MDHHS
Michigan Department of Health & Human Services

Pfizer-BioNTech COVID-19 Vaccination in 12-15 Year Old's

May 20, 2021

Housekeeping

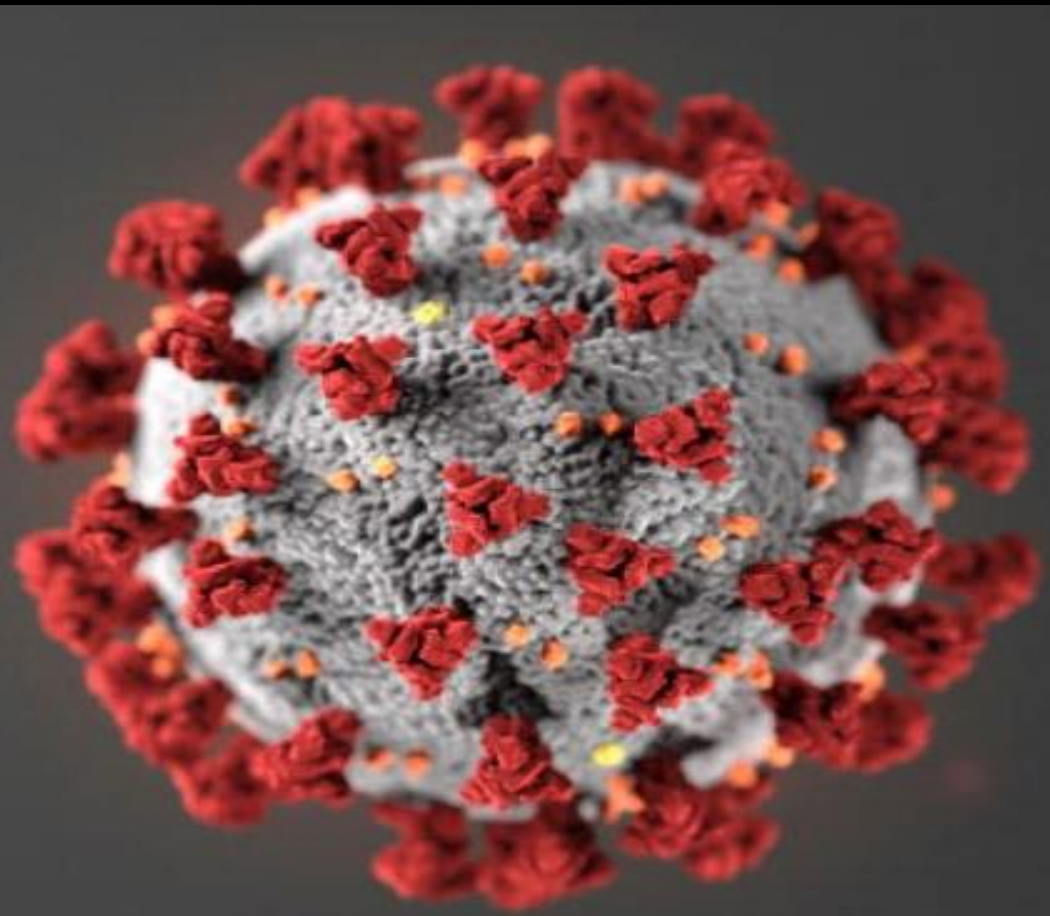
- **How to Ask Questions**
  - Click on the 

 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

- Public Health Problem: Summary of Available Evidence
- Safety and Efficacy
- Clinical Considerations
- Strong Provider Recommendation

Public Health Problem: Summary of Available Evidence



Summary of Available Evidence?

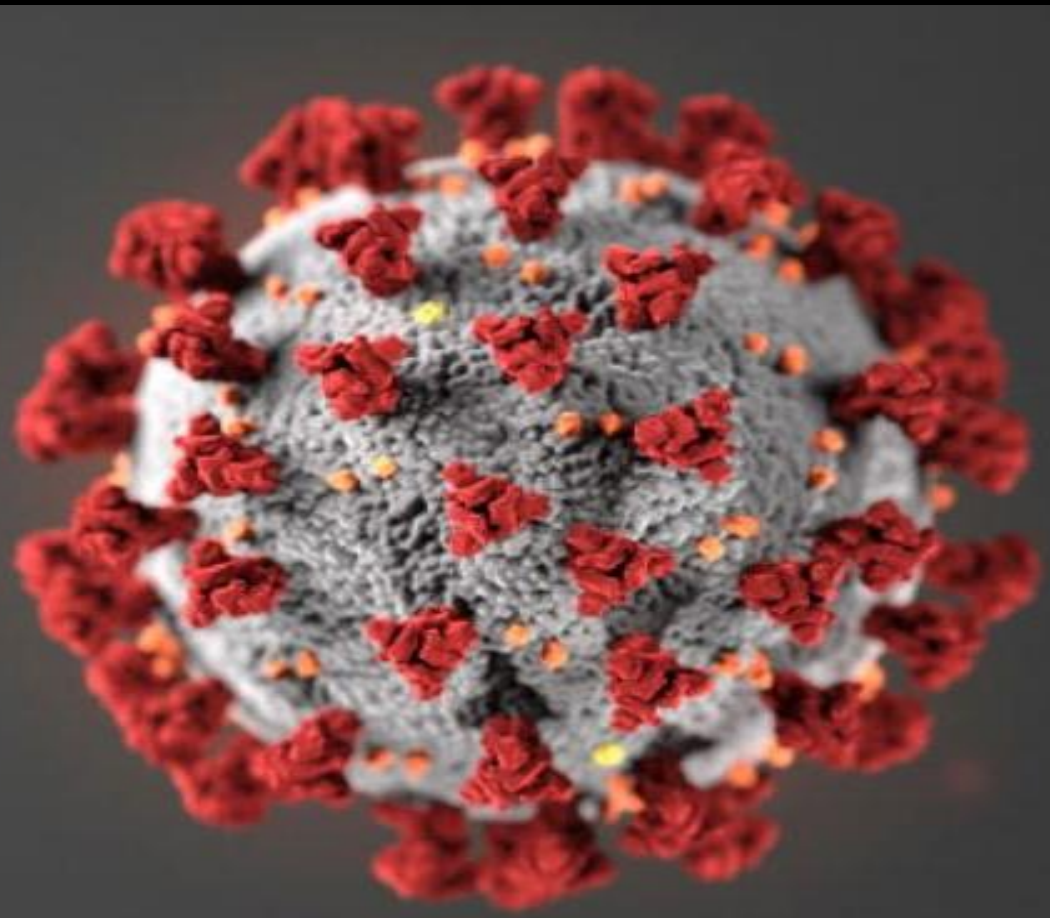
Adolescents 12-17 years of age are at risk of severe illness from COVID-19

- Over 1.5 million reported cases and >13,000 hospitalizations to date
  - Hospitalization rate higher than 2009-10 H1N1 pandemic
- Clinical presentation of Multisystem Inflammatory Syndrome in Children (MIS-C) more severe in adolescents than in younger children

COVID-19 in Adolescents may also indirectly impact others' health

- Adolescents contribute to transmission in households and communities
  - Including older adults at higher risk for COVID-19
- Adolescents represent an increasing proportion of recent COVID-19 cases

Safety and Efficacy



Safety: Reactogenicity
Pfizer-BioNTech COVID-19 Vaccine, 12-15 Year Old's

- Local reactions within 7 days occurred in 91% of vaccine recipients
  - Pain at the injection site most common
- Systemic reactions within 7 days occurred in 91% of vaccine recipients
  - Fatigue and headache most common
- Most symptoms resolved in 1-2 days
- Severe reactions were more common in vaccine recipients; a grade ≥ 3 reaction (interfering with daily life) was reported by 10.7% of vaccinated vs. 1.9% placebo
  - Fatigue, fever, headache most common
- No deaths were reported among trial participants

Safety Cont..
Pfizer-BioNTech COVID-19 Vaccine, 12-15 Year Old's

- No cases of anaphylaxis reported in the adolescent (12-15 years of age) study participants
- No cases of Bell's Palsy or facial paralysis reported in adolescent participants
- Among adolescents 12-15 years of age, 7 (0.6%) in the vaccine group had lymphadenopathy, compared to 1 (0.1%) participant
  - Most lymphadenopathy was local (arm or neck region), occurred on the same side as vaccination, and occurred within 2-10 days

Clinical Efficacy

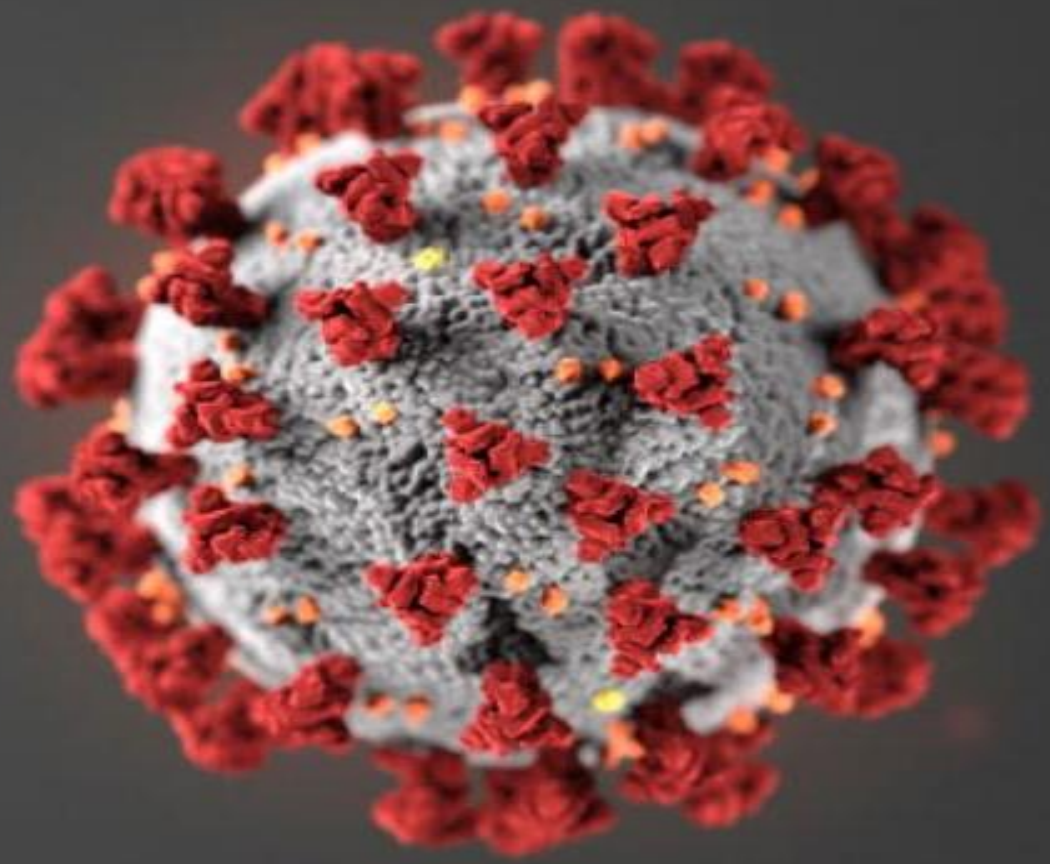
Pfizer-BioNTech COVID-19 vaccine, 12-15 year olds

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The efficacy was **100%**

Population	Events/Vaccine (n/N)	Events/Placebo (n/N)	Vaccine efficacy (95% CI)
Primary outcome			
No evidence of prior infection, ≥7 d post dose 2	0/1001[a]	16/972[a]	100.0%[b]
Secondary outcomes			
± evidence of prior infection, ≥7 d post dose 2	0/1109[a]	18/1094[a]	100.0%[c]
All available efficacy (± evidence of prior infection, post dose 1)	3/1120[a]	35/1119[a]	91.4% (72.2%, 97.4%)

a. Number of subjects at risk for the endpoint; b. With a standard continuity correction of 0.5 applied, the estimated VE (95% CI) is 97.1% (51.0%, 99.8%)
c. With a standard continuity correction of 0.5 applied, the estimated VE (95% CI) is 97.3% (55.8%, 99.8%)

Clinical Considerations



Interim Clinical Considerations

- These considerations apply only to the vaccine products currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines)

- Clinical considerations have been updated to include guidance for adolescents and recommendations regarding vaccine coadministration and vaccination after Multisystem Inflammatory Syndrome in Children (MIS-C) and Adults (MIS-A)

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

Pfizer-BioNTech Dosing and Administration

Authorized age groups	≥ 12 years
Number of doses in series	2 doses
Interval between 1st and 2nd doses*	3 weeks
Dose volume	0.3 ml
Route	Intramuscular

*If it is not feasible to adhere to the recommended interval, the second dose may be administered up to 6 weeks (42 days) after the first dose.

Coadministration

- COVID-19 vaccines and other vaccines **may now be administered without regard to timing.** This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as coadministration within 14 days

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

Coadministration Cont..

- It is unknown whether reactogenicity is increased with coadministration, including with other vaccines known to be more reactogenic, such as adjuvanted vaccines or live vaccines

- When deciding whether to coadminister another vaccine(s) with COVID-19 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 or occupational exposures)
  - The reactogenicity profile of the vaccines

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

Coadministration Cont..

- If multiple vaccines are administered at a single visit, administer each injection in a different injection site
- For adolescents and adults, the deltoid muscle can be used for more than one intramuscular injection
- Best practices for multiple injections include:
  - Label each syringe to identify the vaccine it contains
  - Separate injection sites by 1 inch or more, if possible
  - Administer COVID-19 and vaccines that may be more likely to cause a local reaction (e.g., tetanus-toxoid-containing and adjuvanted vaccines) in different limbs, if possible

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

Considerations for People with a History of MIS-C or MIS-A

- People with a history of MIS-C* or MIS-A* may choose to be vaccinated
- Considerations for vaccination may include:
  - Clinical recovery from MIS-C or MIS-A, including return to normal cardiac function
  - Personal risk of severe acute COVID-19 (e.g., age, underlying conditions)
  - Level of COVID-19 community transmission and personal risk of reinfection
  - Lack of safety data of COVID-19 vaccines following these illnesses
  - Timing of any immunomodulatory therapies

*Multisystem Inflammatory Syndrome in Children (MIS-C) and adults (MIS-A)

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

Considerations for People with a History of MIS-C or MIS-A

- Current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. Thus, people with a history of MIS-C or MIS-A **should consider delaying vaccination until they have recovered from illness and for 90 days after the date of diagnosis of MIS-C or MIS-A**, recognizing that the risk of reinfection and, therefore, the benefit from vaccination, might increase with time following initial infection.

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

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

Contraindications for COVID-19 Vaccine

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- Known polysorbate allergy is no longer a contraindication to mRNA vaccination but is a contraindication to Janssen COVID-19 vaccine and thus, a precaution to mRNA COVID-19 vaccination

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

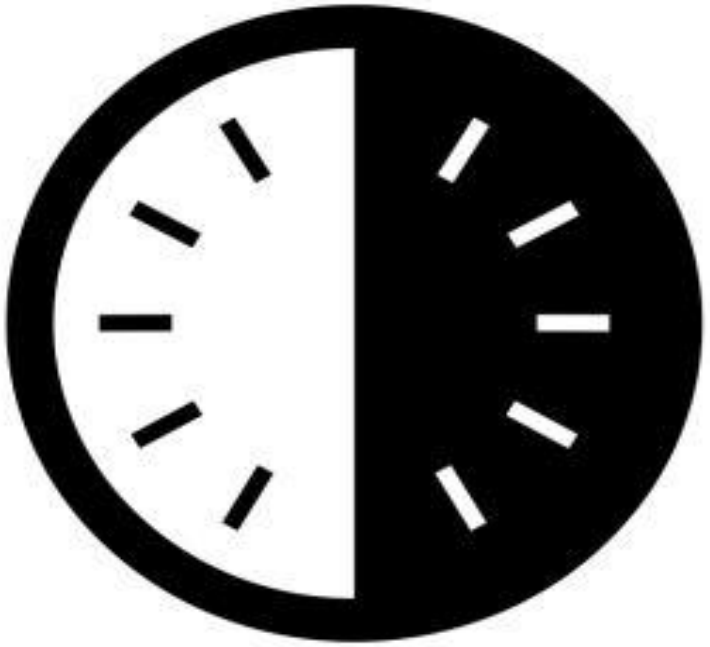
Syncope

- Syncope (fainting) may occur in association with any injectable vaccine
- Procedures should be in place to prevent falling injuries and manage syncopal reactions following vaccination
- All people are recommended to be observed following vaccination for at least 15 minutes; patients should be seated or lying down during the observation period to decrease the risk for injury should they faint. If syncope develops, patients should be observed until symptoms resolve

https://www.cdc.gov/vaccinesafety/concerns/fainting.html

Observation Period Following Vaccination

- History of immediate allergic reaction (any severity) to a vaccine or injectable therapy
- Contraindication to a different type of COVID-19 vaccine
- History of anaphylaxis (due to any cause)

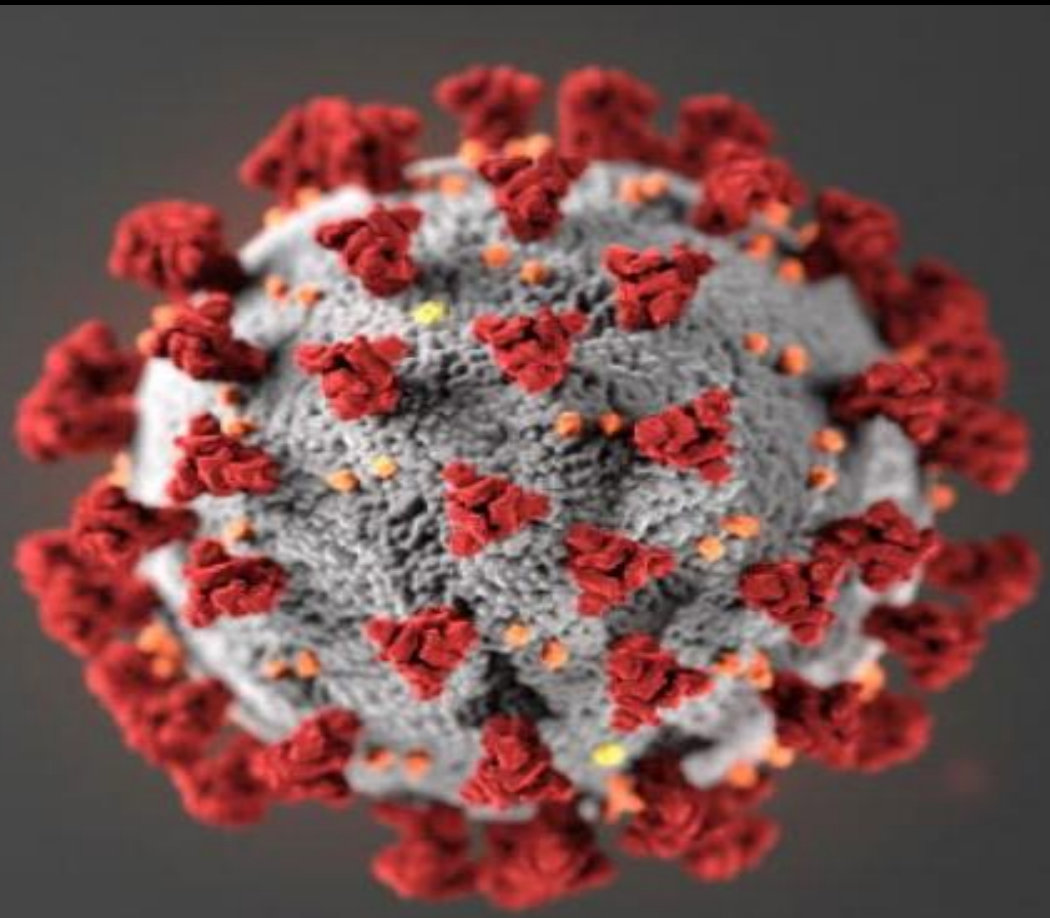


30 minutes

All other persons

15 minutes

Strong Provider Recommendation

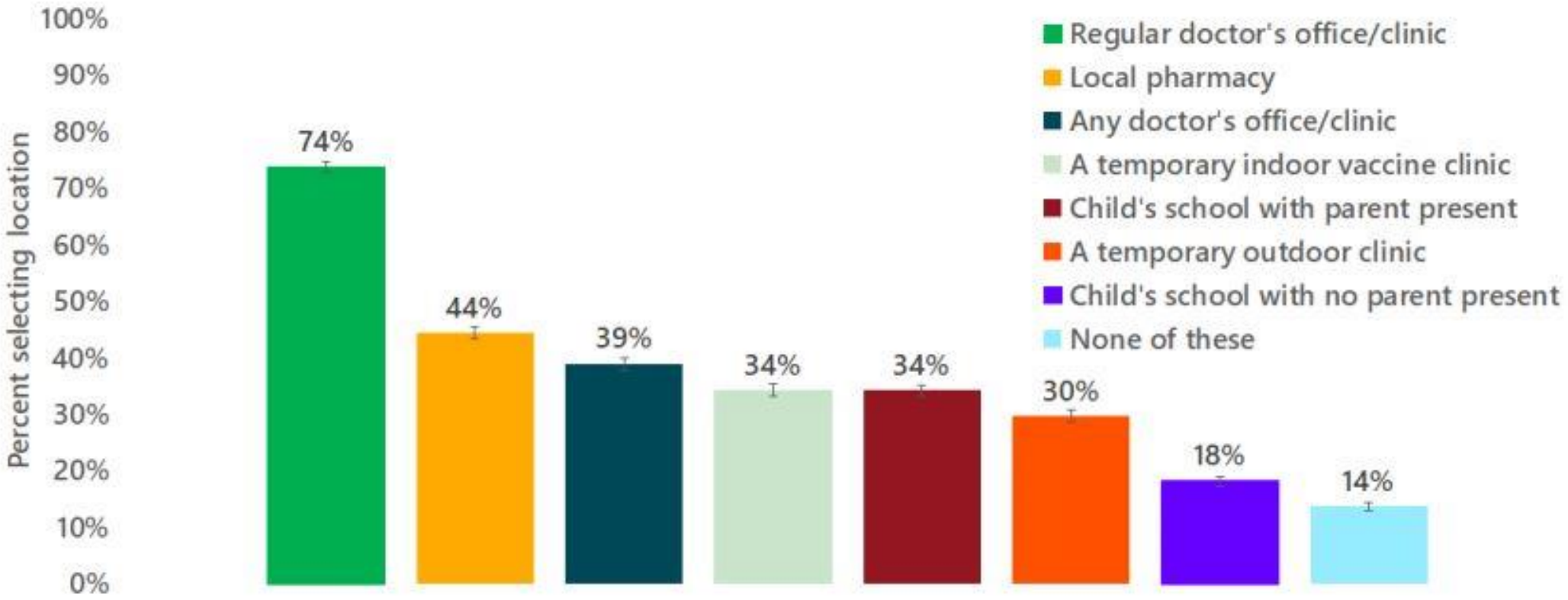


Surveys of Parents (intent to have children vaccinated)

- Among parents surveyed, **46-60**% plan to get their children vaccinated[1-4]
- Reasons for not vaccinating[2]:
  - not sure it will be safe (59%)
  - vaccine developed too quickly (59%)
  - don't trust info being published about the vaccine (48%)
  - won't trust right away (44%)
  - don't have enough info (43%)
- Parents reported similar or slightly lower intent to vaccinate their children compared to intent to vaccinate themselves[3,4]

1. Axios/Ipsos April 2-5; Axios/Ipsos April 16-19; Calarco and Anderson preprint; WebMD March 2021.
2. National Parents Union Survey January 2021
3. Simonson M, Baum M, Lazer D, et al. The COVID States Project #45: Vaccine hesitancy and resistance among parents.OSF Preprints, 19 Mar. 2021. https://doi.org/10.31219/osf.io/e95bc
4. Parents Together March 2021 Survey

Acceptability: Comfort with adolescent receiving COVID-19 vaccine at each site

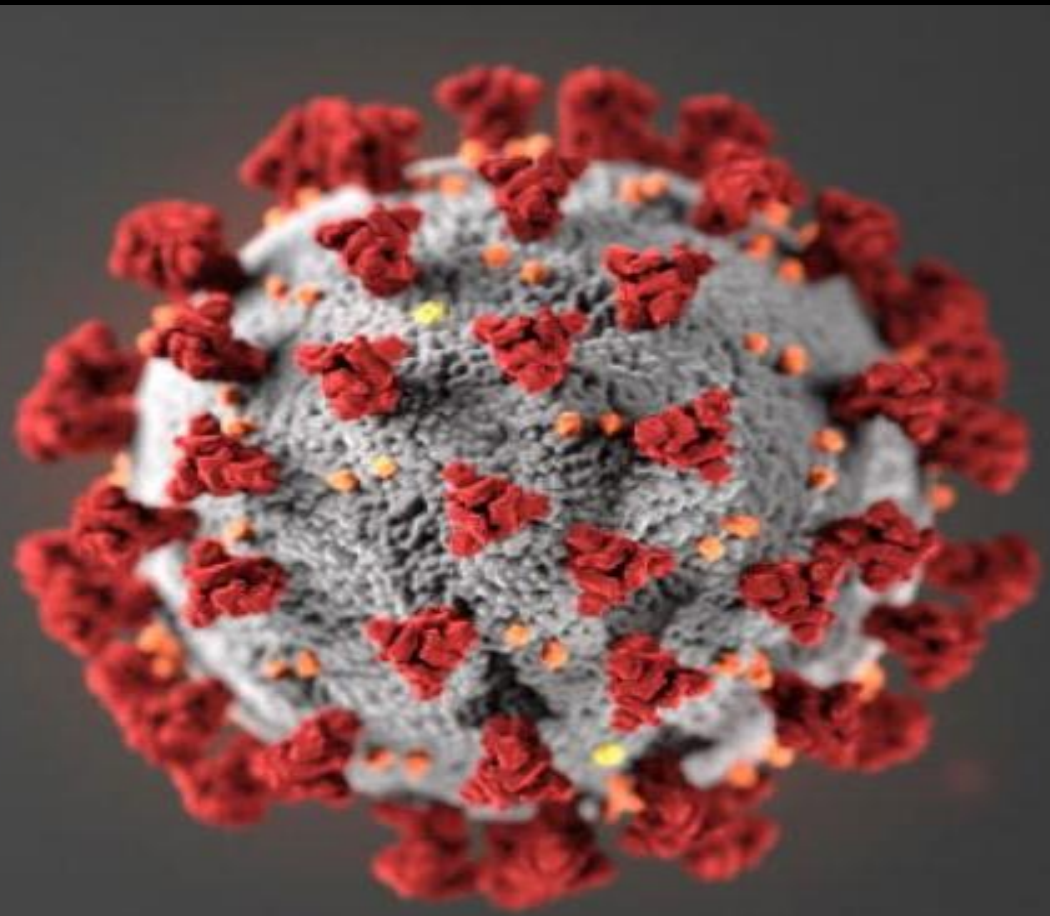


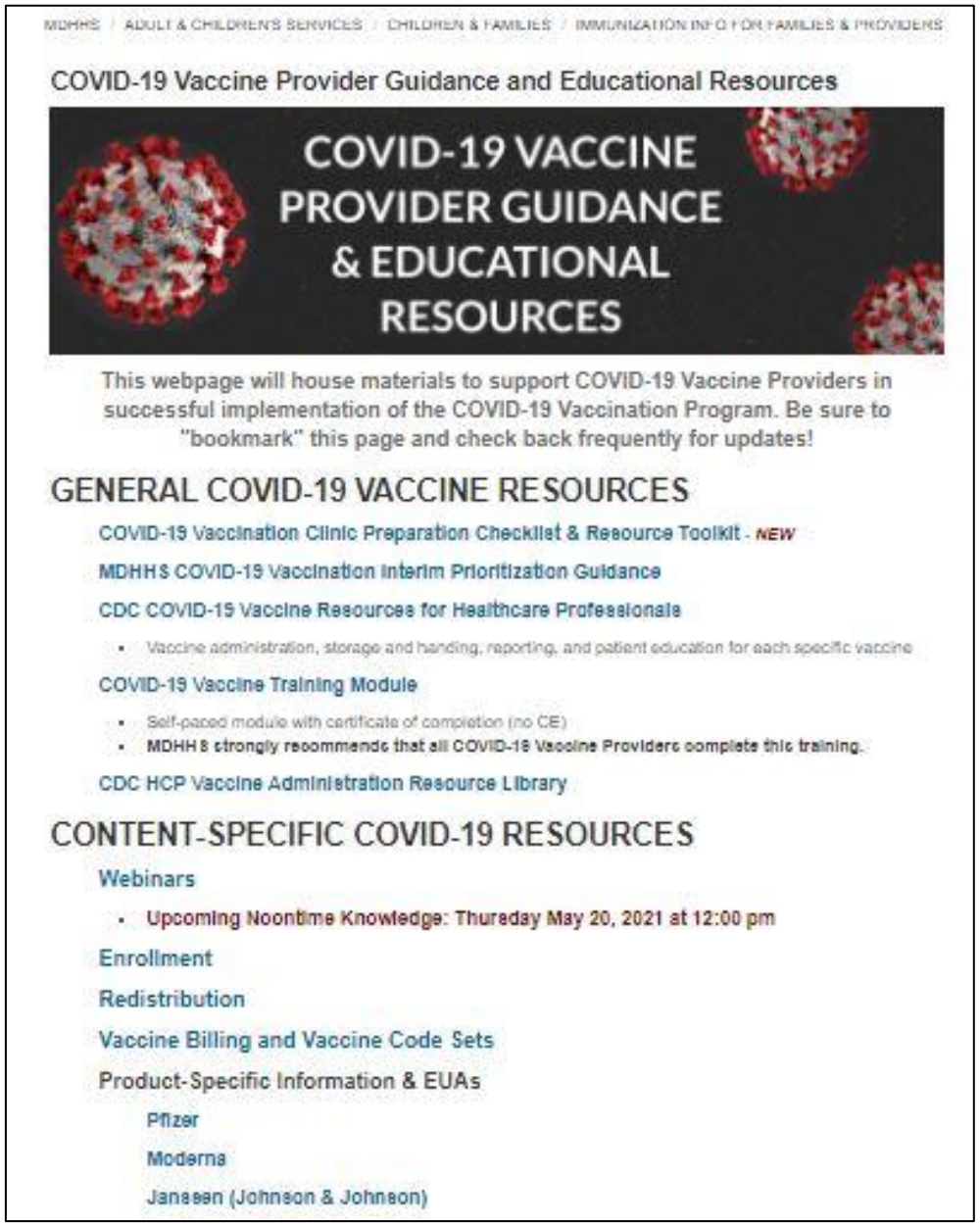
CDC/U Iowa Survey of Parents and Adolescents, April 2021

Making a Strong Recommendation to Get a COVID-19 Vaccine

- Make it clear to your patients that you recommend COVID-19 vaccination for them
- Tell your patients how important COVID-19 vaccines are to protect their health, as well as the health of their family and friends
- COVID-19 vaccines are new, and it's understandable that your patients may have questions. Your answers can help them make an informed decision about getting vaccinated
- Make it clear that you understand they may have questions, and you want to answer them, so they feel confident in choosing to get vaccinated
- If you are not currently offering COVID-19 vaccination, send them to www.vaccines.gov to find a location

Resources



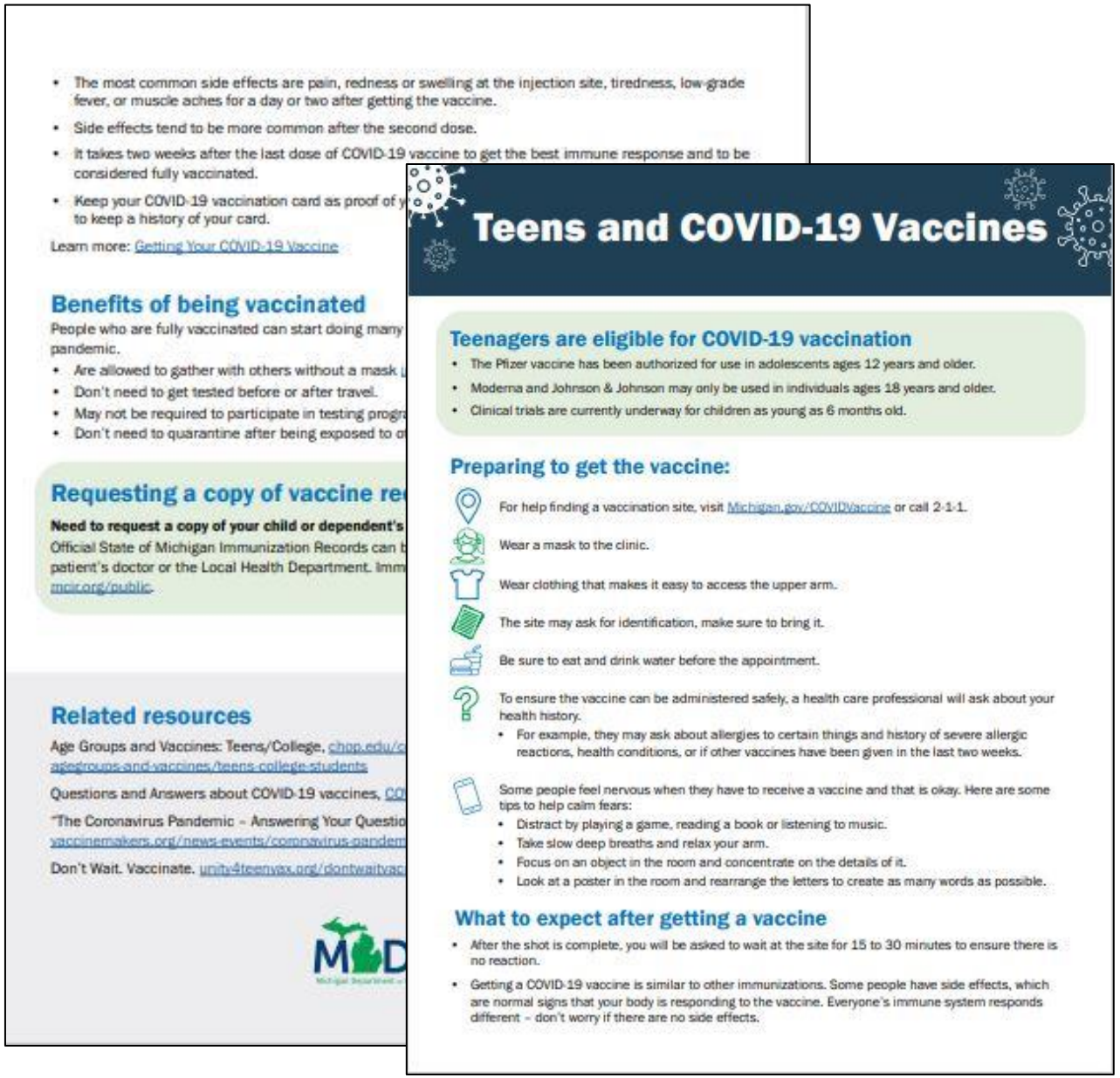


MDHHS COVID-19 Provider Guidance and Education Website

www.michigan.gov/covidvaccineprovider

MDHHS
“Teens and COVID-19 Vaccines”
Parent Handout

https://www.michigan.gov/documents/coronavirus/Teens_and_COVID-19_Vaccines_v6_725127_7.pdf



- The most common side effects are pain, redness or swelling at the injection site, tiredness, low-grade fever, or muscle aches for a day or two after getting the vaccine.
- Side effects tend to be more common after the second dose.
- It takes two weeks after the last dose of COVID-19 vaccine to get the best immune response and to be considered fully vaccinated.
- Keep your COVID-19 vaccination card as proof of y
to keep a history of your card.

Learn more: Getting Your COVID-19 Vaccine

Benefits of being vaccinated

People who are fully vaccinated can start doing many
pandemic.

- Are allowed to gather with others without a mask
- Don't need to get tested before or after travel.
- May not be required to participate in testing progr
- Don't need to quarantine after being exposed to o

Requesting a copy of vaccine re

Need to request a copy of your child or dependent's
Official State of Michigan Immunization Records can b
patient's doctor or the Local Health Department. Imm
mcir.org/public.

Related resources

Age Groups and Vaccines: Teens/College, chop.edu/c
agegroups-and-vaccines/teens-college-students

Questions and Answers about COVID-19 vaccines, CO

"The Coronavirus Pandemic – Answering Your Questio
vaccinemakers.org/news-events/coronavirus-pandem

Don't Wait. Vaccinate. unity4teenvax.org/dontwaitvac

Teens and COVID-19 Vaccines

Teenagers are eligible for COVID-19 vaccination

- The Pfizer vaccine has been authorized for use in adolescents ages 12 years and older.
- Moderna and Johnson & Johnson may only be used in individuals ages 18 years and older.
- Clinical trials are currently underway for children as young as 6 months old.

Preparing to get the vaccine:

For help finding a vaccination site, visit Michigan.gov/COVIDVaccine or call 2-1-1.

Wear a mask to the clinic.

Wear clothing that makes it easy to access the upper arm.

The site may ask for identification, make sure to bring it.

Be sure to eat and drink water before the appointment.

To ensure the vaccine can be administered safely, a health care professional will ask about your health history.

- For example, they may ask about allergies to certain things and history of severe allergic reactions, health conditions, or if other vaccines have been given in the last two weeks.

Some people feel nervous when they have to receive a vaccine and that is okay. Here are some tips to help calm fears:

- Distract by playing a game, reading a book or listening to music.
- Take slow deep breaths and relax your arm.
- Focus on an object in the room and concentrate on the details of it.
- Look at a poster in the room and rearrange the letters to create as many words as possible.

What to expect after getting a vaccine

- After the shot is complete, you will be asked to wait at the site for 15 to 30 minutes to ensure there is no reaction.
- Getting a COVID-19 vaccine is similar to other immunizations. Some people have side effects, which are normal signs that your body is responding to the vaccine. Everyone's immune system responds different – don't worry if there are no side effects.

ACCESS THE STATE'S VACCINE DATA | GET YOUR QUESTIONS ANSWERED | ATTEND AN UPCOMING TOWN HALL

RESOURCES

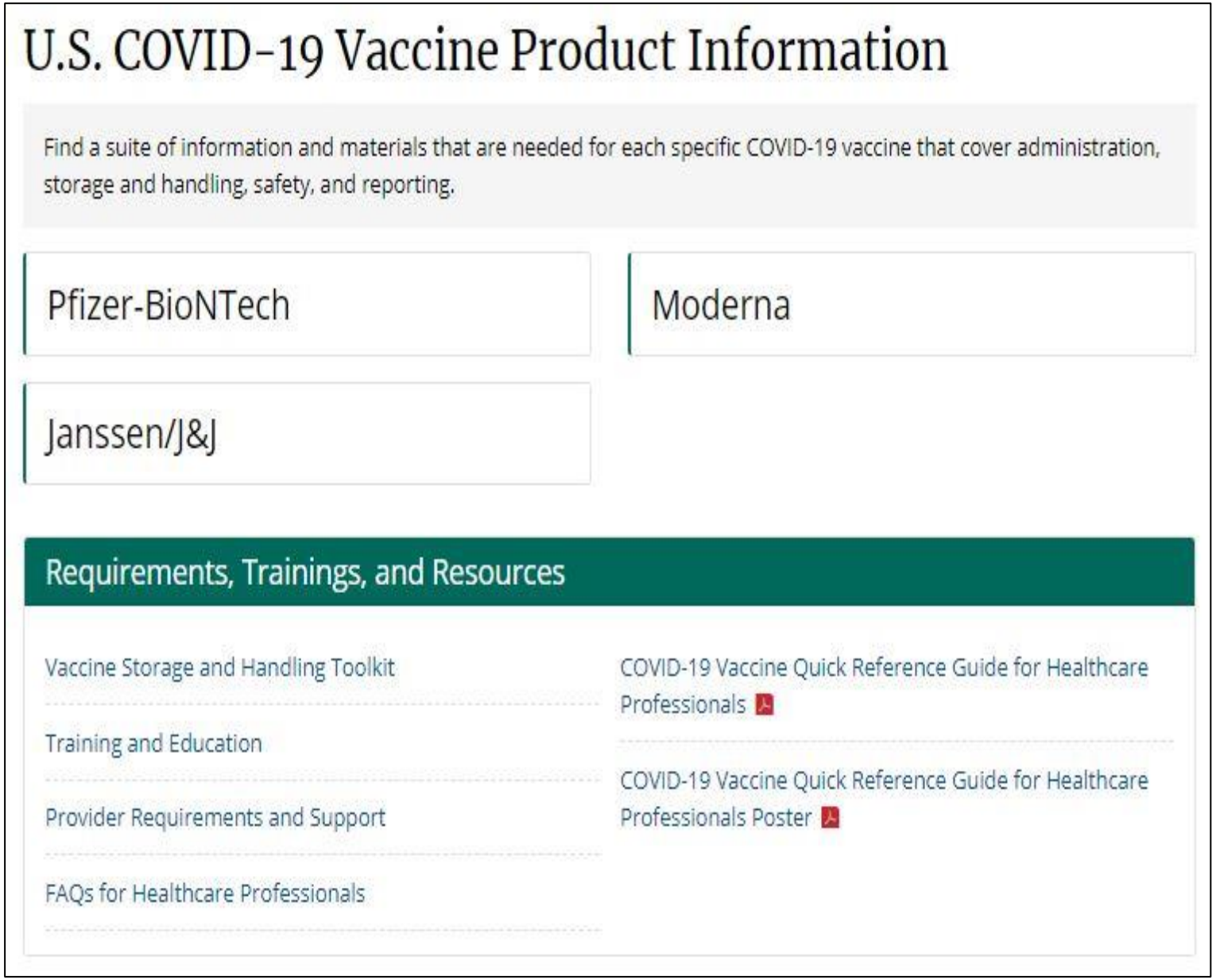
COVID-19 VACCINE QUESTIONS AND ANSWERS FOR PARENTS	TEENS AND COVID-19 VACCINES	LOCAL HEALTH DEPARTMENT VACCINE INFORMATION	COVID-19 VACCINES & FETAL CELLS
FOOD PROCESSING & AGRICULTURAL WORKERS	COMMUNITY OUTREACH PILOT PROGRAM	PROTECT MICHIGAN COMMISSION	INTERIM COVID-19 VACCINATION STRATEGY
SOCIAL VULNERABILITY AND COVID-19	VACCINE ALLOCATION PLANNING	VACCINE TESTIMONIALS	COVID-19 VACCINE COMMUNICATION MATERIALS

www.michigan.gov/covidvaccine

CDC Resources by Vaccine Product

Learn more with CDC's COVID-19 vaccine tools and resources. Find information for COVID-19 vaccination administration, storage, reporting, training and education

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

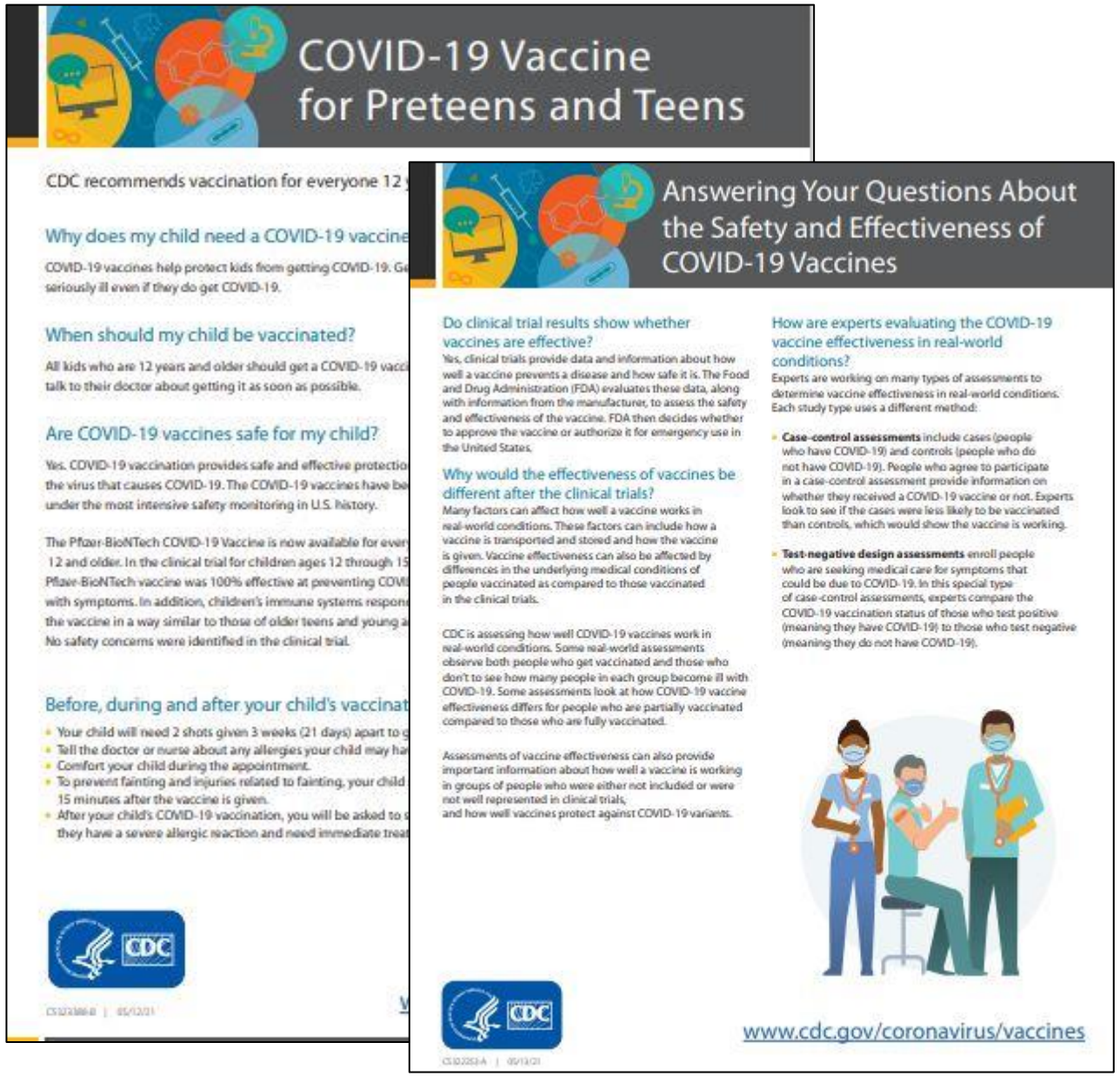


CDC Toolkit for Medical Centers, Clinics, and Clinicians

https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

Pediatric Healthcare Professionals COVID19 Vaccination Toolkit

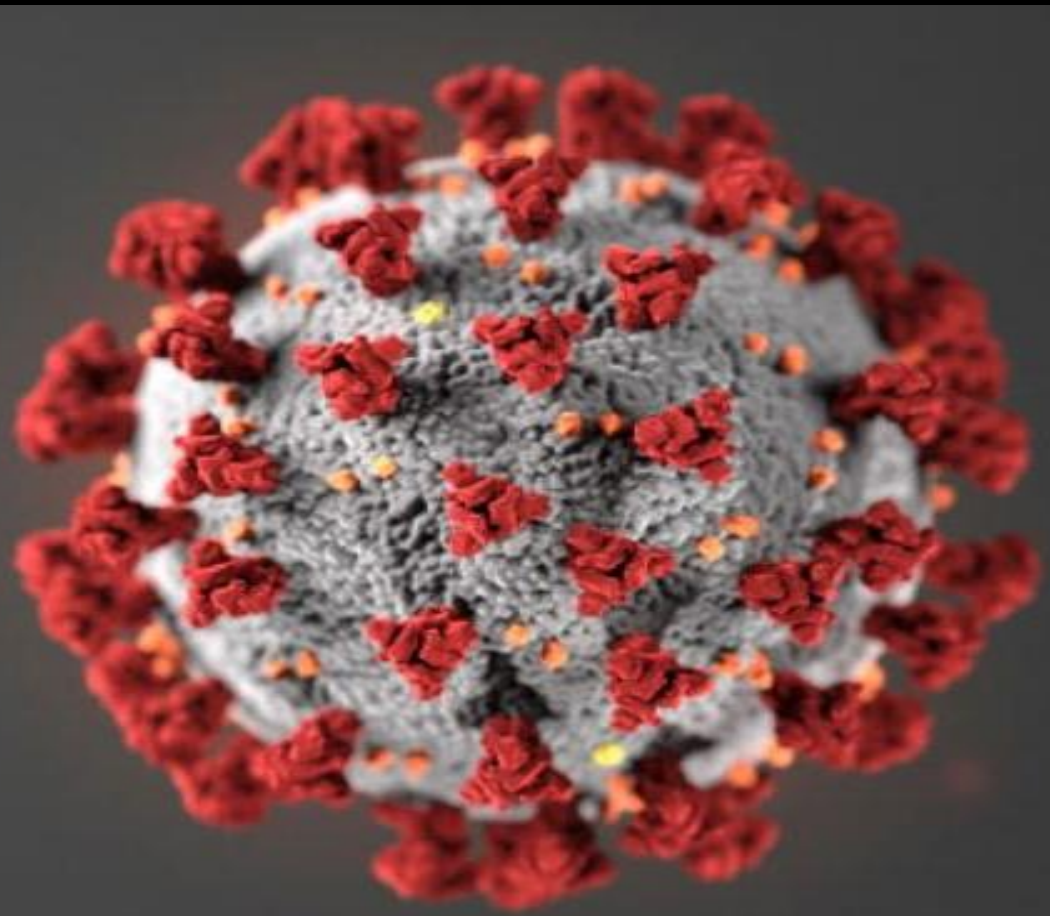
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/toolkits/pediatrician.html



Thank You!

Next “Noontime Knowledge” Update: June 3, 2021, at 12:00p.m. Topic: TBD

Please watch your email for an updated link and topic!



www.michigan.gov/COVIDvaccineprovider