related to COVID-19 vaccine storage, handling and administration based on ACIP recommendations, the ACIP General Best Practice Guidelines for Immunization, product information from vaccine manufacturers, and results of scientific studies. For a list of resources, visit https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-for-HCPs.pdf.

**Has there been an update regarding the storage of the Pfizer/BioNTech vaccine?**
On May 19, the Food and Drug Administration (FDA) announced that it has authorized undiluted, thawed Pfizer-BioNTech COVID-19 vaccine vials to be stored in the refrigerator at 2°C to 8°C (35°F to 46°F) for up to 1 month (31 days).

Making COVID-19 vaccines widely available is key to getting people vaccinated and bringing the pandemic under control. This change should make this vaccine more widely available to the American public by facilitating the ability of vaccine providers, such as community doctors’ offices, to receive, store and administer the vaccine.

**Should jurisdictions invest in ultra-cold storage units at this time?**
Jurisdictions are not advised to purchase ultra-cold storage equipment at this time. Ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice. Storage and handling instructions for ultra-cold vaccine will address repacking these coolers for extended storage.

**Will there be additional funding for jurisdictions to purchase ultra-cold storage units?** Because CDC does not recommend jurisdictions invest in ultra-cold storage units at this time, there will be no additional funding available.

**How is the Department making sure that sites are keeping the vaccines in the proper conditions and not wasting doses?**
All COVID-19 vaccine providers must sign and comply with the CDC’s provider agreement which requires healthcare providers to submit vaccine administration data within 24 hours to the statewide New Jersey Immunization Information System (NJIIIS). Daily temperature logs are required on-site to ensure vaccine efficacy and are submitted to NJIIIS on the 1st and 16th of each month.
How do I transfer vaccines?
For vaccine transfers, temperature excursions, or other questions related to vaccine inventory that have not been answered, please email COVID19.Provider@doh.nj.gov. Please note you must receive approval from the COVID-19 program prior to initiating vaccine transfer.

Can providers donate COVID-19 vaccines internationally?
As a COVID-19 provider participating in the CDC COVID-19 Vaccination Program, you cannot transfer or donate COVID-19 vaccines allocated to you directly or from your jurisdiction outside of the United States. Any international transfer or donation of COVID-19 vaccines must be undertaken by the federal government. There are a complex array of legal issues involved, as well as questions about proper storage and handling of these vaccines that may raise potential safety concerns. As a reminder, all of the doses that have been provided to you or your jurisdiction have been allocated under the CDC COVID-19 Vaccination Program, which has stringent requirements for how such doses may be used. Such requirements apply to any COVID-19 vaccine (i.e., refrigerated Janssen vaccine, and frozen Moderna and Pfizer vaccine) regardless of storage location.

The U.S. Government recommends optimizing the use of all vaccines across vaccination sites, and we are committed to making sure that available and unused COVID-19 vaccine is utilized appropriately, whether in your own state, tribal community, or elsewhere. U.S.-based providers and partners with questions regarding donating vaccine internationally or sharing within their jurisdictions or domestically should contact CDC’s Distribution and Federal Programs functional box (eocevent551@cdc.gov). Inquiries from international partners may be referred to the Department of Health and Human Services Office of Global Affairs (OGAPETFlu@hhs.gov).

Has there been an update regarding J&J vaccine expiration date?
Effective June 10, 2021, the US FDA has authorized an extension of the shelf life for the J&J COVID-19 Vaccine from 3 months to 4.5 months when stored at 36-46 degrees Fahrenheit (2-8 degrees Celsius). Prior to discarding any doses of the Janssen COVID-19 Vaccine, vaccine providers are recommended to check their expiration dates. To view a video detailing the process of checking the Janssen COVID-19 Vaccine expiry information, please visit https://www.janssencovid19vaccine.com/hcp/check-expiration.html.

Vaccine Administration

The Pfizer vaccine can be administered to those 12 and older. Is a consent form required for vaccination of minors?
The EUA fact sheet for caregivers must be provided to the parents/guardians in advance. Informed consent must be obtained from a parent/guardian in order for the minor to be vaccinated. Informed consent can be obtained (a) by a parent/guardian signing an informed consent form or (b) if the parent/guardian is physically present and verbally consents to the child receiving the vaccine.
Points of Dispensing (PODs) should follow existing laws regarding consent for minors for medical procedures and each POD should consult with their own legal counsel regarding the facility's specific policies and procedures for consent.

Does CDC recommend an observation period after vaccination?
ACIP currently recommends that providers should consider observing vaccine recipients for 15 minutes after receipt of a vaccine. Persons with a history of anaphylaxis (due to any cause) should be observed for 30 minutes. For more information, please visit https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/anaphylaxis-management.pdf.

What are the personal protective equipment (PPE) requirements when administering vaccines during the COVID-19 pandemic?

Is one COVID-19 vaccine preferred over the other?
The CDC does not state a product preference. All the vaccines that are currently available were studied in different trials, among different people and different timelines. They were not studied in head-to-head comparisons or trials; therefore, they should not be compared to each other.

Persons who are eligible to get vaccinated, you should not wait for a specific vaccine to become available. Vaccine supply is still limited.

Are the COVID-19 vaccines interchangeable?
• Any COVID-19 vaccine can be used when indicated; no product preference

• COVID-19 vaccines are not interchangeable – Safety and efficacy of a mixed series has not been evaluated

• If first dose of mRNA COVID-19 vaccine was received but patient unable to complete series with same or different mRNA vaccine (e.g., contraindication) –
  o Single dose of J&J COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose*
  o Considered to have received valid, single-dose J&J vaccination, not mixed vaccination series (mRNA/viral vector)

*Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to J&J COVID-19 vaccine. In these patients, vaccination should be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions. Consider referral to allergist-immunologist.
For more information, visit https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

What do I do if my mRNA (Pfizer or Moderna) vaccine is no longer available when it is time to get my second dose?

In exceptional situations in which the vaccine product given for the first dose cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.

In situations where the same mRNA vaccine product is temporarily unavailable, it is preferable to delay the 2nd dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product.

If two doses of different mRNA COVID-19 vaccine products are administered in these situations (or inadvertently), no additional doses of either product are recommended at this time.

For more information, visit https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

I have patients who have been partially or fully vaccinated outside the United States. Are these doses valid?

Some people may have received a COVID-19 vaccine outside of the United States. Consider the following for these patients:

- People who received an FDA-authorized COVID-19 vaccine and have received all the recommended doses do not need any additional doses. People who received the first dose of an FDA-authorized COVID-19 vaccine that requires two doses do not need to restart the vaccine series in the United States but should receive the second dose as close to the recommended time as possible.
- People who have received all recommended doses of a COVID-19 vaccine listed for emergency use by the World Health Organization (WHO) do not need any additional doses with an FDA-authorized COVID-19 vaccine. See Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States for a list of WHO vaccines listed for emergency use.
- People who have not received all the recommended doses of a COVID-19 vaccine listed for emergency use by WHO may be offered a complete FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-FDA-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.
- People who received all or some of the recommended doses of a COVID-19 vaccine not listed for emergency use by WHO and not authorized by FDA may be offered a complete FDA-authorized COVID-19 vaccine series. Wait at least 28 days after the last dose of the non-authorized vaccine before administering an FDA-authorized COVID-19 vaccine.
I am not receiving the appropriate number of doses per vial of COVID-19 vaccine. What can I do?
NJDOH does not have control over what brand of items are sent within the ancillary kits. We understand that dead space is different with different brands and sizes. The appropriate number of doses per vial as of 4/1/2021 is 10 or 14 doses of Moderna, 6 doses for Pfizer and 5 doses of Janssen.

If you are receiving less than this due to the ancillary kit sent, please enter your doses under a waste transaction as “Other- Doses Not Obtained” and in the comments put the brand and model of syringe sent to you.

Has there been a change to Moderna’s EUA label?
On April 1, the FDA announced that they have authorized a new vial presentation with a range of 13 to 15 doses of Moderna’s COVID-19 vaccine. The FDA authorized a maximum of 11 doses per vial in the current format, from the previously authorized 10 doses per vial. Moderna expects to begin shipping the 15-dose vials in the coming weeks.

FDA also has authorized Moderna’s COVID-19 vaccine to be kept at room temperature once removed from the refrigerator for 24 hours, an increase from the previous 12 hours. Additionally, a punctured vial is now useable for up to 12 hours, instead of the previous 6 hours.

These new guidelines are reflected in an updated Emergency Use Authorization (EUA) label available at https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf

If I have leftover COVID-19 vaccine at the end of the day, can I use this vaccine for walk-in patients?
Yes, please use any COVID-19 vaccine available to prevent any missed opportunities for vaccination and/or vaccine wastage. Be sure to follow all vaccine storage and handling requirements and to document doses administered into NJIIS.

Follow guidelines for infection control and patient safety to administer vaccine properly:

- Never combine or “pool” partial doses from two or more vials to obtain a full dose of vaccine.
- Withdraw only the number of doses authorized for the specific vaccine.
- Discard vaccine vial and remaining vaccine if the amount of vaccine left in the vial is not a full dose.
Has CDC provided clinical guidance on what to do if an error occurs while administering COVID-19 vaccinations?
Yes. On February 10, 2021, CDC published a new appendix to its “Interim Clinical Considerations for Use of mRNA Vaccines Currently Authorized in the United States.” This appendix provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as a simple table outlining actions to take after an error has occurred: www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Appendix-A.

Errors addressed include the following:

- Incorrect route or site
- Incorrect age
- Incorrect dosing interval
- Incorrect dose (high or low)
- Administration after improper storage conditions
- Administration after the expiration/beyond use date
- Diluent errors (wrong diluent, too much or too little) with the Pfizer-BioNTech vaccine

If a person gets sick with COVID-19 after receiving the first dose, when should the second dose be administered?
A person can get the second shot at the recommended interval (i.e., 21 days for Pfizer: 28 days for Moderna) after COVID disease as long as they are not acutely ill and after they have met the criteria to discontinue isolation.

If a person got monoclonal antibodies as treatment for COVID-19 infection, then they should wait 90 days after the monoclonal antibodies to get the vaccine. For further information, visit https://www.cdc.gov/vaccines/covid-19/hcp/faq.html.

Protection from Vaccine/Efficacy

How soon do antibodies form after getting the vaccine (i.e., how soon after getting vaccine am I protected)?
It usually takes about one to two weeks for immunity to develop following vaccination, but the specific timeline for any coronavirus vaccine will depend to some extent on which type of vaccine it is.

How effective are the mRNA vaccines under real-world conditions?
A recent study among health care personnel, first responders, and other essential and frontline workers demonstrated mRNA vaccine effectiveness of full immunization (≥14 days after second dose) was 90% against SARS-CoV-2 infections regardless of symptom status; vaccine effectiveness of partial immunization (≥14 days after first dose but before second dose) was 80%. For more information, please visit https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7013e3-H.pdf.
If my patient had COVID-19 and recovered do they need to get the vaccine?
Yes, you should be vaccinated regardless of whether you already had COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. A recent study found that those who were previously infected with COVID-19 had a significantly higher likelihood of reinfection if they were unvaccinated. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

Anyone currently infected with COVID-19 should wait to get vaccinated until after their illness has resolved and after they have met the criteria to discontinue isolation.

If my patient had COVID less than 90 days ago, can they get the vaccine?
Yes, you may get the vaccine unless you received monoclonal antibodies within the last 90 days. If you received monoclonal antibody therapy for COVID-19, you should wait for 90 days after the treatment.

If a person had COVID-19 illness or multisystem inflammatory syndrome in adults or children (MIS-A or MIS-C), should they get tested before getting the COVID-19 vaccine?
You should not be required to have an antibody test before you are vaccinated.

If you were treated for COVID-19 with monoclonal antibodies or convalescent plasma, you should wait 90 days before getting a COVID-19 vaccine.

If you or your child has a history of (MIS-A or MIS-C), consider delaying vaccination until you or your child have recovered from being sick and for 90 days after the date of diagnosis.

After getting a COVID-19 vaccine, will I test positive for COVID-19 on a viral test?
No. None of the authorized and recommended COVID-19 vaccines cause you to test positive on viral tests, which are used to see if you have a current infection. Neither can any of the COVID-19 vaccines currently in clinical trials in the United States.

If your body develops an immune response to vaccination, which is the goal, you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results.

Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination. For more information, please see https://www.fda.gov/medical-devices/safety-communications/antibody-testing-not-currently-recommended-assess-immunity-after-covid-19-vaccination-fda-safety.
Is an additional dose (third dose) recommended now?
The Centers for Disease Control and Prevention’s Advisory Committee on Immunization Practices (ACIP) recommended that people with moderately to severely compromised immune systems (weakened immune system) receive an additional dose of an mRNA COVID-19 vaccine (Pfizer-BioNTech and Moderna) at least four weeks after completing the two-dose series of Pfizer or Moderna. There is no additional approval for individuals who received the (J&J/Janssen) COVID-19 vaccine because more studies are needed regarding its benefits.

For more information, please visit Clinical Considerations for use of COVID-19 vaccines and guidance for talking with immunocompromised patients.

Does it matter which vaccine I receive?
The additional dose should be the same vaccine (Pfizer or Moderna) you received for the first two doses. But, if the same vaccine given for the first two doses is not available, the other vaccine may be given. A person should not receive more than three mRNA COVID-19 vaccine doses.

Who is eligible to receive this additional dose?
CDC’s recommendation includes people with a range of conditions, such as recipients of organ or stem cell transplants, people with advance or untreated HIV infection, active recipients of treatment for cancer, people who are taking some medications that weaken the immune system, and others. A full list of conditions can be found on the CDC website.

Why is the third dose recommended only for this specific group?
At this time, additional doses are only recommended for people with moderately to severely compromised immune systems because they may not have received enough protection from their original two-dose vaccine series. People who have a weakened immune system are at higher risk of serious, prolonged illness. Studies have found that among fully vaccinated people hospitalized with COVID-19, immunocompromised people accounted for a large proportion (40–44%) of those breakthrough cases even though they only make up about 3 percent of the adult population. People who are immunocompromised are also more likely to spread COVID-19 to household contacts. These updated recommendations can help to protect these individuals at a time when COVID-19 cases are on the rise.

While vaccination is likely to increase protection in this population, even after vaccination, people who are immunocompromised should continue to follow current prevention measures (including wearing a mask, staying 6 feet apart from others they do not live with, and avoiding crowds and poorly ventilated indoor spaces) to protect themselves and those around them against COVID-19.

If eligible, how soon can someone get the third shot?
Those who are eligible should be able to get a third dose now at any location offering COVID-19 vaccines. All existing active points of dispensing Points of Dispensing (PODs) are being
instructed to offer third doses. All sites are being advised to accept walk-ins for third dose administration. To find a vaccination location, visit covid19.nj.gov/finder.

Is a doctor’s note or proof of completing the COVID-19 vaccine series required before receiving the additional dose?
A person should not be asked for proof of their condition or need a doctor’s note. If a person doesn’t have their vaccine card or their digital COVID-19 record via the Docket app, (available in the App store or on Google Play), the vaccine provider should look up the individual’s vaccine record in the New Jersey Immunization Information System (NJIIIS), the statewide immunization registry.

Why isn’t the additional dose recommendation for those who received the J&J/Janssen COVID-19 vaccine?
The recommendation only applies to mRNA COVID-19 vaccines (Pfizer or Moderna) because studies have shown that those who have low or no protection after completing the two-dose series may have greater protection after receiving an additional dose. More studies are needed to see if immunocompromised people who received the (J&J/Janssen) vaccine will also benefit from an additional dose.

What is the difference between an “additional dose” and a “booster dose?”
An “additional dose” refers to people with weakened immune systems who are recommended to receive another dose of an mRNA COVID-19 Vaccine (Pfizer-BioNTech or Moderna) at least 28 days after the completion of the two-dose vaccine series. This is because they may not have received enough protection from their 2-dose vaccine series.

A “booster dose” refers to people who received protection after completing their vaccine dose(s), but an extra dose may be needed because that protection decreases over time. The extra dose is given to help boost (increase) their level of protection. The need for and timing of a COVID-19 booster dose has not been established, and no booster doses are recommended at this time.

What are the travel recommendations in New Jersey?
New Jersey residents returning home and travelers visiting New Jersey do not need to quarantine, but should follow travel guidance from the CDC, the NJ Department of Health, and all local health and safety protocols of their travel destination.

International travelers need to pay close attention to the situation at their international destinations before traveling due to the spread of new variants and because the burden of COVID-19 varies globally.

CDC prevention measures continue to apply to all travelers, including those who are vaccinated. All travelers are required to wear a mask on all planes, buses, trains, and other forms of public transportation traveling into, within, or out of the United States and in U.S. transportation hubs such as airports and stations.
What are the current recommendations for healthcare personnel regarding exposures to COVID-19 and COVID-19 vaccination?
Guidance for residents and staff of healthcare settings can be found in the Updated Healthcare Infection Prevention Control Recommendations in Response to COVID-19.


Were the COVID-19 vaccines tested against the variants?
The J&J vaccine was tested against the South Africa and Brazil variants. All of the current vaccines are testing the effectiveness against the variants and the possible benefits of additional vaccine doses.

I am fully vaccinated, but tested positive for COVID-19, how is that possible?
Yes, it is possible to test positive for COVID-19 even if you are fully vaccinated. COVID-19 vaccines in the US are highly effective, including against the Delta variant, but they are not 100% effective and some fully vaccinated people will become infected (called a breakthrough infection) and experience illness. For such people, the vaccine still provides them strong protection against serious illness and death.

Infections happen in only a small proportion of people who are fully vaccinated, even with the Delta variant. However, fully vaccinated people who become infected with the Delta variant can spread the virus to others. To reduce their risk of becoming infected with the Delta variant and potentially spreading it to others: CDC recommends that fully vaccinated people:

- Wear a mask in public indoor settings if they are in an area of substantial or high transmission.
- Get tested if experiencing COVID-19 symptoms.
- If you came into close contact with someone with COVID-19 get tested 3-5 days after the date of your exposure and wear a mask in public indoor settings for 14 days after exposure or until a negative test result.
- Isolate if they have tested positive for COVID-19 in the prior 10 days or are experiencing COVID-19 symptoms.
- Follow any applicable federal, state, local, tribal, or territorial laws, rules, and regulations.

CDC will continue to monitor variants to see if they have any impact on how COVID-19 vaccines work in real-world conditions. For more information about variants, visit https://www.cdc.gov/coronavirus/2019-ncov/variants/variant.html and https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html#vaccinated.
Masking and Vaccine Requirements

What are New Jersey’s masking guidelines?
Face masks are strongly recommended for both vaccinated and unvaccinated individuals in indoor settings where there is increased risk, including:

- Crowded indoor settings
- Indoor settings involving activities with close contact with others who may not be fully vaccinated
- Indoor settings where the vaccine status of other individuals in the setting is unknown
- Where an individual is immunocompromised or at increased risk for severe disease

Social distancing, masking, and other safety measures are still required in high-risk areas such as healthcare settings, public transportation, child care centers, correctional facilities, and homeless shelters. The combination of COVID-19 vaccination and continued precautions to protect yourself and others will offer the best protection from getting and spreading COVID-19.

Note: Cloth face coverings are not recommended for children under 2 years, people who are incapacitated, people who have difficulty breathing, or any other person who cannot easily remove their own mask.

Will school staff be required to wear a mask?
Yes, all students, educators, staff, and visitors will be required to wear face masks indoors for the start of the 2021-2022 school year. Effective Monday, August 9, 2021, masks are required in the indoor premises of all public, private, and parochial preschool, elementary, and secondary school buildings, with limited exceptions.

Is wearing two masks more effective than wearing one?
The CDC is recommending the use of mask-fitters and other strategies to improve the fit of masks to enhance protection. In a recently published study “Maximizing Fit for Cloth and Medical Procedure Masks to Improve performance and Reduce SARS-CoV-2 Transmission and Exposure, 2021” the CDC found wearing a cloth mask over a surgical mask offers more protection against the coronavirus, as does tying knots on the ear loops of surgical masks. For the best protection, the CDC says to make sure the mask fits snugly against your face and to choose a mask with at least two layers. For more details, please visit https://www.cdc.gov/mmwr/volumes/70/wr/mm7007e1.htm.

What employees are required to receive the COVID-19 vaccine or weekly testing?
New Jersey has announced that all workers in preschool to Grade 12 schools, all workers in certain health facilities and high-risk congregate settings, and all workers at state agencies, authorities, and colleges and universities will be required to be fully vaccinated against COVID-19 or be subject to COVID-19 testing at minimum one to two times per week.
By September 7th, 2021, all workers in certain state and private health care facilities and high-risk congregate settings will be required to be fully vaccinated or subject to testing.

By October 18th, 2021, all workers in preschool through Grade 12 schools will be required to be fully vaccinated or subject to testing.

By October 18th, 2021, all workers at state agencies, authorities, and colleges and universities will be required to be fully vaccinated or subject to testing.

These requirements will strengthen protections against the spread of COVID-19, including the highly transmissible Delta variant, to those who work with vulnerable populations such as those who can’t receive the COVID-19 vaccine for medical or religious purposes or those who are too young to be vaccinated. For more information, visit COVID-19 vaccine requirement.

Can an employer access an employee’s COVID-19 vaccination records in the New Jersey Immunization Information System (NJIIS) to verify their vaccination status?

No, an employer cannot access an employee’s vaccination records for the purposes of verifying vaccination for employment.

Authorized NJIIS users can access information in NJIIS only for purposes specified by law. Users shall only access information on a registrant whom they have claimed in NJIIS as their patient and/or to whom they are currently providing healthcare services. Child care centers, schools, colleges and universities shall only access immunization information on a registrant that they have enrolled or are in the process of enrolling in their institutions.

Employers should have employees submit vaccination documentation for verification. Please see COVID-19 Vaccination Documentation FAQs for more details on valid vaccine documentation.

All authorized users should review the statute and regulations to ensure use is consistent with existing laws. The NJIIS is the official Immunization Registry pursuant to the Statewide Immunization Registry Act – N.J.S.A. 26:4-131 et seq. (P.L. 2004, c. 138), N.J.A.C. 8:57, subchapter 3.

Other Vaccines

Can you receive COVID-19 at the same time as other vaccines?

COVID-19 vaccines and other vaccines may now be administered on the same day. Currently it is unknown if there is a potential for increased reactions when COVID-19 is given with other vaccines. If multiple vaccines are administered at a single visit, administer each injection in a different injection site. For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection. For more information, visit https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#Coadministration.
**Will getting the flu vaccine protect me against coronavirus?**

No. Influenza viruses and coronaviruses are different. Getting a flu vaccine will not protect against COVID-19; however, the vaccine can reduce flu illnesses, hospitalizations, and can help to conserve potentially scarce healthcare resources during the pandemic. It’s likely that flu viruses and the virus that causes COVID-19 will both be spreading this fall and winter, making it more important than ever to get a flu vaccine! It is the best way to protect yourself and others – especially those who are particularly vulnerable to both COVID-19 and influenza such as older adults and those with chronic health conditions.

**Medical Therapies**

**What are monoclonal antibodies?**

Monoclonal antibodies are laboratory-produced molecules that act as substitute antibodies that can restore, enhance, or mimic the immune system's attack on cells. Monoclonal antibodies for COVID-19 may block the virus that causes COVID-19 from attaching to human cells, making it more difficult for the virus to reproduce and cause harm. Monoclonal antibodies may also neutralize a virus.

Antibody treatment can be used by people with mild to moderate COVID-19 who:

- Test positive for SARS-CoV-2.
- Are within 10 days of the start of their symptoms.
- Are age 12 or older and weigh at least 88 pounds.
- Are at high risk of getting very sick from COVID-19 or of needing to be admitted to a hospital because of COVID-19.

This treatment is not authorized for use in patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19.

More information about monoclonal antibody treatment can be found at the following websites:

https://www.state.nj.us/health/cd/topics/covid2019_community.shtml#3 and
https://combatcovid.hhs.gov/

**How does the use of monoclonal antibodies to treat symptomatic COVID-19 affect the scheduling of COVID-19 vaccination?**

There are no data on the effect of passive antibody therapies for COVID-19, including monoclonal antibodies and convalescent plasma, on the effectiveness of vaccination with mRNA COVID-19 vaccines. As a precautionary measure, CDC recommends waiting at least 90 days after receipt of passive antibody therapy for COVID-19 illness before initiating the COVID-19 vaccine series. Individuals who develop COVID-19 illness after the first COVID-19 vaccination and receive passive antibody therapy should wait 90 days after antibody therapy to
receive the second dose. There is no need to restart the vaccination series. For more information, please visit https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html.

Additional Information

- [covid19.nj.gov/](covid19.nj.gov/)
- [covid19.nj.gov/vaccine](covid19.nj.gov/vaccine)
- [covid19.nj.gov/finder](covid19.nj.gov/finder) (search for vaccine appointments)
- COVID-19 Hotline 1-800-962-1253 or 2-1-1 *(for information only. NOT for scheduling vaccine appointments)*
- Call 855-568-0545 for provider information. Live agents are available.
- CDC clinician on-call center 800-CDC-INFO (800-232-4636)
- Call 856249-7007 to get appointment assistance for seniors 65 and older.