

April 2021 ~ Resource #370401

Communicating About COVID-19 Vaccination

COVID-19 vaccines currently available for use either have an Emergency Use Authorization (EUA; in the U.S.) or an Interim Order (Canada). See our chart, *COVID-19 Vaccines*, for a comparison of available COVID-19 vaccines. The chart below answers common questions your patients may have about COVID-19 vaccination and includes talking points and strategies to address COVID-19 vaccine misconceptions.

Question	Answer/Pertinent Information
<p>COVID-19 vaccines are being approved more rapidly than other vaccines. How can you reassure patients about this expedited approval process?</p>	<ul style="list-style-type: none"> • COVID vaccines have been developed at a more rapid pace than what is normally seen with other vaccines. This does NOT mean safety steps have been skipped.³⁴ The development process has been expedited because of the pandemic (e.g., early funding to ramp up manufacturing, overlapping phases of trials).³⁴ <ul style="list-style-type: none"> ○ Operation Warp Speed^b (U.S.) and International Coalition of Medicines Regulatory Authorities (ICMRA [Canada]) are helping ensure the rapid development process still adheres to safety and efficacy standards.^{11,28} • COVID-19 vaccines are going through the same RIGOROUS approval process as other approved vaccines. Data are reviewed/analyzed by independent experts (i.e., not scientists employed by the manufacturer). The independent reviewer recommendations are then presented to the approving agency (e.g., FDA, Health Canada).⁵⁰ • Reassure patients that COVID-19 vaccine safety is a top priority.^{21,27} COVID-19 vaccines are being studied through phased testing to ensure safety and efficacy before they are made available to the public. <ul style="list-style-type: none"> ○ In addition to phase 1 and 2 trials, phase 3 trials are enrolling between 30,000 and 40,000 participants per trial.²³ Trials are expanding the patient populations being studied. In the initial studies, most participants have been adults, including those with chronic conditions (e.g., diabetes, hypertension, cardiovascular disease, chronic respiratory disease [e.g., asthma, chronic obstructive pulmonary disease (COPD)]).^{17,19} As we get further into the trial process, more trials will be including patients as young as 12 years old.^{23,42} ○ Safety monitoring will continue even after vaccines are authorized or approved for use. Explain that in addition to standard monitoring (e.g., vaccine adverse event reporting system [VAERS]) additional monitoring is being done. <ul style="list-style-type: none"> ▪ For example, in the U.S., V-SAFE^a is a new smartphone-based healthcare checker to use after vaccination. It will use CDC text messages and web-based surveys to check in with recipients of a COVID-19 vaccine.¹⁷
<p>Which patients were excluded from early COVID-19 vaccine trials?</p>	<ul style="list-style-type: none"> • Some early COVID-19 vaccine trials' exclusion criteria included: <ul style="list-style-type: none"> ○ acutely ill or febrile ○ known history of SARS-CoV-2 infection or use of investigational meds to prevent SARS-CoV-2 infection ○ bleeding disorders involving contraindications to IM injections ○ immunosuppression (e.g., HIV, active hepatitis B or C infection, receiving cytotoxic therapy or systemic steroids for cancer or autoimmune disease)

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<p>Some of the COVID vaccines are utilizing new types of technology. How can you reassure patients these newer vaccines are safe?</p>	<p>Many COVID-19 vaccines are new types of vaccines (e.g., messenger ribonucleic acid [mRNA], viral vectors).^{22,35}</p> <ul style="list-style-type: none"> • Explain to patients how COVID-19 vaccines work.^{22,35,73} <ul style="list-style-type: none"> ○ mRNA vaccines (e.g., mRNA-1273 [Moderna], BNT162b2 mRNA [Pfizer/BioNTech]) give our cells a blueprint for how to make a piece of a SARS-CoV-2 “spike” protein (note this piece of the SARS-Co-V-2 “spike protein” is harmless to the vaccine recipient). This triggers an immune response. Once the blueprint is delivered, the messenger (mRNA) is broken down. ○ Vector vaccines (e.g., ChAdOx1-S [AstraZeneca], Ad26.COV2.S [Janssen; J&J]) use a weakened version (e.g., non-replicating, modified) of a different live virus with a viral vector (genetically inserted material from COVID-19). The virus used poses no threat of causing illness in humans because of the modification or because the type of virus cannot cause disease in humans. The viral vector teaches the vaccinated person’s body to build cells to fight COVID-19. • Explain that available COVID-19 vaccines do NOT contain the SARS-CoV-2 virus.^{22,35,73} • Reassure patients that available COVID-19 vaccines do NOT affect a person’s genetic material (DNA).^{22,73} • Reassure patients that scientists have been studying mRNA and viral vector vaccines for >15 years.^{34,73} Even though COVID-19 vaccines will be the first mRNA and viral vector vaccines to come to market, it is not new science. Over the years of studying mRNA and viral vector vaccines (e.g., influenza, Zika, cytomegalovirus, rabies, Ebola) researchers have been able to solve problems that previously kept these vaccines from coming to market (e.g., vaccine instability, inflammatory outcomes, modest immune response).^{22,73}
<p>What are some talking points to use with patients who may be hesitant to get vaccinated for COVID-19?</p> <p><i>Continued...</i></p>	<ul style="list-style-type: none"> • Remind patients about the benefits of COVID-19 vaccination. Vaccination may:¹⁶ <ul style="list-style-type: none"> ○ reduce illness severity if you become infected with COVID-19. ○ protect friends, family, co-workers, and close contacts from getting COVID-19. • Explain that the COVID-19 vaccine is one important tool in the toolbox to end the pandemic.¹⁶ <ul style="list-style-type: none"> ○ Social distancing and masks reduce the chance of exposure to the coronavirus that causes COVID-19.¹⁶ ○ Vaccination gets your immune system ready to fight COVID-19 infection if exposed.¹⁶ ○ Vaccination is also an important step in the development of herd immunity.²⁰ <ul style="list-style-type: none"> ▪ Herd immunity is when it is unlikely that a bacteria or virus can spread and cause disease because a large enough proportion of people are protected or considered immune.²⁰ More data are needed to know how many people need to be protected to achieve herd immunity against COVID-19.²⁰ Some predict that about 75% to 80% of the U.S. population would need to be vaccinated to achieve herd immunity.³² ▪ Caution patients that relying on natural immunity to achieve herd immunity to COVID-19 would mean hundreds of millions of people would have to recover from COVID-19; and during the time it would take for that many to recover, many more people could experience COVID-19 complications or death.⁵¹ • Encourage vaccination as the safer path toward immunity. <ul style="list-style-type: none"> ○ There is no way to predict COVID-19 infection severity for anyone, and infections can be fatal.^{4,12,16}

Question	Answer/Pertinent Information
Talking points for vaccine hesitant patients, continued	<ul style="list-style-type: none"> ○ COVID-19 infection has been associated with long-term consequences, even in young healthy people (e.g., lung, heart, and memory problems; mood changes; kidney damage).^{4,5} ○ Tell patients that we don't know how long natural immunity (antibodies from exposure to the virus through infection) or vaccine-induced immunity (antibodies from vaccination) lasts.³ Natural immunity varies in duration. Explain that limited vaccine data suggests vaccine-induced immunity may last longer.⁴⁶
What age groups should receive a COVID-19 vaccine?	<ul style="list-style-type: none"> ● The Pfizer/BioNTech vaccine is authorized for ages 16 years and older.^{49,69} ● Moderna, AstraZeneca (Canada only), and Janssen/J&J vaccines are authorized for ages 18 years and older.^{49,69,81} ● Generally, children and adolescents outside of these authorized age groups should not receive a COVID-19 vaccine.^{49,69} In Canada, the Pfizer/BioNTech vaccine may be considered for adolescents between the ages of 12 and 15 years who are at very high risk of severe outcomes (e.g., due to other medical conditions known to increase risk for hospitalization or mortality) and at increased risk of exposure (e.g., living in a congregate care facility).⁶⁹
What are the expected short-term adverse effects with COVID-19 vaccination?	<ul style="list-style-type: none"> ● Be transparent that patients may experience short-term adverse effects after vaccination (i.e., don't downplay these). For other two-dose vaccines, this has been a well-received strategy to ensure patients return for their second dose (e.g., <i>Shingrix</i> vaccine).⁵² <ul style="list-style-type: none"> ○ Note that younger patients may be more likely than older patients to experience side effects.⁴¹ ○ Explain that most patients can expect mild to moderate injection-site pain or soreness (redness and swelling are significantly less common).^{15,18,33,41} <ul style="list-style-type: none"> ▪ About a week after receiving an mRNA COVID-19 vaccine, some patients may notice "COVID arm" (large localized area of redness; may be tender or warm). COVID arm is a sign of immune system overdrive. Reassure patients this usually goes away in a few days. Encourage completion of the vaccine series. Cold compresses can be used for symptomatic relief. Consider using the other arm for the second dose.⁹⁴ ○ Many patients will experience systemic reactions, within about two days of vaccination. These usually go away within a day or two.³³ This is a normal response to a vaccine and means the body is building antibodies to prevent infection. Systemic adverse effects may be more likely with the second dose.^{7,41,55} ○ Example systemic reactions and frequency over placebo with the BNT162b2 mRNA (Pfizer/BioNTech), mRNA-1273 (Moderna), and ChAdOx1-S vaccine (AstraZeneca [Canada]) vaccines:^{1,41,79} <ul style="list-style-type: none"> ▪ fatigue/malaise/headache: 10% to 24% (first dose); 10% to 45% (second dose) ▪ fever/chills: <20% (first dose); 10% to 20% (fever; second dose); 20% to 42% (chills; second dose) ▪ myalgia/arthralgia: ≤30% (first dose); 5% to 35% (second dose) ○ Example systemic reactions and frequency over placebo with the Ad26.COV2.S Janssen/J&J vaccine are fatigue/malaise/headache (~20%), fever/chills (<15%), and myalgia/arthralgia (≤30%).^{61,81,82} ● Temporary post-vaccination lymphadenopathy (swollen lymph nodes in neck or underarm) after receiving an mRNA COVID-19 vaccine may lead to unnecessary breast biopsies. See https://www.nccn.org/covid-19/pdf/COVID-19_Vaccination_Guidance_V2.0.pdf for guidance on breast imaging after vaccination and administering vaccine to patients with cancer.⁸⁸⁻⁹⁰

Question	Answer/Pertinent Information
<p>What can patients do to minimize expected vaccine adverse effects?</p>	<ul style="list-style-type: none"> • Help patients reduce and prepare for adverse effects. For example: <ul style="list-style-type: none"> ○ Over the years limited data from older pediatric vaccine studies have raised questions about the effect of acetaminophen on vaccine immune response.^{68,75} Some COVID-19 vaccine trials allowed the use of acetaminophen post vaccination.^{1,10,15,41,93} For example, up to 45% of participants (Pfizer/BioNTech), 57% (Moderna), and 5.2% (Janssen/J&J) used a fever-reducing medication (e.g., acetaminophen) after at least one of the vaccine doses to treat vaccine-related symptoms.^{1,41,93} The impact of prophylactic use of acetaminophen was not evaluated in the Pfizer/BioNTech, Moderna, or Janssen/J&J vaccine trials. Some of the testing sites for the ChAdOx1-S viral vector (AstraZeneca) vaccine did allow prophylactic acetaminophen use (e.g., 1 gram prior to vaccination and continued every six hours for 24 hours after vaccination).¹⁵ <ul style="list-style-type: none"> ▪ All studies found reduced adverse effects in those that used acetaminophen.^{1,15,41} ▪ Acetaminophen use with ChAdOx1-S vaccine (AstraZeneca) did not impact immunogenicity.¹⁵ ▪ Currently the CDC supports use of antipyretic or analgesic meds (e.g., acetaminophen, ibuprofen) AFTER VACCINATION TO TREAT SYMPTOMS from a COVID-19 vaccine. However, routine use of prophylactic acetaminophen before or after vaccination with a COVID-19 vaccine is not recommended until we know more about the impact on immunogenicity.⁴⁹ ○ Suggest that patients get vaccinated when they will have a few days to rest and recover (i.e., on a Friday if they don't work weekends). Similarly, healthcare facilities may want to stagger staff vaccinations in order to minimize personnel shortages in case people are unable to work for a day or two after vaccination.²⁹
<p>Have there been serious or unusual adverse effects from COVID-19 vaccination?</p> <p><i>Continued...</i></p>	<ul style="list-style-type: none"> • Serious adverse effects from COVID-19 vaccination seem extremely rare. But it takes time and large numbers of people getting vaccinated before we may know more about possible adverse effects. Safety monitoring will continue even after a COVID-19 vaccine is approved.⁴ <ul style="list-style-type: none"> ○ If a safety issue is identified, it will be evaluated to see if it is related to the vaccine.⁴ For example: <ul style="list-style-type: none"> ▪ Bell's palsy was noted more often in vaccinated patients than those who received a placebo in COVID-19 vaccine trials. However, per the FDA, the rate was NOT more than is expected in the general population and they have NOT concluded these cases were caused by vaccination. Patients who have previously had Bell's palsy may receive a COVID-19 vaccine.^{1,8,70} ▪ Transverse myelitis was noted in an ChAdOx1-S (AstraZeneca viral vector vaccine) trial. Monitoring for neurologic events will continue and will be provided to experts for review.⁴⁴ • There have been reports of severe allergic reactions, including possible anaphylaxis, after receiving a COVID-19 vaccine (Moderna, Pfizer/BioNTech, AstraZeneca, Janssen/J&J).^{45,47,58,76,82,91} Anaphylaxis is a known, but rare side effect with any vaccine.^{45,76} <ul style="list-style-type: none"> ○ Reassure patients that in general anaphylaxis due to a vaccination is rare.⁴⁵ In fact, in the U.S. studies, 0.63% (Pfizer/BioNTech) or 1.5% (Moderna) of vaccinated patients versus 0.51% (Pfizer/BioNTech) or 1.1% (Moderna) of placebo patients reported possible allergic reactions in trials.^{1,8} Initial numbers after authorization

Question	Answer/Pertinent Information
<p>Serious or unusual adverse effects, continued</p>	<p>in the U.S. show the rate of anaphylaxis with the Pfizer/BioNTech vaccine to be 11.1 cases per million doses given.⁴⁵</p> <ul style="list-style-type: none"> ○ Contraindications to a COVID-19 vaccine includes:^{10,38,49,58,69,79,80} <ul style="list-style-type: none"> ▪ history of a severe allergic reaction (e.g., anaphylaxis) after a dose of the same type of COVID-19 vaccine (e.g., mRNA, viral vector). <ul style="list-style-type: none"> • Patients who experience anaphylaxis after an mRNA COVID-19 vaccine should NOT receive any other mRNA COVID-19 vaccine. • Patients who experience anaphylaxis after a viral vector COVID-19 vaccine should NOT receive any other viral vector COVID-19 vaccine. ▪ history of an immediate allergic reaction of any severity within four hours (e.g., wheezing, hives) to: <ul style="list-style-type: none"> • a previous dose of the COVID-19 vaccine • any component of the vaccine such as: <ul style="list-style-type: none"> ○ polyethylene glycol (PEG) (an ingredient in mRNA vaccines) ○ polysorbate (potentially cross-reactive with PEG and an ingredient in viral vector vaccines) ○ A contraindication to an mRNA vaccine is a precaution to a viral vector vaccine (and vice versa). ○ Consider referrals to an allergist-immunologist with the following precautions to COVID-19 vaccination:^{49,69} (In the U.S. consider using the Clinical Immunization Safety Assessment [CISA] consultation by phone or online. Details can be found at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html.) <ul style="list-style-type: none"> ▪ People with a contraindication to an mRNA COVID-19 vaccine have a precaution against viral vector COVID-19 vaccines (and vice versa). <ul style="list-style-type: none"> • If one type of COVID-19 vaccine is given (despite precautions) because of a contraindication to the other type of COVID-19 vaccine.^{47,49,69} <ul style="list-style-type: none"> ○ give the COVID-19 vaccine at least 28 days after a dose of the contraindicated COVID-19 vaccine (if one was given). ○ obtain informed consent (Canada). • A history of Guillain-Barre syndrome (GBS) is NOT a contraindication. As of March 5, 2021:⁷⁰ <ul style="list-style-type: none"> ○ no cases of GBS have been reported after vaccination with an mRNA COVID-19 vaccine in clinical trials. ○ one case of GBS was reported after the Janssen/J&J COVID-19 vaccine and one in the placebo group. • There have been reports of blood clots after vaccination with the AstraZeneca COVID-19 vaccine (authorized in Canada). As of March 11, 2021, there is no confirmation that the AstraZeneca vaccine caused the blood clots. These adverse events are being reviewed. Health Canada is working with international regulators, including the European Medicines Agency (EMA), to assess and evaluate these reported blood clots.⁵⁷

Question	Answer/Pertinent Information
How long should patients be monitored after receiving a COVID-19 vaccine?	<ul style="list-style-type: none"> • Monitor patients receiving a COVID-19 vaccine for 30 minutes if they have a history of severe allergic reaction (e.g., anaphylaxis) to anything, an immediate allergic reaction of any severity to a vaccine or injectable medication, or have a contraindication to the other type of COVID-19 vaccine.^{47,49,69} • Monitor all other patients for 15 minutes after receiving a COVID-19 vaccine (including patients with a history of severe allergies to foods, pets, latex, and oral medications [excluding oral med allergies that are related to polysorbate or PEG]).^{47,49,69}
What are long-term safety concerns with COVID-19 vaccination?	<ul style="list-style-type: none"> • More time and data are needed to assess long-term safety of the COVID-19 vaccines.
Is the single-dose viral vector COVID-19 vaccine as effective as two-dose COVID-19 vaccines?	<ul style="list-style-type: none"> • There are no head-to-head data directly comparing the available COVID-19 vaccines.^{62,77} • Experts believe that the single-dose Ad26.COV2.S Janssen/J&J COVID-19 vaccine is NOT inferior to the two-dose mRNA vaccines. Differences in efficacy rates are likely due to differences in when and where trials were conducted and circulating variants.^{62,77} <ul style="list-style-type: none"> ○ All currently available vaccines in U.S. and Canada are good vaccines.^{62,69,77} All four vaccines (Pfizer/BioNTech, Moderna, Janssen/J&J, AstraZeneca) have documented:^{62,69,77} <ul style="list-style-type: none"> ▪ ≥85% efficacy against severe COVID-19. ▪ 60% to 95% efficacy against symptomatic, laboratory confirmed COVID-19 within approved age ranges. • Experts state no preference among available COVID-19 vaccines. Think of COVID-19 vaccines like the flu vaccines, encourage eligible patients to get whichever vaccines is available to them.^{62,77}
What are strategies to encourage patients to return for the second dose of a two-dose COVID-19 vaccine?	<ul style="list-style-type: none"> • Stress the importance of completing the vaccination series with the same vaccine (COVID-19 vaccines are NOT interchangeable), if more than one dose is needed.^{36,49} <ul style="list-style-type: none"> ○ Give patients vaccine cards with product specific information about the vaccine they received and second-dose reminders/date to return.⁴⁸ ○ Consider searching immunization registries if patients received their first dose somewhere else and they are not sure which vaccine they received. U.S. subscribers can review our <i>Immunization Registry FAQs</i>, to learn more about registry capabilities. ○ In RARE circumstances, if the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be given with a minimum interval of 28 days between doses to complete the mRNA COVID-19 vaccination series.⁴⁹ <ul style="list-style-type: none"> ▪ If two doses of DIFFERENT mRNA vaccines are mistakenly given, instead of using the same product for the entire series, no additional doses are currently recommended.^{49,72} ○ In Canada, it is NOT recommended to use different vaccine types within the series (e.g., mRNA, viral vector).⁶⁹

Continued...

Question	Answer/Pertinent Information
Encouraging patients to return for the second dose, continued	<ul style="list-style-type: none"> • Help patients understand why two doses are used for many vaccines. <ul style="list-style-type: none"> ○ Vaccines work by teaching the body to recognize and fight a specific foreign substance (e.g., virus, bacteria).²⁶ ○ Vaccines do NOT replicate in our bodies like viruses and bacteria do.²⁶ ○ Think of the first dose as a primer. The body is starting from scratch to recognize and fight the virus.²⁶ ○ Think of the second dose as a booster. It provides the body another opportunity to learn how to respond, and to create even more memory cells against the virus.²⁶ • Consider these tips to improve the likelihood patients will return for second doses: <ul style="list-style-type: none"> ○ Make a strong recommendation to return for second doses. This can be a powerful motivator.²³ ○ Utilize reminder systems within your computer systems.²³ ○ Have patients schedule their appointment for their second dose when they receive their first dose ○ Use technology to remind patients (e.g., apps, texts, emails, phone calls) • See our toolbox, <i>Medication Adherence Strategies</i>, for other adherence ideas.
What happens if the second COVID-19 vaccine dose is not given on schedule (too soon or too late)?	<ul style="list-style-type: none"> • To get the most benefit from vaccination, adhere to recommended vaccine dosing intervals.^{53,71} <ul style="list-style-type: none"> ○ In general, when vaccine doses are given too close together, this can lead to a smaller immune response to the vaccine compared to when doses are given according to recommended schedules.⁵³ ○ For some vaccines, the series needs to be restarted if subsequent doses are delayed too long.⁵⁴ • For COVID-19 vaccines, it is too soon to know how early or late second doses will impact immunity.⁷¹ Follow local health authority guidance for specifics in your area. Generally, in: <ul style="list-style-type: none"> ○ U.S.: Schedule the second dose of the Pfizer/BioNTech vaccine 21 days after the first dose or the second dose of the Moderna vaccine 28 days after the first dose. If it is not possible to adhere to these dosing intervals the CDC supports scheduling a second dose for the Pfizer/BioNTech mRNA vaccine between 17 and 42 days after the first dose,⁴⁹ and for the Moderna mRNA vaccine between 24 and 42 days after the first dose).⁴⁹ <ul style="list-style-type: none"> ▪ If a dose is given earlier than day 17 (Pfizer/BioNTech) or 24 (Moderna), it is not necessary to repeat.⁴⁹ ▪ If a dose is given later than day 21 (Pfizer/BioNTech) or 28 (Moderna), give the second dose as soon as possible, preferably within 42 days, as there are limited data beyond 42 days. Even if doses are not given within 42 days, it is not necessary to restart the series.⁴⁹ Explain that the immune system “remembers” the first dose and responds to the second dose (after the minimum dosing interval) when it is given.⁶⁷ ○ Canada: Ideally give second vaccine doses between:⁶⁹ <ul style="list-style-type: none"> ▪ Pfizer/BioNTech: 19 to 28 days after the first dose. ▪ Moderna: 21 to 28 days after the first dose ▪ AstraZeneca: 28 days (4 weeks) to 12 weeks after the first dose ▪ If doses are being delayed in your area, second doses may be delayed up to 4 months from the first dose. • More data are needed before guidance can be given about how to handle early or late second doses of other COVID-19 vaccines being studied.

Question	Answer/Pertinent Information
<p>How long does it take to develop immunity after COVID-19 vaccination and how long does immunity last?</p>	<ul style="list-style-type: none"> • It usually takes a few weeks after any vaccination to develop immunity.³⁵ See our chart, <i>Vaccines for COVID-19</i>, for specific timing to develop immunity for each of the available COVID-19 vaccines. <ul style="list-style-type: none"> ○ Though some protection may be provided with first doses of vaccines that require two doses, maximal protection does not seem to take effect until days to weeks after the second dose.^{10,41} Regardless, after vaccination, safety measures should still be used until we know more about real world protection from COVID-19.^{2,9} • We still don't know how long immunity after vaccination will last.^{2,34} Explain that we only have data for as long as the trials have been going on.⁹ Once we have more data about how long vaccine-induced immunity lasts, it will be possible to determine how often patients may need to be vaccinated against COVID-19 to maintain immunity.²
<p>What are some talking points about dos and don'ts after patients are fully vaccinated?</p>	<ul style="list-style-type: none"> • It's okay to be indoors without wearing masks with:⁷⁸ <ul style="list-style-type: none"> ○ other people who are fully vaccinated (at least two weeks after the final vaccine dose). ○ unvaccinated people from ONE other household (as long as no one is at increased risk for severe infection [e.g., pregnancy, immunocompromised, heart failure]) • It is NOT necessary to isolate after COVID-19 exposure or get tested unless you develop COVID-19 symptoms. <ul style="list-style-type: none"> ○ The exception to this is people who live in group settings (i.e., group home, correctional facility) should stay away from others and get tested, regardless of symptoms.⁷⁸ • Encourage patients to continue to:^{69,78} <ul style="list-style-type: none"> ○ protect themselves and others (e.g., socially distancing, wearing masks, hand washing/sanitizing) when:⁷⁸ <ul style="list-style-type: none"> ▪ in public. ▪ around people who are unvaccinated from more than one household. ▪ around unvaccinated people at risk for severe COVID-19 infection. ○ avoid medium or large gatherings ○ delay unnecessary travel, both domestic and international ○ watch for COVID-19 symptoms, especially if you have been around someone who is sick • Explain we are still learning:^{9,78} <ul style="list-style-type: none"> ○ about vaccine efficacy against COVID-19 variants. ○ how well vaccines prevent spread of COVID-19, including asymptomatic spread. <ul style="list-style-type: none"> ▪ For example, it may be possible that if someone was vaccinated and then exposed to the virus, though they might not get sick, they could still spread the virus to others.⁹ ○ how long vaccines are protective against COVID-19. • Implementation of safety precautions may change over time as we learn more about the protection provided by COVID-19 vaccination. The number of people who get vaccinated and virus spread in local communities may also play a role in determining this.²

Question	Answer/Pertinent Information
Can a COVID-19 vaccine cause a COVID-19 infection?	<ul style="list-style-type: none"> • No.³⁴ None of the COVID-19 vaccines that are available or are currently in development use the live SARS-CoV-2 virus.^{6,73}
Will COVID-19 vaccination lead to a positive COVID-19 test?	<ul style="list-style-type: none"> • COVID-19 vaccination may lead to a positive test for COVID-19 antibodies (serology tests).⁶ • COVID-19 vaccination will NOT lead to a positive test for active COVID-19 infection (molecular or polymerase chain reaction [PCR] tests and/or antigen tests).⁶
If vaccine supplies are limited, who will be prioritized for vaccination?	<ul style="list-style-type: none"> • Vaccination may occur in multiple phases. Sub-prioritization within the phases may be needed when vaccine supplies are limited. For example:^{14,25,29} <ul style="list-style-type: none"> ○ Phase 1a: healthcare workers and residents living in long-term care facilities ○ Phase 1b: people 75 years or older and frontline essential workers ○ Phase 1c: people between 65 and 74 years, people 16 to 64 with high-risk conditions (see below), essential workers not vaccinated in phase 1b ○ Phase 2: everyone 16 years and older, not vaccinated during phase 1 • If vaccine supply is limited/sub-prioritization is needed, follow local guidance and consider priority for people:¹³ <ul style="list-style-type: none"> ○ who are older ○ with high-risk medical conditions (e.g., cancer, chronic obstructive pulmonary disease [COPD], heart failure, severe obesity, type 2 diabetes) ○ who live in congregate settings (e.g., homeless shelters, group homes) ○ workers that are most critical to societal functions ○ workers at higher risk of exposure (e.g., can't perform duties remotely, work in high-risk situations such as crowded environments) ○ in settings with documented higher rates of transmission and outbreaks (e.g., meat packing plants, correctional facilities) ○ who are disproportionately affected by COVID-19 (e.g., health disparities, migrant workers)
What do we know about COVID-19 vaccines during pregnancy and lactation? <i>Continued...</i>	<ul style="list-style-type: none"> • Pregnant patients are at higher risk for severe illness from a COVID-19 infection or possibly preterm birth.⁴⁹ • There are currently little to no data available about the safety or efficacy of COVID-19 vaccines during pregnancy.^{1,8,29} The medication and vaccine approval process typically assesses safety and efficacy in healthy women of childbearing age, before testing them in pregnant patients.³⁰ • Though pregnant patients were excluded from initial trials, information about vaccine effects and possible adverse effects are being collected (and will be evaluated) in patients that became pregnant during clinical trials.^{1,8} In addition, there are no safety concerns from animal data with COVID-19 vaccines.⁴⁹

Question	Answer/Pertinent Information
Vaccines during pregnancy and lactation, continued	<ul style="list-style-type: none"> • Gynecology and obstetrics experts, as well as the CDC, support offering COVID-19 vaccines to pregnant and lactating patients.^{49,56,59} <ul style="list-style-type: none"> ○ As of February 16, 2021, there no noted safety signals from over 30,000 pregnancies reported to the CDC’s V-SAFE^a program.^{55,59} ○ It is NOT necessary to test for pregnancy PRIOR to receiving an authorized COVID-19 vaccine.^{49,56,59} ○ It is NOT necessary to avoid or delay pregnancy AFTER receiving an authorized COVID-19 vaccine.^{49,56,59} (In Canada it is suggested to delay pregnancy for at least 28 days after completing the vaccine series.⁶⁹) ○ It is NOT necessary to withhold RhoGAM immune globulin (e.g., <i>Rhogam</i> [U.S.], <i>WinRho S/D</i>). It will NOT interfere with the immune response to an authorized COVID-19 vaccine.⁵⁹ ○ Reassure patients that reproductive experts do NOT expect available COVID-19 vaccines to impact fertility, pregnancy loss, still birth, or congenital abnormalities.^{66,87} ○ Reassure patients that available COVID-19 vaccines do NOT affect a person’s genetic material (DNA).^{22,56}
What do we know about safety and efficacy of COVID-19 in patients who are immunocompromised?	<ul style="list-style-type: none"> • We know that people who are immunocompromised are at risk for severe illness from COVID-19.³⁷ • We also know that people who are immunocompromised may have a lesser response to vaccinations.^{40,92} • Per the CDC, it is acceptable to offer a COVID-19 vaccine to patients with immunocompromising conditions (e.g., cancer, HIV, taking an immunosuppressant or biologics).^{49,70} These are NOT live vaccines. Be sure to counsel these patients about the lack of data and the potential for a reduced immune response.^{49,70} • For patients who opt not to receive the vaccine, counsel them to follow recommendations to reduce risk of infection (e.g., social distancing, hand washing) and wait until we have more vaccine data in these patient populations.^{39,49}
Can COVID-19 vaccines be given with other vaccines?	<ul style="list-style-type: none"> • No data are available about safety or efficacy of coadministration of a COVID-19 vaccine and other vaccines.³¹ • Separate vaccinations whenever possible. This way it is possible to collect “clean adverse effect data” associated with COVID-19 vaccines and specifically linked to individual vaccines.⁶⁹ <ul style="list-style-type: none"> ○ U.S.: For COVID-19 vaccines, give alone or with a minimum of 14 days before or after other vaccines.⁴⁹ If a COVID-19 vaccine is given within 14 days of another vaccine, neither vaccine dose needs to be repeated.⁴⁹ ○ Canada: Ensure a minimum 14 days AFTER receiving other vaccines before a COVID-19 vaccine is given and wait at least 28 days after the COVID-19 vaccine series before giving other vaccines.⁶⁹ An exception to this could be when a vaccine is needed for postexposure prophylaxis.⁶⁹

Question	Answer/Pertinent Information
Should COVID-19 vaccines be avoided in patients taking anticoagulants or antiplatelets?	<ul style="list-style-type: none"> • Taking an anticoagulant or antiplatelet is NOT a contraindication to receiving a COVID-19 vaccine (e.g., aspirin, warfarin, enoxaparin, clopidogrel, apixaban).⁶³⁻⁶⁵ • As with all other vaccines given IM, consider the following to minimize bleeding risk:⁶³⁻⁶⁵ <ul style="list-style-type: none"> ○ Use a fine-gauge needle (e.g., 23-gauge, 25-gauge). ○ Apply firm pressure (without rubbing) to the injection site for at least two to three minutes after the injection. • Reassure patients that vaccination benefits outweigh the small risk of bruising. Serious effects are NOT expected. Advise patients to monitor for bleeding or bruising and to report unusual or excessive bleeding or bruising to their healthcare provider.⁶⁵
Should someone who has COVID-19 or who was previously infected get vaccinated?	<ul style="list-style-type: none"> • Previous COVID-19 infection (with or without symptoms) is NOT a contraindication to COVID-19 vaccination.²⁹ • It may be reasonable for people with recent COVID-19 infections to temporarily delay COVID-19 vaccination (especially when vaccine supply is limited), as the risk of reinfection is low in the months after initial infection, but infection risk may increase over time.^{29,49} • Defer vaccination with a COVID-19 vaccine until patients have recovered from the acute COVID-19 illness and meet criteria to stop isolation (including patients who develop COVID-19 in between doses one and two of the vaccine).⁴⁹ • There is NOT clear guidance on whether or not to give COVID-19 vaccines to someone with an acute illness (other than COVID-19). In general, moderate to severe illness is considered a precaution against vaccination (as vaccination side effects can make it difficult to assess management of the acute illness), while vaccination during a mild illness (with or without fever) is not a precaution.⁴³
Should someone who previously received monoclonal antibodies or convalescent plasma for COVID-19 get vaccinated?	<ul style="list-style-type: none"> • There are no data about the use of COVID-19 vaccines in patients who received either monoclonal antibody therapy or convalescent plasma.^{49,69} • To avoid any possibility of lessening a patient's immune response to a COVID-19 vaccine, wait at least 90 days before vaccinating a patient who received either monoclonal antibody therapy (e.g., bamlanivimab, bamlanivimab/etesevimab [U.S. only], casirivimab/imdevimab [U.S. only]) or convalescent plasma to treat COVID-19.⁴⁹ Waiting 90 days before vaccinating applies to patients before receiving any dose of a COVID-19 vaccine or who are in the middle of the vaccination series.⁴⁹ In Canada, no specific timing recommendations can be made. Instead, involve an expert and make timing decisions on a case-by-case basis.⁶⁹

Question	Answer/Pertinent Information
Do COVID-19 vaccines contain aborted fetal cells?	<ul style="list-style-type: none"> • Available COVID-19 vaccines do NOT contain fetal cells.^{60,83-86} • Fetal cells lines are used in development, production, and/or confirmatory tests of available COVID-19 and some other vaccines (e.g., hepatitis A, rubella, shingles).^{83,85} For example, decades old fetal cell lines are used:^{60,83-86} <ul style="list-style-type: none"> ○ to confirm that COVID-19 mRNA vaccines are taken up by cells and used as a blueprint to make a SARS-CoV-2 spike protein. ○ to grow the adenovirus used in the viral vector vaccines, but are filtered out during the vaccine production process.
What should U.S. healthcare providers know about billing for COVID-19 vaccinations?	<ul style="list-style-type: none"> • There will be no charge to patients for the COVID-19 vaccine. COVID-19 vaccines are currently purchased by the government. You will only be billing for the administration fee, not for the vaccine itself.² • To ensure pharmacies are appropriately reimbursed for the administrative fee, it is recommended to enter the following:²⁴ <ul style="list-style-type: none"> ○ Quantity: use the volume to be injected for the specific vaccine being administered ○ Days' supply: "1" ○ Professional services code: MA ○ Ingredient cost: \$0.00 or \$0.01 depending on the payer ○ Submission clarification code (SCC) (for vaccines requiring two doses): <ul style="list-style-type: none"> ▪ "2" for the first dose (i.e., "other override" defined as, "used when authorized by the payer in business cases not currently addressed by other SCC values," to indicate giving the first dose of a two-dose vaccine). ▪ "6" for the second dose (i.e., "starter dose" defined as, "the pharmacist is indicating that the previous medication was a starter dose and now additional medication is needed to continue treatment," to indicate giving the final dose of a two-dose vaccine). • Proposed reimbursement rates for COVID-19 vaccine administration fees:⁷⁴ <ul style="list-style-type: none"> ○ First or second dose of a two-dose vaccine: \$40 (a total of \$80 for a two-dose series) ○ Dose of a single-dose vaccine: \$40 • COVID-19 vaccine and administrative CPT (current procedural technology) billing codes:²⁴ <ul style="list-style-type: none"> ○ Pfizer/BioNTech: 91300 (vaccine); 0001A (administering first dose); 0002A (administering second dose) ○ Moderna: 91301 (vaccine); 0011A (administering first dose); 0012A (administering second dose) ○ AstraZeneca: 91302 (vaccine); 0021A (administering first dose); 0022A (administering second dose) ○ Janssen/J&J: 91303 (vaccine); 0031A (single dose) • For additional medicare billing information (how to submit claims including institutional, professional, and for centralized billing), go to https://www.cms.gov/medicare/covid-19/medicare-billing-covid-19-vaccine-shot-administration.

Continued...

Question	Answer/Pertinent Information
Billing for COVID-19 vaccines, continued	<ul style="list-style-type: none">• For additional pharmacist-specific reimbursement information for COVID-19 vaccine administration (e.g., steps to take to ensure eligibility for reimbursement, becoming eligible to give vaccines under Medicare, how to handle uninsured patients), go to https://www.pharmacist.com/sites/default/files/audience/APhACOVIDReimbursementforAdmin_1220_web.pdf.

- a. For more information about the V-SAFE monitoring system go to <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-09/COVID-03-Shimabukuro.pdf>.
- b. Operation Warp Speed is comprised of Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD).

Users of this resource are cautioned to use their own professional judgment and consult any other necessary or appropriate sources prior to making clinical judgments based on the content of this document. Our editors have researched the information with input from experts, government agencies, and national organizations. Information and internet links in this article were current as of the date of publication.

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