MDHHS
Michigan Department of Health & Human Services

Janssen COVID-19 Vaccine (Johnson & Johnson) Update

March 3, 2021

Topics Covered

- Advisory Committee on Immunization Practices (ACIP) Recommendations and Approval Timeline
- Adenovirus Vaccine
- Vaccine Efficacy
- Contraindications and Precautions
- Recommendations for Use (Including Special Populations)
- Storage and Handling
- Administration
- Documentation
- Adverse Reaction Management and Reporting
- Resources

Approval Timeline & ACIP Recommendations

- Timeline:
  - Johnson & Johnson submitted for an Emergency Use Authorization (EUA) on February 4, 2021
  - Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended authorization to the U.S. Food and Drug Administration (FDA) on February 26, 2021
  - FDA issued an EUA for the Janssen COVID-19 vaccine on February 27, 2021
  - ACIP met on February 28, and March 1, 2021 to give recommendations for use
- ACIP recommends the Janssen COVID-19 vaccine for persons **18 years of age and older** under the FDA's EUA
- ACIP states no preference for any of the three authorized COVID-19 vaccines
- Results of the Janssen phase III clinical trials not comparable with mRNA vaccines
  - Different calendar time
  - Different geography

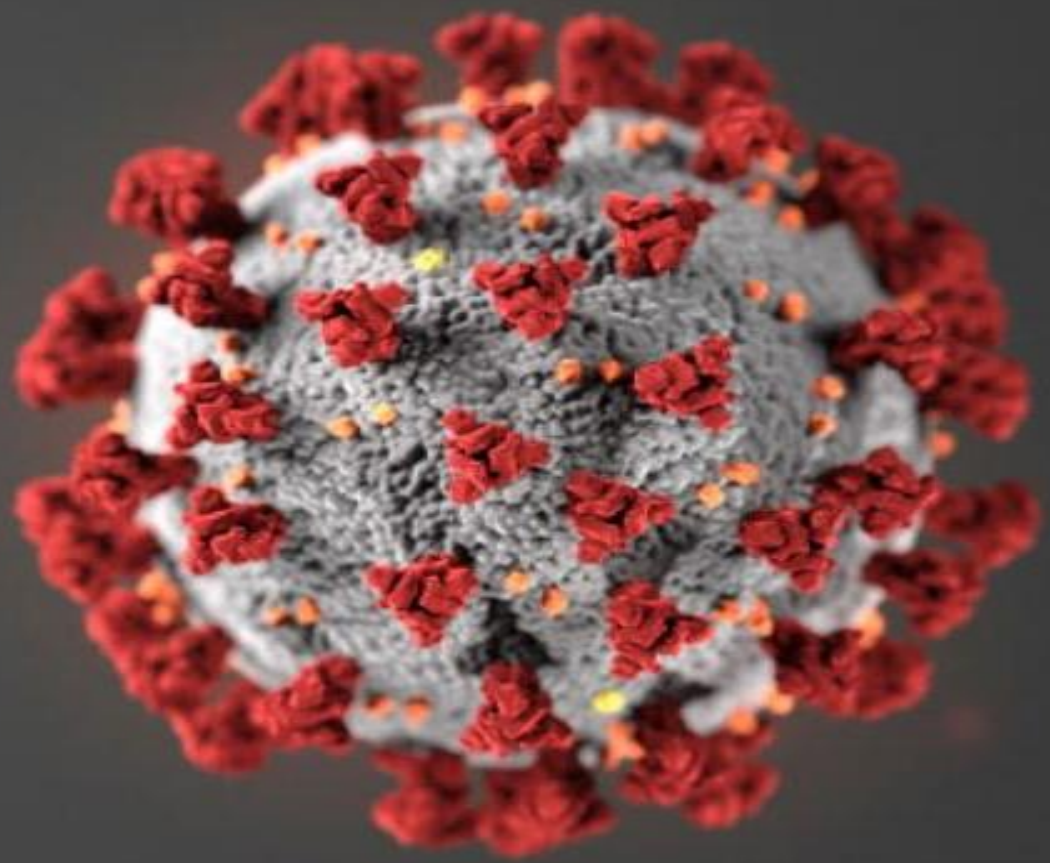
Explaining Viral Vector COVID-19 Vaccines

- Viral vector vaccines use a modified version of a **different virus as a vector** to deliver instructions, in the form of genetic material (a gene), to a cell
  - These **do not contain live virus** and cannot cause infection with either COVID-19 or the virus that is used as the vector
  - Like all vaccines, viral vector vaccines for COVID-19 have been **rigorously tested** for safety before being authorized for use in the United States
  - Vaccines of this type have been **well-studied in clinical trials**, and viral vector vaccines have been **used to respond to recent Ebola outbreaks**
  - The genetic material delivered by the viral vector **does not integrate into a person's DNA**

Janssen COVID-19 Vaccine Efficacy

- The clinical trial demonstrated an overall efficacy of **66.3%** against symptomatic, laboratory-confirmed COVID-19
- Efficacy estimates for severe outcomes **assessed ≥28 days** post vaccination were higher: **83.5%** for severe disease, **100%** for hospitalization
- Higher efficacy against severe outcomes than for any symptomatic COVID-19
  - VE against **deaths** due to COVID-19**: 100%**
- Efficacy against severe disease remained high across world regions (**73-82%**), suggesting protection against severe illness with variant strains
- Similar vaccine efficacy demonstrated by age, comorbidities, sex, race, and ethnicity

Janssen COVID-19 Vaccine (Johnson & Johnson)

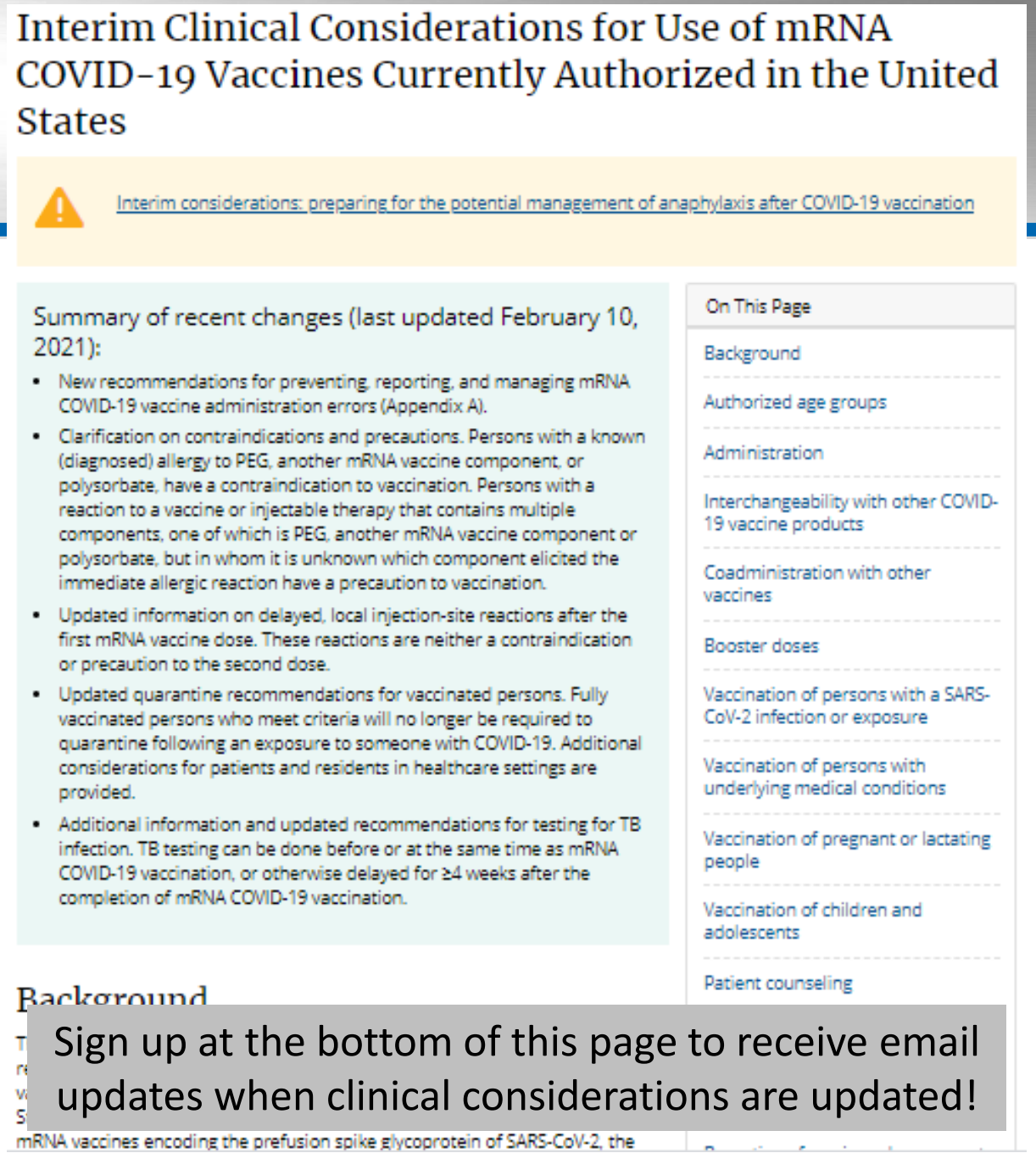


Janssen COVID-19 Vaccine

- We now have 3 COVID-19 vaccines to help in the fight against SARS-CoV-2
- Our focus for this presentation is for the Janssen COVID-19 vaccine but some clinical considerations are similar for all 3 of the COVID-19 vaccines
  - Differences come with vaccine platform, age indication, dosing schedule, and storage and handling

This website will be updated to include the Janssen COVID-19 vaccine

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



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

Interim considerations: preparing for the potential management of anaphylaxis after COVID-19 vaccination

Summary of recent changes (last updated February 10, 2021):

- New recommendations for preventing, reporting, and managing mRNA COVID-19 vaccine administration errors (Appendix A).
- Clarification on contraindications and precautions. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.
- Updated information on delayed, local injection-site reactions after the first mRNA vaccine dose. These reactions are neither a contraindication or precaution to the second dose.
- Updated quarantine recommendations for vaccinated persons. Fully vaccinated persons who meet criteria will no longer be required to quarantine following an exposure to someone with COVID-19. Additional considerations for patients and residents in healthcare settings are provided.
- Additional information and updated recommendations for testing for TB infection. TB testing can be done before or at the same time as mRNA COVID-19 vaccination, or otherwise delayed for ≥4 weeks after the completion of mRNA COVID-19 vaccination.

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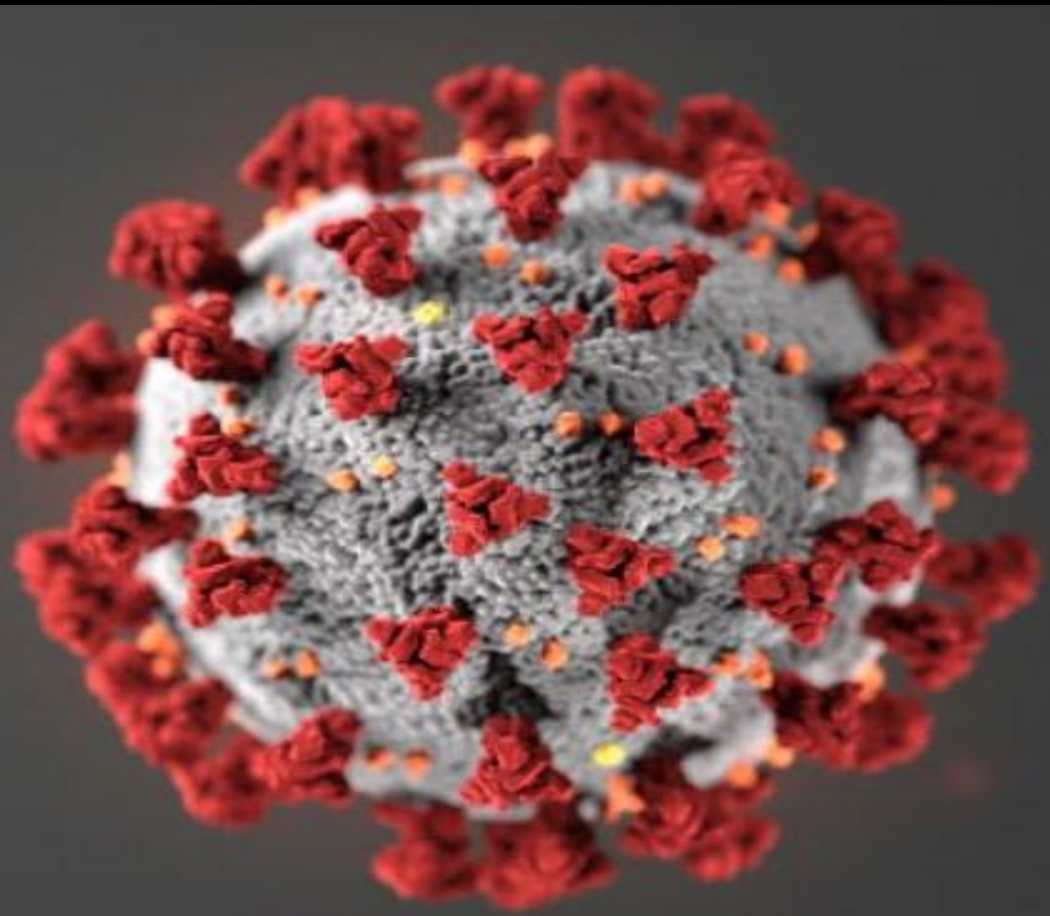
Background

mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the

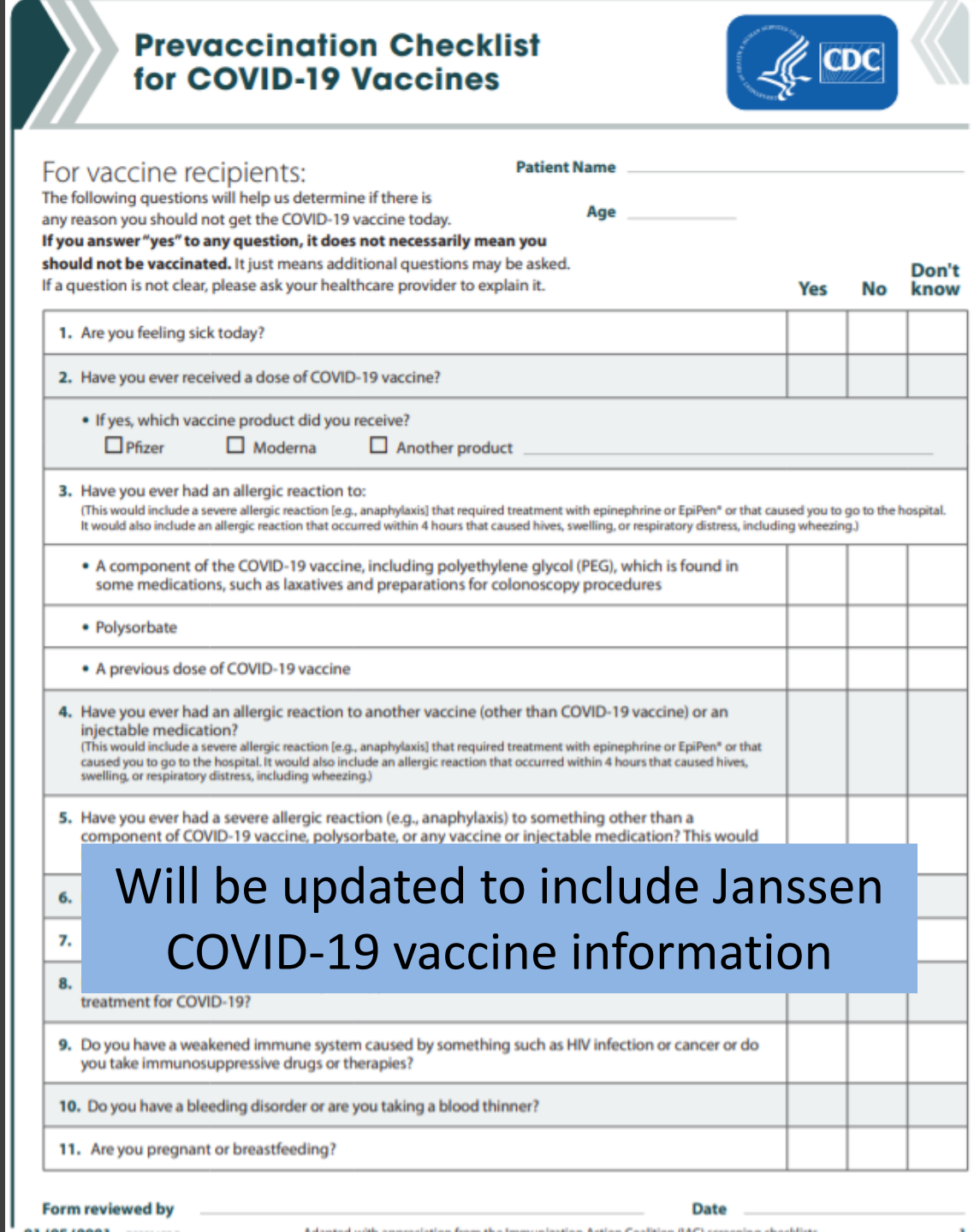
Sign up at the bottom of this page to receive email updates when clinical considerations are updated!

Contraindications and Precautions for Janssen COVID-19 Vaccine (Johnson & Johnson)



Tools to Identify Persons with Contraindications and Precautions

- Screen patients prior to receipt of each vaccine dose to identify if there is a contraindication or precaution
- CDC Prevaccination Questionnaire to assist with screening https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf
- Persons with a contraindication should not be vaccinated



Prevaccination Checklist for COVID-19 Vaccines

CDC

For vaccine recipients:

Patient Name _____

Age _____

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.

	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 ☐ Moderna ☐ Another product _____			
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 occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
• A component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures			
• Polysorbate			
• 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 occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would			
6.			
7.			
8. treatment for COVID-19?			
9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
10. Do you have a bleeding disorder or are you taking a blood thinner?			
11. Are you pregnant or breastfeeding?			

Will be updated to include Janssen COVID-19 vaccine information

Form reviewed by _____ Date _____

Precautions for COVID-19 Vaccines

- **Precautions:**
  - Any immediate allergic reaction (e.g., anaphylaxis) **to any other vaccine or injectable therapy** (e.g., intramuscular, intravenous, or subcutaneous [excluding subcutaneous immunotherapy for allergies, i.e., “allergy shots”])
    - Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, **but in whom it is unknown** which component elicited the immediate allergic reaction
    - Risk assessment should be conducted in persons who report history of severe allergic reaction (e.g., whether reaction required use of epinephrine [EpiPen®, etc.], resulted in hospitalization)
  - These persons may still receive vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination; consider a referral to an allergist-immunologist

Contraindications for COVID-19 Vaccines

- **Contraindications:**
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to any component of the vaccine (list of ingredients found in Appendix C of clinical considerations)
  - Immediate allergic reaction of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine
    - Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration
  - **The Provider Fact Sheet for Janssen:** https://www.janssenlabels.com/emergency-use-authorization/Janssen+COVID-19+Vaccine-HCP-fact-sheet.pdf

Allergies Not A Contraindication or Precaution to Vaccination

- Persons with the following allergies do not have a contraindication or precaution to vaccination:
  - History of food, pet, insect, venom, environmental, latex, or other allergies **not related** to vaccines or injectable therapies
  - History of allergy to oral medications (including the oral equivalent of an injectable medication)
  - Family history of allergies
  - Any other history of anaphylaxis that is not related to a vaccine or injectable therapy

Contraindications and precautions for COVID-19 vaccines

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
History of the following: • Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† • Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† Actions: • Do not vaccinate. • Consider referral to allergist-immunologist. • Consider other vaccine alternative.†	Among persons without a contraindication, a history of: • Any immediate allergic reaction* to other vaccines or injectable therapies‡ Actions: • Risk assessment • Consider referral to allergist-immunologist • 30-minute observation period if vaccinated	Among persons without a contraindication o precaution, a history of: • Allergy to oral medications (including th equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies • Family history of allergies Actions: • 30-minute observation period: persons history of anaphylaxis (due to any cause • 15-minute observation period: all other persons

† See Appendix C for a list of ingredients. Persons with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* Immediate allergic reaction to a vaccine or medication is defined as any hypersensitivity-related signs or symptoms consistent with urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis tha within four hours following administration.

‡Includes persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is a vaccine component, but in whom it is unknown which component elicited the immediate allergic

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensi between these compounds may occur. Persons with a contraindication to mRNA COVID-19 vaccines (including due to a known [diagnosed] allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among persons received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 Persons with a contraindication to Janssen COVID-19 vaccine (including due to a known [diagnosed] allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination

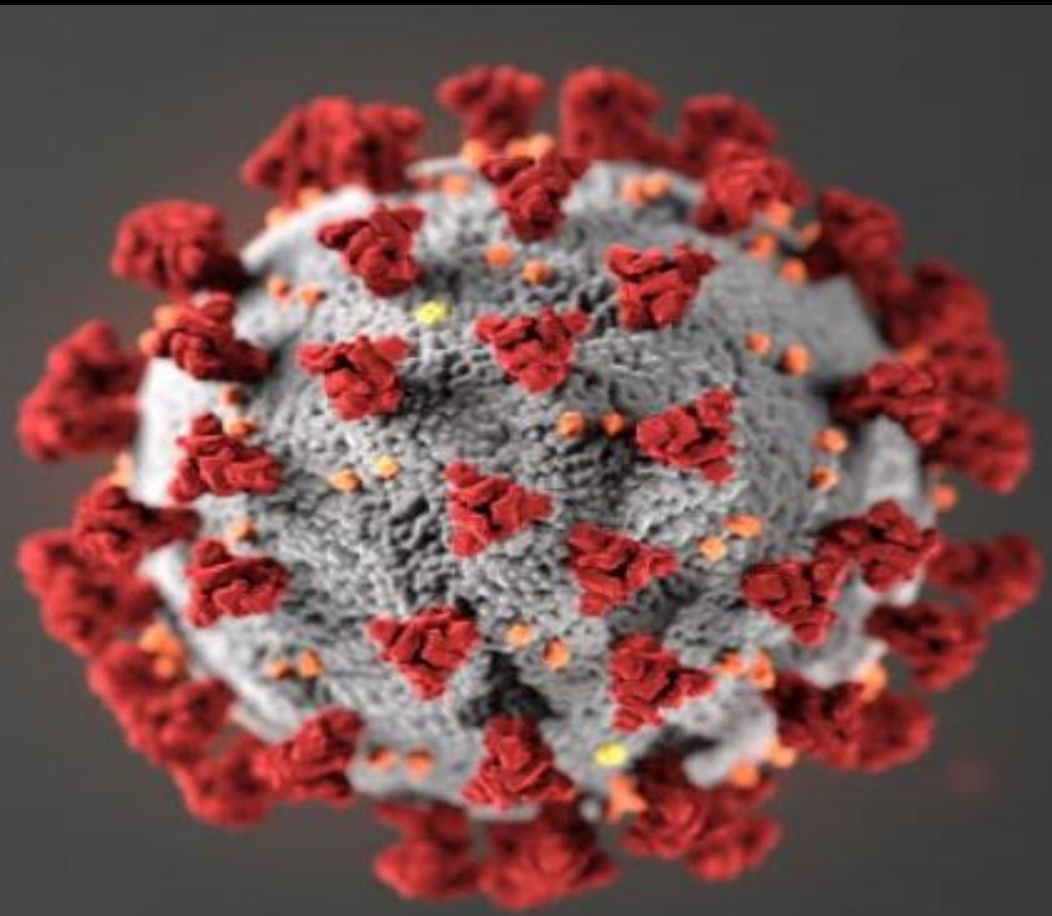
Chart available at: https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Observation Periods After COVID-19 Vaccine

CDC currently recommends that persons without contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods

- **30 minutes:**
  - Persons with a history of an immediate allergic reaction of any severity to another (non-mRNA COVID-19) vaccine or injectable therapy
  - Persons with a history of anaphylaxis due to any cause
- **15 minutes:** All other persons

Recommendations for Use of Janssen COVID-19 Vaccine (Johnson & Johnson) in Special Populations



Persons with **Prior** SARS-CoV-2 Infection

- Vaccination **should be offered** to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
  - Data from clinical trials indicate vaccination safe in these persons
- Viral or serologic testing for acute or prior infection, respectively, **is not recommended** for the purpose of vaccine decision-making

Persons With Known **Current** SARS-CoV-2 Infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) **and** criteria have been met to discontinue isolation
- No minimal interval between infection and vaccination
- However, **current evidence** suggests reinfection is uncommon in the months after initial infection
  - Thus, persons with documented acute infection may choose to temporarily delay vaccination until the end of this period, **if desired**
  - Risk of reinfection, and need for vaccination, might increase with time following initial infection

Persons who **Previously Received** Passive Antibody Therapy for COVID-19

- Currently no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
- Vaccination **should be deferred for at least 90 days** to avoid interference of the treatment with vaccine-induced immune responses
  - Based on estimated half-life of therapies and evidence suggesting reinfection is uncommon within 90 days of initial infection
- Recommendation does not apply to persons receiving antibody therapies not specific to COVID-19 treatment

Persons with Underlying Medical Conditions

- Any currently authorized COVID-19 vaccine can be administered to persons with underlying medical conditions who have no contraindications to vaccination, including
  - Immunocompromised persons
  - People with autoimmune conditions
  - People with history of Guillain-Barré syndrome, Bell's palsy, dermal filler use
- Clinical trials demonstrate similar safety and efficacy profiles in persons with underlying medical conditions, including those that place them at increased risk for severe COVID-19, compared to persons without comorbidities

Immunocompromised Persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19 infection
- Immunocompromised persons **may receive COVID-19 vaccine unless otherwise contraindicated**
  - All currently authorized vaccines are inactivated vaccines
- Individuals **should be counseled** about:
  - Unknown vaccine safety and efficacy profiles in immunocompromised persons
  - Potential for reduced immune responses
  - Need to continue to follow all current guidance to protect themselves against COVID-19

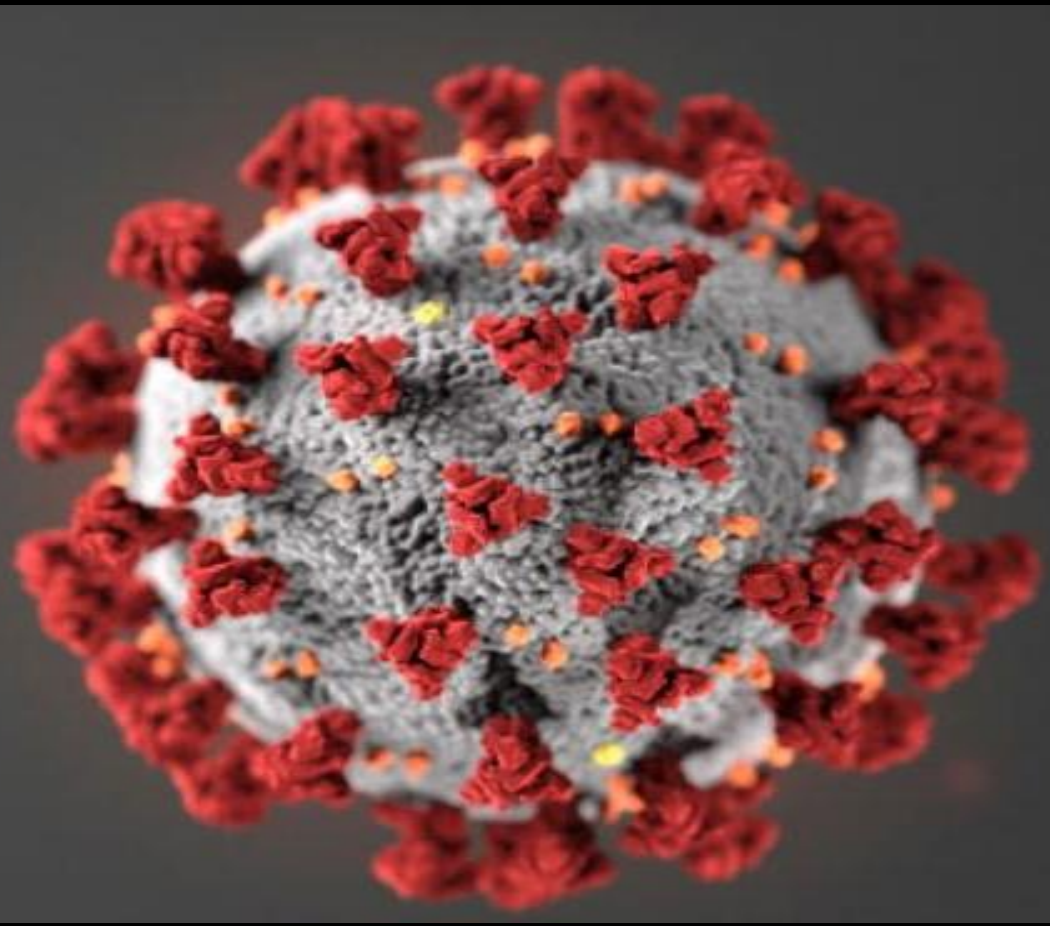
Pregnant Women

- COVID-19 and Pregnancy
  - Increased risk of severe illness (ICU admission, mechanical ventilation, and death)
  - Might be at an increased risk of adverse pregnancy outcomes
- Currently limited data on safety of COVID-19 vaccines in pregnant people
  - No concerns demonstrated in animal developmental and reproductive toxicity (DART) studies
  - Janssen adenovirus vector platform previously used for other clinical development programs that included pregnant people, including a large-scale Ebola vaccine trial
- Currently authorized COVID-19 vaccines are all inactivated vaccines
- Clinical trials to evaluate safety and efficacy of COVID-19 vaccines in pregnant people planned or underway

Pregnant Women Continued

- Pregnant people may choose to receive COVID-19 vaccine when eligible
  - A conversation between the patient and their clinical team may assist with decision, but is not required
  - Conversation should consider:
    - Level of COVID-19 community transmission
    - Personal risk of contracting COVID-19
    - Risks of COVID-19 to patient and fetus
    - Efficacy and side effects of vaccine
    - Limited data about vaccine during pregnancy

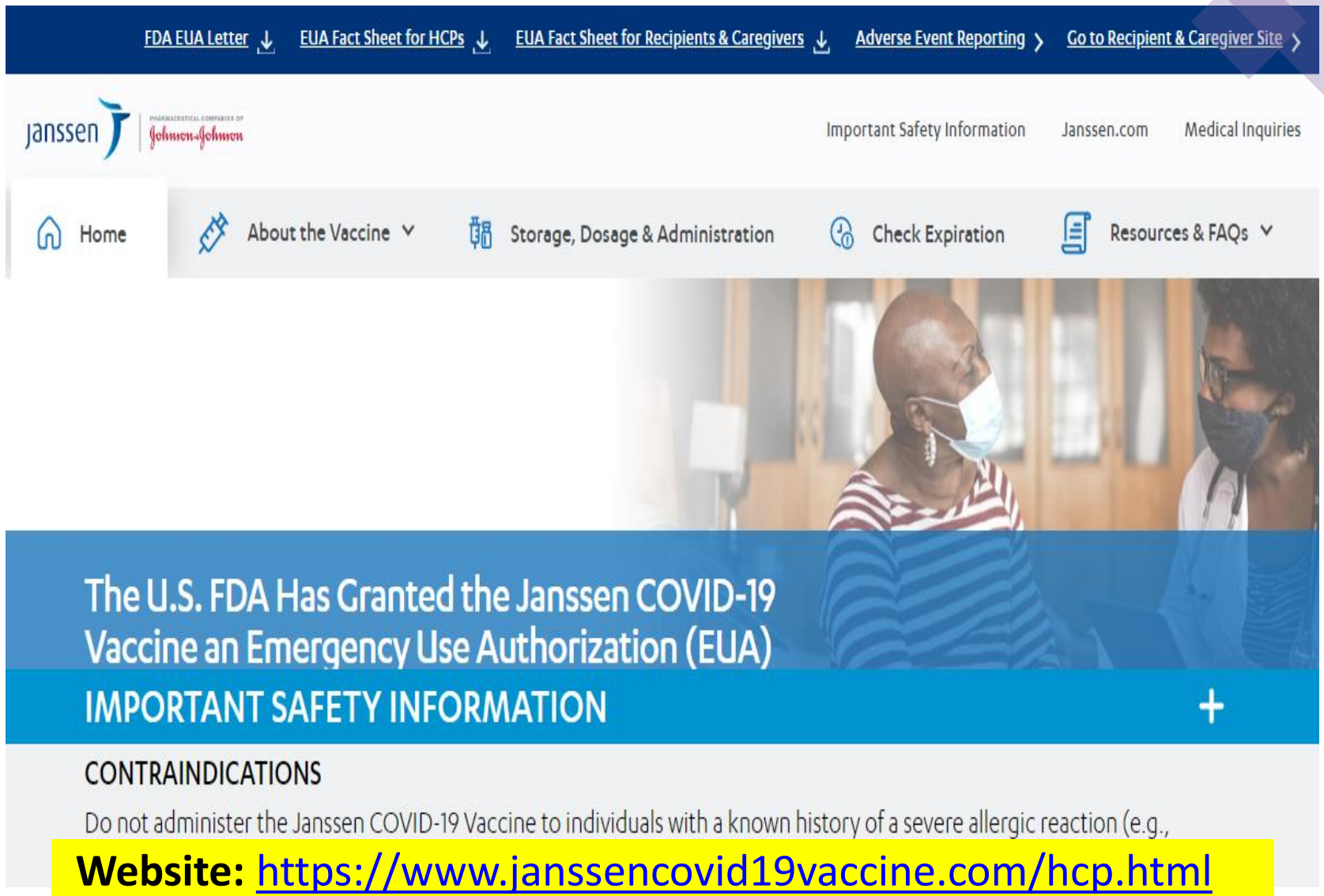
Storage and Handling for Janssen COVID-19 Vaccine (Johnson & Johnson)



NEW INFORMATION: https://www.janssencovid19vaccine.com/hcp.html
CDC site: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

Janssen COVID-19 Vaccine Website

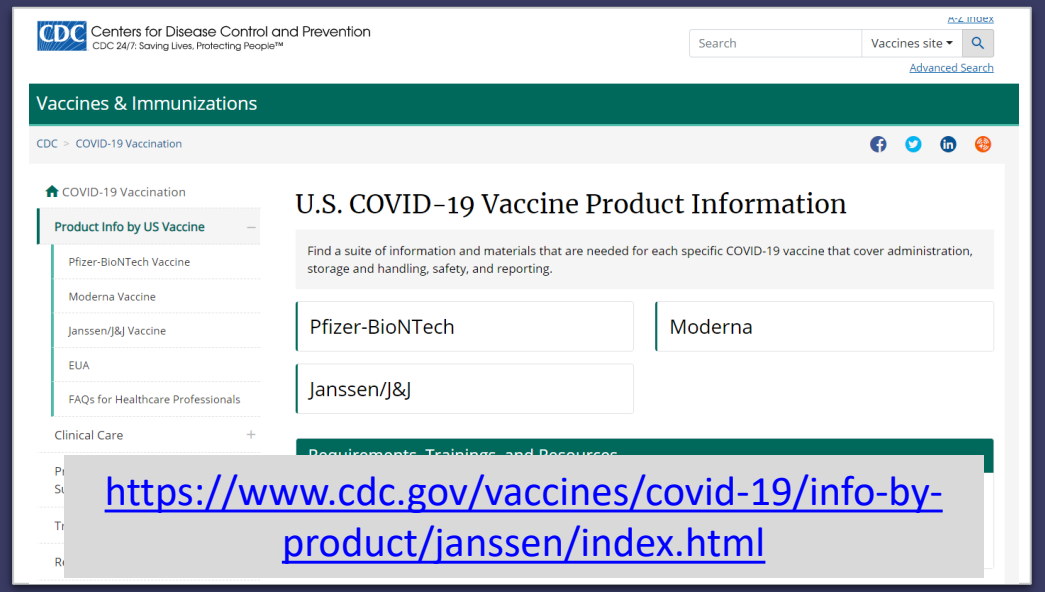
- **NEW—Website from Janssen COVID-19 Vaccine:
  - Important Safety Information
  - EUA
  - Storage and Administration
  - Adverse Reactions
  - Reporting Adverse Events and Vaccine Administration Errors



Website: https://www.janssencovid19vaccine.com/hcp.html

CDC's Janssen COVID-19 Vaccine Website

- Updated late last night
- Top image and link is the main COVID-19 Vaccine webpage at CDC
- Bottom image is the NEW Janssen COVID-19 vaccine webpage at CDC
  - Material will continue to be posted on this webpage as it is made available
    - Storage and handling
    - Vaccine prep and admin
    - Standing orders
    - And more



Janssen COVID-19 Vaccine Basics

- Each carton contains 10 multidose vials
- Each multidose vial contains **five** doses
- Minimum order size and increment for Janssen COVID-19 vaccine is 100 doses
  - 2 cartons of 10 multidose vials, 5 doses per vial per order
- Store in a refrigerator between 2°C and 8°C (36°F and 46°F)
  - **Do NOT freeze**
- Each dose is 0.5 mL

Receiving Vaccine

- Vaccine deliveries should only be scheduled at times when staff is guaranteed to be present
- Upon arrival, shipments of vaccine should be immediately examined for signs of damage and stored properly
- Unpack shipment following manufacturer's direction
  - Check the TagAlert
- Review Janssen COVID-19 Vaccine Storage and Handling Summary

Janssen COVID-19 Vaccine (Johnson & Johnson)

Storage and Handling Summary

Basics

- Store vaccine in a refrigerator. See guidance below for further details.
- Each carton contains 10 multidose vials (50 doses).
  - A carton is approximately 3.7 in x 3.7 in x 2.1 in.
  - Each multidose vial contains 5 doses.
- Check and record storage unit temperatures each workday. See guidance below for each type of temperature monitoring device. Save storage records for 3 years, unless your jurisdiction requires a longer time period.

Deliveries

Vaccine

1. The vaccine will arrive refrigerated between 2°C and 8°C (36°F and 46°F).
2. Examine the shipment for signs of damage.
3. Open the box and remove the TagAlert Temperature Monitor (placed in the inner box next to vaccine).
4. Check the TagAlert temperature monitoring device by pressing the blue "start and stop" button.
   - Left arrow points to a **green check mark**: The vaccine is ready to use. Store the vaccine at proper temperatures immediately.
   - Right arrow points to a **red X**: The numbers 1 and/or 2 will appear in the display. Store the vaccine at proper temperatures and label **"DO NOT USE!"**. Call the phone number indicated in the instructions or your jurisdiction's immunization program **IMMEDIATELY!**
5. The expiration date is NOT printed on the vaccine vial or carton. To determine the expiration date:
   - Scan the QR code on the outer carton, or
   - Call 1-800-565-4008, or
   - Visit www.vaxcheck.jnj.

   Write the expiration date on the carton.

Ancillary Supply Kit

- An ancillary supply kit will be provided and includes enough supplies to administer 100 doses of vaccine.
- Administration supplies include needles, syringes, sterile alcohol prep pads, vaccination record cards (shot cards), and some PPE.
- The kit is delivered separately from the vaccine. Unpack the kit and check for receipt of the correct administration supplies and quantities.

https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-summary.pdf

Arrival of Janssen COVID-19 Vaccine

- Initially stored frozen by the manufacturer
- Shipped at refrigerated temperature between 2°C and 8°C (36°F and 46°F)
- If frozen upon receipt thaw between 2°C and 8°C (36°F and 46°F)
- If needed immediately thaw at room temperature
  - Room Temperature: (maximally 25°C/77°F)
  - Thaw times:
    - Carton of 10 vials will take approximately 2 hours to thaw
    - Individual vial will take approximately 1 hour to thaw

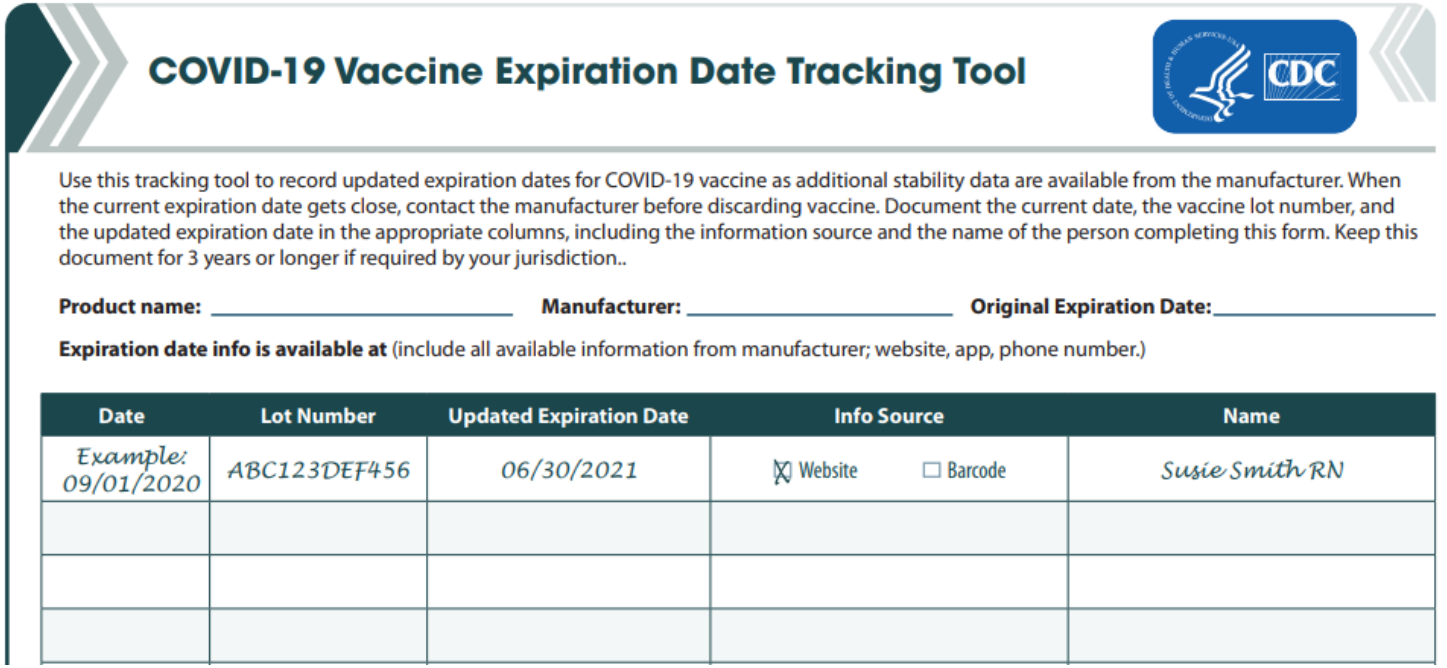
Do not refreeze once thawed

Unpunctured Multi-dose Vials of Janssen COVID-19 Vaccine

- Storage prior to first puncture:
  - Unpunctured multi-dose vials of the Janssen COVID-19 Vaccine should be stored between 2°C and 8°C (36°F and 46°F)
    - Until the expiration date
  - Unpunctured vials of Janssen COVID-19 Vaccine may be stored at room temperatures between 9°C and 25°C (47°F and 77°F) for up to 12 hours
- Protect Janssen COVID-19 vaccine from light
- **Do not store frozen**

Janssen COVID-19 Vaccine MDV Determine the Expiration Date

- The expiration date is NOT printed on the vaccine vial or carton
- To determine expiration date:
  - Scan the QR code on the outer carton, or
  - Call 1-800-565-4008, or
  - Visit www.vaxcheck.jnj
- As the expiration date approaches, check the expiration date again
  - Repeat above steps



COVID-19 Vaccine Expiration Date Tracking Tool

Use this tracking tool to record updated expiration dates for COVID-19 vaccine as additional stability data are available from the manufacturer. When the current expiration date gets close, contact the manufacturer before discarding vaccine. Document the current date, the vaccine lot number, and the updated expiration date in the appropriate columns, including the information source and the name of the person completing this form. Keep this document for 3 years or longer if required by your jurisdiction..

Product name: _____ **Manufacturer:** _____ **Original Expiration Date:** _____

Expiration date info is available at (include all available information from manufacturer; website, app, phone number.)

Date	Lot Number	Updated Expiration Date	Info Source	Name
Example: 09/01/2020	ABC123DEF456	06/30/2021	☒ Website ☐ Barcode	Susie Smith RN

CDC COVID-19 Vaccine Expiration Date Tracking Tool

Punctured Multi-dose Vials of Janssen COVID-19 Vaccine

- Storage after first dose has been withdrawn:
  - Hold the vial between 2° and 8°C (36° and 46°F) for up to 6 hours

    OR
  - May also be stored at room temperature (maximally 25°C/77°F) for up to 2 hours
  - Note the date and time the vial was punctured
  - Discard the vial if vaccine is not used within these times

Question and Answer

Q: After first puncturing the vial, can the vaccine be held at room temperature for 2 hours, then in the refrigerator for an additional 6 hours, for a total of 8 hours?

A: NO

- After the vial is first punctured, the vaccine vial may be held:
  - For up to 2 hours at room temperature; discard any vaccine not used within 2 hours
    ——OR——
  - For up to 6 hours refrigerated between 2°C and 8°C; discard any vaccine not used within 6 hours
  - Do not add these time limits together

~If you **do not reach the 2-hour time limit at room temperature**, you may transfer the punctured vial to a refrigerated storage unit between 2°C and 8°C for the remaining time, up to 6 hours.~

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

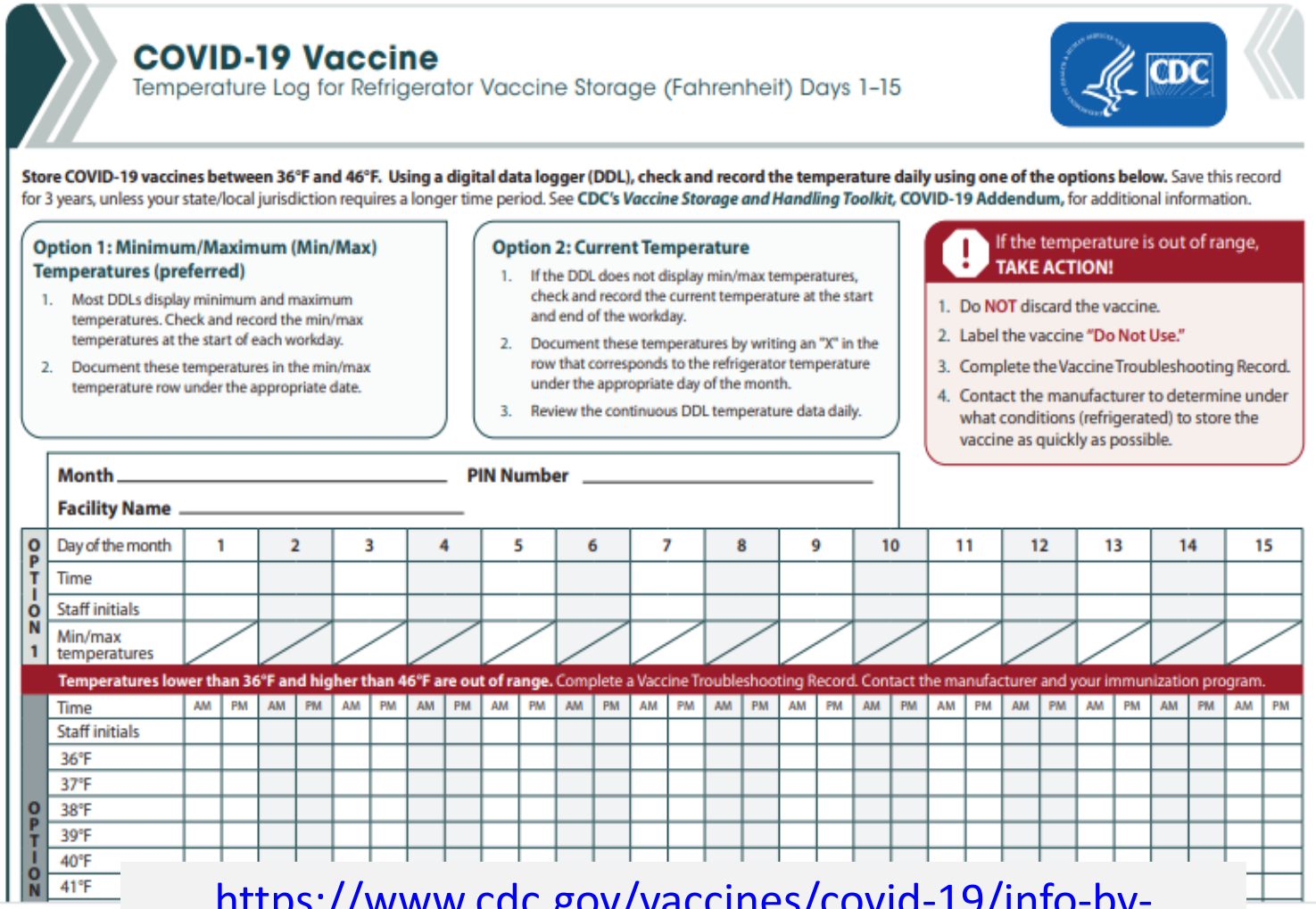
Overview of Janssen COVID-19 Vaccine (Johnson & Johnson)

Doses Per Shipment	100 doses minimum
Storage Temperature	Store at refrigerated temperatures between 2°C and 8°C (36°F and 46°F) until the expiration date before vials are punctured
If Arrive Frozen By Manufacturer—Thaw Time	If frozen upon receipt thaw at refrigerated temperatures If need immediately, thaw at room temperature (max 25°C/77°F)
Unpunctured Vials	Unpunctured vials should be stored at refrigerated temperatures until the expiration date Unpunctured vials may be stored at room temperatures between 9°C and 25°C (47°F and 77°F) for up to 12 hours
Punctured Vials	After the first dose has been withdrawn, vial should be held between 2°C and 8°C (36°F and 46°F) for up to 6 hours OR at room temperature (max 25°C/77°F) for up to 2 hours Discard the vial if not used within these times
Refreeze Vaccine?	**NO**

For further information on Janssen COVID-19 vaccine storage and handling requirements go to:
https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/index.html

Daily Temperature Monitoring

- Temperatures must always be monitored to ensure viability
- Use a digital data logger (DDL) for continuous monitoring (24/7) and record storage temperatures
- Document temperatures on temperature log at least twice daily (AM and PM) and min/max temperature
  - Must include temperature, name/initials of person documenting, and excursions if noted



COVID-19 Vaccine
Temperature Log for Refrigerator Vaccine Storage (Fahrenheit) Days 1–15

Store COVID-19 vaccines between 36°F and 46°F. Using a digital data logger (DDL), check and record the temperature daily using one of the options below. Save this record for 3 years, unless your state/local jurisdiction requires a longer time period. See **CDC's *Vaccine Storage and Handling Toolkit*, COVID-19 Addendum,** for additional information.

Option 1: Minimum/Maximum (Min/Max) Temperatures (preferred)
1. Most DDLs display minimum and maximum temperatures. Check and record the min/max temperatures at the start of each workday.
2. Document these temperatures in the min/max temperature row under the appropriate date.

Option 2: Current Temperature
1. If the DDL does not display min/max temperatures, check and record the current temperature at the start and end of the workday.
2. Document these temperatures by writing an "X" in the row that corresponds to the refrigerator temperature under the appropriate day of the month.
3. Review the continuous DDL temperature data daily.

If the temperature is out of range, TAKE ACTION!
1. Do NOT discard the vaccine.
2. Label the vaccine "Do Not Use."
3. Complete the Vaccine Troubleshooting Record.
4. Contact the manufacturer to determine under what conditions (refrigerated) to store the vaccine as quickly as possible.

Month _____ **PIN Number** _____
Facility Name _____

OPTION 1	Day of the month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	Time															
	Staff initials															
	Min/max temperatures															

Temperatures lower than 36°F and higher than 46°F are out of range. Complete a Vaccine Troubleshooting Record. Contact the manufacturer and your immunization program.

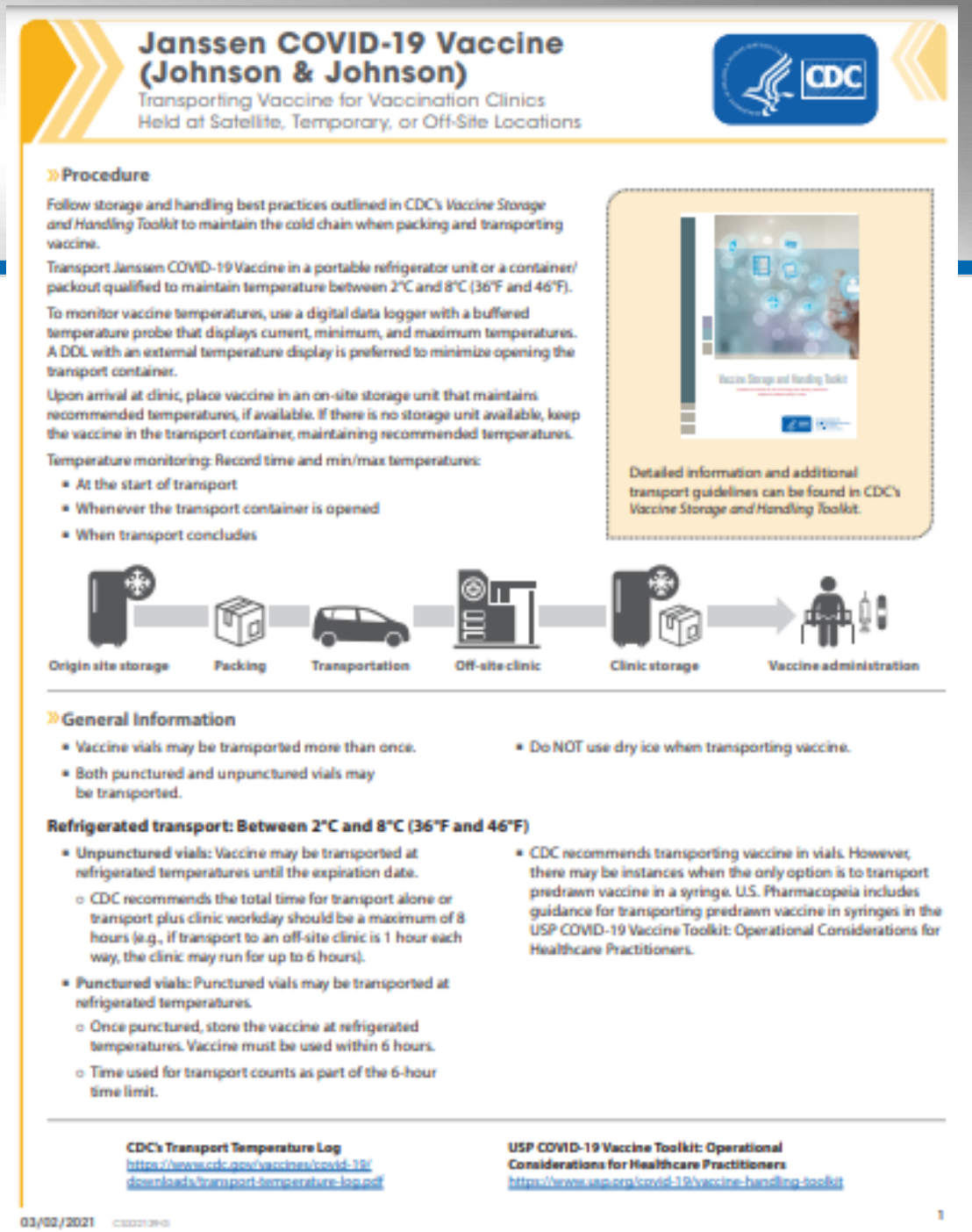
OPTION	Time	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM	AM	PM
	Staff initials																														
	36°F																														
	37°F																														
	38°F																														
	39°F																														
	40°F																														
	41°F																														

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

Other Janssen COVID-19 Vaccine Tools

- Clinical Considerations—Updated soon
- Vaccine Prep and Admin—Arriving Soon
- Standing orders—Arriving Soon
- Storage and Handling Summary (NEW)
- Storage and Handling labels (NEW)
- Temperature logs (NEW)
- Transportation guidance (NEW)

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



Janssen COVID-19 Vaccine (Johnson & Johnson)

Transporting Vaccine for Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations

CDC

Procedure

Follow storage and handling best practices outlined in CDC's *Vaccine Storage and Handling Toolkit* to maintain the cold chain when packing and transporting vaccine.

Transport Janssen COVID-19 Vaccine in a portable refrigerator unit or a container/packout qualified to maintain temperature between 2°C and 8°C (36°F and 46°F).

To monitor vaccine temperatures, use a digital data logger with a buffered temperature probe that displays current, minimum, and maximum temperatures. A DDL with an external temperature display is preferred to minimize opening the transport container.

Upon arrival at clinic, place vaccine in an on-site storage unit that maintains recommended temperatures, if available. If there is no storage unit available, keep the vaccine in the transport container, maintaining recommended temperatures.

Temperature monitoring: Record time and min/max temperatures:

- At the start of transport
- Whenever the transport container is opened
- When transport concludes

Detailed information and additional transport guidelines can be found in CDC's *Vaccine Storage and Handling Toolkit*.

General Information

- Vaccine vials may be transported more than once.
- Both punctured and unpunctured vials may be transported.
- Do NOT use dry ice when transporting vaccine.

Refrigerated transport: Between 2°C and 8°C (36°F and 46°F)

- **Unpunctured vials:** Vaccine may be transported at refrigerated temperatures until the expiration date.
  - CDC recommends the total time for transport alone or transport plus clinic workday should be a maximum of 8 hours (e.g., if transport to an off-site clinic is 1 hour each way, the clinic may run for up to 6 hours).
- **Punctured vials:** Punctured vials may be transported at refrigerated temperatures.
  - Once punctured, store the vaccine at refrigerated temperatures. Vaccine must be used within 6 hours.
  - Time used for transport counts as part of the 6-hour time limit.
- CDC recommends transporting vaccine in vials. However, there may be instances when the only option is to transport predrawn vaccine in a syringe. U.S. Pharmacopeia includes guidance for transporting predrawn vaccine in syringes in the USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners.

CDC's Transport Temperature Log
https://www.cdc.gov/vaccines/covid-19/downloads/transport-temperature-log.pdf

USP COVID-19 Vaccine Toolkit: Operational Considerations for Healthcare Practitioners
https://www.usp.org/covid-19/vaccine-handling-toolkit

03/02/2021

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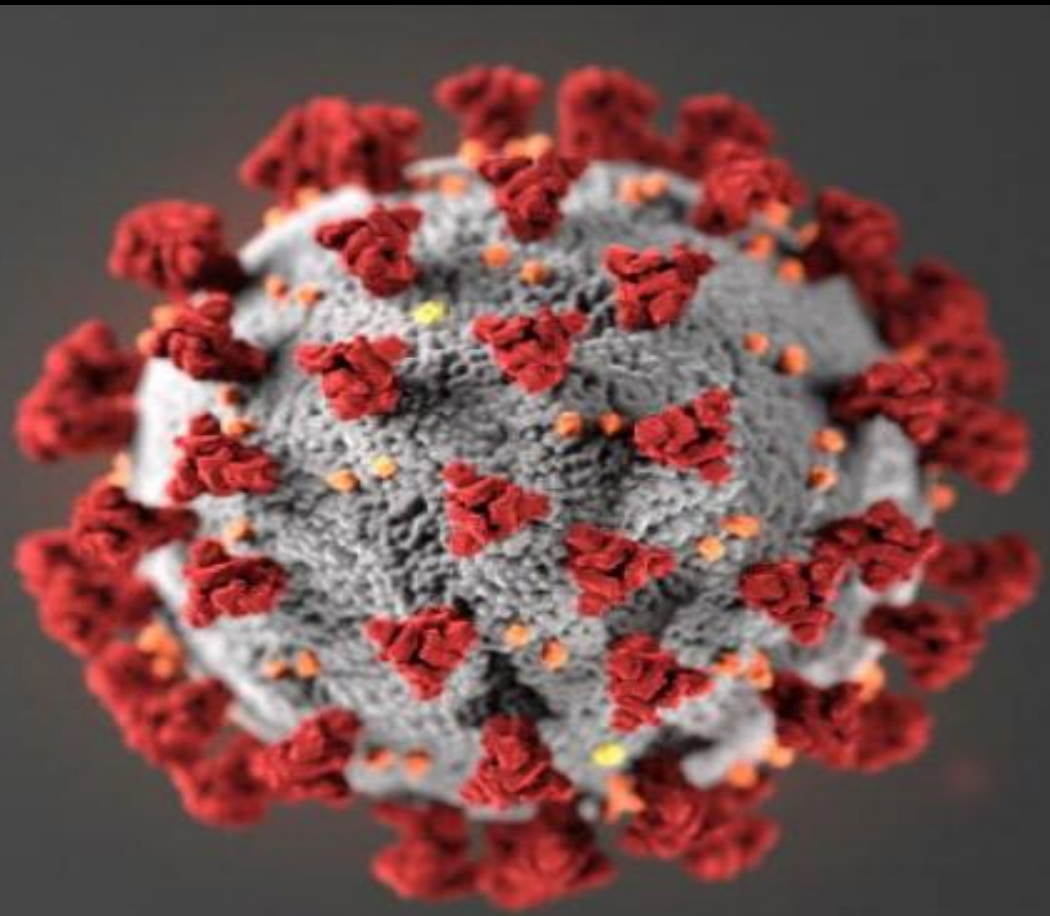
Janssen COVID-19 Vaccine (Johnson & Johnson) Administration



Interchangeability with Other COVID-19 Vaccines

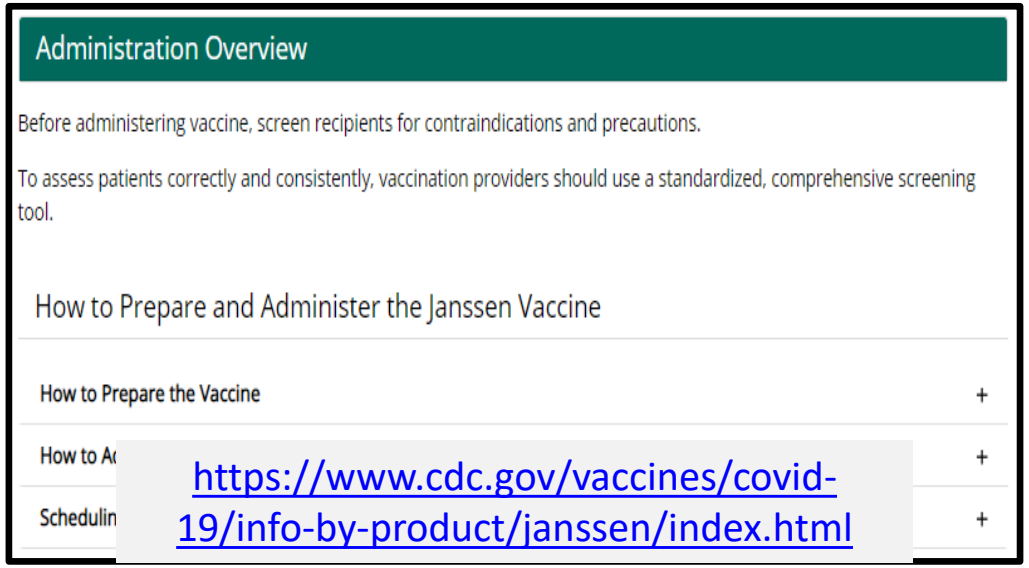
- Any COVID-19 vaccine can be used when indicated, no product preference
- COVID-19 vaccines are **NOT** interchangeable
  - Safety and efficacy of a mixed series has not been evaluated
- Persons initiating a 2-dose series should complete series with same product
- If 1st dose of mRNA COVID-19 vaccine was received but patient was unable to complete the series with the same or different mRNA vaccine (e.g., contraindication)
  - Single dose of Janssen COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose
  - Considered to have received valid, single-dose Janssen vaccination, not mixed vaccination series

Coadministration with Other Vaccines

- Currently, all authorized COVID-19 vaccines are inactivated vaccines
- COVID-19 vaccines **should be administered alone** with a minimum interval of 14 days before or after administration of any other vaccines
  - Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines
- A shorter interval may be used in situations where the benefits of vaccination outweigh the potential unknown risks or to avoid barriers or delays to vaccination
  - Wound management—tetanus vaccine

Key Points on Janssen COVID-19 Vaccine Preparation

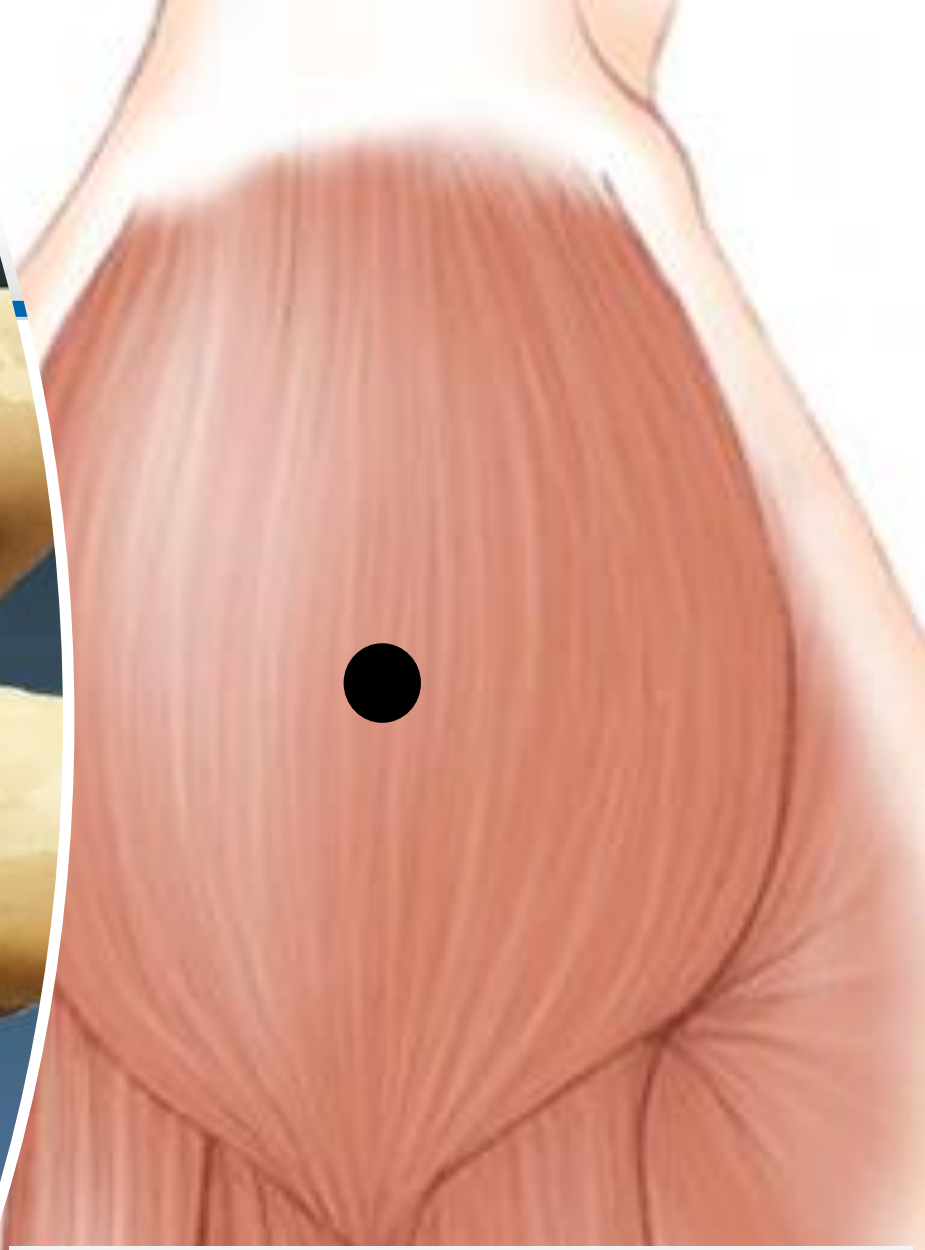
- Presentation: preservative free multi-dose vial (5 doses per vial)
- A single dose series, authorized for persons aged 18 years and older
- No diluent required
- Swirl vial gently for 10 seconds and before withdrawing subsequent doses
- **Do Not Shake**
- Cleanse the vial stopper with antiseptic before every withdrawal from the vial
  - This is a key step as the Janssen COVID-19 vaccine is preservative-free
- Do not pool excess vaccine from multiple vials
- Dose is 0.5 mL administered intramuscularly (IM)



Proper IM Injection Technique

- Administer in thickest, most central part of the muscle
- Use needle length based on patient's age and weight
- Insert the needle into the muscle at a 90° angle
- Administer alone (14 days before or after other vaccines)

Image Courtesy of CDC



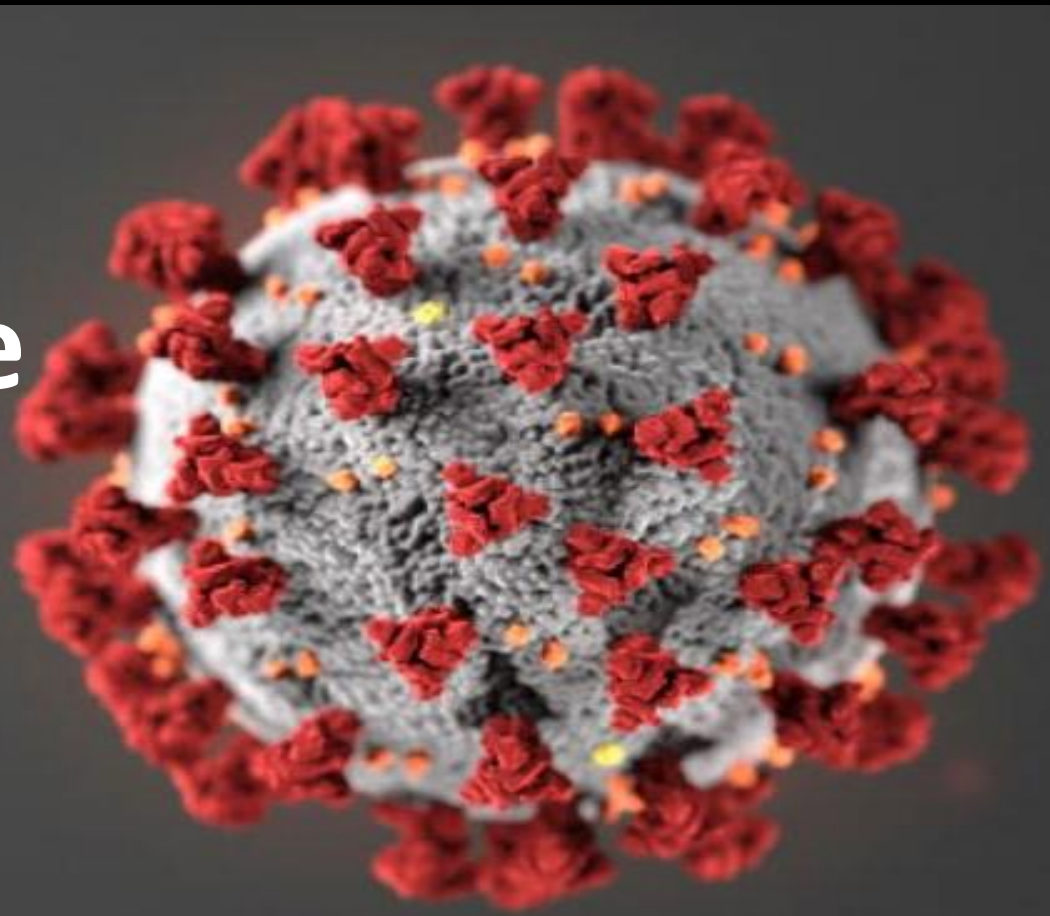
https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf

Recap of Administration of COVID-19 Vaccines

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

Vaccine	Age Group	Dose Volume	Number Doses/Series	Interval Between Doses
Pfizer-BioNTech	16 years and older	0.3 mL	2	3 weeks (21 days)
Moderna	18 years and older	0.5 mL	2	1 month (28 days)
Janssen	18 years and older	0.5 mL	1	N/A

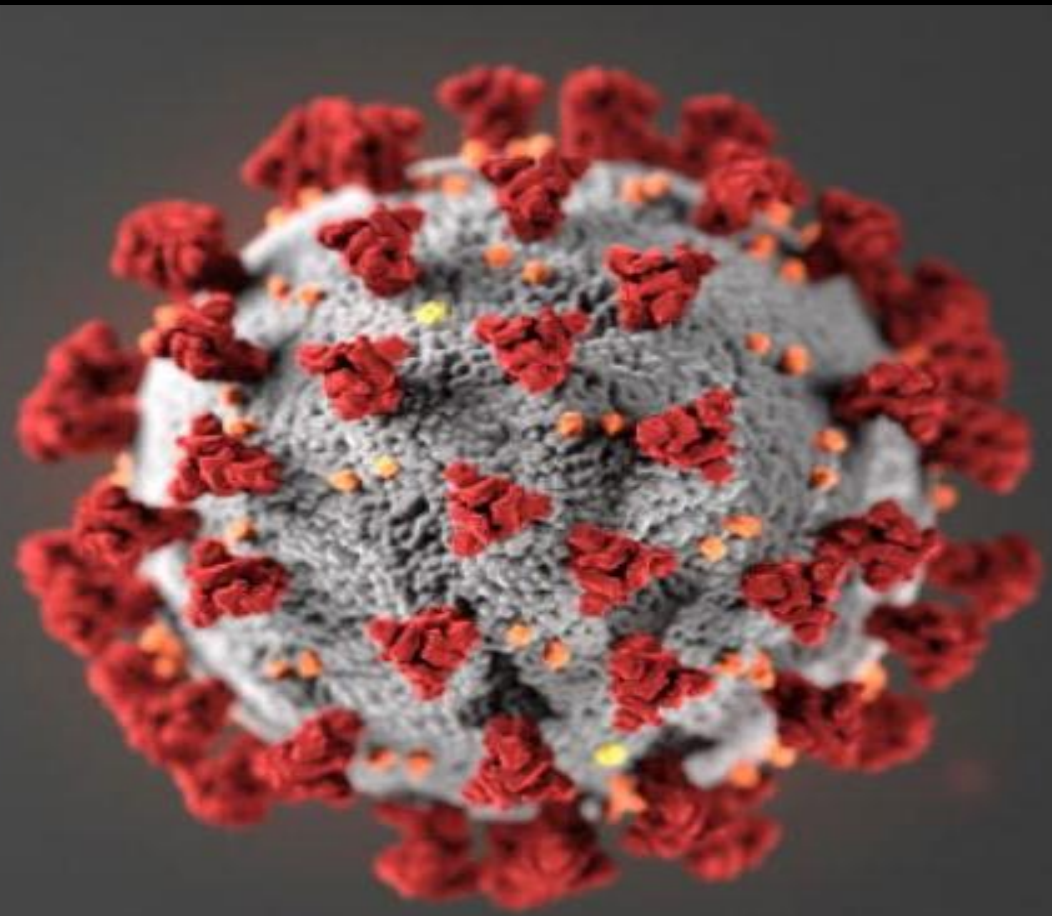
Janssen COVID-19 Vaccine (Johnson & Johnson) Documentation



Documentation and EUA Fact Sheet for Vaccine Recipients

- Vaccine administration must be documented in the Michigan Care Improvement Registry (MCIR) within **24 hours** of vaccination
- As indicated in the Provider Agreement, providers must provide a COVID-19 vaccination record card and EUA fact sheet to each vaccine recipient/parent/legal guardian
- **Written informed consent is not required under EUA**
- Translations anticipated to be available

Adverse Reaction Management & Reporting for Janssen COVID-19 Vaccine (Johnson & Johnson)



COVID-19 Common Side Effects

Common side effects

On the arm where you got the shot:

- Pain
- Swelling

Throughout the rest of your body

- Fever
- Chills
- Tiredness
- Headache

What to Expect after Getting A COVID-19 Vaccine https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

Helpful Tips in Managing Common Side Effects

To reduce pain and discomfort where you got the shot

- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

To reduce discomfort from fever

- Drink plenty of fluids.
- Dress lightly.

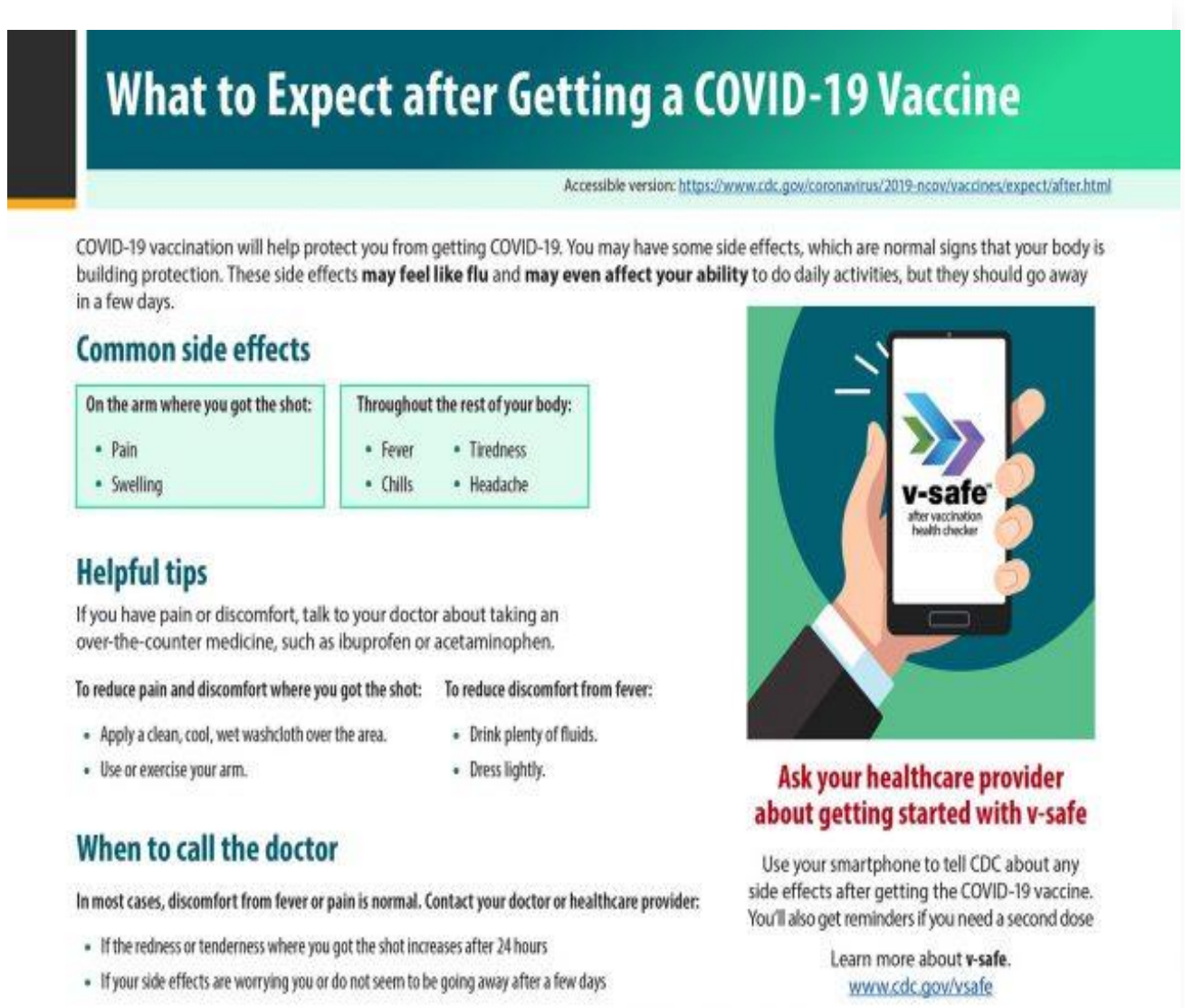
When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:

- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Printable Handout for Vaccine Recipients

- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html
- More information about V-safe can be found at: https://www.cdc.gov/vsafe



What to Expect after Getting a COVID-19 Vaccine

Accessible version: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

COVID-19 vaccination will help protect you from getting COVID-19. You may have some side effects, which are normal signs that your body is building protection. These side effects **may feel like flu** and **may even affect your ability** to do daily activities, but they should go away in a few days.

Common side effects

On the arm where you got the shot:
- Pain
- Swelling

Throughout the rest of your body:
- Fever
- Chills
- Tiredness
- Headache

Helpful tips

If you have pain or discomfort, talk to your doctor about taking an over-the-counter medicine, such as ibuprofen or acetaminophen.

To reduce pain and discomfort where you got the shot:
- Apply a clean, cool, wet washcloth over the area.
- Use or exercise your arm.

To reduce discomfort from fever:
- Drink plenty of fluids.
- Dress lightly.

When to call the doctor

In most cases, discomfort from fever or pain is normal. Contact your doctor or healthcare provider:
- If the redness or tenderness where you got the shot increases after 24 hours
- If your side effects are worrying you or do not seem to be going away after a few days

Ask your healthcare provider about getting started with v-safe

Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second dose

Learn more about **v-safe**.
www.cdc.gov/vsafe

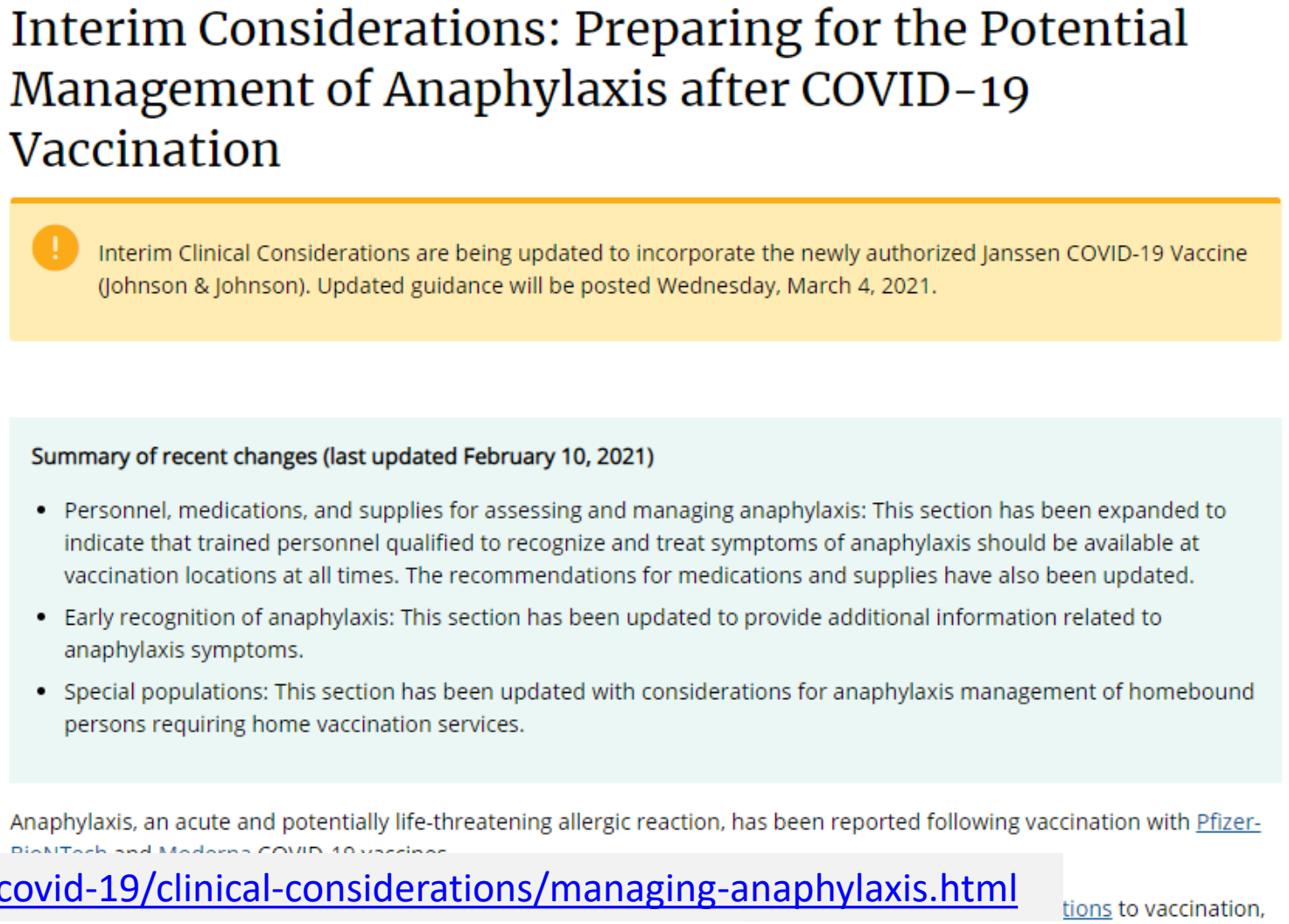
Available in English and Spanish!

Medical Management of Adverse Reactions

- Administering any medication, including vaccines, has the potential to cause an adverse reaction
- When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to rare and serious (e.g., anaphylaxis)
- Be prepared, know how to recognize allergic reactions, including anaphylaxis
- Have a plan in place and supplies available to provide appropriate medical care should such an event occur
- CDC has Interim Considerations for Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites:
  - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html

Important—Be Prepared for Possible Adverse Event

- Information on this site includes:
  - Early recognition of anaphylaxis
  - Medications and supply list
  - Management of anaphylaxis at the vaccination site
  - Recommendation for immediate activation of emergency medical services and transportation to higher level medical care
  - Patient counseling
  - Reporting of anaphylaxis



Interim Considerations: Preparing for the Potential Management of Anaphylaxis after COVID-19 Vaccination

Interim Clinical Considerations are being updated to incorporate the newly authorized Janssen COVID-19 Vaccine (Johnson & Johnson). Updated guidance will be posted Wednesday, March 4, 2021.

Summary of recent changes (last updated February 10, 2021)

- Personnel, medications, and supplies for assessing and managing anaphylaxis: This section has been expanded to indicate that trained personnel qualified to recognize and treat symptoms of anaphylaxis should be available at vaccination locations at all times. The recommendations for medications and supplies have also been updated.
- Early recognition of anaphylaxis: This section has been updated to provide additional information related to anaphylaxis symptoms.
- Special populations: This section has been updated with considerations for anaphylaxis management of homebound persons requiring home vaccination services.

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following vaccination with Pfizer-

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

tions to vaccination,

Key Messages

- Prepare for the potential management of anaphylaxis at COVID-19 vaccination sites

Early recognition of anaphylaxis symptoms

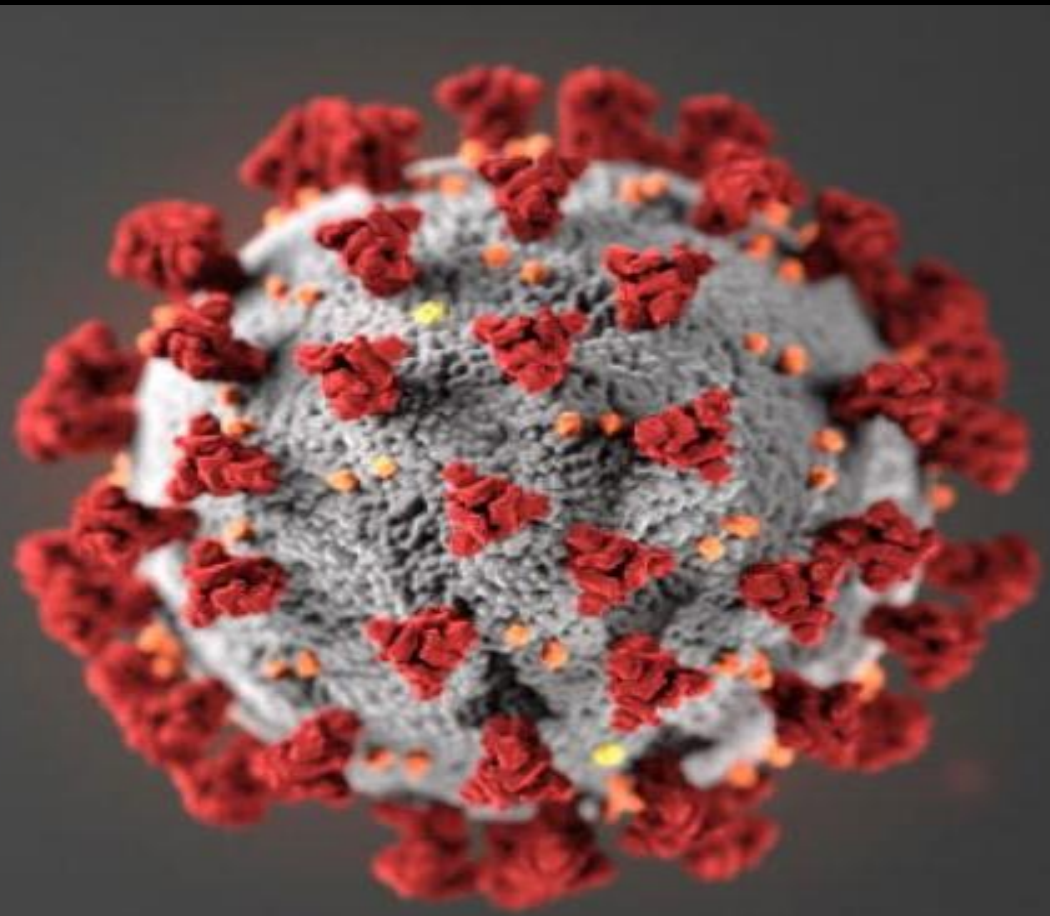
Prompt treatment with epinephrine

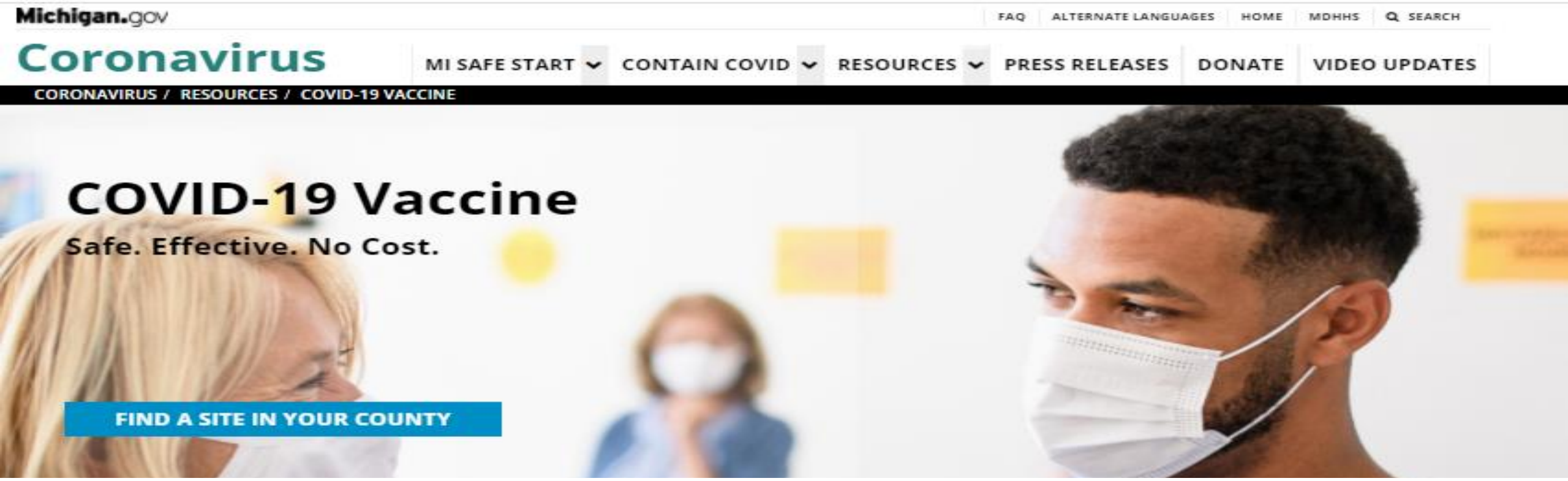
Activate emergency medical services

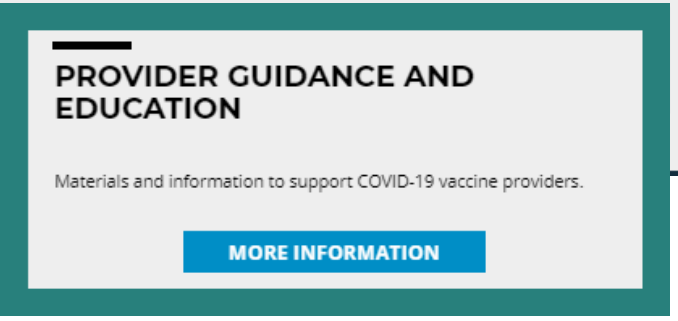
Adverse Event Reporting

- Adverse events (AE) that occur in a recipient following COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS)
- Vaccination providers are required to report the following that occur after COVID-19 vaccination under Emergency Use Authorization (EUA):
  - Vaccine administration errors (whether associated with an AE or not)
  - Serious AEs (irrespective of attribution to vaccination)
  - Multisystem Inflammatory Syndrome (MIS)
  - Cases of COVID-19 that result in hospitalization or death after the recipient has received COVID-19 vaccine
- Any clinically significant AEs that occur after vaccine administration should also be reported to VAERS
- Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.htmlexternal icon or 1-800-822-7967

Janssen COVID-19 Vaccine (Johnson & Johnson) Resources

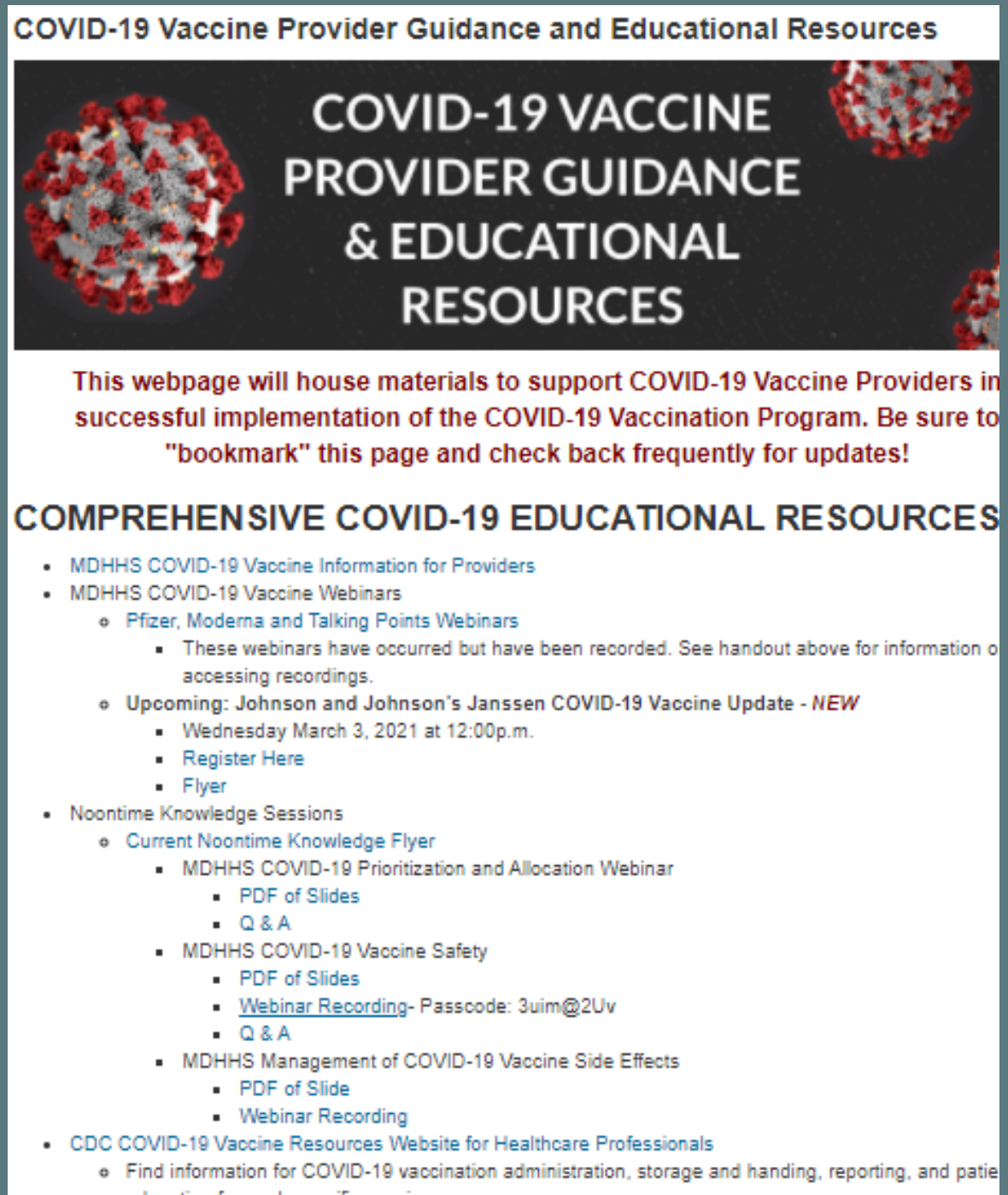






MDHHS COVID-19 Web Page

www.Michigan.gov/COVIDVaccine



COVID-19 Vaccine Provider Guidance and Educational Resources

COVID-19 VACCINE PROVIDER GUIDANCE & 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!

COMPREHENSIVE COVID-19 EDUCATIONAL RESOURCES

- MDHHS COVID-19 Vaccine Information for Providers
- MDHHS COVID-19 Vaccine Webinars
  - Pfizer, Moderna and Talking Points Webinars
    - These webinars have occurred but have been recorded. See handout above for information o accessing recordings.
  - **Upcoming: Johnson and Johnson's Janssen COVID-19 Vaccine Update - *NEW***
    - Wednesday March 3, 2021 at 12:00p.m.
    - Register Here
    - Flyer
- Noontime Knowledge Sessions
  - Current Noontime Knowledge Flyer
    - MDHHS COVID-19 Prioritization and Allocation Webinar
      - PDF of Slides
      - Q & A
    - MDHHS COVID-19 Vaccine Safety
      - PDF of Slides
      - Webinar Recording- Passcode: 3uim@2Uv
      - Q & A
    - MDHHS Management of COVID-19 Vaccine Side Effects
      - PDF of Slide
      - Webinar Recording
- CDC COVID-19 Vaccine Resources Website for Healthcare Professionals
  - Find information for COVID-19 vaccination administration, storage and handing, reporting, and patie

MDHHS COVID-19 Vaccine Provider Web Page

COVID-19 vaccine webpage www.michigan.gov/COVIDvaccine, then selecting "Provider Guidance and Education"

COVID-19 Vaccination

Clinical Resources for Each COVID-19 Vaccine

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

Product Information by US Vaccine

***CDC's **UPDATED** Web Page for COVID-19 Vaccination Education

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

CDC COVID-19 Vaccine Information for You and Your Family

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

Thank you for all that you do!!

- **For COVID-19 Vaccine questions email:**
  - checcimms@michigan.gov

Next “Noontime Knowledge” Update: March 11, 2021 at 12:00p.m.

Topic: Janssen COVID-19 Vaccine (Johnson and Johnson) Update
Please watch your email for an updated link!
Information will be posted at: www.michigan.gov/COVIDvaccine → Provider Guidance and Education