




Overview of the Recent ACIP Meeting (including COVID-19 vaccine)

July 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

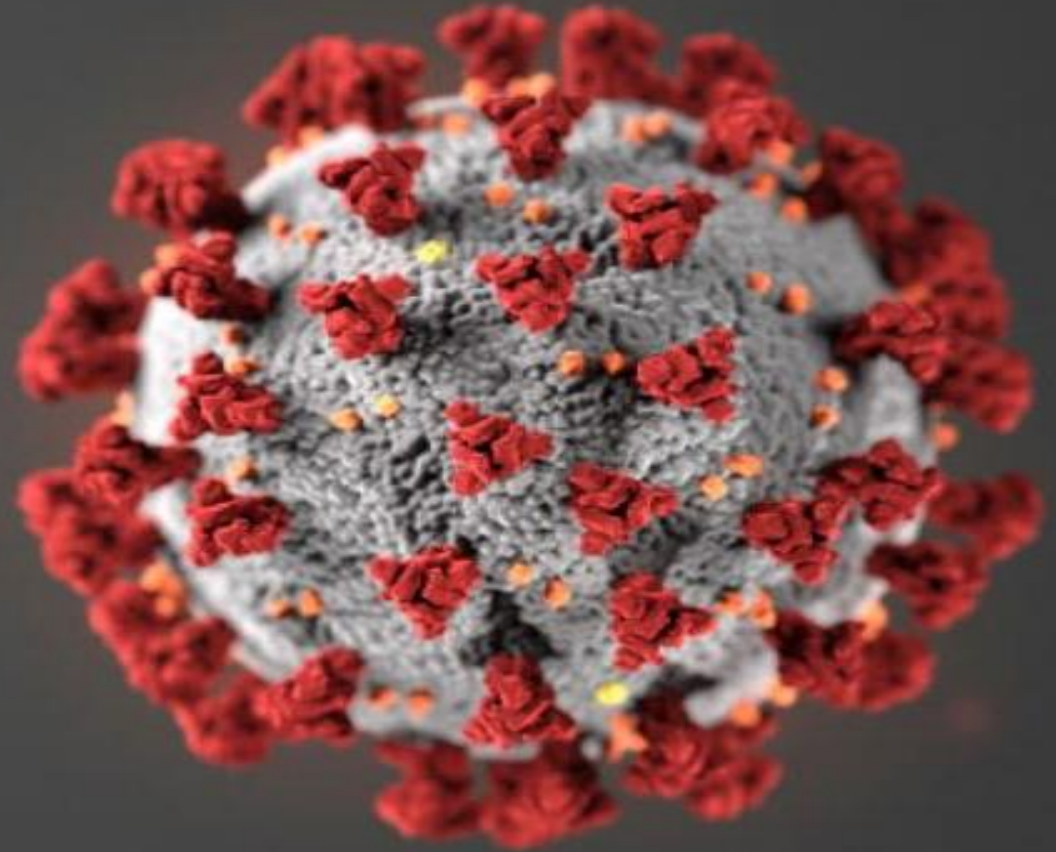
- **Slides & Recording**

- 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

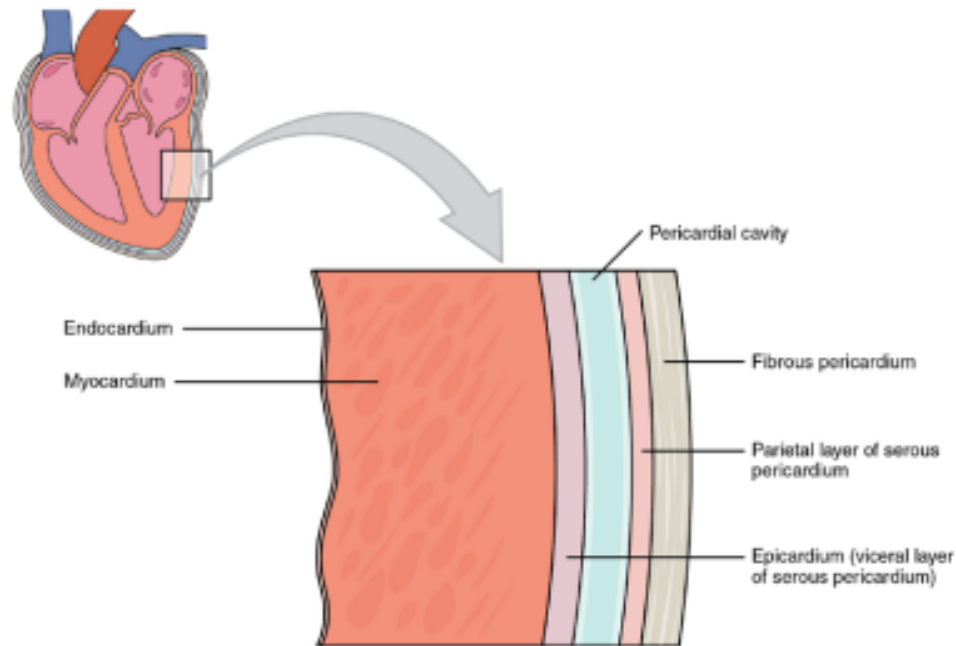
- Myocarditis and Pericarditis after receipt of mRNA COVID-19 vaccines
- Booster Doses of COVID-19 vaccines
- Dengue Vaccine
- Influenza Vaccines
- Rabies Vaccines
- Zoster Vaccine
- Pneumococcal Vaccines
- Resources

Myocarditis and Pericarditis After Receipt of mRNA COVID-19 Vaccines



What are Myocarditis and Pericarditis?

- Myocarditis: Inflammation of the myocardium (the heart muscle)
- Pericarditis: Inflammation of the pericardium (the lining around the heart)
- Myopericarditis: When both myocarditis and pericarditis are present



Causes of traditional myocarditis

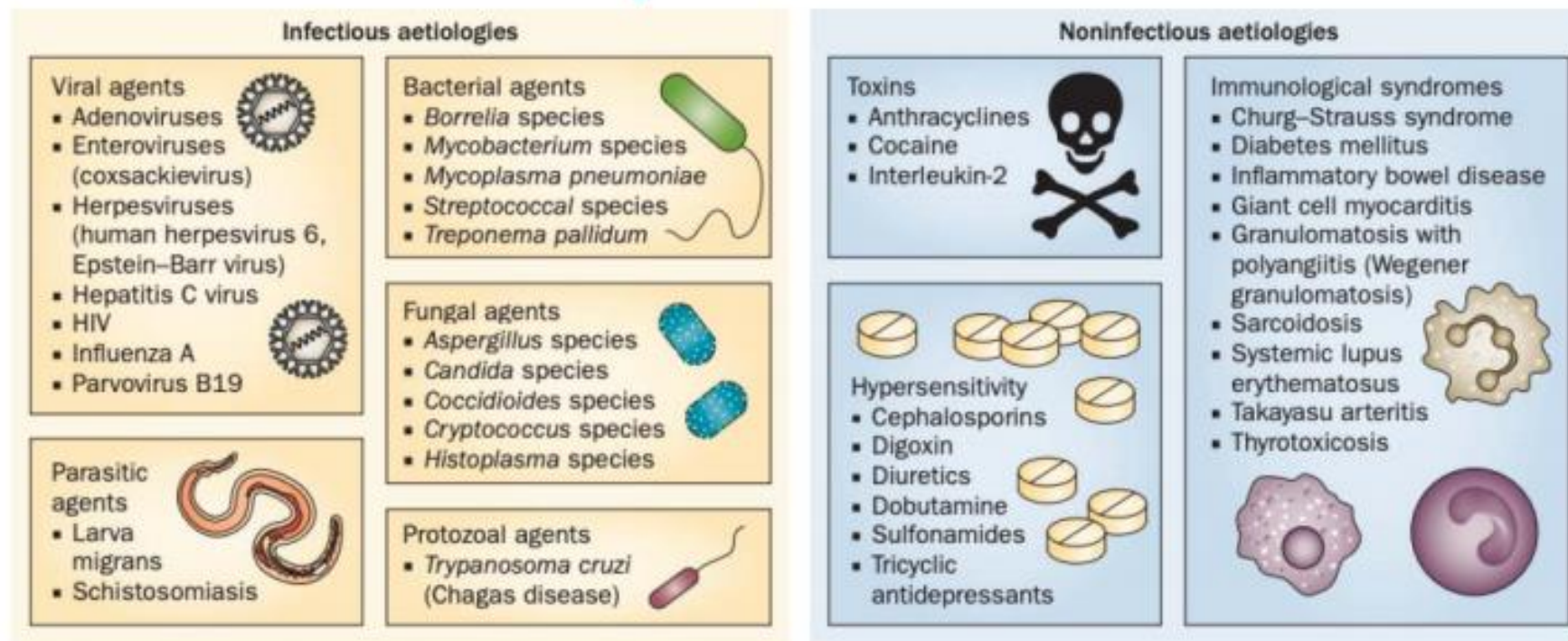
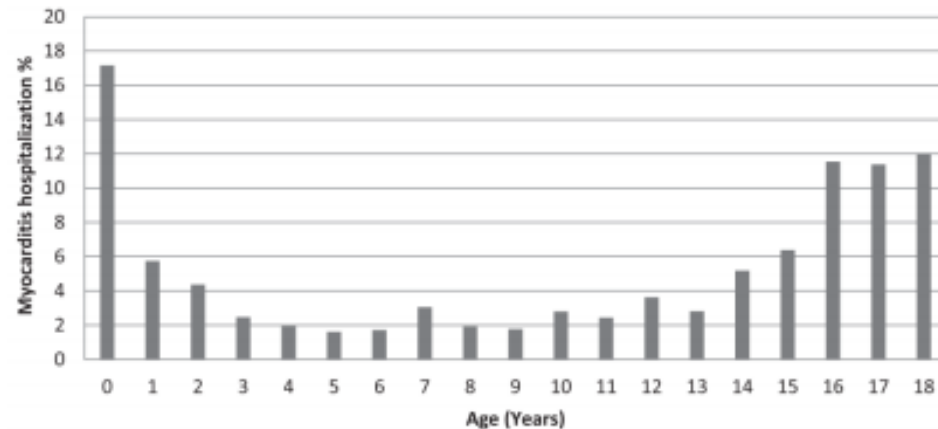


Figure 1 | Common causes of myocarditis. Viral infection is the most common aetiology, but several other aetiologies of myocarditis have also been implicated.

Epidemiology of myocarditis

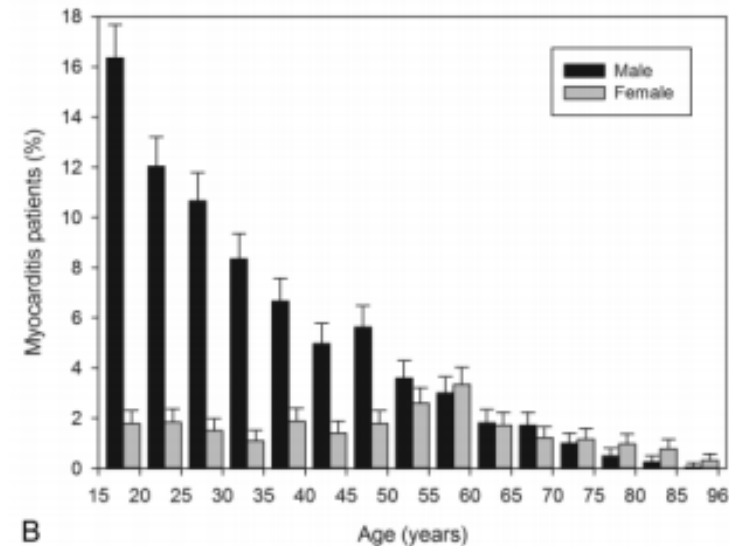
Children

- Annual incidence 0.8 per 100,000
 - In 15-18yo, 1.8 per 100,000 in 2015-2016
- 66% male
- Median LOS 6.1 days



Adults

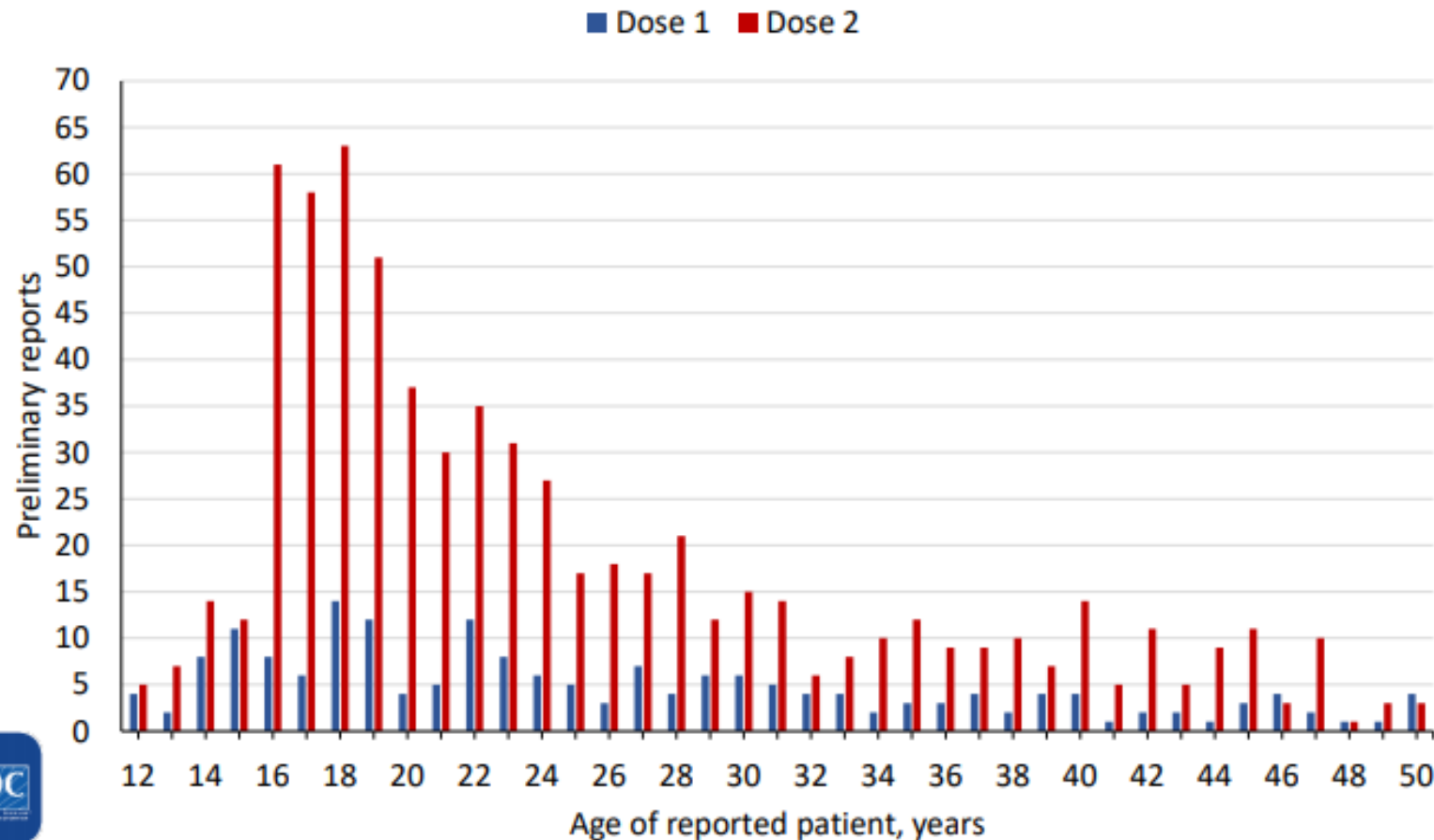
- Gradual decrease in incidence with age
- 76% male



Vasudeva et al. *American J Cardiology*. 2021.

Kyto et al. *Heart*. 2013.

Preliminary reports of myocarditis/pericarditis to VAERS after mRNA COVID-19 vaccination by age and dose number* (as of Jun 11, 2021)

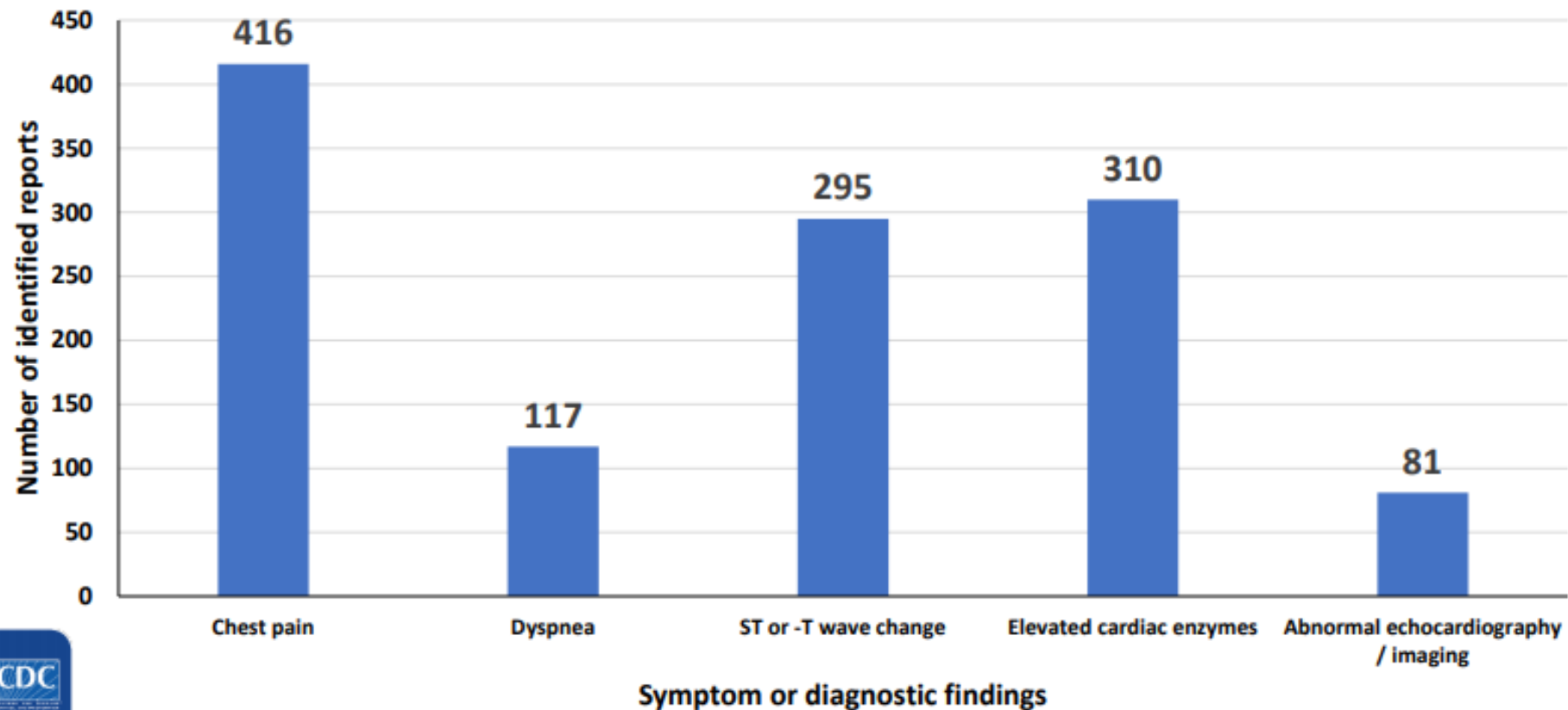


* Age truncated at >50yr:
Reports of persons >50yr
of age include 70 after
Dose 1, 119 after Dose 2

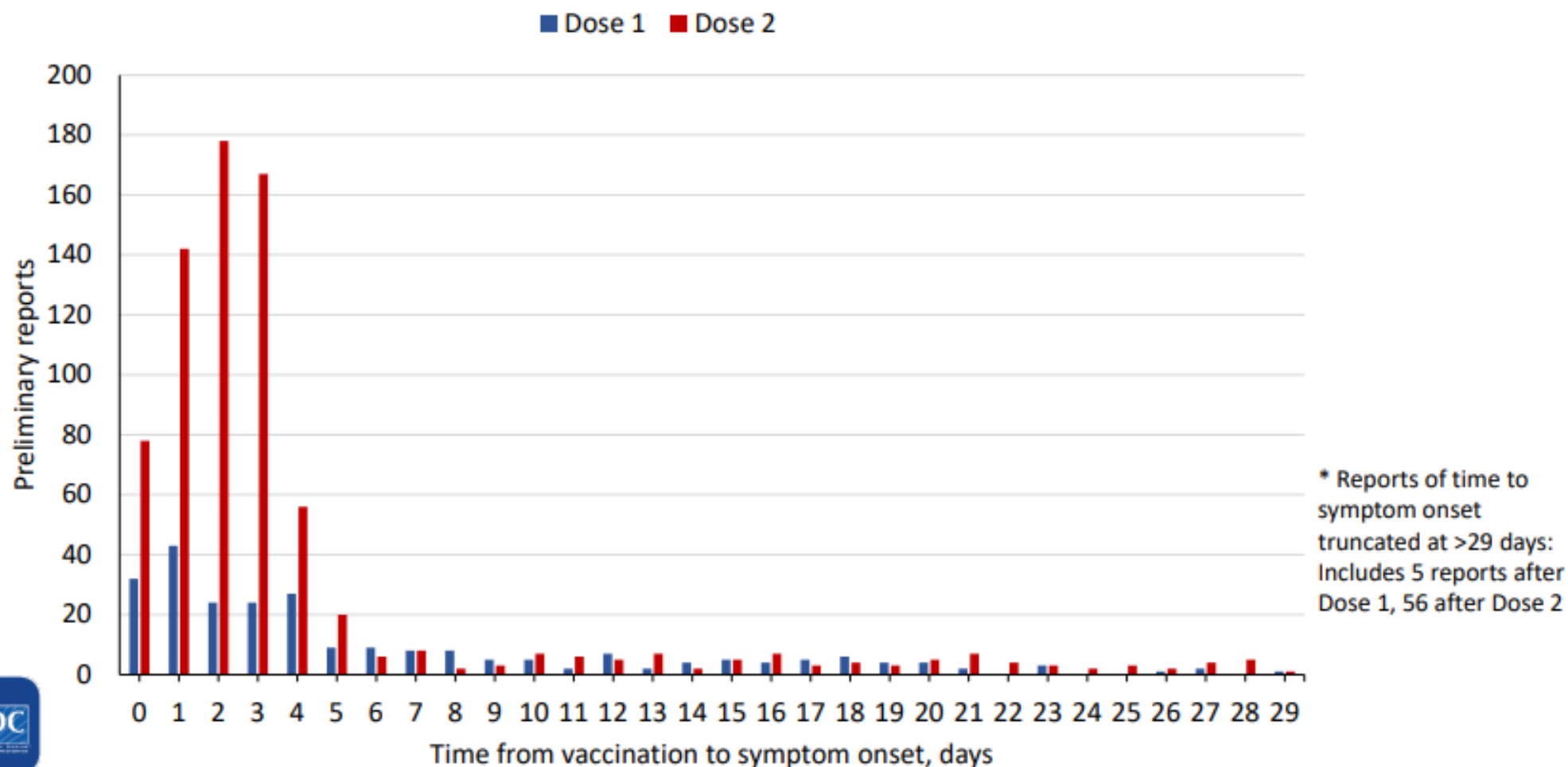


Symptoms and diagnostic findings of preliminary myocarditis/pericarditis reports after mRNA COVID-19 vaccination under review, limited to ≤29 years old (N=484)

(data thru Jun 11, 2021)



Preliminary reports of myocarditis/pericarditis to VAERS after mRNA COVID-19 vaccination by dose number and time to symptom onset* (as of Jun 11, 2021)



Myocarditis/Pericarditis after mRNA COVID-19 Vaccination-Summary of Data Presented

- Myocarditis is rare but is not a new disease
- Treatment largely supportive
- Myocarditis after mRNA vaccines:
 - Most common in males, less than 30 years old, within a few days after 2nd dose
 - Early data of acute outcomes of myocarditis after mRNA vaccines have been good
 - No long-term data available yet
- Currently the benefits still clearly outweigh the risks for COVID-19 vaccination in adolescents and young adults
- CDC continues to recommend COVID-19 vaccination for everyone 12 years of age and older given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death

Next Steps for Assessing Myocarditis/Pericarditis Following mRNA COVID-19 Vaccination

- Continue monitoring in VAERS
 - Follow-up to obtain medical records, conduct case reviews, apply CDC working case definition, and adjudicate case reports
 - Surveillance review focusing on myocarditis and myopericarditis to describe epidemiology and characterize clinical features of cases is in progress
- Continue monitoring and assessment in VSD
- Conduct follow-up on vaccine-associated cases to assess longer-term outcomes (i.e., at 3-6 months)

Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Summary

Since April 2021, increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults. There has not been a similar reporting pattern observed after receipt of the Janssen COVID-19 Vaccine (Johnson & Johnson).

In most cases, patients who presented for medical care have responded well to medications and rest and had prompt improvement of symptoms. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically within several days after mRNA COVID-19 vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating these reports of myocarditis and pericarditis following mRNA COVID-19 vaccination.

CDC continues to recommend [COVID-19 vaccination](#) for everyone 12 years of age and older given the risk of COVID-19 illness and related, possibly severe complications, such as long-term health problems, hospitalization, and even death.

Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

Updated June 23, 2021 Languages Print

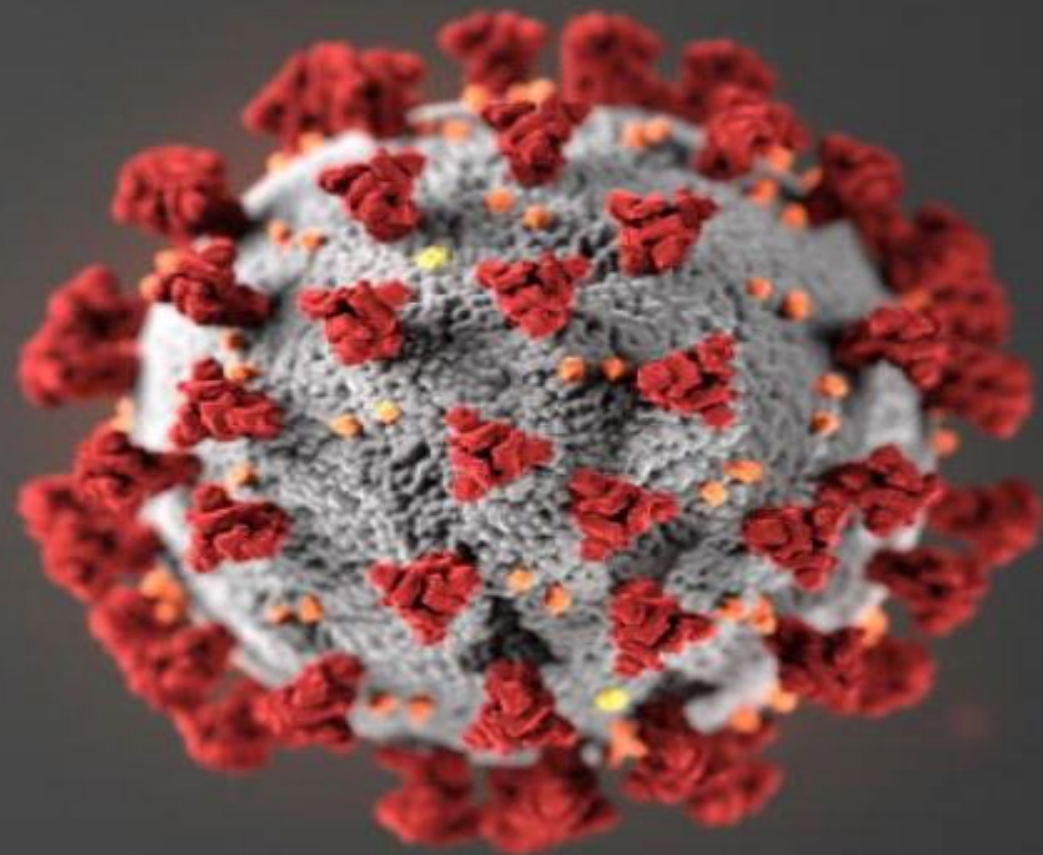
What You Need to Know

- More than 177 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- Since April 2021, there have been more than a thousand reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (i.e., Pfizer-BioNTech, Moderna) in the United States.
- These reports are rare, given the hundreds of millions of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination, particularly in adolescents and young adults. [View the latest information.](#)
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to understand any relationship to COVID-19 vaccination.
- Most patients who received care responded well to treatment and rest and quickly felt better.
- Confirmed cases have occurred:

CDC Educational Materials

<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html> and
<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.htm>

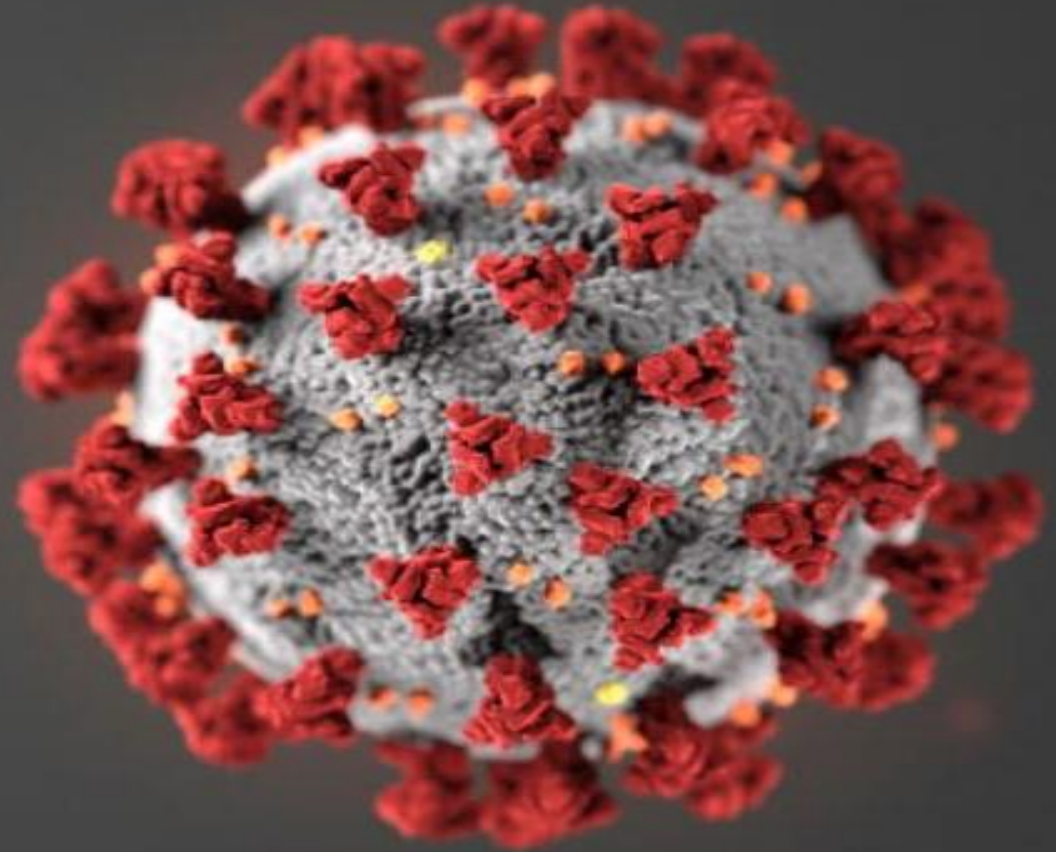
COVID-19 Vaccine Booster Doses



COVID-19 Booster Dose Discussion

- Main policy question—Are booster doses of COVID-19 vaccines needed for those previously vaccinated with a primary series?
- And additional questions:
 - Are booster doses needed for all persons or only in specific populations (e.g., long-term care facilities, adults 65+, healthcare personnel, and immunocompromised persons)?
 - What is the optimal timing of booster doses after primary series?
 - Can these be given as a ‘mixed dose’, or do they need to be matched to a primary series?

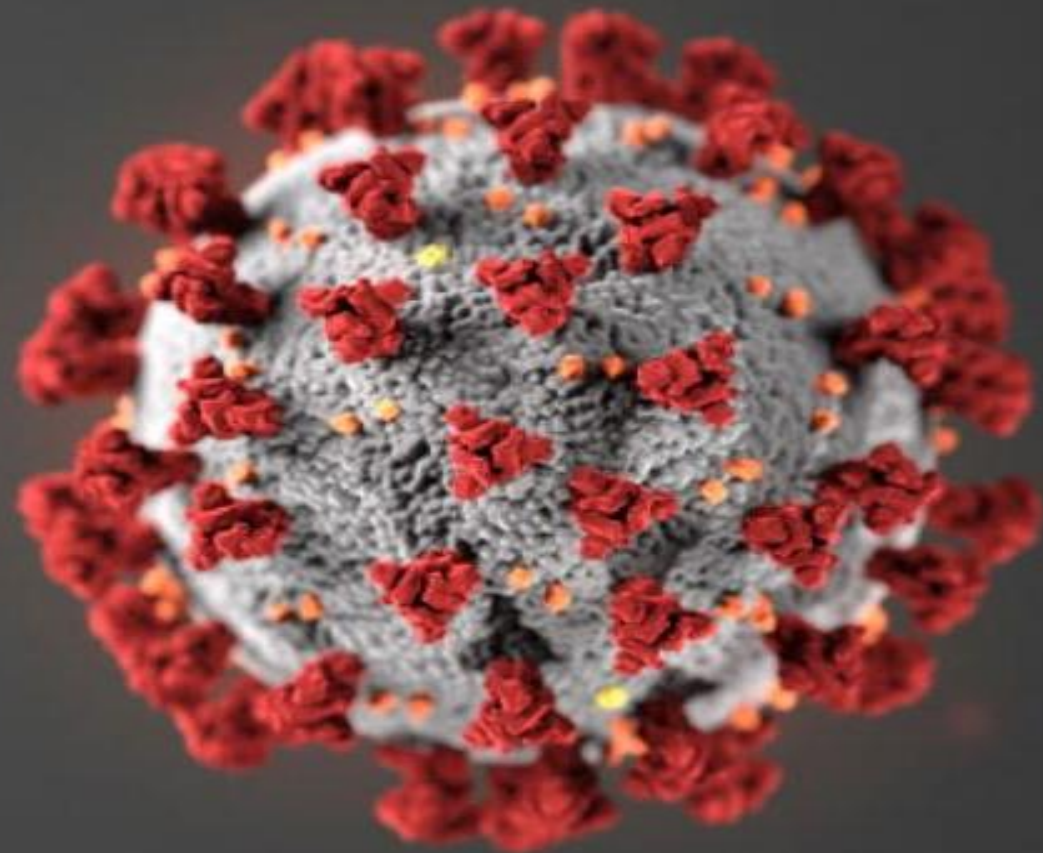
Dengue Vaccine



Draft Dengue Vaccine Recommendation

- ACIP recommends 3-doses of Dengvaxia administered 6 months apart at month 0, 6, and 12, in persons 9-16 years of age **with a laboratory confirmation of previous dengue infection** and living in endemic areas (i.e., Puerto Rico, American Samoa, and the US Virgin Islands)
- Vote (including VFC): Unanimous Yes
 - **Not official until signed by CDC director and published in MMWR**
- Dosage and Contraindications and Precautions
 - Refer to Package Insert: <https://www.fda.gov/media/124379/download>

Influenza Vaccine



2021-22 Influenza Vaccine Composition

- Egg-based IIV4s and LAIV4
 - An A/Victoria/2570/2019 (H1N1) pdm09-like virus; (Updated)
 - An A/Cambodia/e0826360/2020 (H3N2)-like virus; (Updated)
 - A B/Washington/02/2019 (Victoria lineage)-like virus; and
 - A B/Phuket/3073/2013 (Yamagata lineage)-like virus
- Cell-culture-based IIV4 and RIV4
 - An A/Wisconsin/588/2019 (H1N1) pdm09-like virus; (Updated)
 - An A/Cambodia/e0826360/2020 (H3N2)-like virus; (Updated)
 - A B/Washington/02/2019 (Victoria lineage)-like virus; and
 - A B/Phuket/3073/2013 (Yamagata lineage)-like virus

<https://www.who.int/publications/m/item/recommended-composition-of-influenza-virus-vaccines-for-use-in-the-2021-2022-northern-hemisphere-influenza-season>

Change in Age Indication for Flucelvax Quadrivalent

- Previously licensed for ages 4 years and greater; approved in March 2021 for ages 2 years and greater
- Changes supported by randomized trial conducted among 4,514 children 2 years through 18 years over three influenza seasons
- Overall vaccine efficacy 54.6% (95%CI 45.7, 62.1) against RT-PCR or culture) influenza associated CDC-defined influenza-like illness
- Vaccine efficacy 62.7% (95%CI 38.1, 80.8) for matched strains

Flucelvax Quadrivalent (cclIV4)* Phase III Immunogenicity & Safety in 6-47 Months

- cclIV4 met all the predefined non-inferiority criteria for immunogenicity as compared to IIV4
- Immunogenicity data consistent against all four strains
- cclIV4 was well tolerated, with similar rates of solicited and unsolicited adverse events between the two vaccination groups, consistent with previously reported data in older children

<https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/02-influenza-sylvester-508.pdf>

*Currently approved for use in persons 2 years of age and older in the United States

Co-administration of Influenza Vaccines with COVID-19 Vaccines

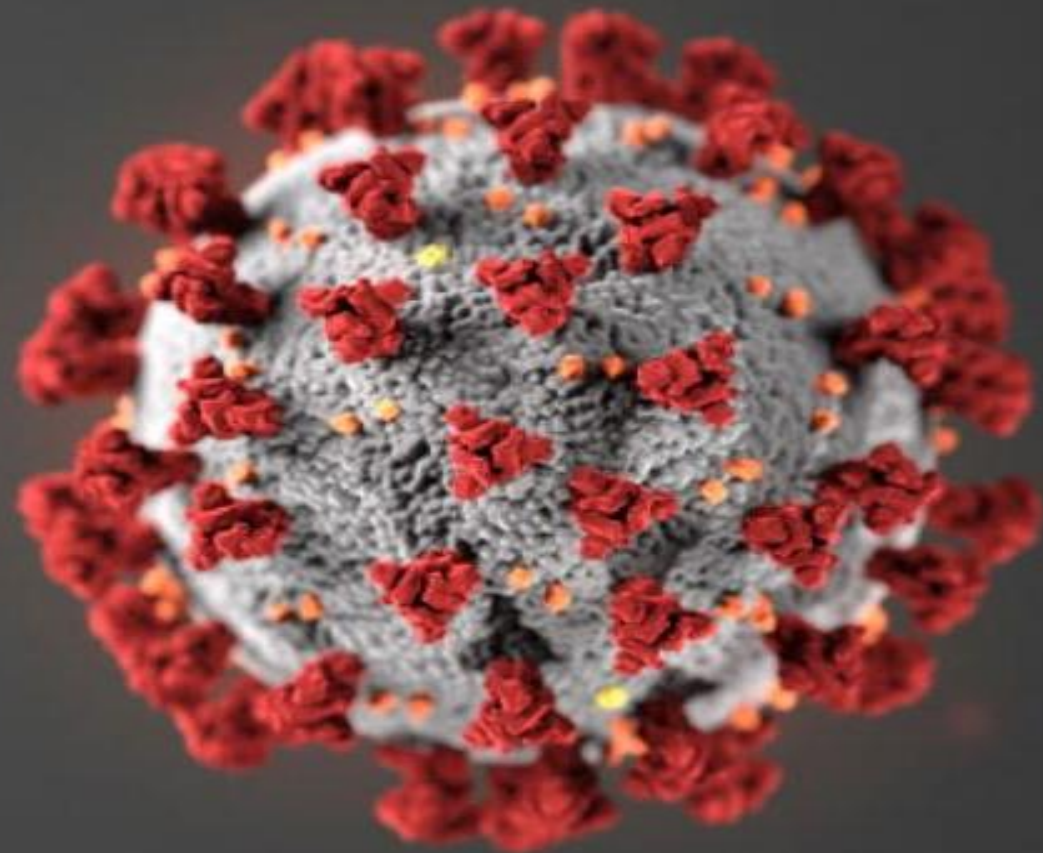
- **Proposed Language** for 2021-22 Influenza Statement
 - Current guidance concerning administration of COVID-19 vaccines with other vaccines (<https://www.cdc.gov/vaccines/covid-19/info-by-product/clinicalconsiderations.html>) indicates that these vaccine may be given with other vaccines, including influenza vaccines. No data are currently available concerning coadministration of currently authorized COVID-19 vaccines and influenza vaccines. Providers should be aware of the potential for increased reactogenicity with coadministration and should consult CDC guidance at the referenced link for updated guidance as more information becomes available. If coadministered, COVID-19 vaccines and vaccines that might be more likely to cause a local reaction (e.g., aIIV4 or HD-IIV4) should be administered in different limbs, if possible

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

Timing of Influenza Vaccination

- ACIP workgroup discussed recent literature concerning waning of immunity to influenza vaccines
 - Appears to be more pronounced among older adults
 - Less evidence for waning among children
- Other considerations discussed included
 - Protection of infants during first months of life
 - Avoiding missed opportunities for vaccination
- Language contains several changes concerning timing of vaccination for children, persons in the third trimester of pregnancy, and adults

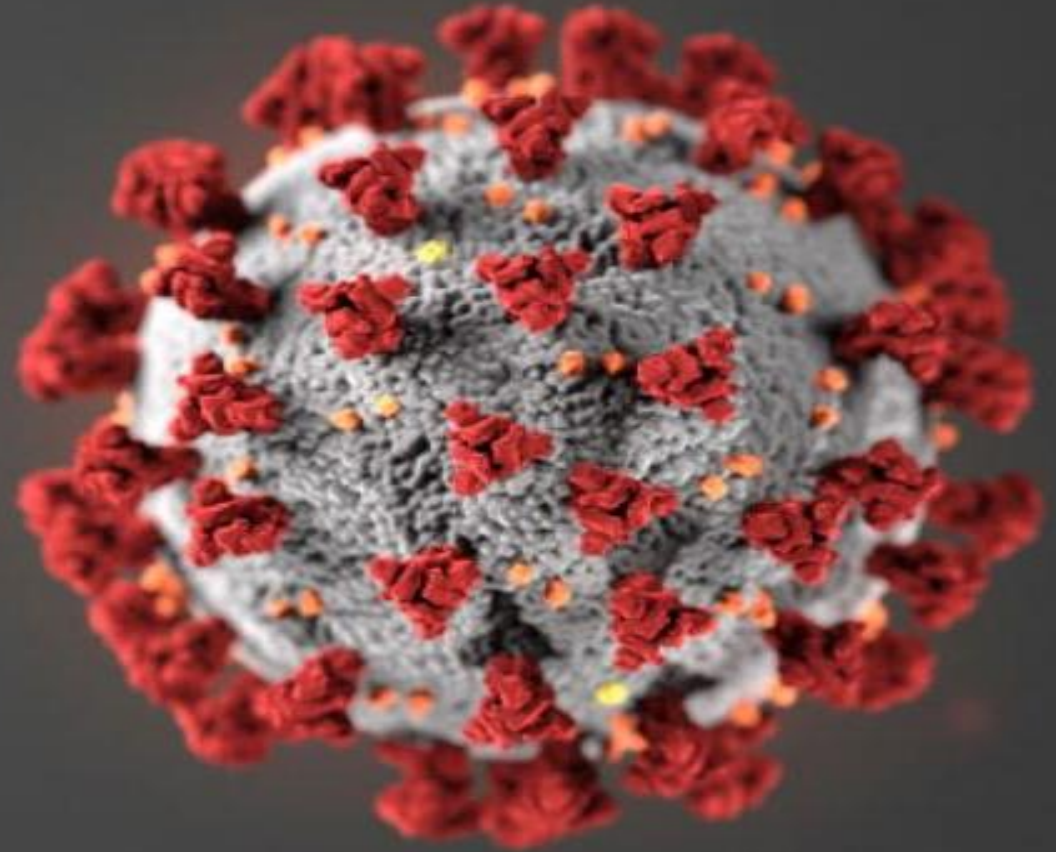
Rabies Vaccine



Rabies Proposed Recommendations

- **Proposed** recommendation #1
 - ACIP recommends a 2-dose (0, 7 days) IM rabies vaccine series in immunocompetent persons under 18 years of age for whom rabies vaccine pre-exposure prophylaxis (PrEP) is indicated
- **Proposed** recommendation #2
 - ACIP recommends an IM booster dose of rabies vaccine, as an alternative to a titer check, for immunocompetent persons less than 18 year of age who have sustained and elevated risk for only recognized rabies exposures (i.e., those in risk category #3 of rabies PrEP recommendations table). The booster dose should be administered no sooner than day 21 but no later than 3 years after the 2-dose PrEP series
- Not official until signed by CDC director and published in MMWR

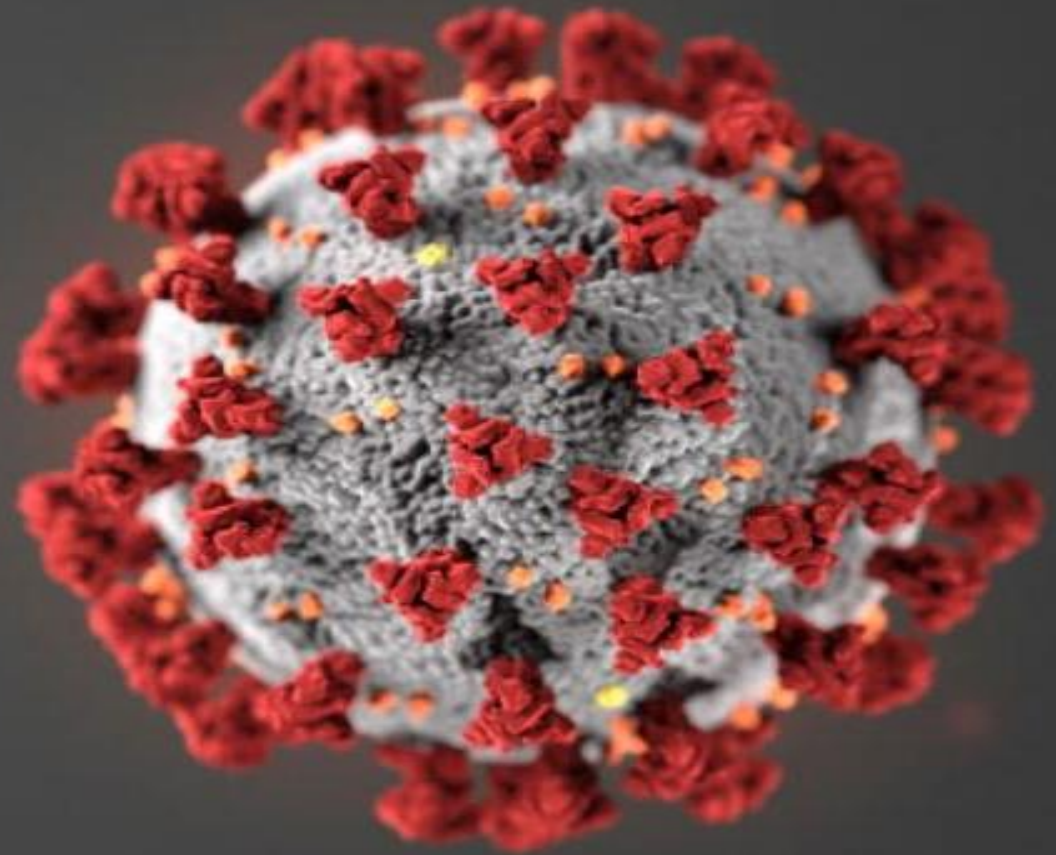
Zoster Vaccine



Zoster Vaccine Discussion

- Should vaccination with RZV be recommended for immunocompromised adults 19 years of age and older
- GSK shared clinical data on the use of RZV in immunocompromised populations
- Immunocompromised populations under consideration
 - Hematopoietic stem cell transplant (HCT) recipients
 - Patients with hematologic malignancies (HM)
 - Renal or other solid organ transplant (SOT) recipients
 - Patients with solid tumor malignancies (STM)
 - People living with HIV
 - Other populations at increased risk not covered in above groups

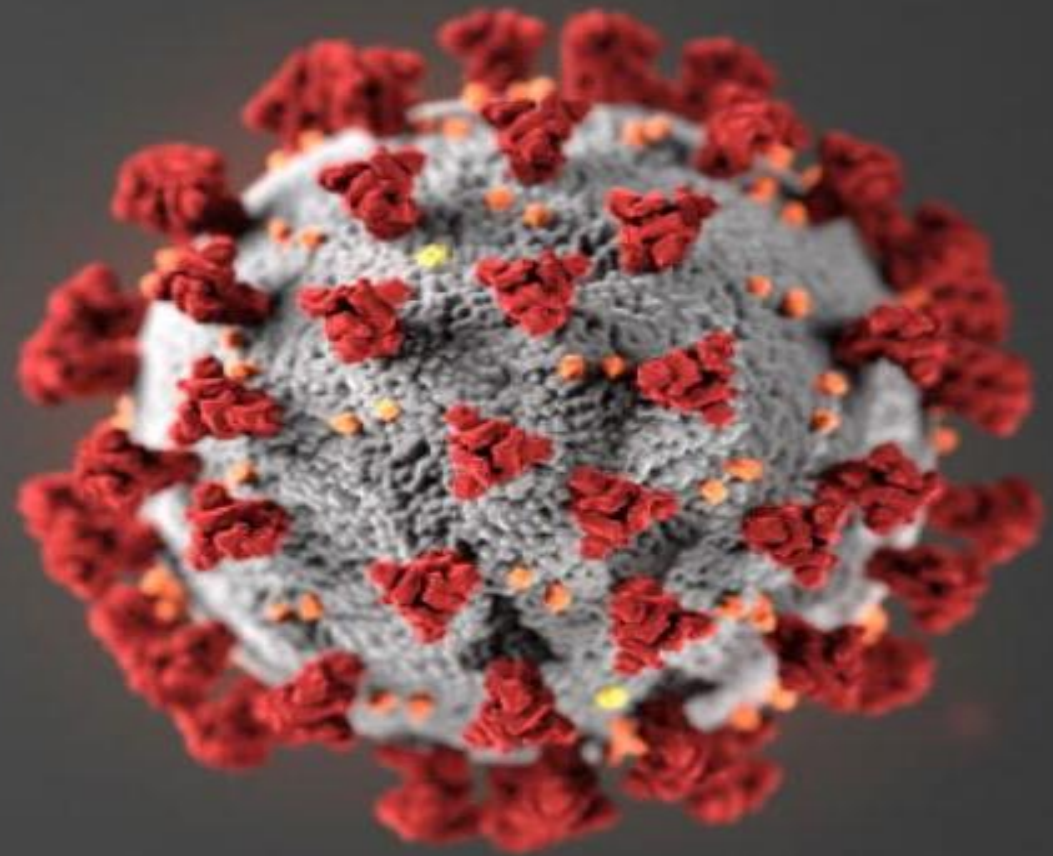
Pneumococcal Vaccine



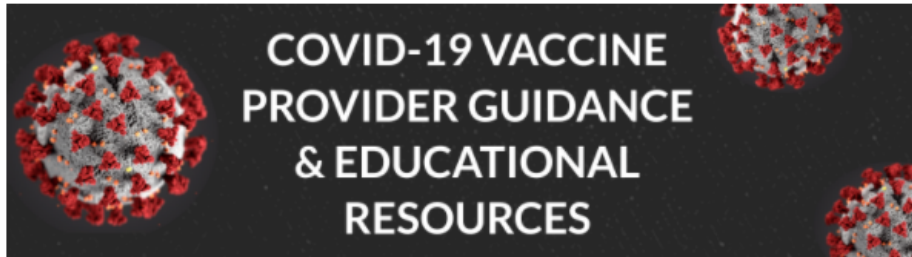
Pneumococcal Vaccine Discussion

- New Pneumococcal Vaccines
 - 20-valent pneumococcal conjugate vaccine (PCV20), Pfizer
 - Licensed for use in adults aged 18 years and older on June 8th
 - <https://www.fda.gov/vaccines-blood-biologics/vaccines/prevnar-20>
 - 15-valent pneumococcal conjugate vaccine (PCV15), Merck
 - BLA filed to FDA, licensure anticipated in July 2021
- Vote on recommendations for all newly licensed vaccines planned for October 21 ACIP meeting

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

[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 handling, reporting, and patient education for each specific vaccine

[COVID-19 Vaccine Training Module](#)

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

[CDC HCP Vaccine Administration Resource Library](#)

CONTENT-SPECIFIC COVID-19 RESOURCES

[Webinars](#)

- [Upcoming Noontime Knowledge: Thursday July 1, 2021 at 12:00 pm](#)

[Education Corner](#)

[Enrollment](#)

[Redistribution](#)

[Vaccine Billing and Vaccine Code Sets](#)

MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider

Meeting Information

Committee Information +

Committee Members +

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Work Groups +

Recommendations +

Evidence Based Recommendations +

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ACIP Meeting Information

The ACIP holds three meetings each year at the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia to review scientific data and vote on vaccine recommendations. Meetings are open to the public and available online via live webcast.

Meeting Registration

Public Comment

Upcoming Meetings

Meeting Materials

In order to attend the ACIP meeting, in person, at CDC's Clifton Road campus, ACIP attendees (participants and visitors) must register online. Registration is not necessary to listen to the meeting via phone or live meeting. For in-person attendance, the week prior to the meeting you will receive a placard for your vehicle (parking tag) and instructions for navigating the secure CDC environment to attend the ACIP meeting.

ACIP Meeting Registration

The June 18, 2021 COVID-19 meeting is being rescheduled due to the observation of the Juneteenth National Independence Day holiday. The discussion will be rescheduled to be included as part of the June 23-25 ACIP meeting.

No Registration is required for the June 23-25, 2021 ACIP Meeting.

Registration is NOT required to watch the live meeting webcast.

Rules of Conduct for ACIP Meetings

- An interested person who wishes to make an oral public comment during an ACIP meeting should submit a request with the Centers for Disease Control and Prevention (CDC) before the meeting according to the instructions in the Federal Register Notice. Those who have not submitted a request before the meeting will only have an opportunity to speak as time permits or at the discretion of the Chair.
- Audience members may not present comments or questions to the Committee unless recognized by the Chair.
- Attendees may be subject to security screening, such as presenting identification, passing through metal detectors, and inspection of briefcases, packages, and so on.
- Attendees at the meeting are asked to maintain order and not display behavior that is disruptive to the meeting.
- The ACIP Chair or Designated Federal Officer will note on the record any disruptive behavior and will ask the person to cease the behavior or else leave the meeting room.
- We ask that attendees not approach the ACIP table area before, during, or after the meeting without permission from a Designated Federal Officer/Executive Secretary.

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

ACIP Meeting Webpage

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

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

