MDHHS
Michigan Department of Health & Human Services

Diving Into COVID-19 Vaccine Clinical Considerations

March 25, 2021

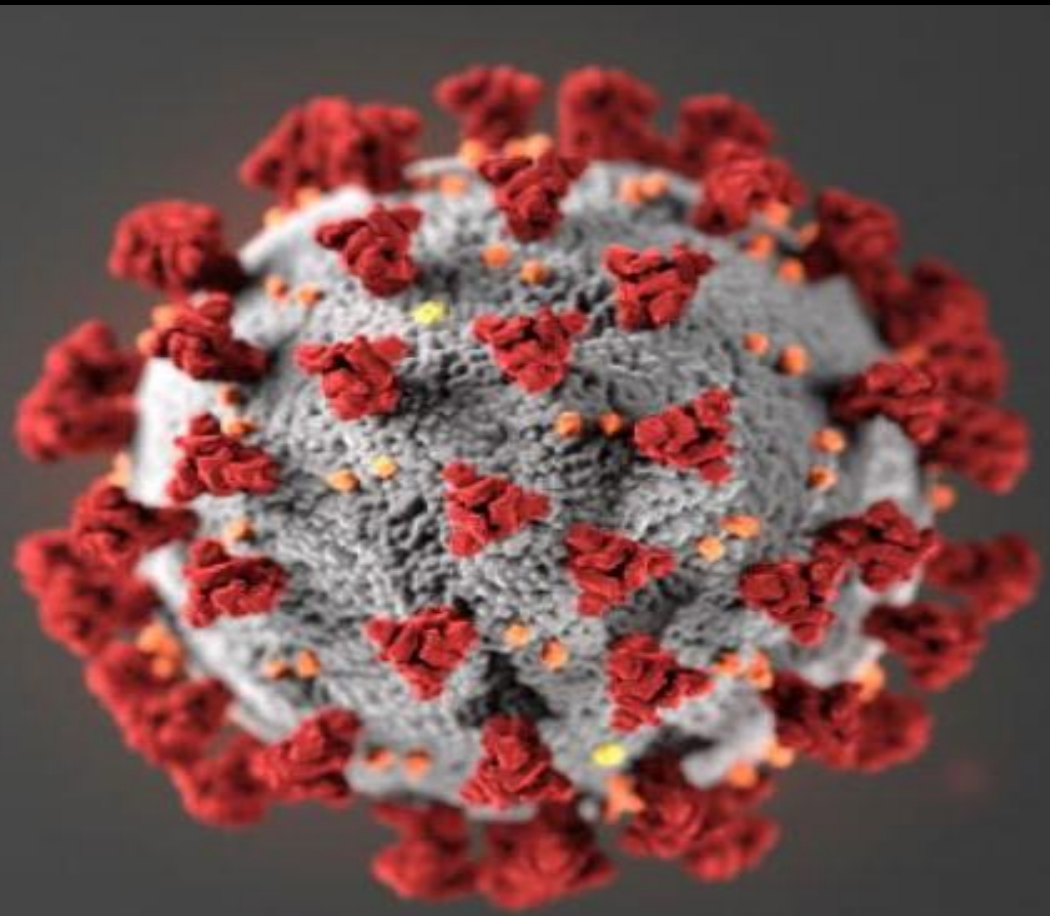
Housekeeping

- **How to Ask Questions**
  - Click on the 

 icon found at the bottom part of your screen
  - A box will open where you can type in questions, comments, indicate sound problems, etc.
  - Use this throughout the webinar to ask questions

- **Slides & Recording**
  - 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

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

Summary of recent changes (last updated March 5, 2021):

- Public health recommendations for vaccinated people have been moved to: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

Key points

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.

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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. 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.

Authorized Age Groups

Authorized age groups

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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Vaccine Administration

Vaccine Administration

COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose.

Vaccine	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	100 µg	0.5 ml	2	1 month (28 days)
Janssen	5×10^{10} viral particles	0.5 ml	1	N/A

A single, valid vaccination series (i.e., either a two-dose mRNA COVID-19 vaccine series or a single dose of Janssen COVID-19 vaccine) should be administered. People are not recommended to receive more than one complete COVID-19 vaccination series.

Interval between mRNA doses

The second dose of Pfizer-BioNTech and Moderna vaccines should be administered as close to the recommended interval as possible, but not earlier than recommended (i.e., 3 weeks [Pfizer-BioNTech] or 1 month [Moderna]). However, second doses administered within a grace period of 4 days earlier than the recommended date for the second dose are still considered valid. If it is not feasible to adhere to the recommended interval and a delay in vaccination is unavoidable, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be administered up to 6 weeks (42 days) after the first dose. Currently, only limited data are available on efficacy of mRNA COVID-19 vaccines administered beyond this window.

Information on preventing, reporting, and managing COVID-19 vaccine administration errors is found in Appendix A. Vaccine administration errors should be reported to the Vaccine Adverse Event Reporting System (VAERS).

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Interchangeability of COVID-19 Vaccine Products

- ACIP does not state a product preference
- COVID-19 vaccines are **not** interchangeable
- The safety and efficacy of a mixed product series have not been evaluated for the mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna)
  - Both doses of the series should be completed with the same product
  - Every effort should be made to determine which vaccine product was administered for the first dose
    - In **exceptional situations** in which the vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered (minimum 28 days between doses)
- The safety and efficacy of Janssen COVID-19 vaccine administered after an mRNA COVID-19 vaccine has not been established
  - In **exceptional situations** where a patient received the first dose of an mRNA COVID-19 vaccine but is unable to complete the series with either the same or different mRNA COVID-19 vaccine (e.g., due to contraindication), a single dose of Janssen COVID-19 vaccine may be considered (minimum interval of 28 days from the mRNA COVID-19 vaccine dose)

Coadministration with Other Vaccines & Booster Doses

Coadministration with other Vaccines:

- None of the currently authorized COVID-19 vaccines are live virus vaccines
- COVID-19 vaccine should routinely be administered alone, with a minimum interval of 14 days before or after administration of any other vaccine
- If COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

Booster Doses:

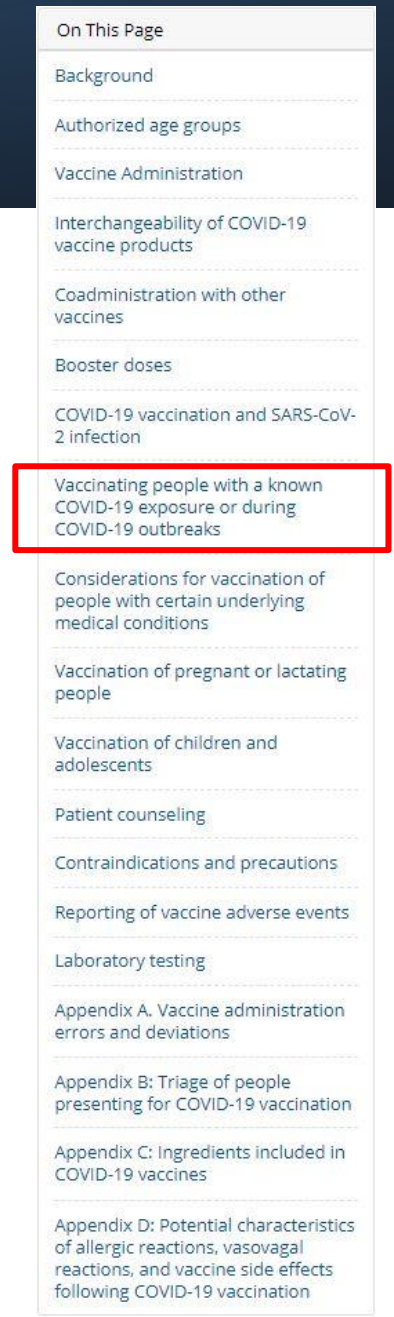
- The need for and timing for COVID-19 booster doses have not been established
- No additional doses are recommended at this time

COVID-19 Vaccination and SARS-CoV-2 Infection

- **Persons with prior or current SARS CoV-2 infection**
  - Offer vaccination regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Defer until recovered from the acute illness (if had symptoms) and met criteria to discontinue isolation
  - No recommended minimum interval between infection and vaccination
- **People who previously received passive antibody therapy**
  - Currently, there are no data on the safety and efficacy of COVID-19 vaccines in people who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
  - Vaccination should be deferred for at least 90 days
  - No recommended minimum interval between antibody therapies not specific to COVID-19 treatment and COVID-19 vaccination.(e.g., intravenous immunoglobulin, RhoGAM)
- **Vaccinated people who subsequently develop COVID-19**
  - Prior receipt of a COVID-19 vaccine should not affect treatment decisions or timing of treatment
  - Information about these cases should be reported to VAERS

Vaccinating People with a Known COVID Exposure or During COVID-19 Outbreaks

- COVID-19 vaccines are not recommended for outbreak management or for post-exposure prophylaxis in a person with a known exposure
- People in the community or in outpatient settings who have had a known COVID-19 exposure should not seek vaccination until their quarantine period has ended
- Residents or patients with a known COVID-19 exposure in congregate healthcare settings or congregate non-healthcare settings may be vaccinated
- People residing in congregate settings who have had an exposure and are awaiting SARS-CoV-2 testing results may be vaccinated if they do not have symptoms consistent with COVID-19



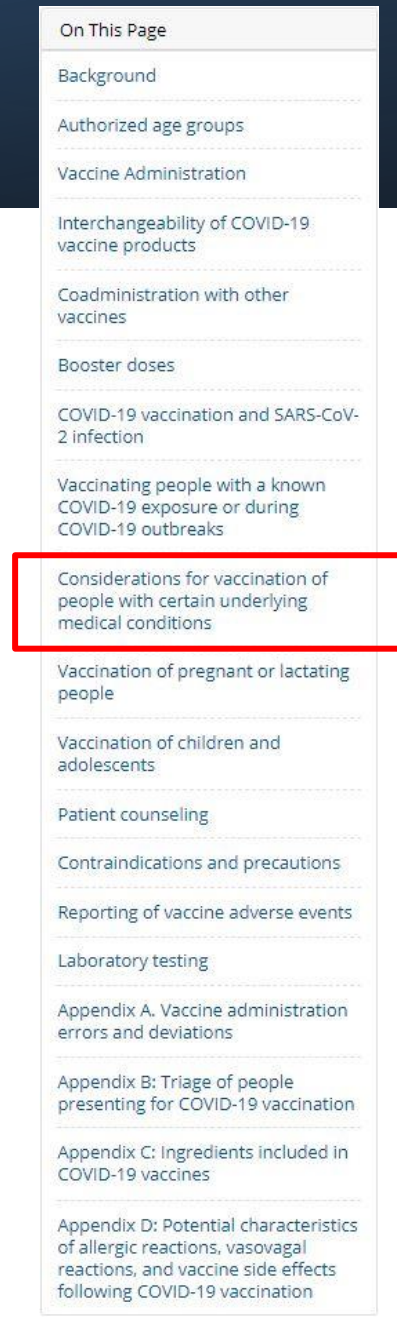
Considerations for Vaccination of People with Certain Underlying Medical Conditions

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.

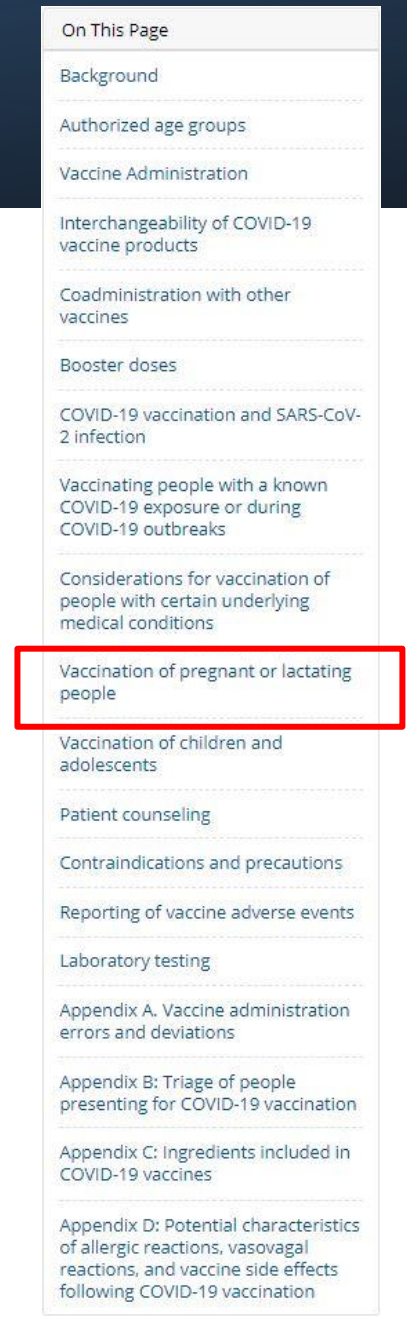
Specific Sections for:

- Immunocompromised people
- People with Autoimmune Conditions
- People with a history of Guillain Barre Syndrome
- People with a history of Bell's Palsy
- People with a history of Dermal Filler Use



Vaccination of Pregnant or Lactating People

- Currently limited data on safety of COVID-19 vaccines in pregnant people
  - No concerns demonstrated in animal developmental and reproductive toxicity (DART) studies
  - Janssen adenovirus vector platform previously used for other clinical development programs that included pregnant people, including a large-scale Ebola vaccine trial
- Currently authorized COVID-19 vaccines are all inactivated vaccines
- Any of the currently authorized COVID-19 vaccines can be administered to pregnant or lactating people; ACIP does not state a product preference
  - A conversation between the patient and their clinical team may assist with decision, but is not required
- Clinical trials to evaluate safety and efficacy of COVID-19 vaccines in pregnant people planned or underway

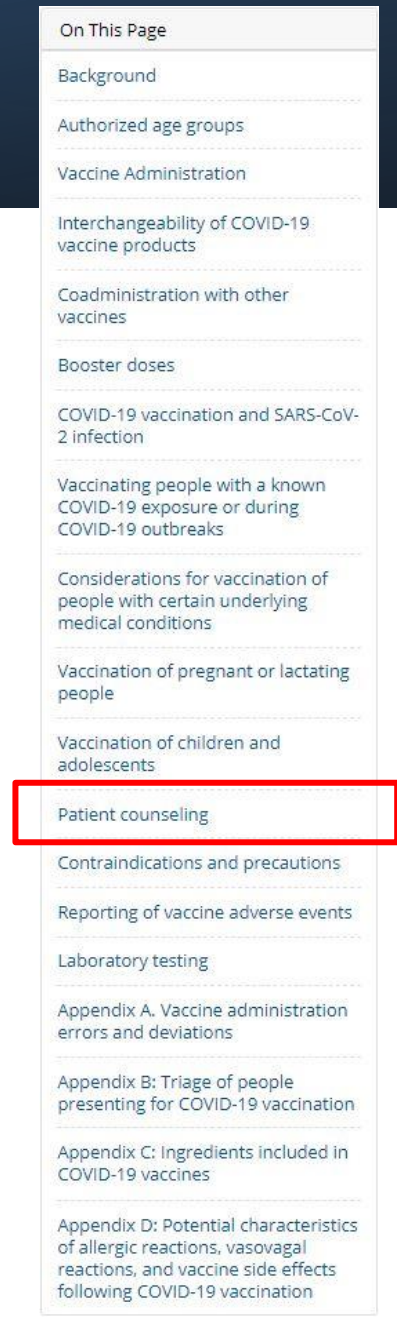


Vaccination of Children and Adolescents

- Adolescents aged 16–17 years are included among people eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA
- 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

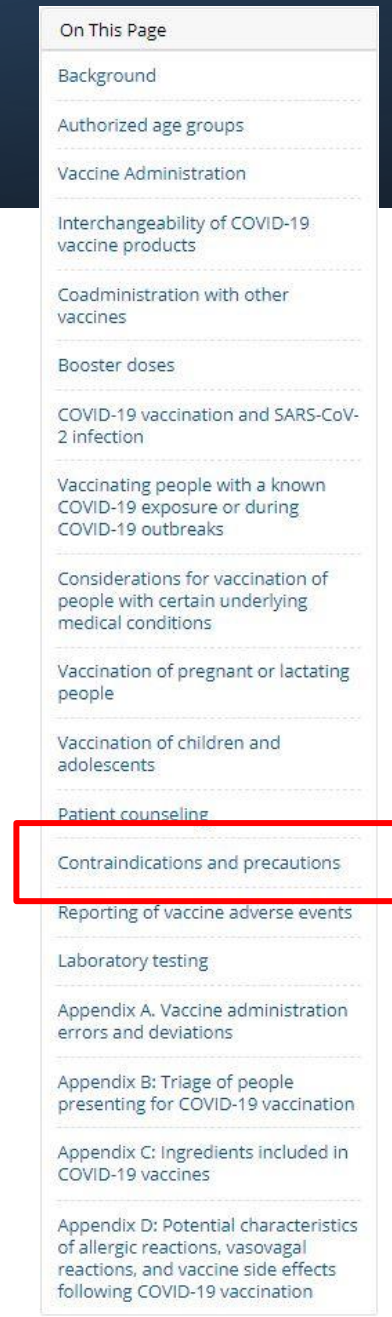
Patient Counseling

- **mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna)**
  - Counsel on the importance of completing the two-dose series
  - Counsel on expected local and post-vaccination symptoms
- **Viral vector COVID-19 vaccine (Janssen)**
  - Counsel on expected local and systemic post-vaccination symptoms
- **Management of post-COVID-19-vaccination symptoms**
  - Administration of antihistamines before vaccination to prevent allergic reactions is not recommended
  - See section on contraindications and precautions to vaccination and interim considerations for anaphylaxis management
  - Antipyretic or analgesic medications can be taken for the treatment of **post-vaccination** local or systemic symptoms, if medically appropriate



Contraindications and Precautions

- An immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration
- Healthcare personnel or health departments in the U.S. can request consultation from the Clinical Immunization Safety Assessment (CISA) COVIDvax project about an individual patient residing in the U.S. by
  - Calling 800-CDC-INFO (800-232-4636), or
  - Submitting a request via CDC-INFO webform
- Providers should attempt to determine whether reactions reported following vaccination are consistent with immediate allergic reactions versus other types of reactions commonly observed following vaccination, such as a vasovagal reaction or post-vaccination side effects **(Appendix D)**



Reporting of Vaccine Adverse Events

Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under EUA:

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

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

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

Laboratory Testing

- **Interpretation of SARS-CoV-2 test results in vaccinated people**
  - Prior receipt of a COVID-19 vaccine will not affect the results of SARS-CoV-2 viral tests
  - Antibody testing is not currently recommended to assess for immunity to SARS-CoV-2 following COVID-19 vaccination
- **Use of immune-based tests for tuberculosis infection, such as the tuberculin skin test and interferon-gamma release assay**
  - COVID-19 vaccines should not be delayed because of testing for TB infection
  - Testing for TB infection with one of the immune-based methods, either the tuberculin skin test (TST) or an interferon release assay (IGRA), can be done before or during the same encounter as COVID-19 vaccination
  - When testing with TST or IGRA cannot be done at the same time as COVID-19 vaccination, these tests should be delayed ≥4 weeks after the completion of COVID-19 vaccination but generally should not be cancelled

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. [§]

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Appendix B: Triage of People Presenting for COVID-19 Vaccination

Appendix B: Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine†	**Among people without a contraindication, a history of:** • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#	**Among people without a contraindication or precaution, a history of:** • Allergy to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies
Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	**Actions:** • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	**Actions:** • 30-minute observation period: people with history of anaphylaxis (due to any cause) • 15-minute observation period: all other people

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Appendix C: Ingredients Included in COVID-19 Vaccines

Description	Pfizer-BioNTech (mRNA)	Moderna (mRNA)	Janssen (viral vector)
Active ingredient	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	Recombinant, replication-incompetent Ad26 vector, encoding a stabilized variant of the SARS-CoV-2 Spike (S) protein
Inactive ingredients	2[(polyethylene glycol (PEG))-2000]-N,N-ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac-glycerol, methoxypolyethylene glycol	Polysorbate-80
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine	2-hydroxypropyl-β-cyclodextrin
	Cholesterol	Cholesterol	Citric acid monohydrate
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate	Trisodium citrate dihydrate
	Sodium chloride	Tromethamine	Sodium chloride
	Monobasic potassium phosphate	Tromethamine hydrochloride	Ethanol
	Potassium chloride	Acetic acid	
	Dibasic sodium phosphate dihydrate	Sodium acetate	
	Sucrose	Sucrose	

Appendix D: Potential Characteristics of Allergic Reactions, Vasovagal Reactions, and Vaccine Side Effects

Characteristic	Allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
Timing after vaccination	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring the day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema, or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache

COVID-19 Vaccination

Clinical Resources for Each COVID-19 Vaccine

Find information for COVID-19 vaccination administration, storage and handing, reporting, and patient education for each specific vaccine

Product Information by US Vaccine

CDC's Web Page for COVID-19 Vaccination Education

- Links to several CDC pages such as the storage and handling toolkit, vaccine administration, ACIP recommendations, and more
- Links to the COVID-19 product information by US vaccine
- There is a "Vaccination Resource Toolkits" tab that reviews the Communication Toolkit
- For further information: https://www.cdc.gov/vaccines/covid-19/index.html

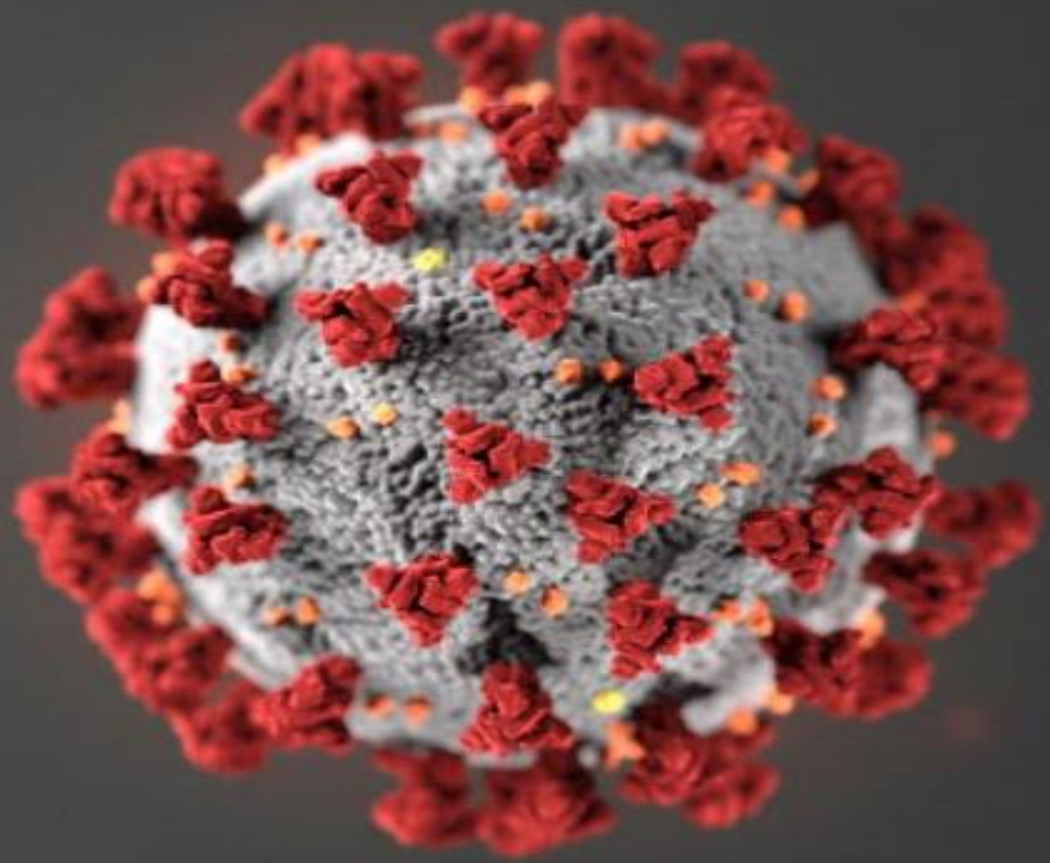
Upcoming Important Webinar Tomorrow!

Who: Primary Care Providers and staff planning to receive and administer COVID-19 vaccine

What: Prepare Your Office For COVID-19 Vaccine Arrival

When: Friday, March 26, 2021 at 12:00p.m. (EST) 45-60 minutes in length and will include time for questions and answers

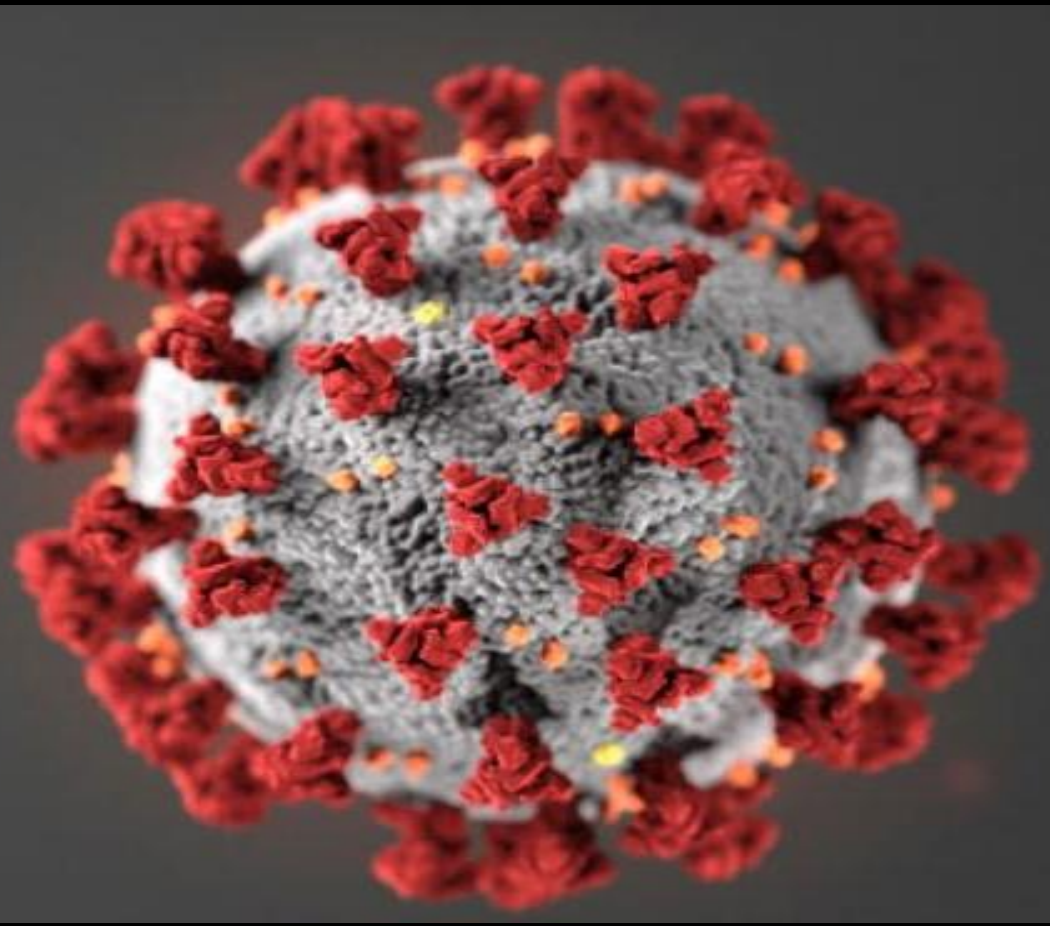
Registration:
https://msu.zoom.us/webinar/register/WN_-KM2pPM9TTmURSq17jz3Xw



Thank You!

Next “Noontime Knowledge” Update: April 8, 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