MDHHS
Michigan Department of Health & Human Services

New Updates to the Interim Clinical Considerations for COVID-19 Vaccines

May 6, 2021

Housekeeping

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  - Use this throughout the webinar to ask questions

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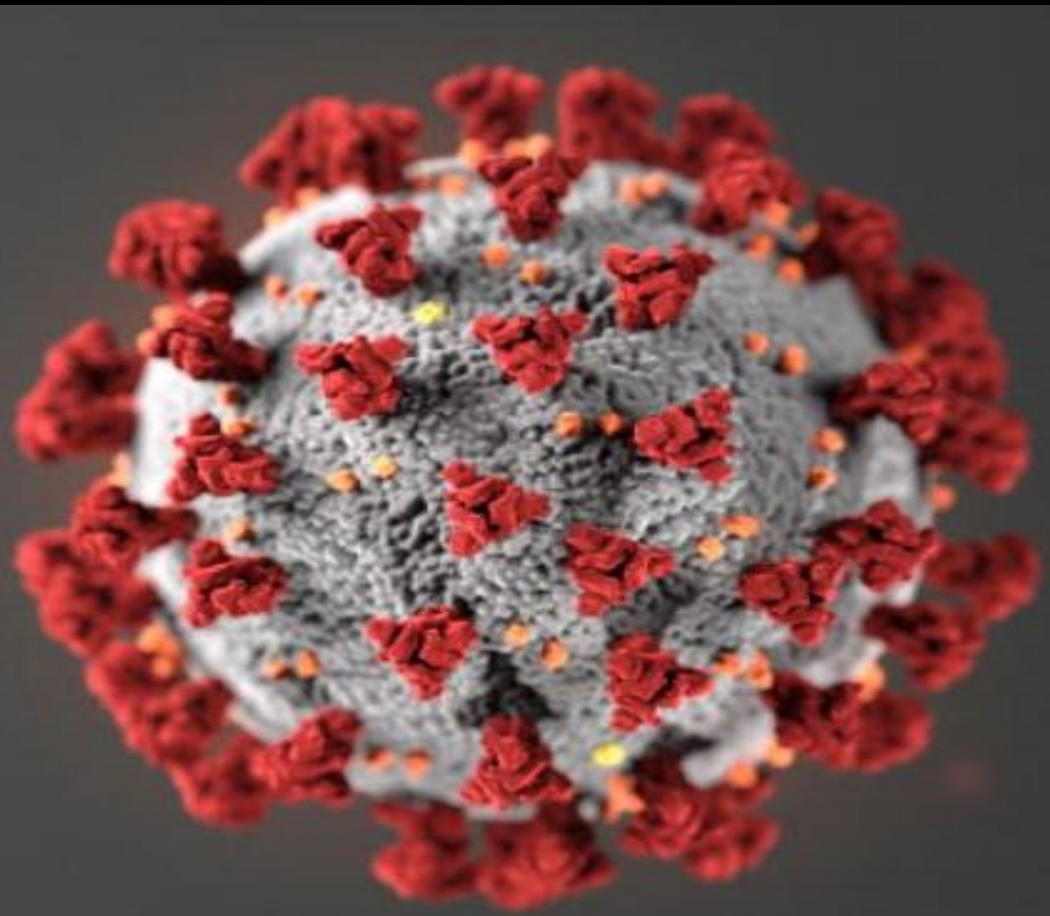
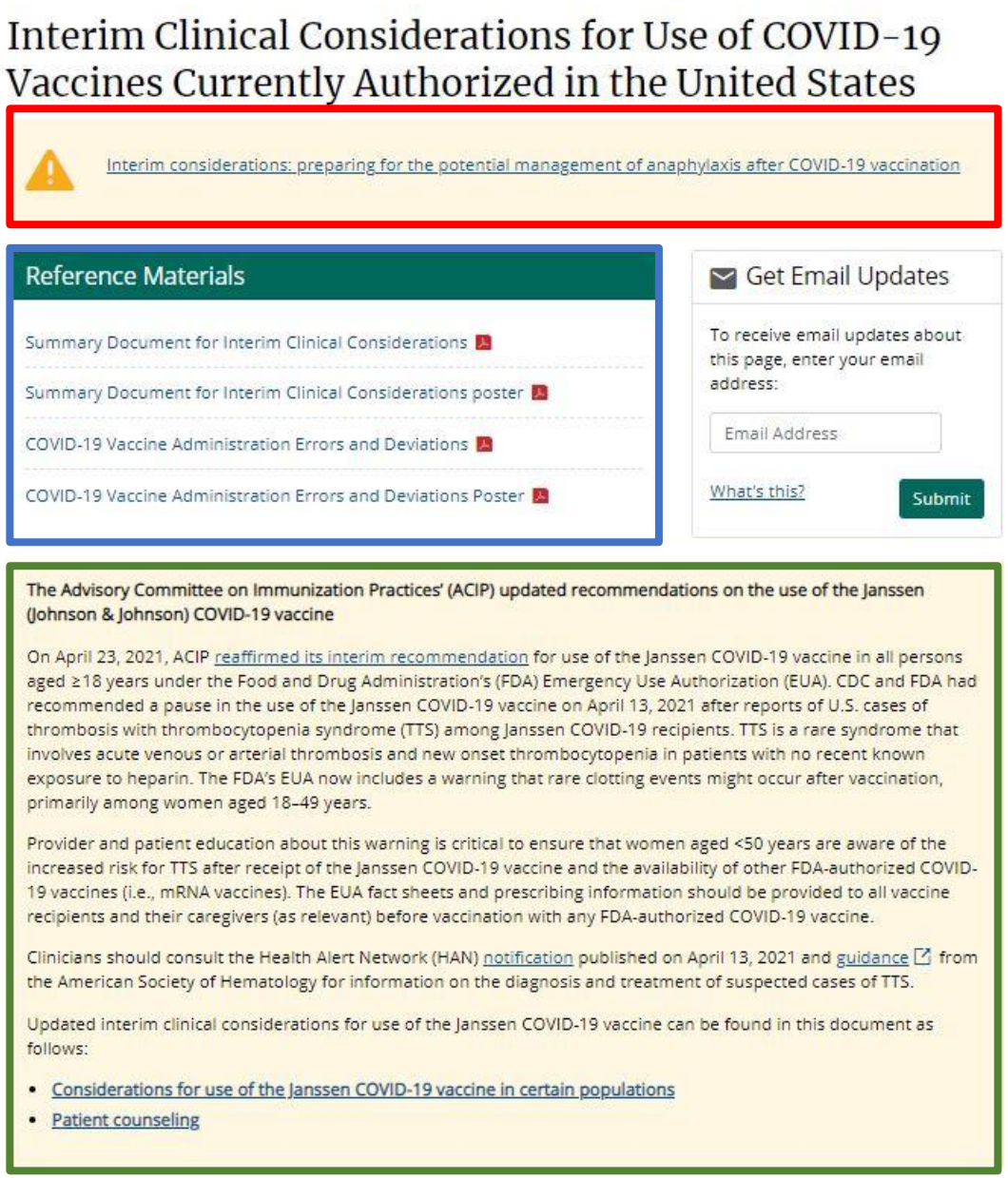
  - This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccine → Provider Guidance and Education

Review of Interim Clinical Considerations for COVID-19 Vaccines



COVID-19 Vaccine Clinical Considerations

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html



Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Reference Materials

- Summary Document for Interim Clinical Considerations
- Summary Document for Interim Clinical Considerations poster
- COVID-19 Vaccine Administration Errors and Deviations
- COVID-19 Vaccine Administration Errors and Deviations Poster

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What's this? Submit

The Advisory Committee on Immunization Practices' (ACIP) updated recommendations on the use of the Janssen (Johnson & Johnson) COVID-19 vaccine

On April 23, 2021, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA). CDC and FDA had recommended a pause in the use of the Janssen COVID-19 vaccine on April 13, 2021 after reports of U.S. cases of thrombosis with thrombocytopenia syndrome (TTS) among Janssen COVID-19 recipients. TTS is a rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent known exposure to heparin. The FDA's EUA now includes a warning that rare clotting events might occur after vaccination, primarily among women aged 18–49 years.

Provider and patient education about this warning is critical to ensure that women aged <50 years are aware of the increased risk for TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines). The EUA fact sheets and prescribing information should be provided to all vaccine recipients and their caregivers (as relevant) before vaccination with any FDA-authorized COVID-19 vaccine.

Clinicians should consult the Health Alert Network (HAN) notification published on April 13, 2021 and guidance from the American Society of Hematology for information on the diagnosis and treatment of suspected cases of TTS.

Updated interim clinical considerations for use of the Janssen COVID-19 vaccine can be found in this document as follows:

- Considerations for use of the Janssen COVID-19 vaccine in certain populations
- Patient counseling

Summary of recent changes (last updated April 27, 2021):

- The Advisory Committee on Immunization Practices' updated interim recommendation for the use of the Janssen (Johnson & Johnson) COVID-19 vaccine.
- Clarification that COVID-19 vaccination is recommended for all people 16 years and older added to key points and vaccine administration.
- Updated information about the Janssen COVID-19 vaccine added to background
- Requirements to be considered fully vaccinated added to vaccine administration and interchangeability of COVID-19 vaccine products.
- New section added for people vaccinated with COVID-19 vaccines not authorized in the United States.
- Clarification on COVID-19 vaccination and SARS-CoV-2 infection. People with prolonged post-COVID-19 symptoms should be offered COVID-19 vaccination.
- New section added on antiviral therapy and COVID-19 vaccination.
- Information on requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project added to considerations for vaccination of people with certain underlying medical conditions.
- New section added on considerations for use of the Janssen COVID-19 vaccine in certain populations
- Updated information and recommendations for vaccination of pregnant or lactating people.
- Updated recommendations for vaccination of children and adolescents.
- Updated information related to axillary lymphadenopathy added to patient counseling for mRNA COVID-19 vaccines.
- Updated information on the Janssen COVID-19 vaccine added to patient counseling.
- Updated recommendations related to contraindications (polysorbate allergy) and precautions (most people with a precaution can and should be administered vaccine) for COVID-19 vaccines.

Key points

COVID-19 vaccination is recommended for all people 16 years and older. The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. On April 23, 2021, ACIP reaffirmed its interim recommendation for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under the Food and Drug Administration's (FDA) Emergency Use Authorization (EUA). ACIP's updated recommendation followed a review of cases of thrombosis with thrombocytopenia syndrome (TTS) among Janssen COVID-19 vaccine recipients and consideration of the risks and benefits of resuming vaccination. FDA has added a warning to the Janssen COVID-19 vaccine EUA fact sheets and prescribing information that rare clotting events might occur after vaccination, primarily among women aged 18–49 years.

The Pfizer-BioNTech and Moderna vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. The Janssen vaccine is a recombinant replication-incompetent adenovirus type 26 (Ad26) vector encoding the stabilized prefusion spike glycoprotein of SARS-CoV-2. None of the currently authorized COVID-19 vaccines are live virus vaccines.

These interim CDC clinical considerations are informed by data submitted to the FDA for Emergency Use Authorization of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. These considerations apply only to the vaccine products currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines). Considerations will be updated when additional information becomes available or if additional vaccine products are authorized.

In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines.

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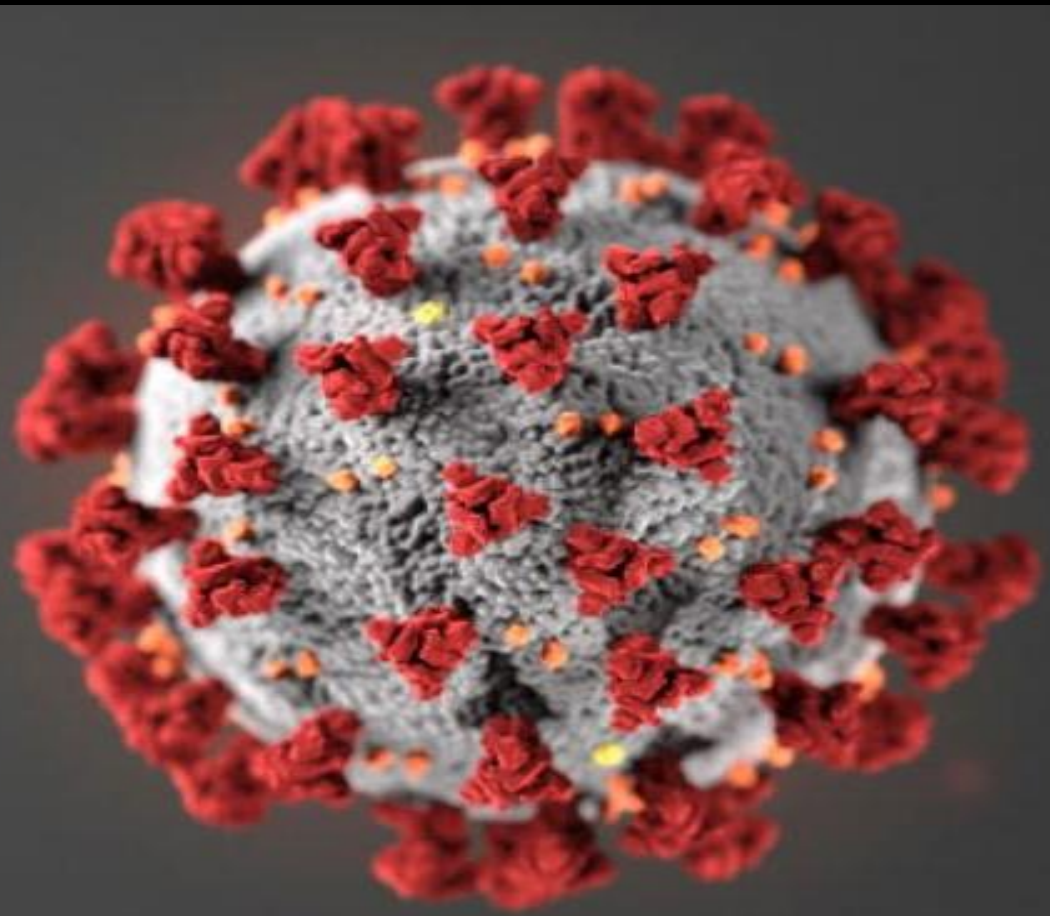
Recent Updates to Interim Clinical Considerations for COVID-19 Vaccines



Updated Background Information

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In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines.

Updated information about the Janssen COVID-19 vaccine added to **background**

Key Points and Administration Update

Clarification that COVID-19 vaccination is recommended for all people 16 years and older added to **key points** and **authorized age groups**

Key points

COVID-19 vaccination is recommended for all people 16 years and older. The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

Authorized age groups

COVID-19 vaccination is recommended for all people 16 years and older. Under the EUAs, the following age groups are authorized to receive vaccination:

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

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

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Considered Fully Vaccinated

Requirements to be considered fully vaccinated added to **vaccine administration** and **interchangeability of COVID-19 vaccine products**

Vaccine Administration Section:

A person is considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose in a 2-dose series (Pfizer-BioNTech and Moderna) or ≥2 weeks after receipt of the single dose of the Janssen vaccine.[1] People who have a contraindication to vaccination or who otherwise cannot complete a vaccination series are not considered fully vaccinated.

Interchangeability of COVID-19 Vaccine Products Section:

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. Such persons are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the second dose of an mRNA vaccine.

COVID-19 vaccine and additional precautions in people with a contraindication to mRNA COVID-19 vaccines. Patients who receive Janssen COVID-19 vaccine after a dose of an mRNA COVID-19 vaccine should be considered to have received a valid, single-dose Janssen vaccination—not a mixed vaccination series—and are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the single dose of the Janssen vaccine.

People vaccinated with COVID-19 vaccines not authorized in the United States-NEW!

People vaccinated with COVID-19 vaccines not authorized in the United States

Some people may have received a COVID-19 vaccine that is not currently authorized in the United States. No data are available on the safety or efficacy of receiving a COVID-19 vaccine currently authorized in the United States after receipt of a non-FDA-authorized COVID-19 vaccine. However, in some circumstances people who received a COVID-19 vaccine not currently authorized in the United States may be offered revaccination with an FDA-authorized vaccine:

- COVID-19 vaccines not authorized by FDA but authorized for emergency use by WHO
  - People who completed a COVID-19 vaccination series with a vaccine that has been authorized for emergency use by the World Health Organization (WHO) **do not need** any additional doses with an FDA-authorized COVID-19 vaccine.
  - People who are partially vaccinated with a COVID-19 vaccine series authorized for emergency use by WHO may be offered an FDA-authorized COVID-19 vaccine series.
- COVID-19 vaccines not authorized by FDA or not authorized for emergency use by WHO
  - People who completed or partially completed a COVID-19 vaccine series with a vaccine that is not authorized by FDA or not authorized for emergency use by WHO may be offered an FDA-authorized COVID-19 vaccine series.

Administration of an FDA-authorized COVID-19 vaccine in these people should comply with all conditions of use specified under the EUA for the vaccine being used. The minimum interval between the last dose of a non-FDA authorized vaccine and an FDA-authorized COVID-19 vaccine is 28 days.

COVID-19 Vaccination and SARS CoV-2 Infection

Clarification on **COVID-19 vaccination and SARS-CoV-2 infection**. People with prolonged post-COVID-19 symptoms should be offered COVID-19 vaccination

People with prior or current SARS-CoV-2 infection

People should be offered vaccination regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection, including people with prolonged post-COVID-19 symptoms. Data from clinical trials indicate that the currently authorized COVID-19 vaccines can be given safely to people with evidence of a prior SARS-CoV-2 infection. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making.

Antiviral Therapy and COVID-19 Vaccination-NEW!

New section added on antiviral therapy and COVID-19 vaccination

Antiviral therapy and COVID-19 vaccination

Administration of an antiviral drug at any interval before or after vaccination with any of the currently FDA-authorized COVID-19 vaccines, including the adenovirus vector Janssen COVID-19 vaccine, is unlikely to impair development of a protective antibody response.

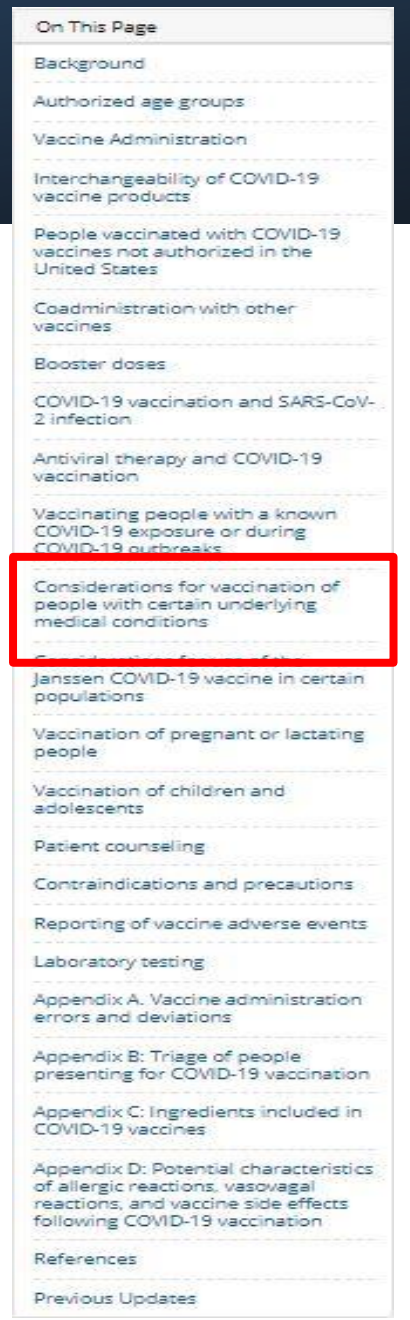
Clinical Immunization Safety Assessment

Information on requesting a consultation from the Clinical Immunization Safety Assessment COVIDvax project added to **considerations for vaccination of people with certain underlying medical conditions**

Considerations for vaccination of people with certain underlying medical conditions

Any currently authorized COVID-19 vaccine can be administered to people with underlying medical conditions who have no contraindications to vaccination; ACIP does not state a product preference. Clinical trials demonstrated similar safety and efficacy profiles in people with some underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to people without comorbidities. Additional information for people with specific underlying medical conditions is included below. Healthcare personnel or health departments in the United States can request a consultation from the Clinical Immunization Safety Assessment COVIDvax project if they have complex COVID-19 vaccine safety questions not readily addressed by CDC guidance.

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html



Considerations for Use of the Janssen COVID-19 Vaccine in Certain Populations-NEW!

- **T**hrombosis with **T**hrombocytopenia **S**yndrome (TTS) definition & summary
- Added warning to the Janssen vaccine EUA Fact Sheets
  - Michigan specific EUA fact sheet should be provided to **all** vaccine recipients **before vaccination**
- **Woman aged < 50 years**
  - Should be made aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized vaccines (i.e., Moderna & Pfizer)
- **People with a history of thrombosis or risk factors for thrombosis**
  - Persons with a history of an episode of an immune-mediated syndrome characterized by thrombosis and thrombocytopenia, such as HIT, be offered another FDA-authorized COVID-19 vaccine if they are within at least 90-180 days after resolution of their illness
- **Use of aspirin or anticoagulants**
  - Persons do not need to stop these medications prior to receipt of the Janssen vaccine
  - It is not recommended to take these prophylactically before any authorized COVID-19 vaccine

Pregnant or Lactating People

Updated information and recommendations for **vaccination of pregnant or lactating people**

Vaccination of pregnant or lactating people

Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference. However, pregnant, lactating, and post-partum people aged <50 years should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized COVID-19 vaccines (i.e., mRNA vaccines). See also People with a history of thrombosis or risk factors for thrombosis.

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Children and Adolescents

Updated recommendations for **vaccination of children and adolescents**

Vaccination of children and adolescents

Adolescents aged 16–17 years are eligible to receive the Pfizer-BioNTech COVID-19 vaccine and may be vaccinated with appropriate assent. While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to differ from those observed in people 18 years of age and older. Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.

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

Patient Counseling-Lymphadenopathy

Updated information related to axillary lymphadenopathy added to **patient counseling** for mRNA COVID-19 vaccines

Before vaccination, providers should counsel mRNA COVID-19 vaccine recipients about expected local (e.g., pain, swelling, erythema at the injection site, localized axillary lymphadenopathy[2] on the same side as the vaccinated arm) and systemic (e.g., fever, fatigue, headache, chills, myalgia, arthralgia) post-vaccination symptoms. Depending on vaccine product (Pfizer-BioNTech vs. Moderna), age group, and vaccine dose, approximately 80%–89% of vaccinated people experience at least one local symptom and 55%–83% experience at least one systemic symptom following vaccination.

- Most routine medical procedures or screenings can be performed before or after getting a COVID-19 vaccine

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/other-procedures.html

Patient Counseling-Janssen Vaccine

Updated information on the Janssen COVID-19 vaccine added to **patient counseling**

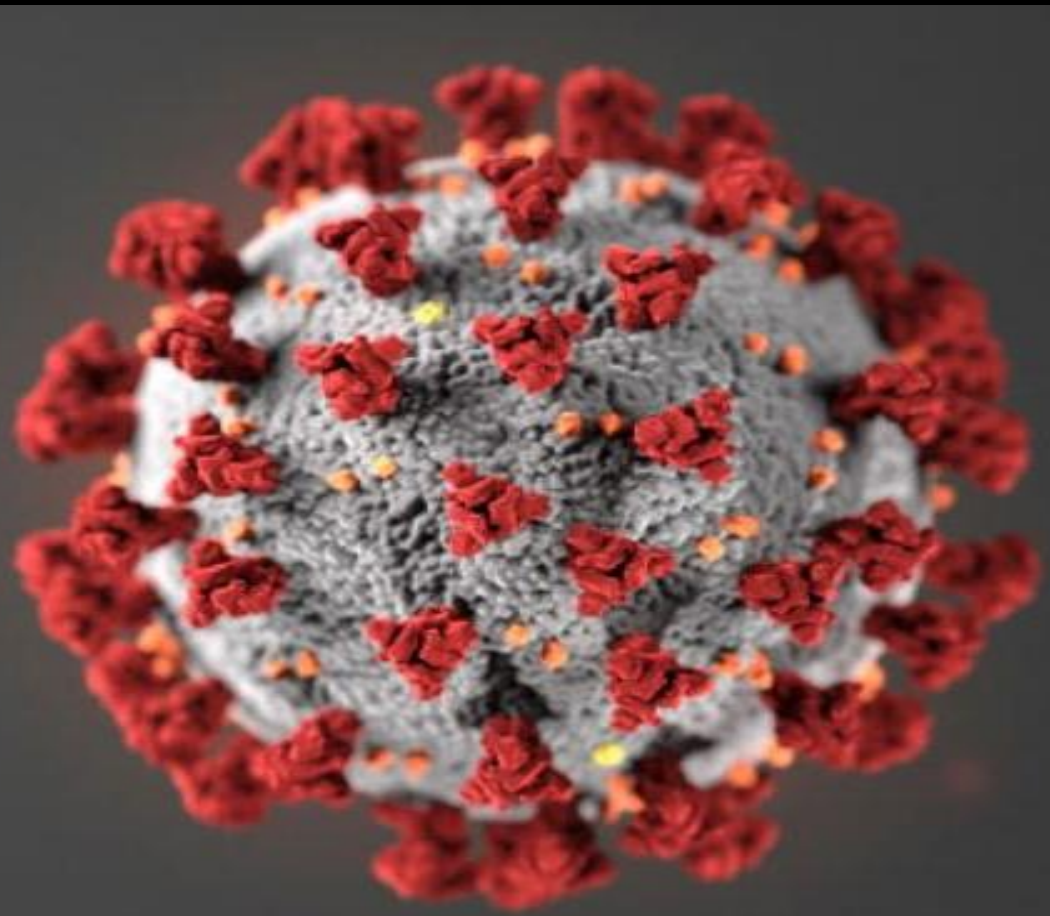
- FDA has added a warning to the Janssen vaccine EUA fact sheet
  - Blood clots involving blood vessels in the brain, abdomen, and legs along with low levels of platelets have occurred in some people who received the Janssen vaccine, and these symptoms began approximately 1-2 weeks following vaccination
  - Most people who developed these clots were women aged 18-49 years
  - Women < 50 years should be made aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine and the availability of other FDA-authorized vaccines (i.e., Moderna & Pfizer)
- Chance of having this occur is remote, people should seek medical attention right away if they have:
  - Shortness of breath
  - Chest pain
  - Leg swelling
  - Persistent abdominal pain
  - Severe or persistent headaches or blurred vision
  - Easy bruising or tiny blood spots under the skin beyond the site of the injection.

Updated Recommendations Regarding Contraindications and Precautions

Updated recommendations related to **contraindications (polysorbate allergy) and precautions** (most people with a precaution can and should be administered vaccine) for COVID-19 vaccines

See Appendix C for a list of ingredients in COVID-19 vaccines. Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna). However, people with a contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa, provided certain measures are taken (see "precautions" below). Known polysorbate allergy is no longer a contraindication to mRNA vaccination; however, known polysorbate allergy is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination.

Review of COVID-19 Vaccine Resources



Appendix A:
Vaccine Administration Errors and Deviations

- This appendix provides resources for preventing and reporting COVID-19 vaccine administration errors, as well as actions to take after an error has occurred

mRNA vaccines only (Pfizer-BioNTech and Moderna)	Intervals	• Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)	• Do **not** repeat dose.
		• Second dose administered more than 42 days after the first dose	• Do **not** repeat dose. This deviation from CDC guidance does **not** require VAERS reporting.
	Mixed series	• Incorrect mRNA COVID-19 vaccine product administered for second dose in 2-dose series	• Do **not** repeat dose. [§]

COVID-19 Vaccine
Quick Reference Guide for Healthcare Professionals

The table below provides basic information on the proper storage, preparation, and administration of the currently authorized COVID-19 vaccine products in the United States. For additional information and detailed clinical guidance go to the manufacturer's and CDC's webpages listed.

		Pfizer	Moderna	Janssen
GENERAL	EUA	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccine	www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine
	CDC Vaccine Information	www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html	www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html
	Manufacturer Contact information	**Website:** www.cvdvaccine.com **Medical information:** 800-438-1985 **Customer service:** 800-879-3477	**Website:** www.modernatx.com **Medical Information:** 866-663-3762	**Website:** www.vaxcheck.jnj. **Medical information:** 1-800-565-4008
STORAGE & HANDLING	How supplied	**Multidose vial:** 6 doses	**Multidose vial:** Maximum of 11 doses	**Multidose vial:** 5 doses
	Diluent	0.9% sodium chloride (preservative-free, normal saline) provided in the ancillary kit. Do NOT use other diluent.	None	None
	Storage Temperatures: Before Puncture	**Between:** -80°C and -60°C (-112°F and -76°F) until the expiration date -25°C and -15°C (-13°F and 5°F) for up to 2 weeks 2°C and 8°C (36°F and 46°F) for up to 120 hours (5 days)	**Between:** -50°C and -15°C (-58°F and 5°F) until the expiration date 2°C and 8°C (36°F and 46°F) for up to 30 days 8°C and 25°C (46° and 77°F) for a total of 24 hours	**Between:** 2°C and 8°C (36°F and 46°F) until the expiration date.
	Storage Temperatures: After puncture	**Between:** 2°C to 25°C (36°F to 77°F) for up to 6 hours. Discard any unused vaccine after 6 hours.	**Between:** 2°C and 25°C (36°F and 77°F) for up to 12 hours. Discard any unused vaccine after 12 hours.	**Between:** 2°C and 8°C (36°F and 46°F) for up to 6 hours. 9°C and 25°C (47°F and 77°F) for up to 2 hours. Discard any unused vaccine after these time frames.
	Transport Temperatures: Before Puncture	**Between:** -80°C and -60°C (-112°F and -76°F) -25°C and -15°C (-13°F and 5°F) 2°C and 8°C (36°F and 46°F)	**Between:** -50°C and -15°C (-58°F and 5°F) 2°C and 8°C (36°F and 46°F) for up to 12 cumulative hours.	**Between:** 2°C and 8°C (36°F and 46°F)
	Transport Temperatures*: After Puncture	**Between:** 2°C to 25°C (36°F to 77°F) for up to 6 hours.	**Between:** 2°C and 25°C (36°F and 77°F) for up to 12 hours.	**Between:** 2°C and 8°C (36°F and 46°F) for up to 6 hours
	Type of Vaccine	mRNA	mRNA	Viral vector
	Age Indications	16 years of age and older	18 years of age and older	18 years of age and older
	Schedule	2-doses, separated by 21 days. Both doses must be Pfizer-BioNTech vaccine	2 doses, separated by 28 days. Both doses should be Moderna vaccine	1 dose only
	Dosage	0.3 mL	0.5 mL	0.5 mL
	Needle gauge/length	22–25 gauge, 1 – 1½"		

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*CDC recommends transporting va

COVID-19 Vaccine
Quick Reference Guide for Healthcare Professionals

		Pfizer	Moderna	Janssen
VACCINE ADMINISTRATION	Route	Intramuscular (IM) injection	Intramuscular (IM) injection	Intramuscular (IM) injection
	Site	Deltoid	Deltoid	Deltoid
	Thawing Frozen Vaccine	**Between:** 2°C and 8°C (36°F and 46°F) or Room temperature up to 25°C (77°F) **Do NOT** refreeze thawed vaccine.	**Between:** 2°C and 8°C (36°F and 46°F) or 8°C to 25°C (46°F to 77°F) **Do NOT** refreeze thawed vaccine.	N/A
	Mixing Vaccine	Mix vaccine with 1.8 mL of 0.9% sodium chloride (preservative-free, normal saline)	**Do NOT** mix with any diluent	**Do NOT** mix with any diluent
	Contraindications/ Precautions	**Contraindications** • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine • Immediate allergic reaction† of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine **Note:** Persons who have a contraindication to an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 vaccine (see footnote).* Persons who have a contraindication to Janssen COVID-19 vaccine may be able to receive an mRNA COVID-19 vaccine (see footnote).* **Precautions** • History of an immediate allergic reaction† to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies) » This includes people with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but for whom it is unknown which component elicited the immediate allergic reaction. • People with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa. (see footnote).* • Moderate to severe acute illness See Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html		
	Post-Vaccination Observation	**30 minutes:** Persons with a history of an immediate allergic reaction of any severity to any other vaccine or injectable therapy or a history of anaphylaxis (from any cause) **15 minutes:** All other persons		
	Most common adverse events	**Injection site:** pain, swelling, redness **Systemic:** fatigue, headache, muscle pain, chills, fever, joint pain	**Injection site:** pain, swelling, redness **Systemic:** fatigue, headache, muscle pain, chills, fever, nausea, joint pain	**Injection site:** pain, redness, swelling **Systemic:** fatigue, headache, muscle pain, nausea, fever

†For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related signs or symptoms, such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within 4 hours following exposure to a vaccine or medication.

*Consider consultation with an allergist-immunologist to help determine if the patient can safely receive vaccination. Healthcare providers and health departments may also request a consultation from the Clinical Immunization Safety Assessment COVID vax Project https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html. Vaccination of these individuals should only be done in an appropriate setting under the supervision of a healthcare provider experienced in the management of severe allergic reactions.

- People with a contraindication to mRNA COVID-19 vaccines (including due to a known PEG allergy) have a precaution to Janssen COVID-19 vaccination. People who have previously received an mRNA COVID-19 vaccine dose but have a contraindication to a second dose should wait at least 28 days to receive Janssen COVID-19 vaccine.

https://www.cdc.gov/vaccines/covid-19/downloads/covid19-vaccine-quick-reference-guide-2pages.pdf

U.S. COVID-19 Vaccine Product Information

Janssen COVID-19 Vaccine (Johnson & Johnson): Effective April 23, 2021, CDC and FDA recommend that use of the Janssen COVID-19 Vaccine resume in the United States. However, women younger than 50 years old should be made aware of a rare risk of blood clots with low platelets following vaccination and the availability of other COVID-19 vaccines where this risk has not been observed. Read the CDC/FDA statement.

CDC will publish 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.

Find a suite of information and materials that are needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.

Pfizer-BioNTech

Moderna

Janssen/J&J

https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

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Experts Answer Questions About Vaccines

Answers to more than a thousand timely questions about vaccines and their administration

- Administering Vaccines
- Billing and Reimbursement
- Combination Vaccines
- Contraindications/Precaut
- COVID-19
- COVID-19 & Routine Vac
- Diphtheria
- Documenting Vaccination
- Hib
- Hepatitis A
- Hepatitis B
- HPV
- Influenza
- MMR
- Meningococcal ACWY
- Meningococcal B
- Pertussis
- Pneumococcal
- Polio
- Rabies
- Rotavirus
- Scheduling Vaccines
- Storage and Handling
- Tetanus
- Travel Vaccines
- Vac Recommendations
- Vaccine Safety
- Varicella (chickenpox)
- Zoster (shingles)

https://www.immunize.org/askexperts/

COVID-19

Disease Issues
Vaccine Recommendations
Vaccine Products
COVID-19 Vaccines for Adolescents and Adults
COVID-19 Vaccines and Pregnancy
Administering Vaccines
Scheduling Vaccines
Contraindications and Precautions
Vaccine Safety
Storage and Handling

Guidance from CDC about COVID-19 vaccines is evolving rapidly. To ensure access to the most current guidance, Ask the Experts answers often connect our readers directly to vaccine resources provided by the Centers for Disease Control and Prevention (CDC).

For a comprehensive collection of COVID-19 tools and resources, visit IAC's Vaccines: COVID-19 main page: www.immunize.org/covid-19. For alerts about new IAC or CDC COVID-19 resources, subscribe to our weekly newsletter, *IAC Express*.

Disease Issues

What is COVID-19?

COVID-19 is the name given to the disease caused by infection with the SARS-CoV-2 coronavirus. This new virus was first detected as a cause of human illness in late 2019 in Wuhan, China, and triggered a global pandemic in 2020. The virus is thought to spread mainly from person to person, mainly through respiratory droplets produced when an infected person coughs, sneezes, or talks. These droplets can land in the mouths or noses of people who are nearby or possibly be inhaled into the lungs.

The incubation period after exposure ranges from 2–14 days, with an average of about 5 days. People with COVID-19 are generally considered infectious up to 48 hours before symptom onset through 10 days after onset, though people with severe illness may be infectious longer. Severity ranges from asymptomatic infection to severe illness. Symptoms may include fever or chills, cough, shortness of breath or difficulty breathing, fatigue, muscle or body aches, headache, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting, and diarrhea.

Where can I find answers to more clinical questions about COVID-19 disease, diagnosis, treatment and care of patients?

The CDC has assembled clinical questions and answers at this site: www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html.

Vaccine Recommendations

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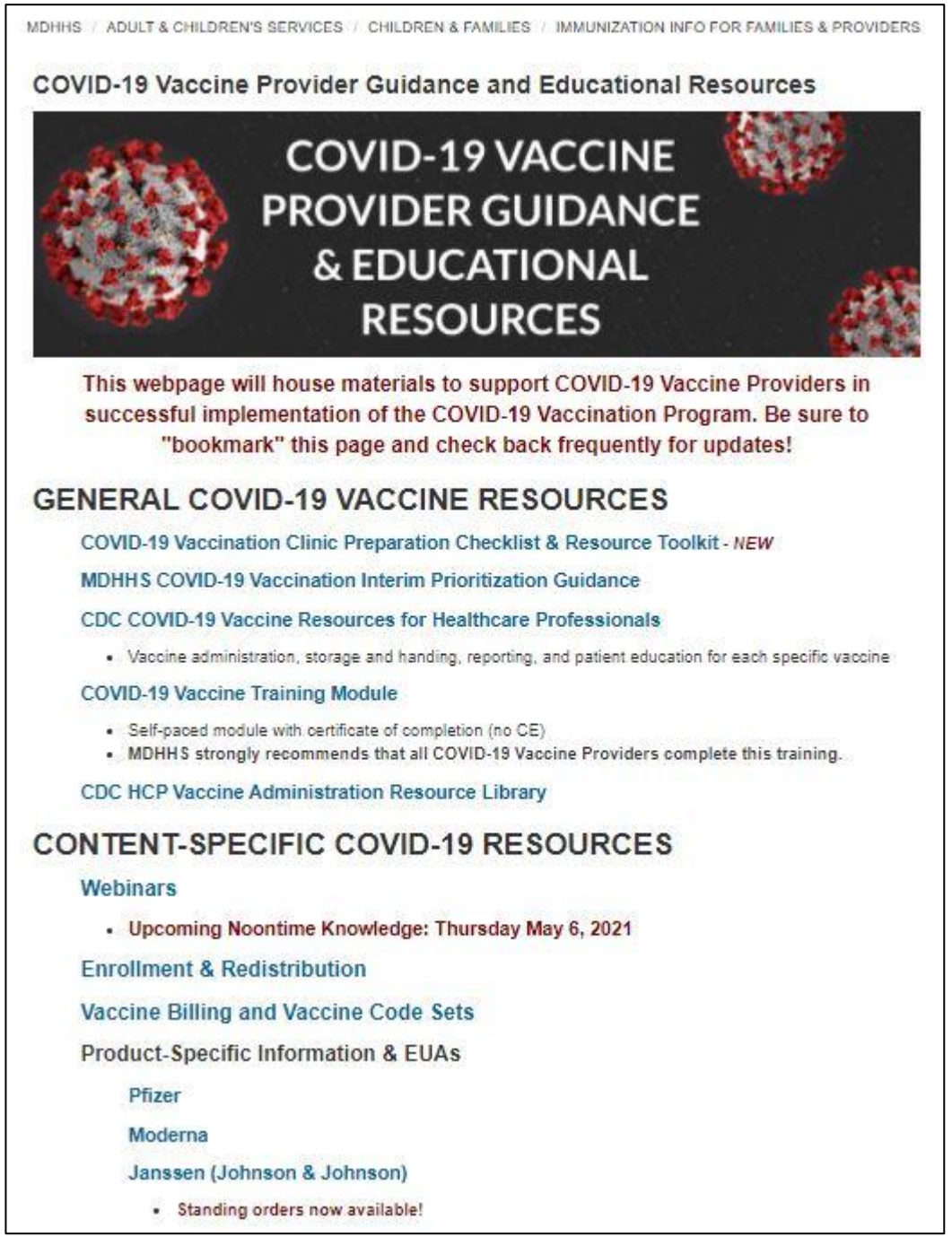


MDHHS / ADULT & CHILDREN'S SERVICES / CHILDREN & FAMILIES / IMMUNIZATION INFO FOR FAMILIES & PROVIDERS

COVID-19 Vaccine Provider Guidance and Educational Resources

COVID-19 VACCINE PROVIDER GUIDANCE & EDUCATIONAL RESOURCES

This webpage will house materials to support COVID-19 Vaccine Providers in successful implementation of the COVID-19 Vaccination Program. Be sure to "bookmark" this page and check back frequently for updates!

GENERAL COVID-19 VACCINE RESOURCES

COVID-19 Vaccination Clinic Preparation Checklist & Resource Toolkit - *NEW*

MDHHS COVID-19 Vaccination Interim Prioritization Guidance

CDC COVID-19 Vaccine Resources for Healthcare Professionals

- Vaccine administration, storage and handing, reporting, and patient education for each specific vaccine

COVID-19 Vaccine Training Module

- Self-paced module with certificate of completion (no CE)
- MDHHS strongly recommends that all COVID-19 Vaccine Providers complete this training.

CDC HCP Vaccine Administration Resource Library

CONTENT-SPECIFIC COVID-19 RESOURCES

Webinars

- Upcoming Noontime Knowledge: Thursday May 6, 2021

Enrollment & Redistribution

Vaccine Billing and Vaccine Code Sets

Product-Specific Information & EUAs

Pfizer

Moderna

Janssen (Johnson & Johnson)

- Standing orders now available!

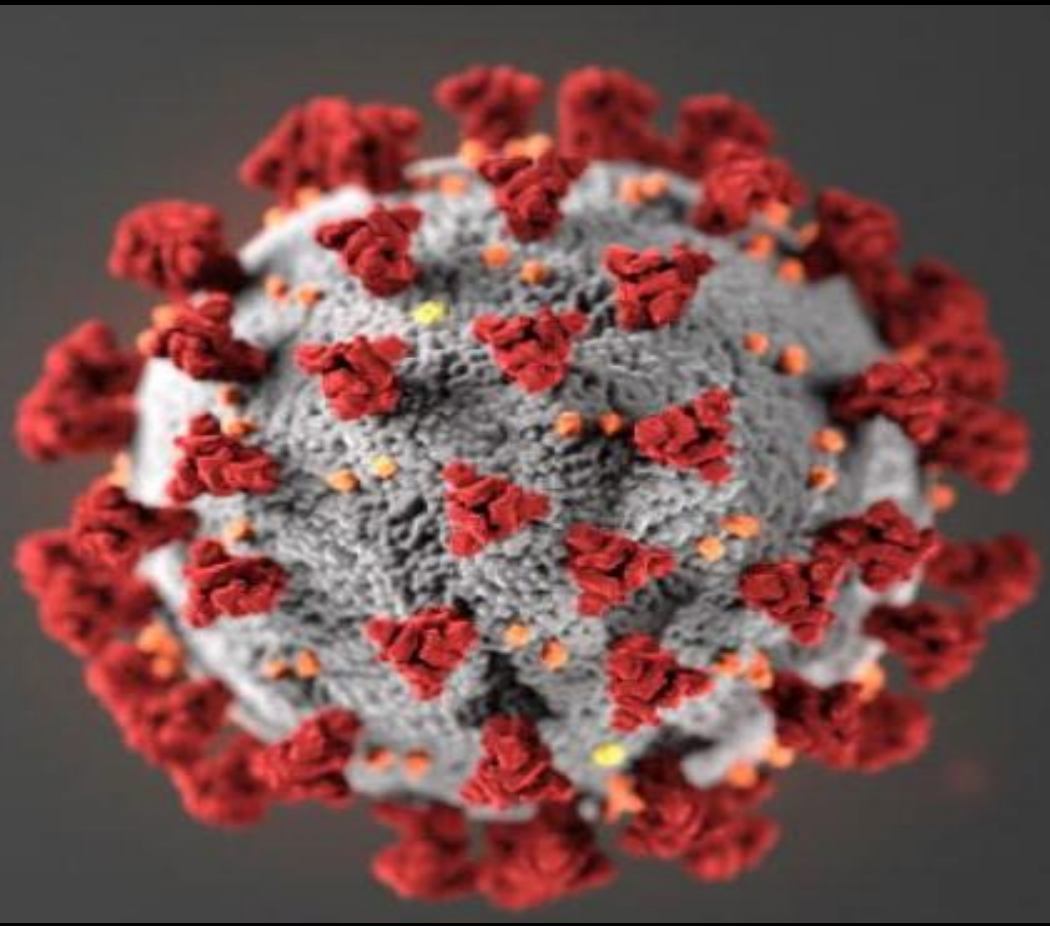
MDHHS COVID-19 Provider Guidance and Educational Resources

www.michigan.gov/COVIDvaccine → Provider Guidance and Education

Thank You!

Next “Noontime Knowledge” Update: May 20, 2021 at 12:00p.m.
Topic: TBD

Please watch your email for an updated link and topic!



www.michigan.gov/COVIDvaccine →Provider Guidance and Education