MDHHS
Michigan Department of Health & Human Services

CDC Recommendations for Pfizer-BioNTech COVID-19 Booster Vaccination

October 1, 2021

Housekeeping

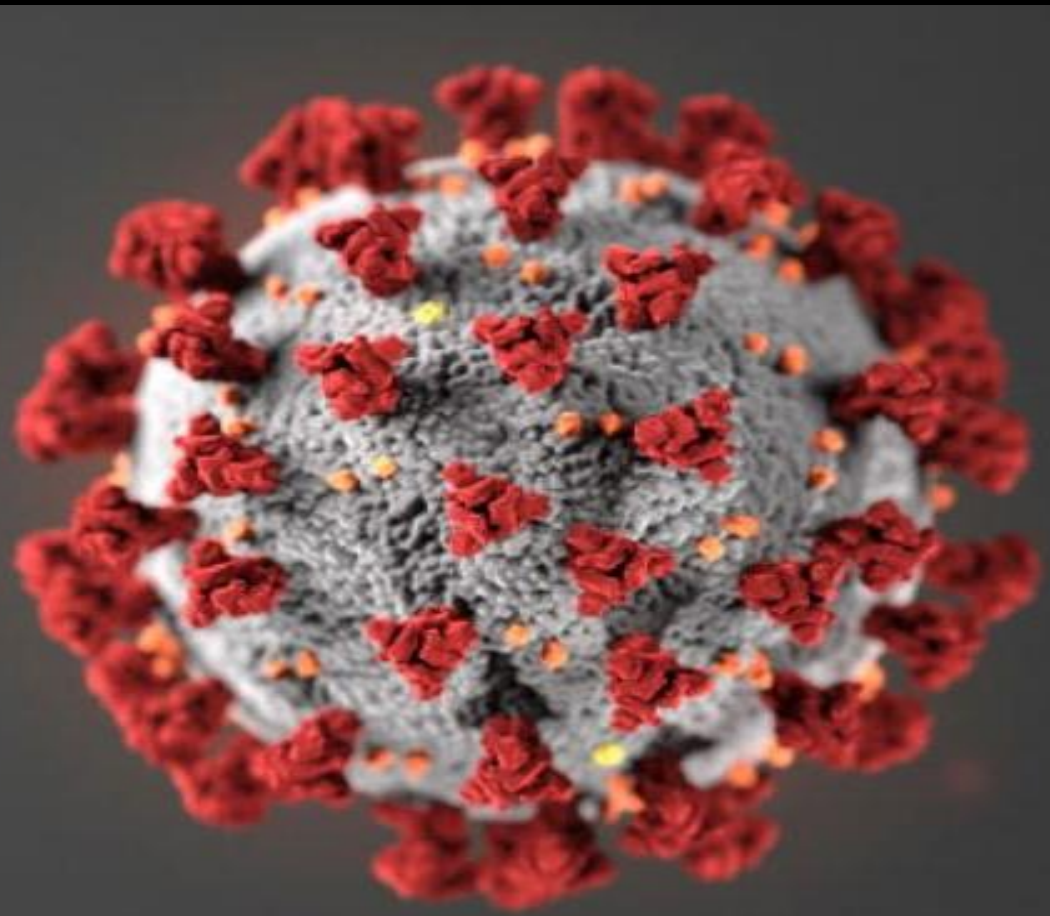
- **How to Ask Questions**
  - Click on the 

 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/COVIDvaccineprovider

Topics Covered

- Pfizer-BioNTech COVID-19 Vaccine EUA Amendment
- Definition of Additional and Booster Dose
- Rationale for Guidance for Booster Dose
- Updated Clinical Considerations
- Administration of Pfizer-BioNTech COVID-19 Booster Dose
- Key Points to Remember & Looking Ahead
- Fact Check
- Resources

Pfizer-BioNTech COVID-19 Vaccine EUA Amendment



Emergency Use Authorization (EUA) Amendment

- **September 22:** FDA Authorized Pfizer-BioNTech COVID-19 vaccine to be used as a single dose booster, to be administered 6 months after completion of the primary series in specific populations
  - This amendment applies only to Pfizer-BioNTech COVID-19 vaccine
- **September 23:** CDC's Advisory Committee on Immunization Practices (ACIP) recommended certain populations receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after the completion of their Pfizer-BioNTech primary vaccine series
  - September 24: CDC released interim booster recommendations

https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations

CONTENT-SPECIFIC COVID-19 RESOURCES

Webinars

- Upcoming Noontime Knowledge: October 1, 2021 at 12:00 p.m. EST

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 9/22/21*
- EUA Fact Sheet for Recipients - *UPDATED 9/22/21*
  - ~~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 Updated 8/23/21
    - Chinese-Traditional
    - Chuukese
    - French
    - German
    - Haitian-Creole
    - Hmong
    - Italian
    - Japanese
    - Marshallese
    - Polish
    - Somali
    - Spanish - Updated 8/23/21

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. Pfizer-BioNTech COVID-19 Vaccine is authorized for use to provide:

- **a two-dose primary series in individuals 12 years of age and older;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by Pfizer for BioNTech that is indicated for active immunization to prevent COVID-19 in individuals 16 years of age and older. It is approved for use as a 2-dose primary series for the prevention of COVID-19 in individuals 16 years of age and older. It is also authorized for emergency use to provide:

- **a two-dose primary series in individuals 12 through 15 years;**
- **a third primary series dose in individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise; and**
- **a single booster dose in individuals:**
  - **65 years of age and older**
  - **18 through 64 years of age at high risk of severe COVID-19**
  - **18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19 including severe COVID-19**

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

as the EUA-authorized vaccine and the products
ination series without presenting any safety or
distinct with certain differences that do not impact

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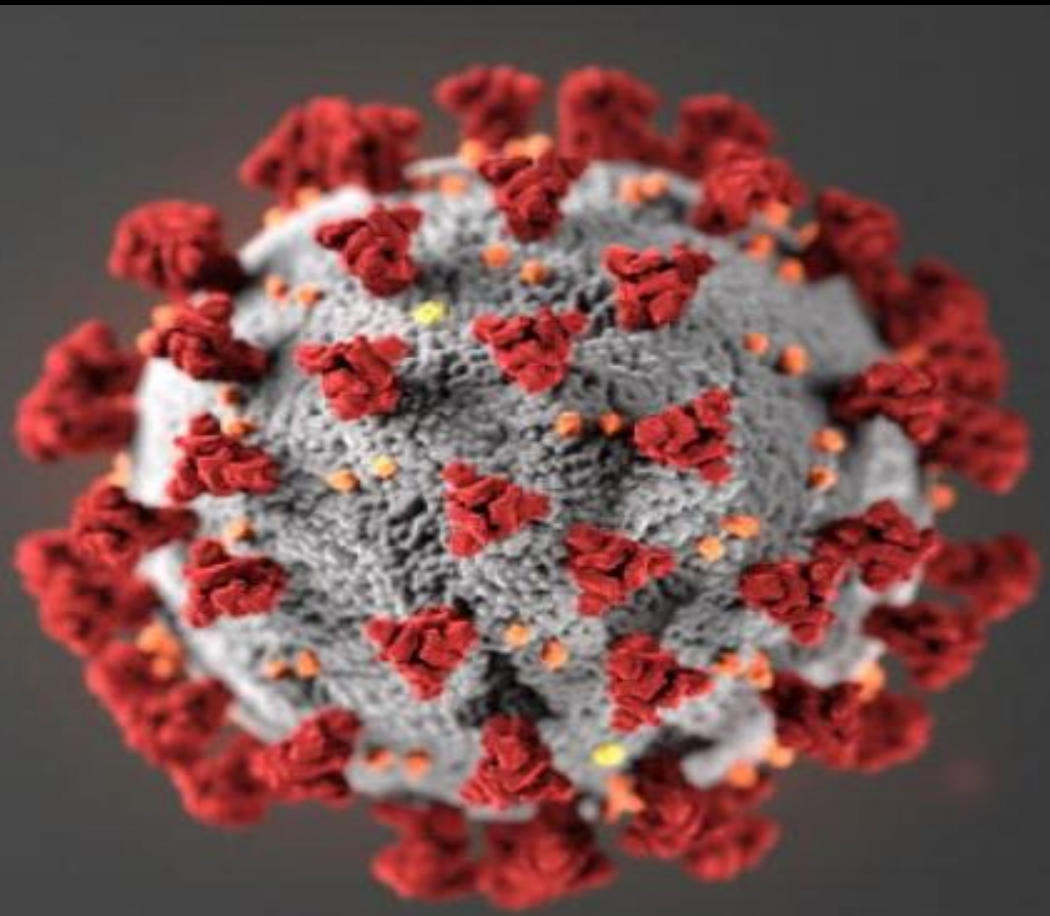
Updated Pfizer-BioNTech EUA Fact Sheet

www.michigan.gov/covidvaccineprovider

Definition of Additional and Booster Dose



Definitions

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

- **Additional dose after a primary vaccine series:** administration of an additional vaccine dose when the initial 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 at least 28 days after an initial 2- dose mRNA primary vaccine series

- **Booster dose:** another dose of vaccine administered when the initial sufficient immune response to a primary vaccine is likely to have waned over time. A single Pfizer-BioNTech vaccine booster dose at least 6 months after completion of a Pfizer BioNTech COVID-19 primary vaccine series is recommended in some populations

What's the difference between a COVID-19 vaccine booster dose and an additional dose?

An **additional dose** is sometimes needed for people who are moderately to severely immuncompromised because they were likely unable to build enough protection after the initial primary vaccine series.

A **booster** is the next dose in a vaccination series to likely boost immunity that has waned over time.

The risk of severe illness from COVID-19 increases with age, and can also increase for adults of any age with underlying medical conditions. Please contact your primary care provider to see if you need an additional or booster dose.

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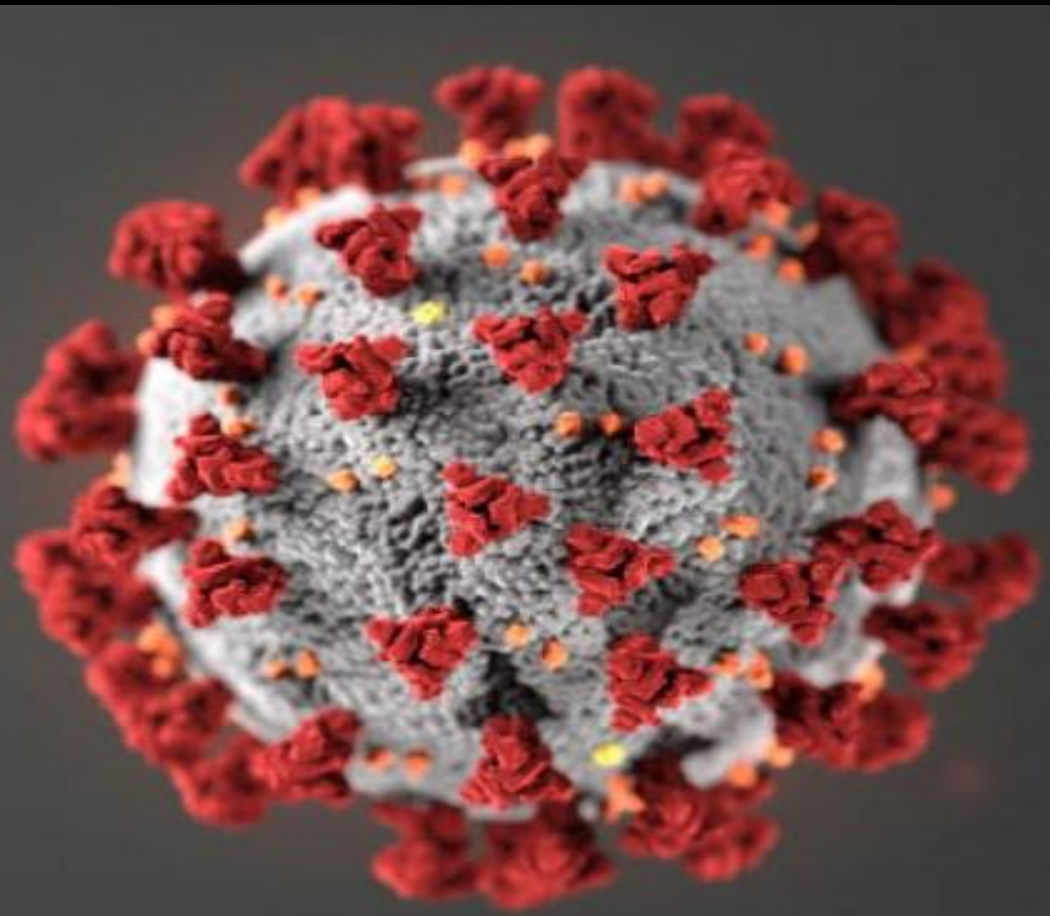
	booster dose	additional dose
For	People aged 65 years and older, residents aged 18 years and older in long-term care settings, and people aged 50–64 years with certain underlying medical conditions **should get a booster dose**. Based on individual benefits and risks, people aged 18–49 years who are at high risk for severe COVID-19 due to certain underlying medical conditions and people aged 18–64 years who are at increased risk for COVID-19 exposure because of occupational* or institutional setting **may get a booster dose**.	People who are moderately to severely immunocompromised **should get an additional dose.**
Minimum time after 2nd dose	**6 months**	**28 days**
Initial vaccine	**Pfizer**	**Pfizer or Moderna**

Plan to get the same type of vaccine for all doses.

*Per CDC, occupations at increased risk for COVID-19 exposure and transmission include frontline essential workers and health care workers.

www.michigan.gov/COVIDvaccine

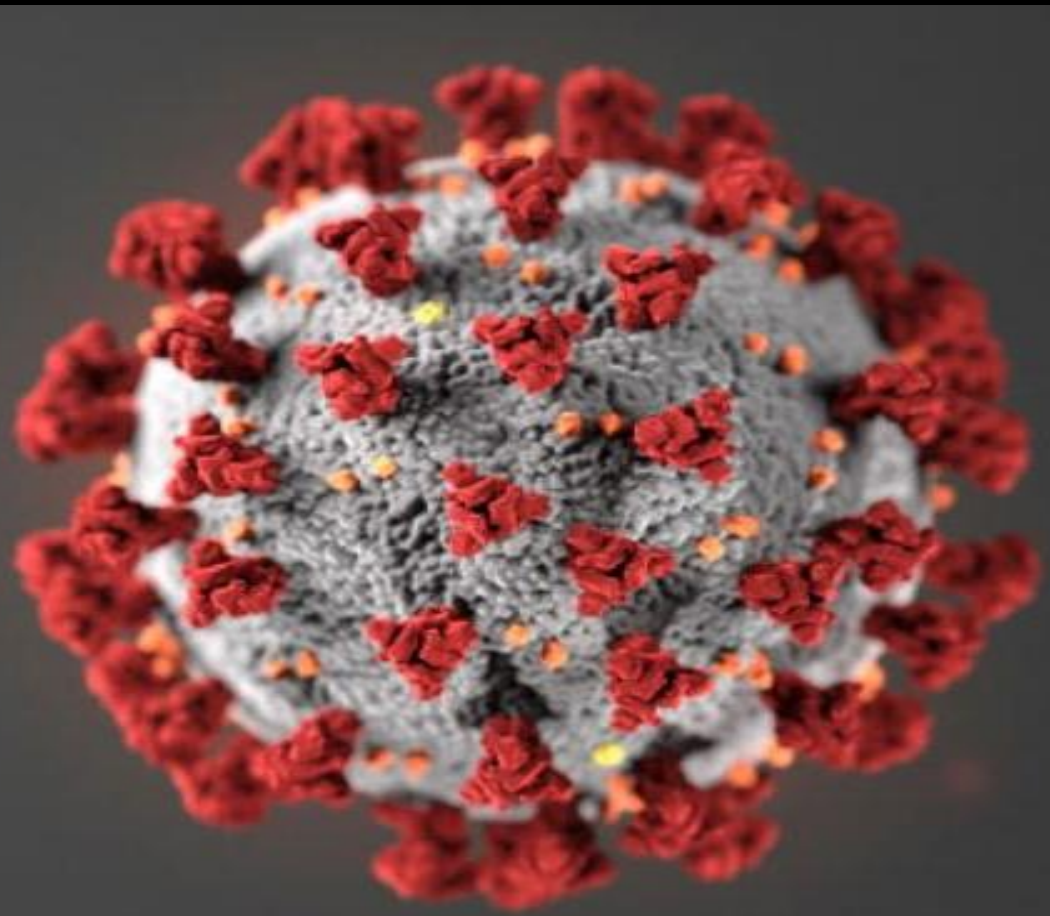
Rationale for Guidance of Pfizer-BioNTech COVID-19 Booster Dose



Rationale for Guidance

- COVID-19 infections with the Delta variant in fully vaccinated persons are associated with less severe clinical outcomes than infections in unvaccinated persons
- Starting around 6 months after primary series vaccination, gradual reduction in COVID-19 vaccine effectiveness is being observed against asymptomatic and mild symptomatic infections with the delta variant of COVID-19
- Waning of COVID-19 vaccine effectiveness against severe disease (hospitalization and death) is being observed in people aged ≥65yrs
- Data continue to emerge as more fully vaccinated people reach a 6-month interval after their primary vaccine series
- Early data suggest use of a Pfizer-BioNTech COVID-19 booster vaccine dose in people who received a primary Pfizer-BioNTech COVID-19 vaccine series may enhance immune response

Updated CDC Interim Clinical Considerations



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

CDC now recommends that people aged 65 years and older, residents in long-term care settings, and people aged 50–64 years with underlying medical conditions **should** receive a booster shot of Pfizer-BioNTech's COVID-19 Vaccine at least 6 months after completing their Pfizer-BioNTech primary series. Other groups **may** receive a booster shot based on their individual risk and benefit. Learn more.

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
- Presentation: Clinical Care Consideration Slides for Healthcare Providers

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

- New section on Considerations for use of a Pfizer-BioNTech COVID-19 vaccine booster dose after completion of a Pfizer-BioNTech primary vaccine series

Key points

- COVID-19 vaccination is recommended for everyone aged 12 years and older in the United States for the prevention of coronavirus disease 2019 (COVID-19).
- COVID-19 vaccines currently approved or authorized by FDA are highly effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death.
- Available evidence suggests vaccines offer protection against known variants, including the Delta variant (B.1.617.2), 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.

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

Considerations for use of a Pfizer-BioNTech COVID-19 vaccine booster dose after completion of a Pfizer-BioNTech primary vaccine series

COVID-19 vaccine effectiveness after a primary vaccine series

Available data indicate declines in the effectiveness of mRNA COVID-19 vaccine products against SARS-CoV-2 infection and severe COVID-19 outcomes (hospitalization and death) in people aged ≥65 years. These observed changes likely reflect waning immunity over time from primary vaccination and reduced vaccine performance against the Delta variant. Declining vaccine effectiveness against infection has also been observed for residents of long-term care facilities; data on vaccine effectiveness against hospitalization and death are limited, given frequent exclusion of this population from studies.

Among adults <65 years of age, COVID-19 vaccines remain effective in preventing hospitalization and severe disease but may be less effective in preventing infection or milder symptomatic illness over time.

Beyond studies of COVID-19 vaccine effectiveness for people with immunocompromising conditions, current data are limited to assess COVID-19 vaccine effectiveness by underlying medical condition over time; available estimates of vaccine effectiveness may not be representative across all underlying medical conditions. Further, these conditions can vary in severity, which may also impact vaccine effectiveness over time.

Recommendations for use of a single Pfizer-BioNTech vaccine booster dose after completion of a Pfizer-BioNTech COVID-19 primary vaccine series

CDC recommends that the following groups **should** receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completing their Pfizer-BioNTech primary vaccine series:

- People aged 65 years and older
- Residents aged 18 years and older in long-term care settings
- People aged 50–64 years with underlying medical conditions

Studies show that SARS-CoV-2 infections with the Delta variant in fully vaccinated persons are associated with less severe clinical outcomes than infections in unvaccinated persons, but at this time, there is uncertainty about how waning immunity amidst circulation of the Delta variant may impact fully vaccinated persons over time. There are certain underlying medical conditions that are known to be associated with increased risk for severe illness from COVID-19 in unvaccinated persons.

CDC recommends that a booster dose of Pfizer-BioNTech's COVID-19 vaccine should be made available so that the following groups may receive a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completing their Pfizer

Individual risk benefit assessment considerations

Given the rapidly changing clinical, public health, and scientific landscape amidst the COVID-19 pandemic, an individual level assessment considering potential benefits and risks of a COVID-19 booster dose is needed where the data are uncertain.

Potential benefits of a booster dose may include a reduced risk of SARS-CoV-2 infection and reduced risk of severe disease. The strongest evidence for reductions in the risk of **severe disease** has been observed in older adults (aged ≥65 years), while the effectiveness of a mRNA COVID-19 primary vaccine series against severe disease remains high for younger age groups. In contrast, waning of vaccine protection against **infection** has been observed in most age groups, including for healthcare workers and other frontline essential workers. Healthcare and other workers were prioritized for earlier doses of COVID-19 vaccines and the interval since receipt of primary series may be longer compared to other groups. Minimizing risk of SARS-CoV-2 infection could reduce transmission of the virus to other at-risk-persons, although data evaluating the immediate and sustained impact of a booster dose on SARS-CoV-2 transmission are not yet available. Regarding underlying conditions, in unvaccinated persons, the risk of severe COVID-19 increases as the number of underlying medical conditions increases in an individual, and this should be considered for persons who have received a primary vaccine series as well. Of note, while a primary vaccination series decreases the risk of future infections in people with prior SARS-CoV-2 infection, the efficacy of a booster dose for fully vaccinated people who have already had COVID-19 is not yet known.

Potential risks of an mRNA COVID-19 booster dose include the rare risks of myocarditis and pericarditis, particularly in males aged <30 years, and the even rarer risk of anaphylaxis (the rate of anaphylaxis after a booster dose is not yet known). Transient local and systemic symptoms are common following receipt of mRNA vaccines.

A person's risk of developing severe COVID-19, if infected, may vary by the type, number, and level of control of specific medical conditions, as well as other yet to be defined variables. Exposure would be expected to vary by the level of community transmission and adherence to current prevention measures. Data are currently limited to adequately assess vaccine effectiveness after completion of a primary vaccine series for specific medical conditions. A person's individual circumstances, such as living with or caring for a medically frail or immunocompromised person or the inability to work or meet other personal obligations, if infected even with mild illness, also merits consideration.

Occupational and institutional settings

In addition to the potential benefits and risks of a COVID-19 booster dose, there are additional considerations related to the potential for work or institutional SARS-CoV-2 exposure and transmission. People likely at highest risk for work-related exposure include those whose work-related duties must be performed in indoor spaces outside their homes, involve close proximity (<6 feet) to other people, and involve unavoidable frequent interactions with unvaccinated people, such as healthcare workers and teachers. Congregate living settings, such as correctional and detention facilities, may also be associated with an increased risk of SARS-CoV-2 exposure for both staff and residents depending on the ability to follow current prevention measures. The levels of community SARS-CoV-2 transmission, COVID-19 vaccination, and adherence to other prevention measures in workers and others in occupational and institutional settings would be expected to influence the risk for exposure and the potential for SARS-CoV-2 infection. Examples of workers at increased risk for COVID-19 exposure include those prioritized during initial roll out of the COVID-19 vaccine in early 2021. These individuals should evaluate their individual risk and benefit to decide on their need for a booster dose after a Pfizer-BioNTech primary series.

Administration of the Pfizer-BioNTech vaccine booster dose

The volume for the booster dose is the same as that for the primary vaccine series, i.e., 0.3 mL, administered via the intramuscular route.

The booster dose of COVID-19 vaccine should be given no earlier than 6 months after completion of the 2-dose primary vaccine series. Since immunity wanes gradually over time, the booster may be given at an interval greater than 6 months after completion of the primary vaccine series.

General considerations for use of the Pfizer-BioNTech vaccine booster dose

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#pfizer-booster

Pfizer-BioNTech Booster Recommendation

CDC recommends that the following groups **should receive** a booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completing their Pfizer-BioNTech primary vaccine series:

- People aged 65 years and older
- Residents aged 18 years and older in long-term care settings
- People aged 50–64 years with underlying medical conditions

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

Pfizer-BioNTech Booster Recommendation Cont.

CDC recommends that the following groups, based on their **individual benefits and risks**, **may receive** a single booster dose of Pfizer-BioNTech's COVID-19 vaccine at least 6 months after completing their Pfizer-BioNTech 2-dose primary vaccine series.

- People aged 18–49 years with underlying medical conditions
- People aged 18–64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting

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

Underlying Medical Conditions

- In unvaccinated persons, there are certain underlying medical conditions that are associated with severe illness from COVID-19
- Improved management of a person's underlying medical condition may decrease risk of severe illness from COVID-19
- Among fully vaccinated persons, having underlying medical conditions may be associated with increased risk of severe illness from COVID-19 over time as antibody titers wane
- Examples:

• Cancer • Chronic kidney disease • COPD (chronic obstructive pulmonary disease) • Diabetes mellitus, type 1 and type 2	• Heart conditions (such as heart failure, coronary artery disease, or cardiomyopathies) • Obesity (BMI ≥30 kg/m2) • Pregnancy and recent pregnancy

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Individual Risk and Benefit Considerations

- **Potential Risks**
  - Very rare risks of myocarditis and pericarditis
  - Likely even rarer risk of anaphylaxis
  - Reactogenicity, including transient local and systemic symptoms
    - The third dose of Pfizer-BioNTech COVID-19 vaccine appears to have similar reactogenicity as the second dose
- **Potential Benefits**
  - Reduced risk of COVID-19 infection and reduced risk of severe disease
  - Strongest evidence for reductions in the risk of severe disease has been observed in older adults (aged ≥65 years); effectiveness of an mRNA COVID-19 primary vaccine series against severe disease remains high for younger age groups
  - Reduced risk of COVID-19 infection could reduce transmission of virus to other at-risk persons, but the immediate and sustained impact of a booster dose on COVID-19 transmission is not yet known

Occupational and Institutional Settings

- People likely at highest risk for work-related exposure include those whose work-related duties must be performed in indoor spaces outside their homes, involve close proximity (<6 feet) to other people, and involve unavoidable frequent interactions with unvaccinated people, such as healthcare workers and teachers
- Congregate living settings, such as correctional and detention facilities, may also be associated with an increased risk of COVID-19 exposure for both staff and residents depending on the ability to follow current prevention measures
- The levels of community COVID-19 transmission, COVID-19 vaccination, and adherence to other prevention measures in workers and others in occupational and institutional settings would be expected to influence the risk for exposure and the potential for COVID-19 infection.

https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#pfizer-booster

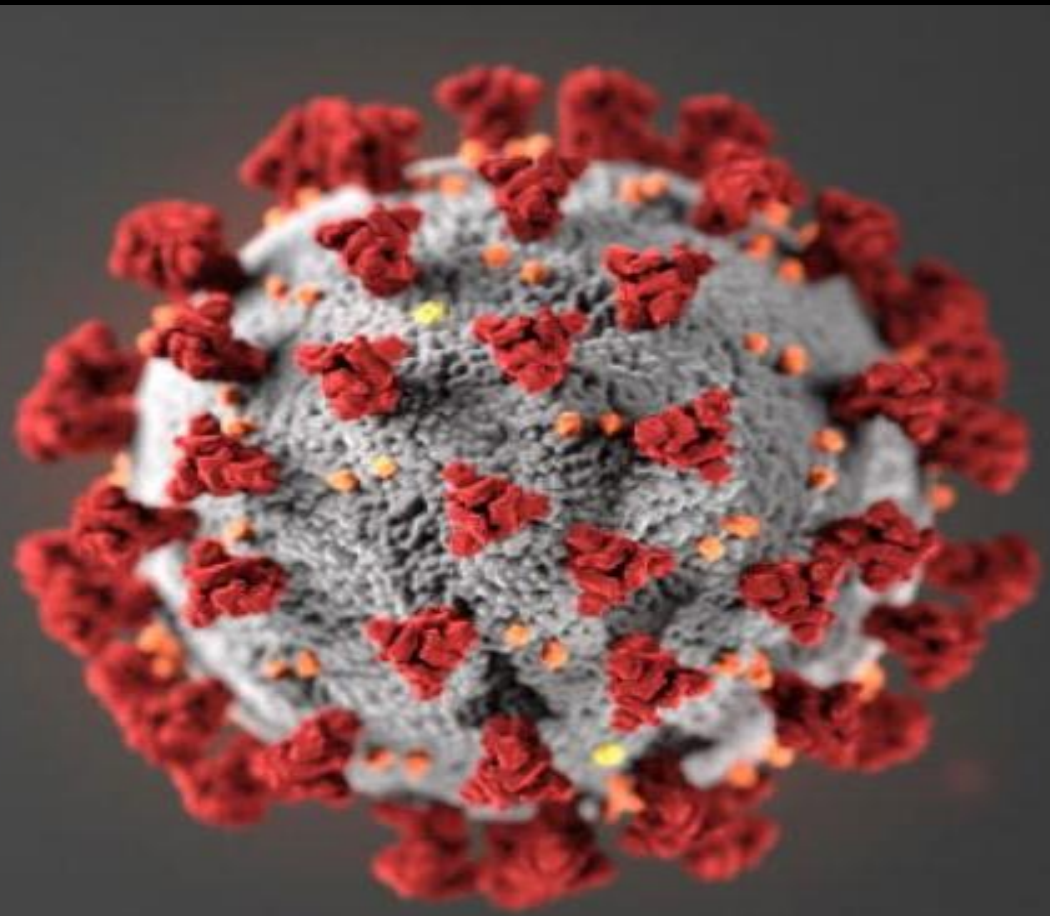
Occupations at Increased Risk

- Examples of workers at increased risk for COVID-19 exposure include those prioritized during initial roll out of the COVID-19 vaccine in early 2021. These individuals should evaluate their individual risk and benefit to decide on their need for a booster dose after a Pfizer-BioNTech primary series
  - First responders (healthcare workers, firefighters, police, congregate care staff)
  - Education staff (teachers, support staff, daycare workers)
  - Food and agriculture workers
  - Manufacturing workers
  - Corrections workers
  - U.S. Postal Service workers
  - Public transit workers
  - Grocery store workers

*List could be updated in the future

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#HighRisk.html

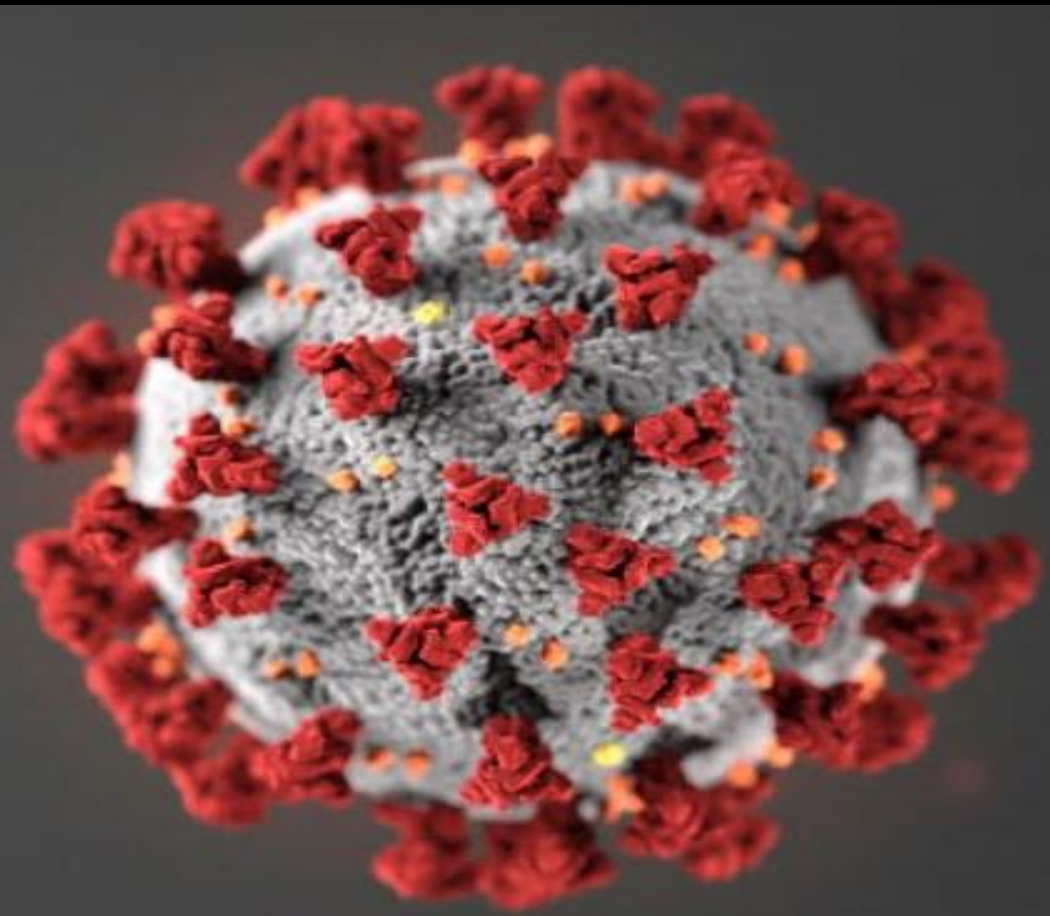
Administration of Pfizer-BioNTech COVID-19 Booster Dose



Administration-Pfizer Booster Dose

- Pfizer-BioNTech COVID-19 vaccine, 0.3ml, intramuscular administration (same dose used in primary series)
- Timing: at least 6 months after completion of the primary series of Pfizer BioNTech
  - Immunity wanes gradually over time, therefore a booster may be given at an interval greater than 6 months
- Currently insufficient data to support the use of the Pfizer-BioNTech COVID-19 vaccine as a booster dose in people who received Moderna or Janssen COVID-19 vaccines as a primary vaccination series
- **Co-administration: a Pfizer-BioNTech COVID-Vaccine booster dose may be given with other vaccines (e.g., influenza), without regard to timing, including administration of COVID-19 and other vaccines on the same day**

Key Points to Remember & Looking Ahead



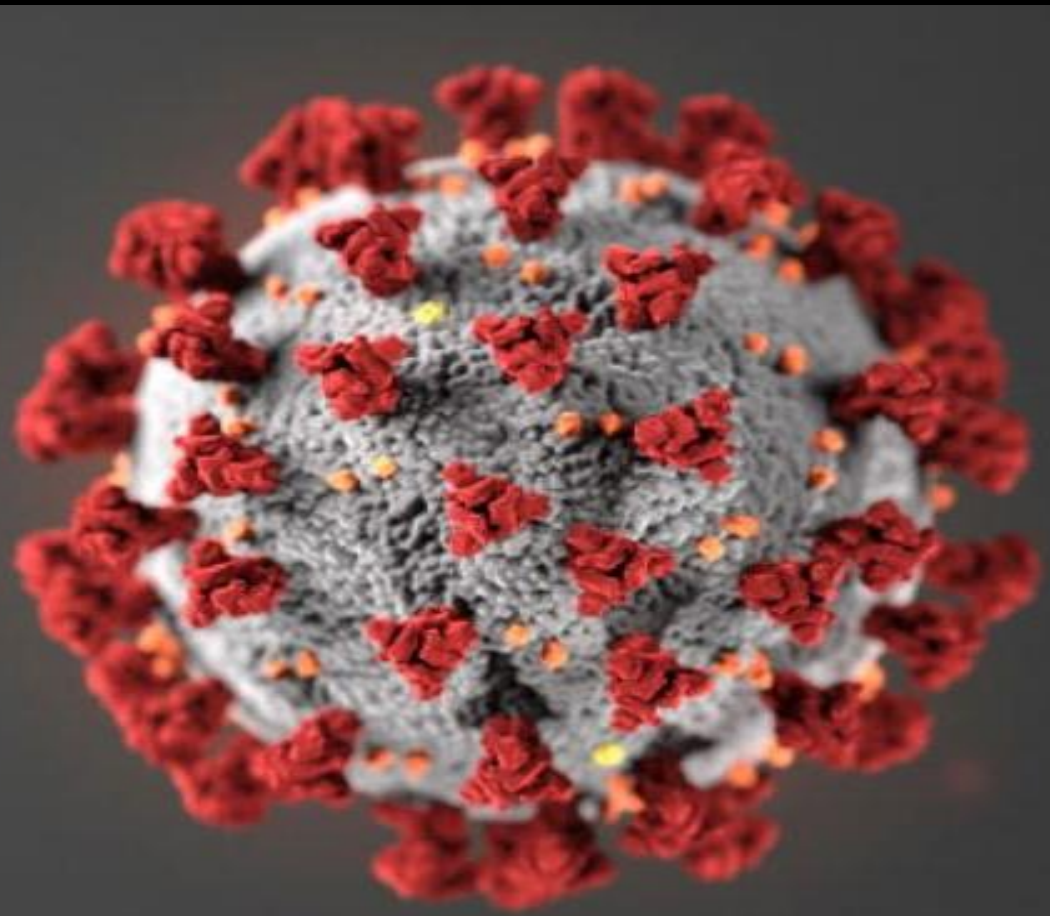
Key Points to Remember

- Getting people vaccinated with a COVID-19 primary vaccine series remains the **highest priority** and is fundamental to reducing COVID-related morbidity and mortality
- All COVID-19 vaccines currently approved or authorized in the United States remain effective against severe disease, hospitalization, and death
- Persons of all ages who have received a primary vaccine series are much less likely than unvaccinated persons to become infected with COVID-19 and to require hospitalization or die because of COVID-19
- CDC's COVID-19 vaccine recommendations will be updated, as needed, to reflect changes in U.S. COVID-19 disease trends, new information on COVID-19 vaccine effectiveness and safety, and updated benefit-risk analyses

Looking Ahead

- Currently there are insufficient data to support the use of the Pfizer-BioNTech COVID-19 vaccine as a booster dose in people who received the Moderna or Janssen COVID-19 vaccines as a primary vaccination series
- There is uncertainty around the risk of transmission following a vaccine booster dose
- To help mitigate the spread of disease, it is recommended that people follow healthy hygiene practices, physical distancing, and use of a face mask regardless of vaccination status
- MDHHS recently revised their face mask guidance: www.Michigan.gov/coronavirus

Fact Check!



Am I still considered “fully vaccinated” if I don’t get a booster shot?

Everyone is still considered fully vaccinated two weeks after their second dose in a 2-dose series, such as the Pfizer-BioNTech or Moderna vaccines, or two weeks after a single-dose vaccine, such as the J&J/Janssen vaccine.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#FAQs

Is a moderately to severely immunocompromised patient who received a 3rd (additional) dose 28 days after their primary series, also recommended to receive a booster dose 6 months later?

Currently, if you get a 3rd (additional) dose of the vaccine because you're moderately to severely immunocompromised, you do not need to get a booster dose (dose 4) 6 months later. That said, the guidance around the COVID-19 vaccine is constantly changing as more data emerges about its efficacy in various scenarios.

A fourth vaccine dose may be needed in immunocompromised patients, but more data is needed to make that determination.

Currently there is NO Emergency Use Authorization (EUA) or recommendation to give a 4th COVID-19 vaccine dose to anyone

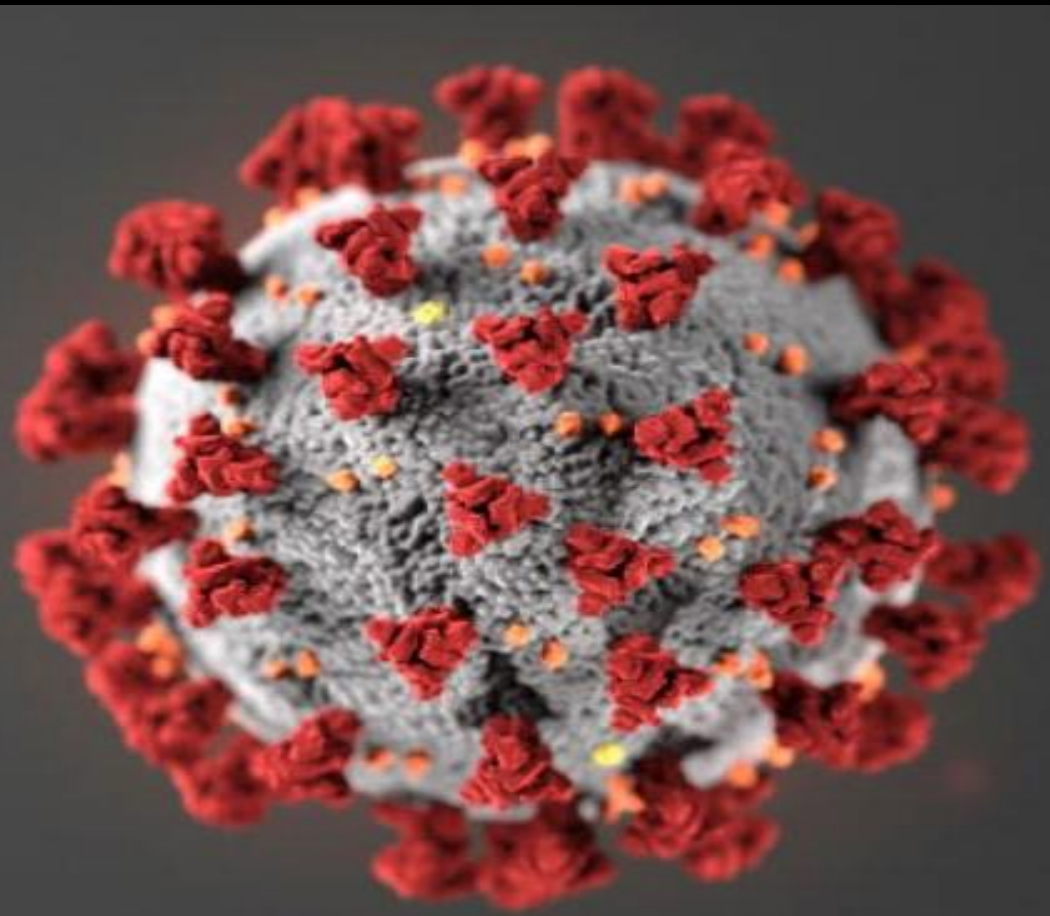
At this time, the recommendation is only for those who have received a full 2-dose primary series of Pfizer-BioNTech COVID-19 vaccine. Currently, this is the only vaccine in which the EUA amendment applies.

What if someone received a mixed series for their primary series (1 dose Pfizer, 1 dose Moderna), can they receive a booster dose.

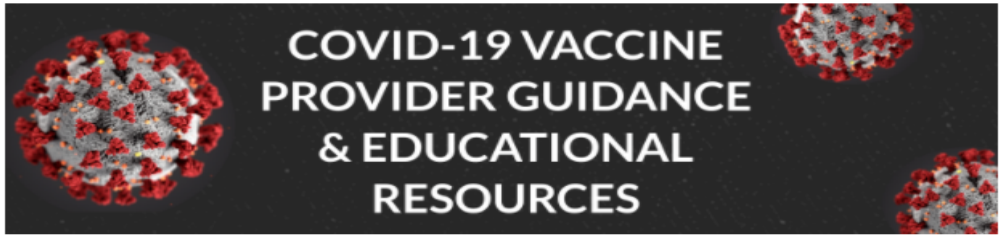
Do I need to wait for Comirnaty vaccine because my patient does not want an EUA approved Pfizer-BioNTech COVID-19 vaccine?

No. The FDA-approved Pfizer-BioNTech product Comirnaty (COVID-19 Vaccine, mRNA) and the FDA-authorized Pfizer-BioNTech COVID-19 Vaccine under EUA have the exact same formulation and can be used interchangeably to provide the COVID-19 vaccination series without presenting any safety or effectiveness concerns. Therefore, providers can use doses distributed under EUA to administer the vaccination series as if the doses were the licensed vaccine.

Resources



COVID-19 Vaccine Provider Guidance and 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

Clinical Guidance for Michigan Providers Regarding Additional Dose of an mRNA COVID-19 Vaccine

Increasing Access to Vaccine Opportunities: Recommendations for Health Care Providers - *Updated 6/18/21*

COVID-19 Vaccines During Hospital Stays and Medical Appointments - *Updated 6/14/21*

COVID-19 Vaccination Clinic Preparation Checklist & Resource Toolkit - *Updated 5/28/21*

ACIP Recommendations for COVID-19 Vaccine

Interim Clinical Considerations for COVID-19 Vaccine

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: October 1, 2021 at 12:00 p.m. EST**

Education Corner

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Vaccine Billing and Vaccine Code Sets

Product-Specific Information & EUAs

MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider

Who Is Eligible for a COVID-19 Vaccine Booster Shot?

Updated Sept. 30, 2021 Languages Print

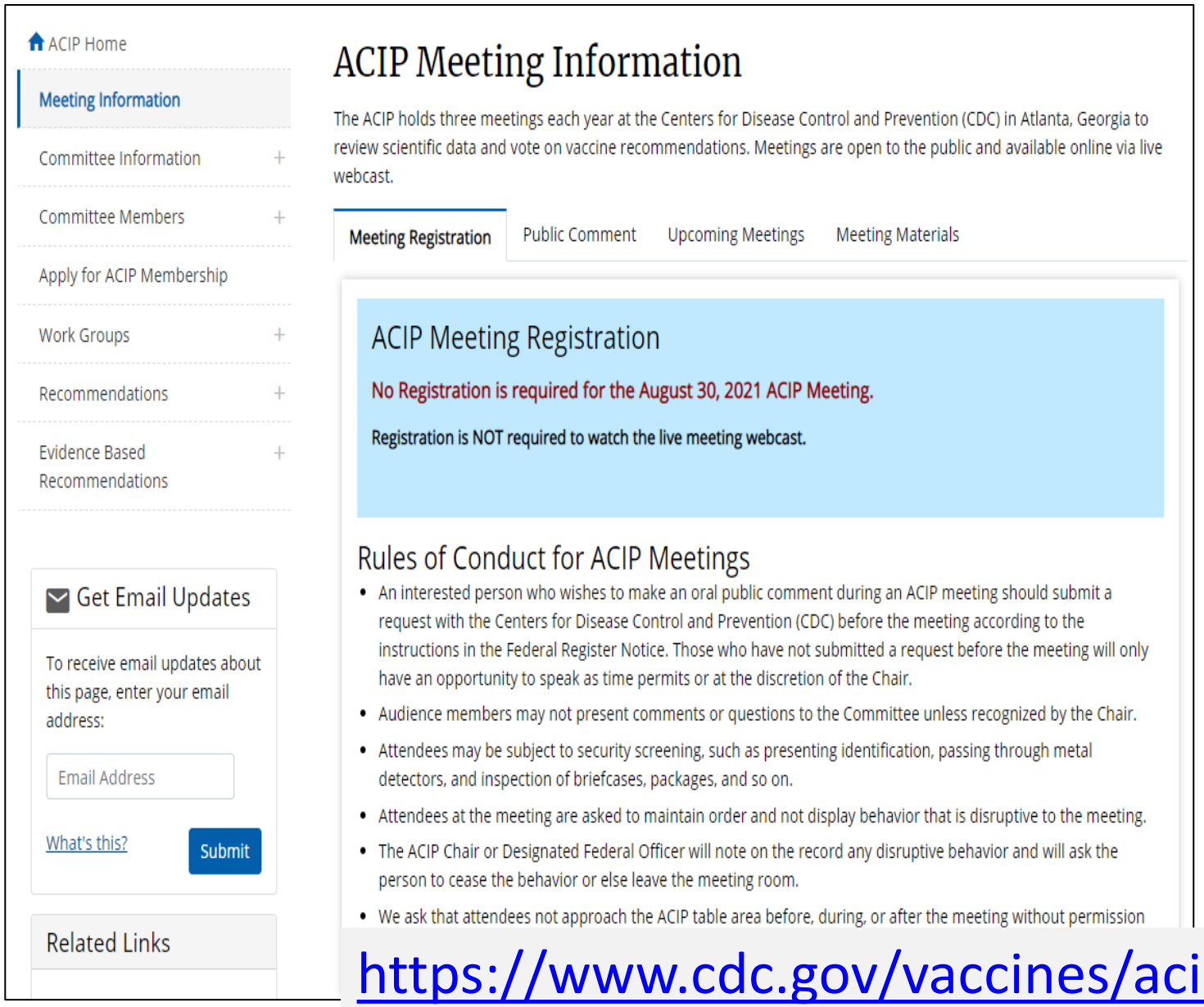
What You Need to Know

COVID-19 Vaccine booster shots are available for the following Pfizer-BioNTech vaccine recipients who completed their initial series at least 6 months ago and are:

- 65 years and older
- Age 18+ who live in long-term care settings
- Age 18+ who have underlying medical conditions
- Age 18+ who work in high-risk settings
- Age 18+ who live in high-risk settings

On this Page

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html

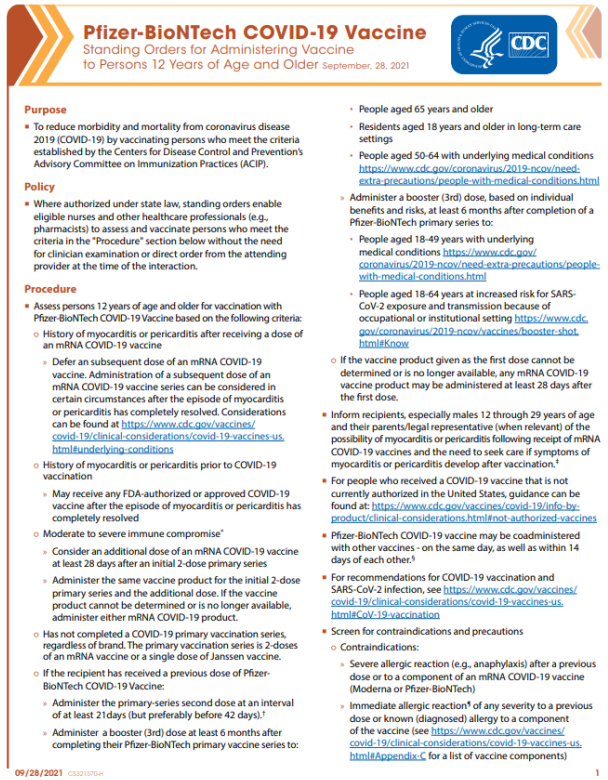


ACIP Meeting Webpage

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

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

Pfizer-BioNTech Standing Order



Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine
to Persons 12 Years of Age and Older September, 28, 2021

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 a dose of an mRNA COVID-19 vaccine
    - Defer an subsequent dose of an mRNA COVID-19 vaccine. Administration of a subsequent 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 or approved 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 primary vaccination series, regardless of brand. The primary vaccination series is 2-doses of an mRNA vaccine or a single dose of Janssen vaccine.
  - If the recipient has received a previous dose of Pfizer-BioNTech COVID-19 Vaccine:
    - Administer the primary-series second dose at an interval of at least 21days (but preferably before 42 days).†
    - Administer a booster (3rd) dose at least 6 months after completing their Pfizer-BioNTech primary vaccine series to:
      - People aged 65 years and older
      - Residents aged 18 years and older in long-term care settings
      - People aged 50-64 with underlying medical conditions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
    - Administer a booster (3rd) dose, based on individual benefits and risks, at least 6 months after completion of a Pfizer-BioNTech primary series to:
      - People aged 18-49 years with underlying medical conditions https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html
      - People aged 18-64 years at increased risk for SARS-CoV-2 exposure and transmission because of occupational or institutional setting https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html#Know
  - If the vaccine product given as the first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine product may be administered at least 28 days after the first dose.
- 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.‡
- 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.§
- 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¶ 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)

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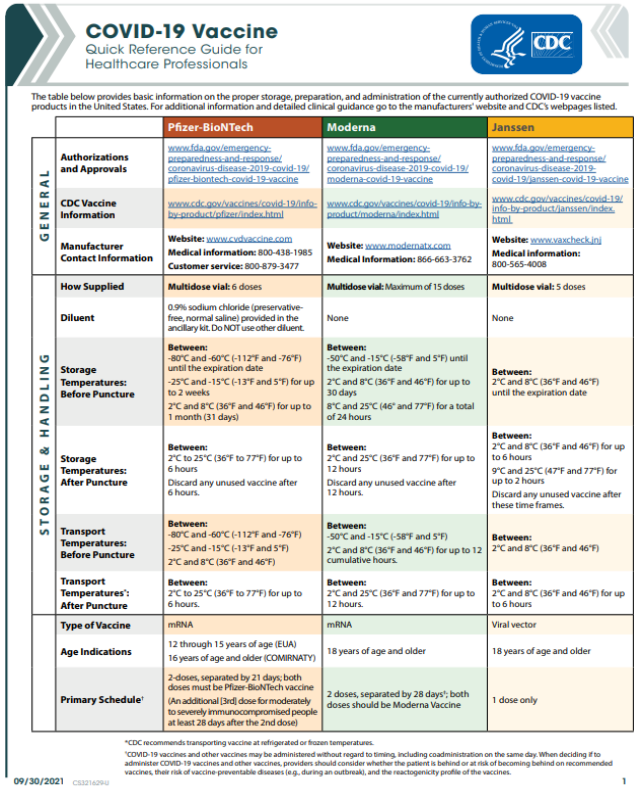
COVID-19 Vaccine Quick Reference



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 manufacturers' website and CDC's webpages listed.

		Pfizer-BioNTech	Moderna	Janssen
GENERAL	Authorizations and Approvals	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:** 800-565-4008
STORAGE & HANDLING	How Supplied	**Multidose vial:** 6 doses	**Multidose vial:** Maximum of 15 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 1 month (31 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	12 through 15 years of age (EUA) 16 years of age and older (COMIRNATY)	18 years of age and older	18 years of age and older
	Primary Schedule†	2-doses, separated by 21 days; both doses must be Pfizer-BioNTech vaccine (An additional [3rd] dose for moderately to severely immunocompromised people at least 28 days after the 2nd dose)	2 doses, separated by 28 days‡; both doses should be Moderna Vaccine	1 dose only

*CDC recommends transporting vaccine at refrigerated or frozen temperatures.
†COVID-19 vaccines and other vaccines may be administered without regard to timing, including coadministration on the same day. When deciding if to administer COVID-19 vaccines and other vaccines, providers should consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable diseases (e.g., during an outbreak), and the reactogenicity profile of the vaccines.

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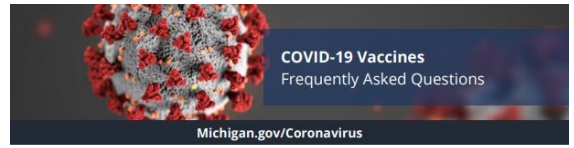
COVID-19 Vaccines FAQ—MDHHS



COVID-19 Vaccines
Frequently Asked Questions
Michigan.gov/Coronavirus

The information in this document will change frequently as we learn more about COVID-19 vaccines. There is a lot we are learning as the pandemic and COVID-19 vaccines evolve. The approach in Michigan will adapt as we learn more. September 29, 2021.

Quick Links

What's new | Why COVID-19 vaccination is important | Booster and additional doses | What to expect when you get vaccinated | Safety of the vaccine | Vaccine distribution/prioritization | Additional vaccine information | Protecting your privacy | Where can I get more information?

What's new

- Pfizer booster doses recommended for some people to boost waning immunity six months after completing the Pfizer vaccine.

Why COVID-19 vaccination is important

- If you are fully vaccinated, you **don't have to quarantine after being exposed to COVID-19**, as long as you don't have symptoms. This means missing less work, school, sports and other activities.
- **COVID-19 vaccination is the safest way to build protection.** COVID-19 is still a threat, especially to people who are unvaccinated. Some people who get COVID-19 can become severely ill, which could result in hospitalization, and some people have ongoing health problems several weeks or even longer after getting infected. Even people who did not have symptoms when they were infected can have these ongoing health problems.
- After you are fully vaccinated for COVID-19, **you can resume many activities that you did before the pandemic**.

CDC recommends that fully vaccinated people wear a mask in public indoor settings if they are in an area of substantial or high transmission.

Will COVID-19 vaccination help keep me from getting COVID-19?
Studies show that COVID-19 vaccines are effective at keeping you from getting COVID-19. Getting a COVID-19 vaccine will also help keep you from getting seriously ill even if you do get COVID-19. Wearing masks and social distancing help reduce your chance of being exposed to the virus or spreading it to others, but these measures are not enough. Vaccines will work with your immune system so it will be ready to fight the virus if you are exposed. Stopping the pandemic requires using all the tools we have available.

MDHHS Michigan Department of Health & Human Services

For more information, visit **Michigan.gov/Coronavirus.**

Updated 09/29/2021

Updated Resources

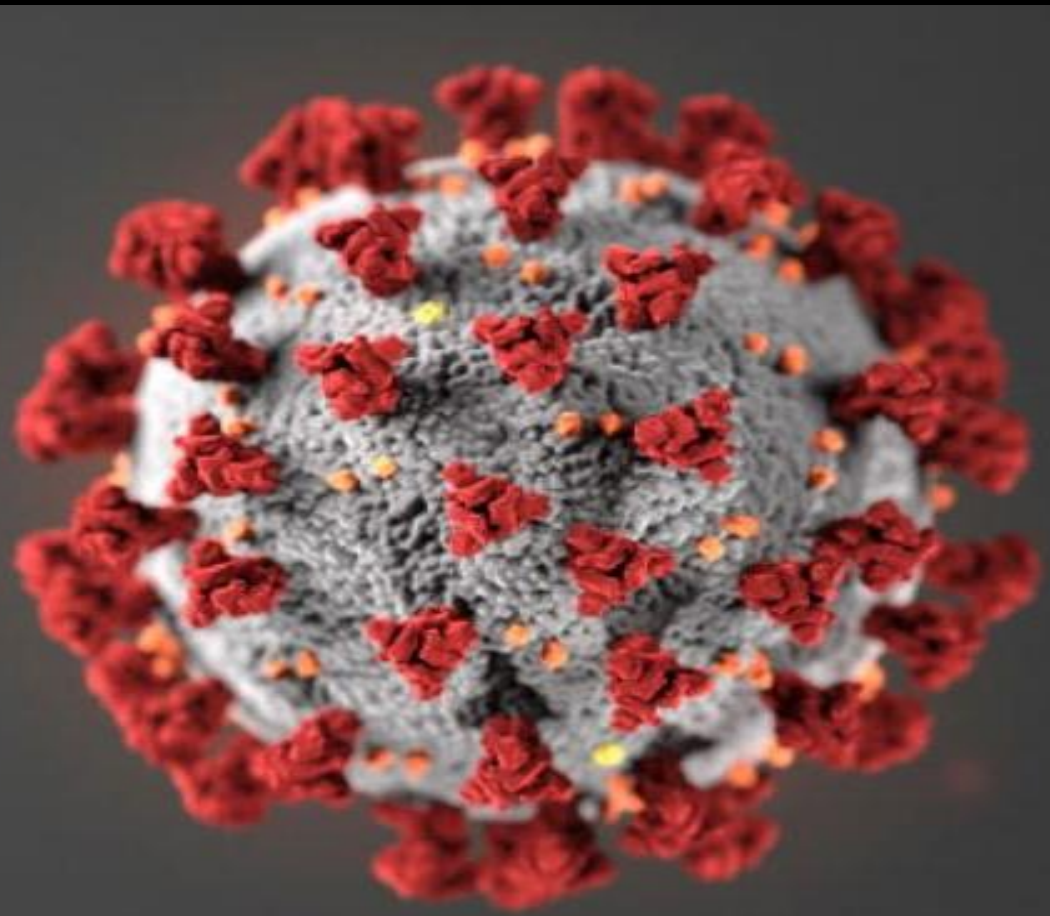
https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

Thank You!

Next “Noontime Knowledge” Update: TBD

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

Questions Email: checcimms@michigan.gov



www.michigan.gov/COVIDvaccineprovider