MDHHS
Michigan Department of Health & Human Services

Hot Off the Press:
Additional Doses of mRNA Vaccine and More

August 26, 2021

Housekeeping

- **How to Ask Questions**
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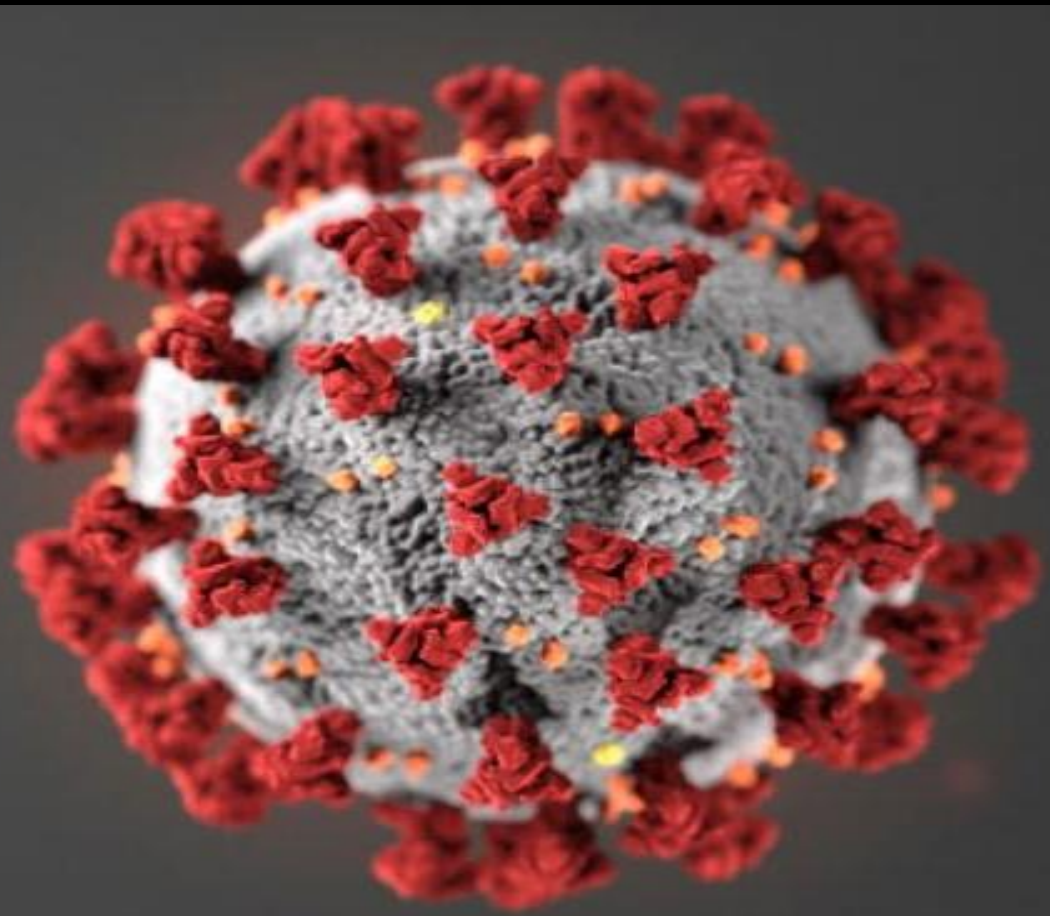
 icon found at the bottom part of your screen
  - A box will open where you can type in questions, comments, indicate sound problems, etc.
  - Use this throughout the webinar to ask questions
- **Slides & Recording**
  - This webinar is being recorded and a link as well as slides will be emailed out through our listserv as well as posted on our website at: www.michigan.gov/COVIDvaccineprovider

Topics Covered

- mRNA COVID-19 Vaccine EUA Amendment and Pfizer-BioNTech FDA Approval
- Additional Dose of mRNA COVID-19 Vaccine
- Updated Clinical Considerations
- Extended Expiration Date
- Fact Check
- Resources

mRNA COVID-19 Vaccine EUA Amendment and Pfizer-BioNTech FDA Approval



Emergency Use Authorization (EUA) Amendment

- **August 12, 2021:** FDA Authorizes Additional Vaccine Dose for Certain Immunocompromised Individuals
  - Other fully vaccinated individuals do not need an additional dose right now
  - Amendment applies to:
    - **Pfizer-BioNTech COVID-19 vaccine** (BNT162b2) (≥12 years old)
    - **Moderna COVID-19 vaccine** (mRNA-1273) (≥18 years old)
- Due to insufficient data, the EUA amendment for an additional dose does not apply to Janssen COVID-19 vaccine or to individuals who received Janssen COVID-19 as a primary series. CDC and FDA are actively engaged to ensure that immunocompromised recipients of Janssen COVID-19 vaccine have optimal vaccine protection

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-vaccine-dose-certain-immunocompromised

FDA Approves Pfizer-BioNTech COVID-19 Vaccine

- **August 23, 2021:** FDA approves the first COVID-19 Vaccine known as the Pfizer-BioNTech COVID-19 vaccine
  - Now marketed as **Comirnaty (koe-mir'-na-tee**)
  - In Individuals 16 years of age and older
    - The vaccine continues to be available **under emergency use authorization (EUA), for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals**

https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

2.3 Dosing and Schedule
The Moderna COVID-19 Vaccine is administered intramuscularly as a series of two doses (0.5 mL each) 1 month apart.

There are no data available on the interchangeability of the Moderna COVID-19 Vaccine with other COVID-19 vaccines to complete the vaccination series. Individuals who have received one dose of Moderna COVID-19 Vaccine should receive a second dose of Moderna COVID-19 Vaccine to complete the vaccination series.

A third dose of the Moderna COVID-19 Vaccine (0.5 mL) administered at least 28 days following the first two doses of this vaccine is authorized for administration to individuals at least 18 years of age who have undergone solid organ transplantation, or who are diagnosed with conditions that are considered to have an equivalent level of immunocompromise.

Moderna-Revised August 12, 2021

ENGLISH

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE PFIZER-BIONTECH COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19)

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product, Pfizer-BioNTech COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 12 years of age and older and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech. It is approved as a 2-dose series for the prevention of COVID-19 in individuals 16 years of age and older and is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise.

The FDA-approved COMIRNATY (COVID-19 Vaccine, mRNA) and the EUA-authorized Pfizer-BioNTech COVID-19 Vaccine have the same formulation and can be used interchangeably to provide the COVID-19 vaccination series.[1]

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Pfizer-BioNTech-Revised August 23, 2021

Updated EUA Fact Sheets

CONTENT-SPECIFIC COVID-19 RESOURCES

- Webinars
  - Upcoming Noontime Knowledge: TBD
- Education Corner
- Enrollment
- Redistribution
- Vaccine Billing and Vaccine Code Sets
- Product-Specific Information & EUAs
  - Pfizer
  - Moderna
  - Janssen (Johnson & Johnson)

EUA Fact Sheets

- EUA Fact Sheet for Healthcare Professionals - *UPDATED 8/23/21*
- EUA Fact Sheet for Recipients - *UPDATED 8/23/21*
  - **Important: Print and provide the above EUA Fact Sheet to each COVID-19 vaccine recipient/caregiver in Michigan.**
  - This version includes the information statement about the MCIR (as indicated in Michigan VISs). Per state law, patients/parents must be informed about MCIR.
  - Translations
    - Arabic Updated 6/25/21
    - Cherokee Updated 6/25/21
    - Chinese-Simplified
    - Chinese-Traditional
    - Chuukese
    - French
    - German
    - Haitian-Creole
    - Hmong
    - Italian
    - Japanese
    - Marshallese
    - Polish
    - Somali
    - Spanish - Updated 6/25/21

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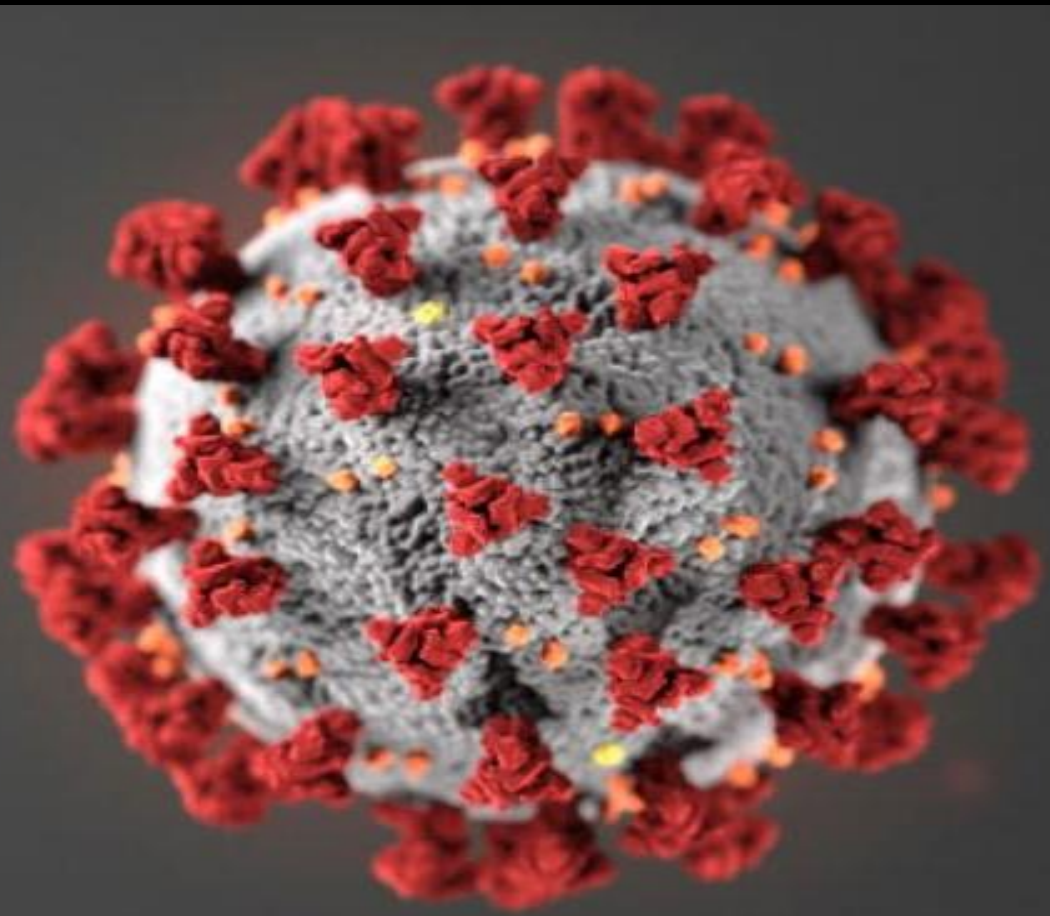
OVID-19 VACCINATION PROVIDERS

EUA Fact Sheets

www.michigan.gov/covidvaccineprovider

Additional Dose of mRNA COVID-19 Vaccine



Additional Dose of mRNA COVID-19 Vaccine

- **August 13, 2021**- The Advisory Committee on Immunization Practices (ACIP) recommended that people whose immune systems are moderately to severely compromised receive an additional dose of mRNA COVID-19 vaccine at least four weeks after an initial two-dose mRnA series
- This decision followed a careful examination of available data, and robust and deliberative discussion around allowing an additional dose of either of the two FDA-authorized mRNA COVID-19 vaccines for moderately to severely immunocompromised individuals who have already received an initial two doses of mRNA COVID-19 vaccine
- Studies show that some people who are immunocompromised don’t build adequate levels of protection after receiving their 2-dose initial mRNA COVID-19 vaccination
- Emerging evidence shows that some within this population benefit from an additional dose of an mRNA vaccine to develop as much protection as possible against COVID-19

Additional Dose vs. Booster Dose

There are two distinct potential uses for an additional vaccine dose:

- **Additional dose after an initial primary vaccine series:** administration of an additional vaccine dose associated with the primary vaccine series when the initial immune response to that primary vaccine series is likely to be **insufficient**
- **Booster dose:** a dose of vaccine administered when the initial **sufficient** immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established

Additional Dose Recommendation for Who?

- Moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:
  - Active treatment for solid tumor and hematologic malignancies
  - Receipt of solid-organ transplant and taking immunosuppressive therapy
  - Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
  - Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
  - Advanced or untreated HIV infection
  - Active treatment with high-dose corticosteroids, alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory

Additional Considerations

- Whenever possible, mRNA COVID-19 vaccination primary series and additional dose should be given at least two weeks before initiation or resumption of immunosuppressive therapies, but timing of COVID-19 vaccination should take into consideration immunosuppressive therapies and optimization of both the patient's medical condition and response to vaccine
- Patient's clinical team is best situated to determine the degree of immune compromise and appropriate timing of vaccination
- Factors to consider in assessing the general level of immune competence of patients include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment
- Utility of serologic testing or cellular immune testing to assess immune response to vaccination and guide clinical care (e.g., need for an additional dose) has not been established and is not recommended at this time

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Implementation Considerations

- The additional dose should be the same mRNA vaccine as the primary series
- Alternate mRNA product can be used if primary series product not available
- Until more data are available, the additional dose should be administered at least 28 days after completion of the initial primary series
- Currently there are not data to support the use of an additional mRNA COVID-19 vaccine dose after a primary Janssen COVID-19 vaccine in immunocompromised people. FDA and CDC are actively working to provide guidance on this issue
- These clinical considerations for use of an additional dose of an mRNA COVID-19 vaccine apply only to people who are moderately or severely immunocompromised

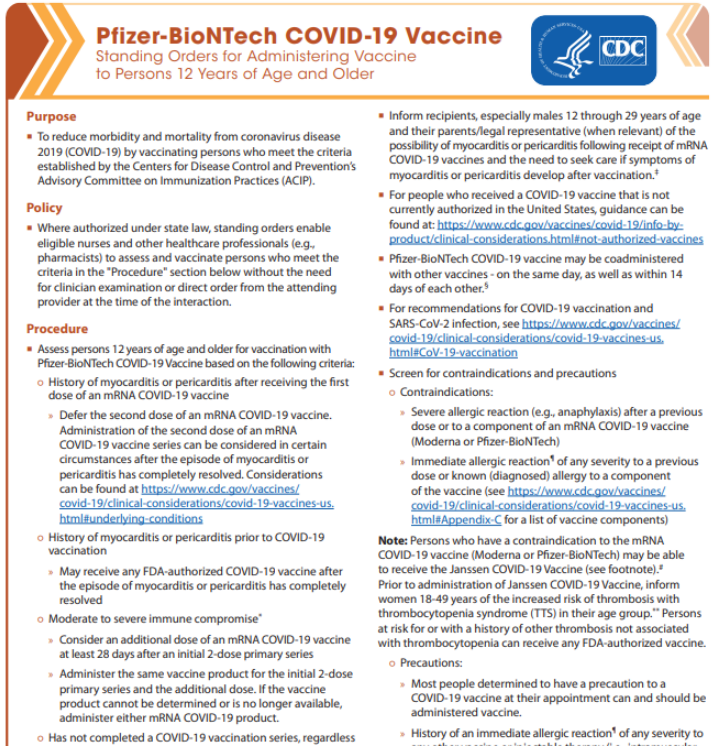
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Importance of Infection Prevention Measures

- Immunocompromised people (including those who receive an additional mRNA dose) should be counseled about the potential for reduced immune response to COVID-19 vaccination and need to follow prevention measures
  - Wear a mask
  - Stay 6 feet apart from others they don't live with
  - Avoid crowds and poorly ventilated indoor spaces until advised otherwise by their healthcare provider
- Strongly encourage close contacts of immunocompromised people to be vaccinated against COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html

Pfizer-BioNTech Standing Order



Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 12 Years of Age and Older

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

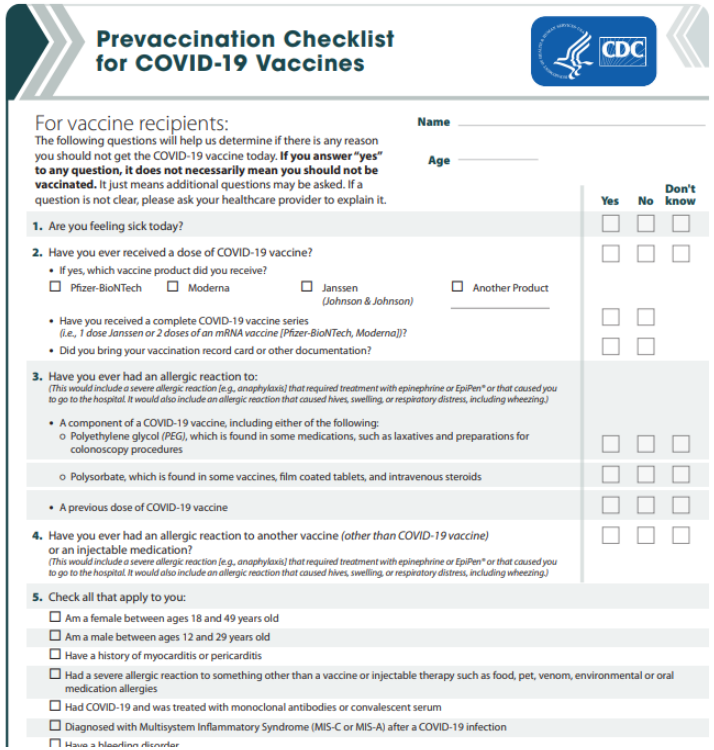
Procedure

- Assess persons 12 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:
  - History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine
    - Defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
  - History of myocarditis or pericarditis prior to COVID-19 vaccination
    - May receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - Moderate to severe immune compromise*
    - Consider an additional dose of an mRNA COVID-19 vaccine at least 28 days after an initial 2-dose primary series
    - Administer the same vaccine product for the initial 2-dose primary series and the additional dose. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 product.
  - Has not completed a COVID-19 vaccination series, regardless
- Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.[4]
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Pfizer-BioNTech COVID-19 vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.[5]
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination
- Screen for contraindications and precautions
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - Immediate allergic reaction[1] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

Note: Persons who have a contraindication to the mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech) may be able to receive the Janssen COVID-19 Vaccine (see footnote).[#] Prior to administration of Janssen COVID-19 Vaccine, inform women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group.[**] Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

- Precautions:
  - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
  - History of an immediate allergic reaction[1] of any severity to

Pre-Vaccination Checklist



Prevaccination Checklist for COVID-19 Vaccines

For vaccine recipients:
The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. **If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated.** It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

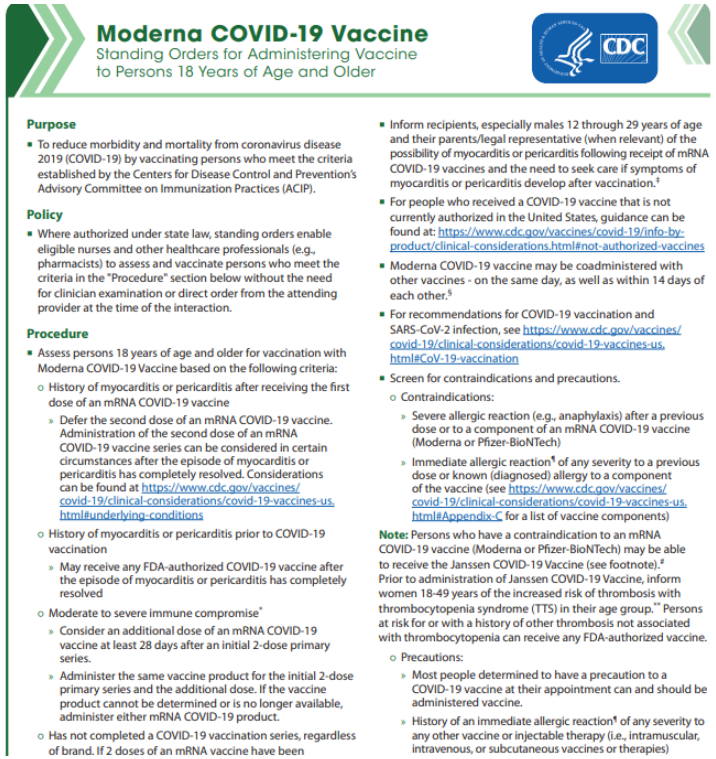
Name _____
Age _____

	Yes	No	Don't know
1. Are you feeling sick today?	☐	☐	☐
2. Have you ever received a dose of COVID-19 vaccine?	☐	☐	☐
• If yes, which vaccine product did you receive? ☐ Pfizer-BioNTech ☐ Moderna ☐ Janssen (Johnson & Johnson) ☐ Another Product _____			
• Have you received a complete COVID-19 vaccine series (i.e., 1 dose Janssen or 2 doses of an mRNA vaccine [Pfizer-BioNTech, Moderna])?	☐	☐	
• Did you bring your vaccination record card or other documentation?	☐	☐	
3. Have you ever had an allergic reaction to: (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)			
• A component of a COVID-19 vaccine, including either of the following: ○ Polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures	☐	☐	☐
○ Polysorbate, which is found in some vaccines, film coated tablets, and intravenous steroids	☐	☐	☐
• A previous dose of COVID-19 vaccine	☐	☐	☐
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? (This would include a severe allergic reaction [e.g., anaphylaxis] that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that caused hives, swelling, or respiratory distress, including wheezing.)	☐	☐	☐

5. Check all that apply to you:

- ☐ Am a female between ages 18 and 49 years old
- ☐ Am a male between ages 12 and 29 years old
- ☐ Have a history of myocarditis or pericarditis
- ☐ Had a severe allergic reaction to something other than a vaccine or injectable therapy such as food, pet, venom, environmental or oral medication allergies
- ☐ Had COVID-19 and was treated with monoclonal antibodies or convalescent serum
- ☐ Diagnosed with Multisystem Inflammatory Syndrome (MIS-C or MIS-A) after a COVID-19 infection
- ☐ Have a bleeding disorder

Moderna Standing Order



Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Purpose

- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

Procedure

- Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:
  - History of myocarditis or pericarditis after receiving the first dose of an mRNA COVID-19 vaccine
    - Defer the second dose of an mRNA COVID-19 vaccine. Administration of the second dose of an mRNA COVID-19 vaccine series can be considered in certain circumstances after the episode of myocarditis or pericarditis has completely resolved. Considerations can be found at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#underlying-conditions
  - History of myocarditis or pericarditis prior to COVID-19 vaccination
    - May receive any FDA-authorized COVID-19 vaccine after the episode of myocarditis or pericarditis has completely resolved
  - Moderate to severe immune compromise*
    - Consider an additional dose of an mRNA COVID-19 vaccine at least 28 days after an initial 2-dose primary series.
    - Administer the same vaccine product for the initial 2-dose primary series and the additional dose. If the vaccine product cannot be determined or is no longer available, administer either mRNA COVID-19 product.
  - Has not completed a COVID-19 vaccination series, regardless of brand. If 2 doses of an mRNA vaccine have been
- Inform recipients, especially males 12 through 29 years of age and their parents/legal representative (when relevant) of the possibility of myocarditis or pericarditis following receipt of mRNA COVID-19 vaccines and the need to seek care if symptoms of myocarditis or pericarditis develop after vaccination.[4]
- For people who received a COVID-19 vaccine that is not currently authorized in the United States, guidance can be found at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#not-authorized-vaccines
- Moderna COVID-19 vaccine may be coadministered with other vaccines - on the same day, as well as within 14 days of each other.[5]
- For recommendations for COVID-19 vaccination and SARS-CoV-2 infection, see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech)
    - Immediate allergic reaction[1] of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine (see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Appendix-C for a list of vaccine components)

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).[#] Prior to administration of Janssen COVID-19 Vaccine, inform women 18-49 years of the increased risk of thrombosis with thrombocytopenia syndrome (TTS) in their age group.[**] Persons at risk for or with a history of other thrombosis not associated with thrombocytopenia can receive any FDA-authorized vaccine.

- Precautions:
  - Most people determined to have a precaution to a COVID-19 vaccine at their appointment can and should be administered vaccine.
  - History of an immediate allergic reaction[1] of any severity to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies)

Updated Resources

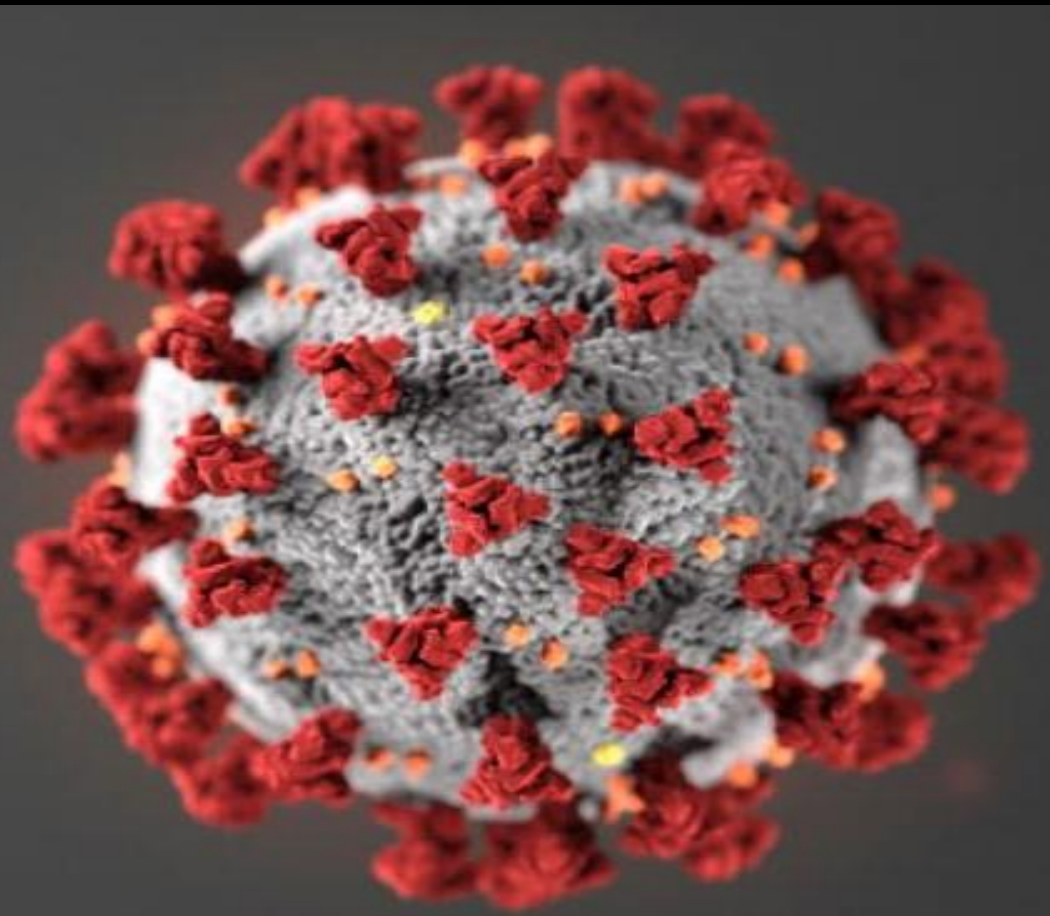
https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Booster Doses

- The need and timing for COVID-19 booster doses have not been established
- No booster doses are recommended at this time
- Guidance may be updated as more information becomes available
- ACIP scheduled to meet August 30th from 10a.m.-4:30p.m. EST

https://www.cdc.gov/vaccines/acip/index.html

Updated CDC Interim Clinical Considerations



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

NOTICE: FDA has granted full approval for Pfizer-BioNTech (COMIRNATY) COVID-19 Vaccine. CDC's Advisory Committee on Immunization Practices is meeting on Monday, August 30, 2021, to discuss its updated recommendation for this vaccine.

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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Summary of recent changes (last updated August 25, 2021):

- New section on people vaccinated for COVID-19 as part of a clinical trial in the United States
- Update considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people

Key points

- COVID-19 vaccination is recommended for everyone aged 12 years and older for the prevention of coronavirus disease 2019 (COVID-19) in the United States.
- COVID-19 vaccines currently authorized by the U.S. Food and Drug Administration are effective against SARS-CoV-2 infections, including asymptomatic and symptomatic infection, severe disease, and death.
- Available evidence suggests that these vaccines offer protection against known variants, including the Delta variant, particularly against hospitalization and death. The Delta variant, currently the predominant SARS-CoV-2 variant in the United States, is associated with increased transmissibility.
- Efforts to maximize the proportion of people in the United States who are fully vaccinated against COVID-19 remain critical to ending the COVID-19 pandemic.
- The Advisory Committee on Immunization Practices has issued interim recommendations for the use of:
  - Pfizer-BioNTech COVID-19 vaccine (in persons aged 12–15 years and aged ≥16 years)
  - Moderna COVID-19 vaccine (in persons aged ≥18 years)
  - Janssen (Johnson & Johnson) COVID-19 vaccine (in persons aged ≥18 years)
- These clinical considerations provide additional information to healthcare professionals and public health officials on use of COVID-19 vaccines.

On This Page

CDC Interim Clinical Considerations for Use of COVID-19 Vaccines

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

People vaccinated for COVID-19 as part of a clinical trial in the United States

Some people in the United States have completed a COVID-19 vaccination series as part of a U.S.-based clinical trial involving a COVID-19 vaccine that is not currently authorized by FDA.

People who received the full series of an active COVID-19 vaccine as part of a U.S.-based clinical trial of a COVID-19 vaccine that is not authorized by FDA but is listed for emergency use by WHO

U.S. clinical trial participants who received all recommended doses of a COVID-19 vaccine that is not authorized for use by FDA but is listed for emergency use by WHO do not need any additional doses of an FDA-authorized COVID-19 vaccine. Once it has been confirmed that a participant in a U.S.-based clinical trial received "active" vaccine, and not placebo, the participant can be considered fully vaccinated 2 weeks after they completed the vaccine series in terms of CDC guidance. Currently, the AstraZeneca COVID-19 vaccine meets these criteria.

People who received the full series of an active COVID-19 vaccine candidate as part of a U.S.-based clinical trial of a COVID-19 vaccine that is neither authorized by FDA nor listed for emergency use by WHO

If a participant in a U.S.-based clinical trial has been documented to have received the full series of an "active" (not placebo) COVID-19 vaccine candidate, and vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board), the participant can be considered fully vaccinated 2 weeks after they completed the vaccine series. Currently, the Novavax COVID-19 vaccine meets these criteria. **This does not imply that the vaccine has been authorized by FDA or is recommended by CDC or ACIP.**

Novavax clinical trial participants who did not receive the full 2-dose series of the active COVID-19 vaccine candidate should be counseled by trial investigators to follow current prevention measures to protect themselves against COVID-19 and offered an FDA-authorized COVID-19 vaccine series.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Considerations for use of an additional dose of COVID-19 vaccine following a primary vaccine series

There are two distinct potential uses for an additional dose of COVID-19 vaccine:

- **Additional dose after an initial primary vaccine series:** an additional dose of vaccine administered when the immune response following a primary vaccine series is likely to be insufficient. An additional mRNA COVID-19 vaccine dose is recommended for moderately to severely immunocompromised people after an initial 2-dose primary mRNA vaccine series.
- **Booster dose:** an additional dose of vaccine administered when the initial sufficient immune response to a primary vaccine series is likely to have waned over time. The need for and timing of a COVID-19 booster dose have not been established. No booster doses are recommended at this time. This guidance may be updated as more information becomes available.

Considerations for use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose COVID-19 mRNA vaccine series for immunocompromised people

People with immunocompromising conditions or people who take immunosuppressive medications or therapies are at increased risk for severe COVID-19 illness. The currently FDA-authorized COVID-19 vaccines are not live vaccines and therefore can be safely administered to immunocompromised people.

COVID-19 vaccine immune response and effectiveness in moderately and severely immunocompromised people

Studies have found evidence of reduced immune response to a 2-dose primary mRNA COVID-19 vaccine series in some groups of immunocompromised people. In addition, reduced vaccine effectiveness has been observed in immunocompromised participants compared to participants who are not immunocompromised in a limited number of studies. Immunocompromised people also may have a higher rate of breakthrough SARS-CoV-2 infections than the general population. Small studies have demonstrated that an additional mRNA COVID-19 vaccine dose in some immunocompromised people who received a primary mRNA COVID-19 vaccine series may enhance antibody response, increasing the proportion of people who respond. However, the exact correlation between antibody level and protection against COVID-19 remains unclear. The reactogenicity profile of the additional dose was similar to prior doses.

Although the clinical benefit of an additional dose of an mRNA COVID-19 vaccine in immunocompromised people who received a primary mRNA COVID-19 vaccine series is not precisely known, the potential to increase immune response coupled with an acceptable safety profile, supports use of an additional mRNA COVID-19 vaccine dose after an initial 2-dose primary mRNA COVID-19 vaccine series in this population.

On August 12, 2021 FDA modified the Emergency Use Authorizations (EUAs) for Pfizer-BioNTech COVID-19 vaccine and Moderna COVID-19 vaccine to allow for administration of an additional dose (i.e., a third dose) of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series for certain immunocompromised people (i.e., people who have undergone solid organ transplantation or have been diagnosed with conditions that are considered to have an equivalent level of immunocompromise). The age groups authorized to receive the additional dose are unchanged from those authorized to receive the primary vaccination series:

- Pfizer-BioNTech: aged ≥12 years
- Moderna: aged ≥18 years

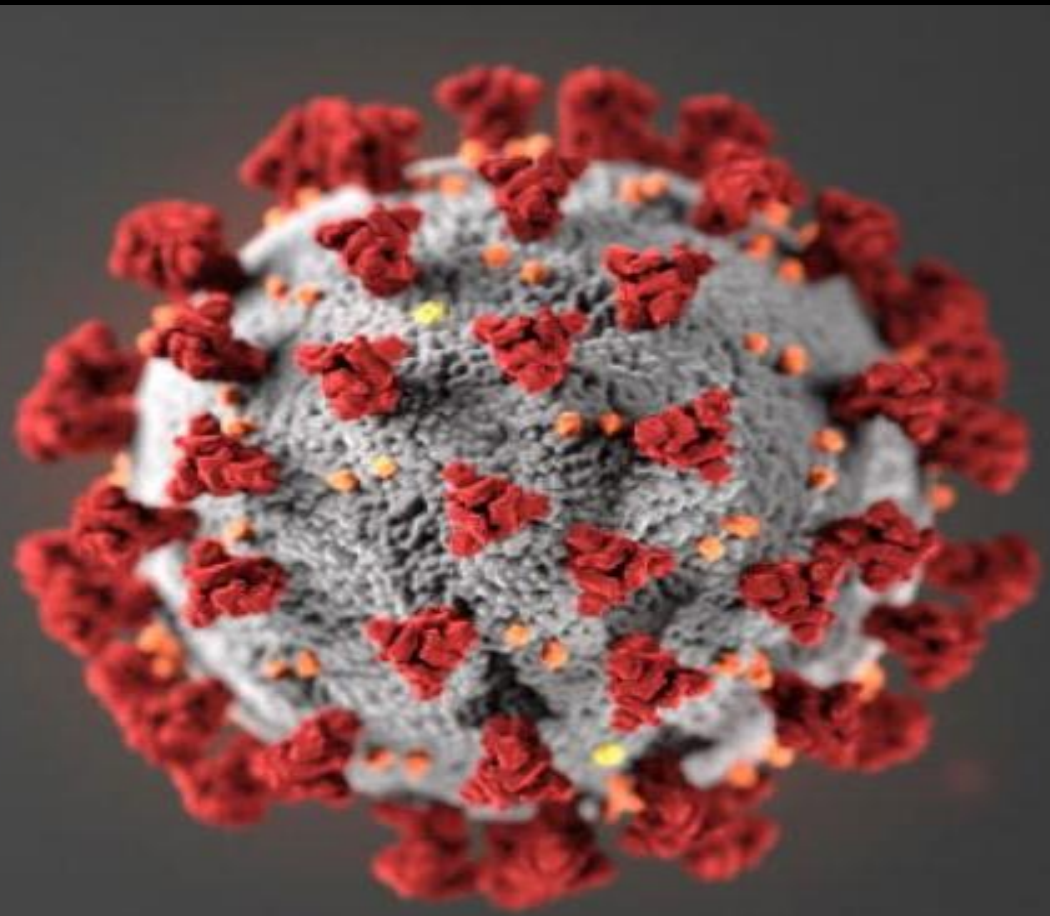
Considerations for use of an additional dose of mRNA COVID-19 vaccine in moderately and severely immunocompromised people

For public health purposes, immunocompromised people who have completed a primary vaccine series (i.e., 2-dose mRNA vaccine series [Pfizer-BioNTech and Moderna] or single dose of the Janssen vaccine) are considered fully vaccinated ≥2 weeks after completion of the series. However, an additional dose of an mRNA COVID-19 vaccine after an initial 2-dose primary mRNA COVID-19 vaccine series should be considered for people with moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments. These conditions and treatments include but are not limited to:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of CAR-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., ≥20mg prednisone or equivalent per day), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

Extended Expiration Date for Pfizer-BioNTech



Initial Notification of Pfizer Expiration Extension

On August 23, 2021:

- FDA approved an amendment to the EUA for Pfizer-BioNTech COVID-19 vaccine extending the expiration dates from **six to nine months** for vaccine that had been stored and maintained at ultra-cold temperatures
- MDHHS sent out a HAN (health alert network) with CDC's guidance which provided updated expiry dates
- MDHHS was receiving several questions pertaining to the beyond use date and vaccine that had an expiration date prior to August 2021
- MDHHS reached out to CDC for clarification

Update to the Pfizer Expiration Extension

- **August 24, 2021:** The Division of Immunization Team received **updated** guidance on a CDC call regarding the expiration extension for Pfizer vaccine
- Based on guidance received, the expiration extension will also apply to doses prior to August 2021
- At this time, please **do not dispose** of any Pfizer COVID-19 vaccine
- CDC will be sending out the clarifying language soon, along with an updated expiry chart which we will be shared as soon as we receive it

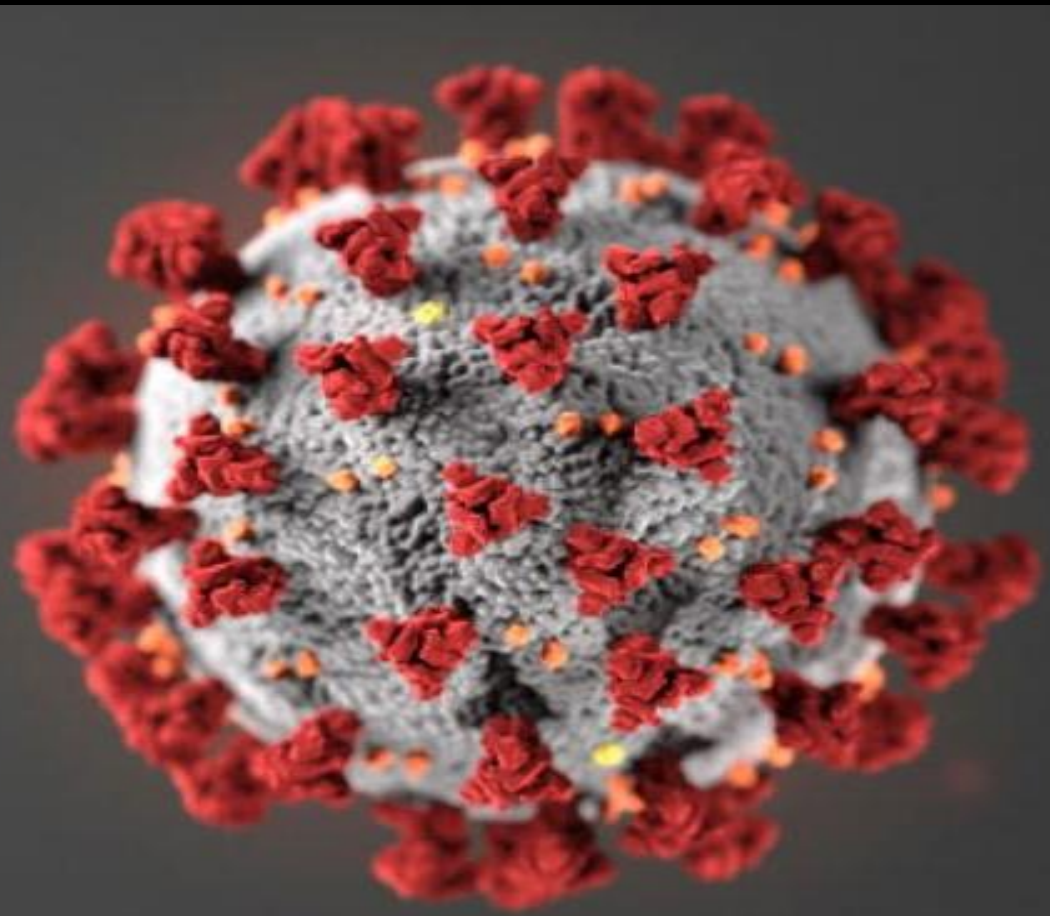
How Does This Affect Beyond Use Date

The Beyond Use Date (BUD) for the Pfizer COVID-19 vaccine will be honored. This means that all Pfizer COVID-19 vaccine stored at ultra-cold temperatures with an August expiration date, even if the vaccine was removed from ultra-cold storage before August 23rd,will be able to maintain the BUD

For Example:

- Vaccine with expiration date 8/31/2021 and stored at ultracold temperatures.
- New expiration date is 11/30/2021 (3-month extension and November only has 30 days)
- Removed from ultracold storage on 8/9/2021 to refrigerated storage. Vaccine may be stored between 2°C and 8°C (36°F and 46°F) for up to 1 month (31 days)
- Applying the 31-day BUD, the vaccine may be used through 9/8 (past the original expiration date but well before the new expiration date)

Fact Check!



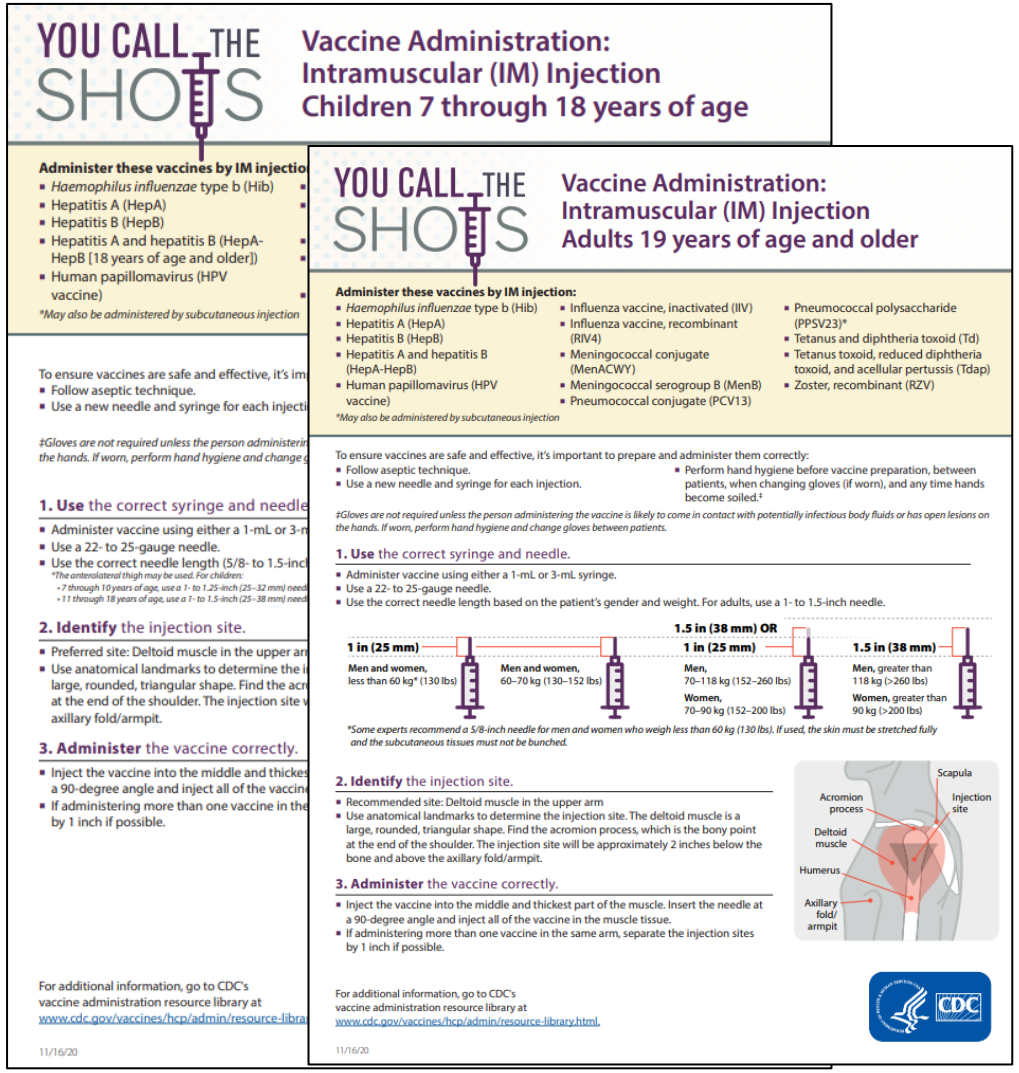
Coadministration

- **COVID-19 vaccines and other vaccines may be administered without regard to timing**
  - Simultaneous administration of COVID-19 vaccines **on the same day**
  - Coadministration **within 14 days**
- Applicable to **ALL** other vaccines
  - Non-live
  - Live, attenuated

Best Practices for Multiple Injections

- Label each syringe
- Separate injection sites by 1 inch or more, if possible
- Administer the COVID-19 vaccines and vaccines that may be more likely to cause a local reaction in different limbs, if possible

https://www.cdc.gov/vaccines/hcp/admin/resource-library.html



YOU CALL THE SHOTS

Vaccine Administration:
Intramuscular (IM) Injection
Children 7 through 18 years of age

Administer these vaccines by IM injectio

- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Hepatitis A and hepatitis B (HepA-HepB [18 years of age and older])
- Human papillomavirus (HPV vaccine)

*May also be administered by subcutaneous injection

To ensure vaccines are safe and effective, it's im

- Follow aseptic technique.
- Use a new needle and syringe for each injecti

‡Gloves are not required unless the person administerin the hands. If worn, perform hand hygiene and change g

1. Use the correct syringe and needle

- Administer vaccine using either a 1-mL or 3-n
- Use a 22- to 25-gauge needle.
- Use the correct needle length (5/8- to 1.5-incl

*The anterolateral thigh may be used. For children:
• 7 through 10 years of age, use a 1- to 1.25-inch (25–32 mm) needl
• 11 through 18 years of age, use a 1- to 1.5-inch (25–38 mm) needl

2. Identify the injection site.

- Preferred site: Deltoid muscle in the upper ar
- Use anatomical landmarks to determine the i large, rounded, triangular shape. Find the acr at the end of the shoulder. The injection site v axillary fold/armpit.

3. Administer the vaccine correctly.

- Inject the vaccine into the middle and thicke a 90-degree angle and inject all of the vaccin
- If administering more than one vaccine in the by 1 inch if possible.

For additional information, go to CDC's vaccine administration resource library at www.cdc.gov/vaccines/hcp/admin/resource-libra

11/16/20

YOU CALL THE SHOTS

Vaccine Administration:
Intramuscular (IM) Injection
Adults 19 years of age and older

Administer these vaccines by IM injection:

- *Haemophilus influenzae* type b (Hib)
- Hepatitis A (HepA)
- Hepatitis B (HepB)
- Hepatitis A and hepatitis B (HepA-HepB)
- Human papillomavirus (HPV vaccine)
- Influenza vaccine, inactivated (IIV)
- Influenza vaccine, recombinant (RIV4)
- Meningococcal conjugate (MenACWY)
- Meningococcal serogroup B (MenB)
- Pneumococcal conjugate (PCV13)
- Pneumococcal polysaccharide (PPSV23)*
- Tetanus and diphtheria toxoid (Td)
- Tetanus toxoid, reduced diphtheria toxoid, and acellular pertussis (Tdap)
- Zoster, recombinant (RZV)

*May also be administered by subcutaneous injection

To ensure vaccines are safe and effective, it's important to prepare and administer them correctly:

- Follow aseptic technique.
- Use a new needle and syringe for each injection.
- Perform hand hygiene before vaccine preparation, between patients, when changing gloves (if worn), and any time hands become soiled.‡

‡Gloves are not required unless the person administering the vaccine is likely to come in contact with potentially infectious body fluids or has open lesions on the hands. If worn, perform hand hygiene and change gloves between patients.

1. Use the correct syringe and needle.

- Administer vaccine using either a 1-mL or 3-mL syringe.
- Use a 22- to 25-gauge needle.
- Use the correct needle length based on the patient's gender and weight. For adults, use a 1- to 1.5-inch needle.

1 in (25 mm)
Men and women, less than 60 kg* (130 lbs)

1 in (25 mm)
Men and women, 60–70 kg (130–152 lbs)

1.5 in (38 mm) OR 1 in (25 mm)
Men, 70–118 kg (152–260 lbs)
Women, 70–90 kg (152–200 lbs)

1.5 in (38 mm)
Men, greater than 118 kg (>260 lbs)
Women, greater than 90 kg (>200 lbs)

*Some experts recommend a 5/8-inch needle for men and women who weigh less than 60 kg (130 lbs). If used, the skin must be stretched fully and the subcutaneous tissues must not be bunched.

2. Identify the injection site.

- Recommended site: Deltoid muscle in the upper arm
- Use anatomical landmarks to determine the injection site. The deltoid muscle is a large, rounded, triangular shape. Find the acromion process, which is the bony point at the end of the shoulder. The injection site will be approximately 2 inches below the bone and above the axillary fold/armpit.

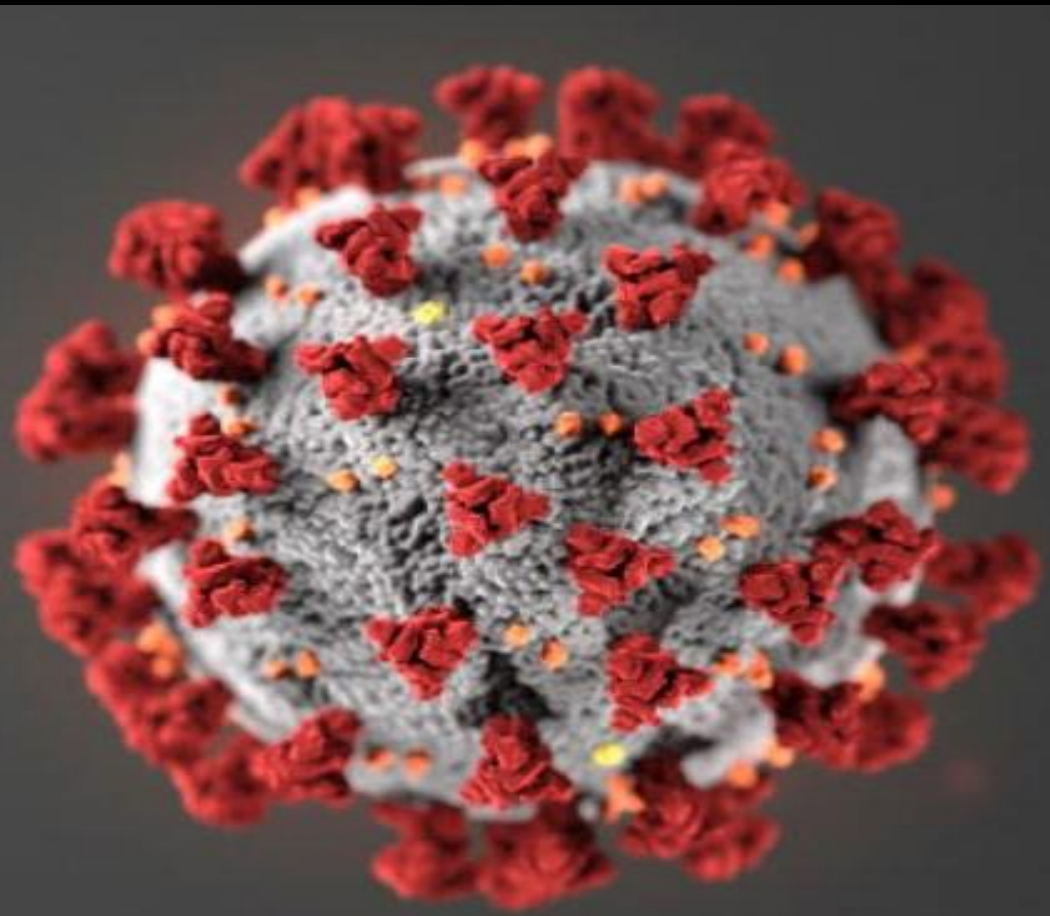
3. Administer the vaccine correctly.

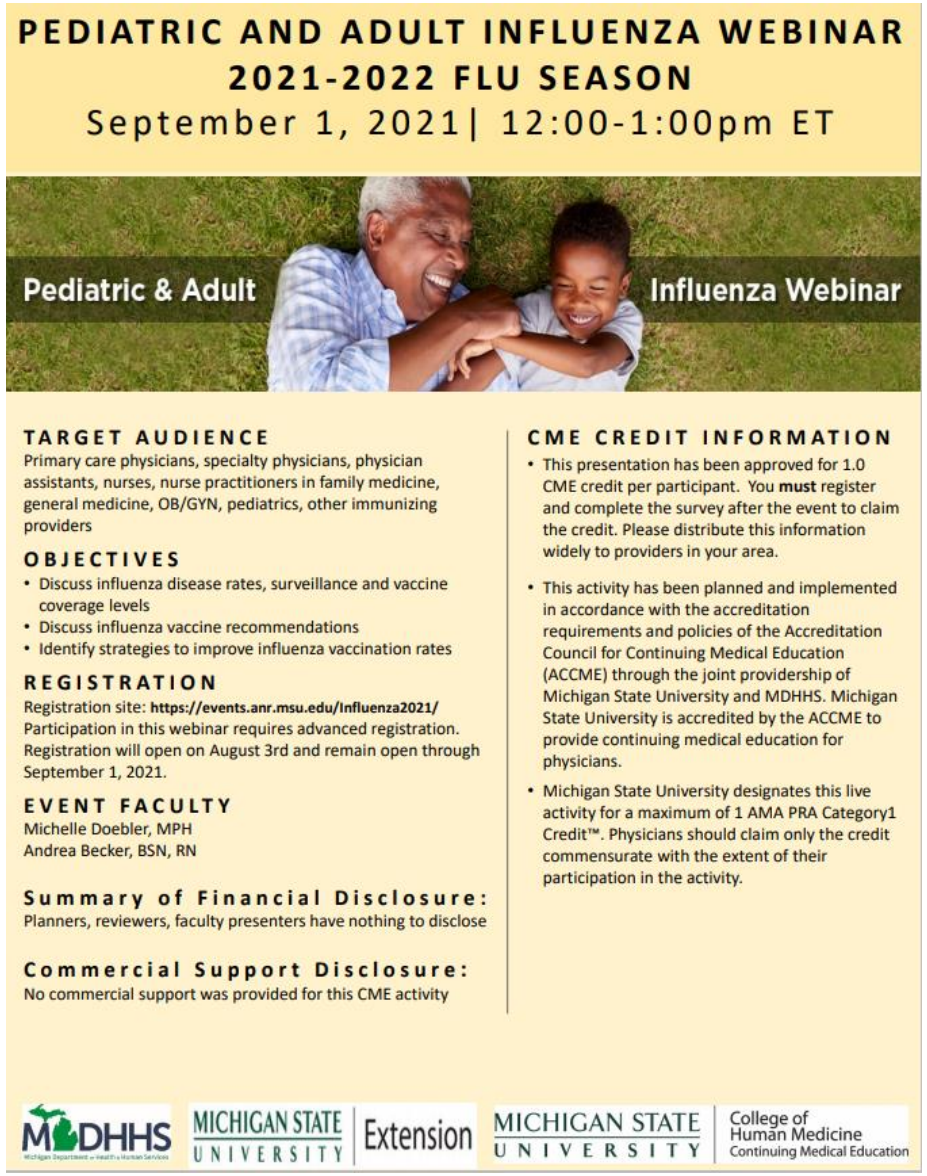
- Inject the vaccine into the middle and thickest part of the muscle. Insert the needle at a 90-degree angle and inject all of the vaccine in the muscle tissue.
- If administering more than one vaccine in the same arm, separate the injection sites by 1 inch if possible.

For additional information, go to CDC's vaccine administration resource library at www.cdc.gov/vaccines/hcp/admin/resource-library.html.

11/16/20

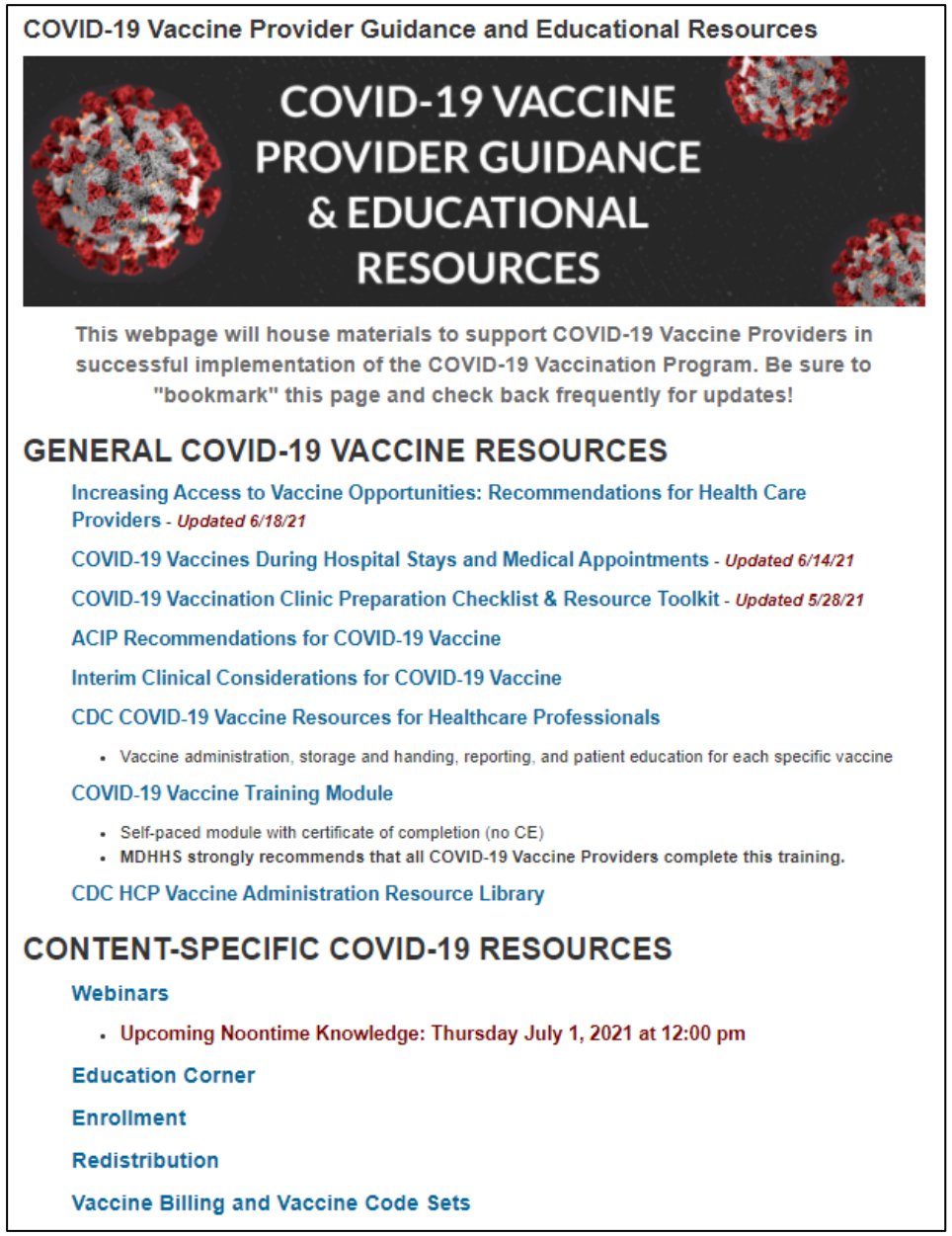
Resources/Upcoming Webinar





10th Annual Pediatric and Adult Influenza Webinar

- September 1, 2021
- 12:00-1:00p.m. ET
- CME/PCE credit available
- The webinar, geared toward physicians, nurses, pharmacists, and other immunizing providers, will communicate important information on the upcoming flu season, including influenza vaccine recommendations, influenza surveillance data, and strategies to increase influenza vaccination rates



MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider

ACIP Meeting Webpage

- Meeting Agendas
- Meeting Minutes
- Live Meetings
- Presentation Slides

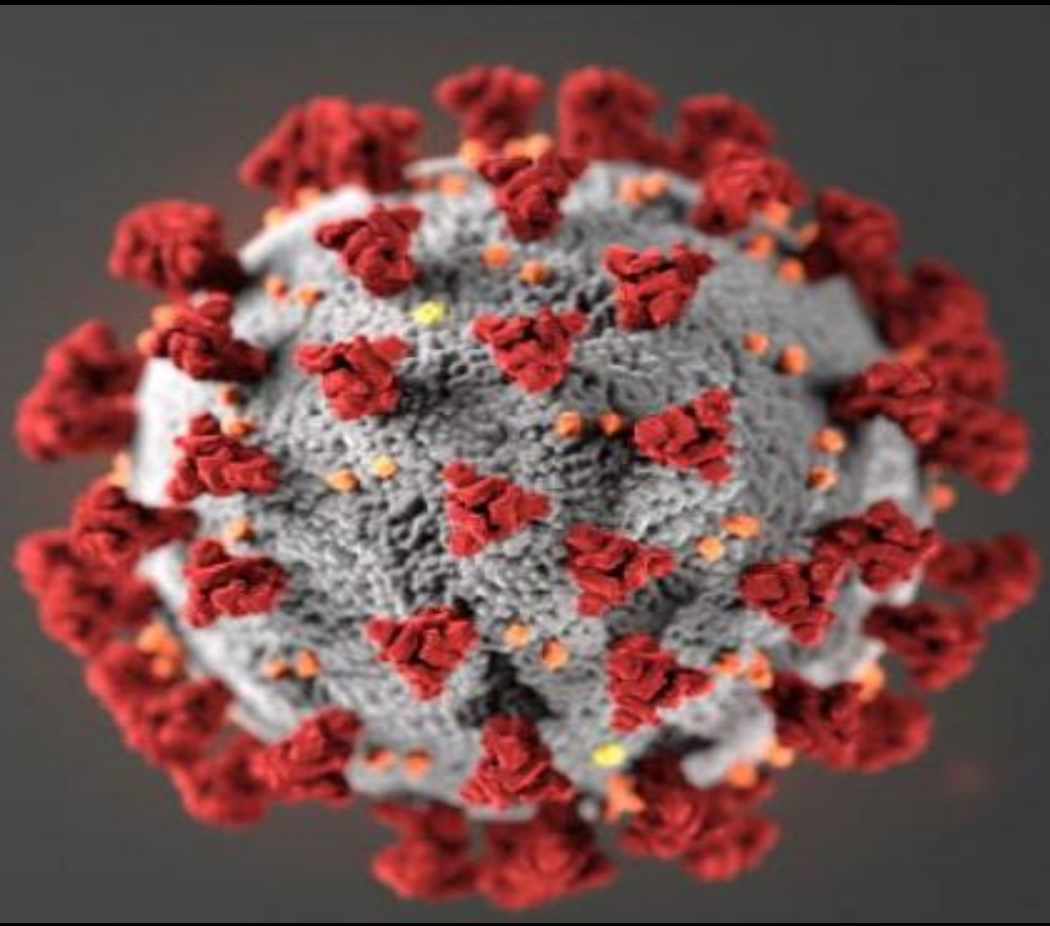
https://www.cdc.gov/vaccines/acip/meetings/index.html

Thank You!

Next “Noontime Knowledge” Update: September 9, 2021

Please watch your email for a date, link, and topic!

Questions Email: checcimms@michigan.gov



www.michigan.gov/COVIDvaccineprovider