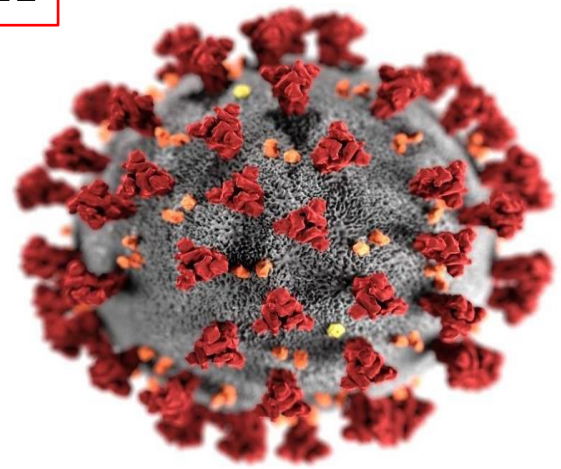
COVID-19 Vaccine Recommendations

Massachusetts Adult Immunization Coaltion

Data and recommendations current as of 6-15-21,
Stay tuned for updates from the ACIP meeting June 23-25, 2021

Immunize MA

Susan M. Lett, MD, MPH Medical Director, Immunization Division
Massachusetts Department of Public Health
6-15-21
susan.lett@mass.gov



Outline

- **Update on COVID Vaccine Recommendations**
  - Tips for Keeping Up to Date
  - Recs Update
    - TTS
    - Myocarditis
- **Catch-Up**
- **Resources**

Recommendations are Rapidly Evolving…

Always check the websites for the latest guidance and information.

- **CDC COVID-19 Main page: https://www.cdc.gov/coronavirus/2019-ncov/index.html**
- **CDC COVID-19 Vaccine Clinical Resources: https://www.cdc.gov/vaccines/covid-19/index.html**
- **Clinical Care Considerations for COVID-19 Vaccines**
  https://www.cdc.gov/vaccines/covid-19/clinical-considerations/index.html
  - **Interim Clinical Considerations for Use of COVID-19 Vaccines Includes TTS Recommendations (updated 6/1/2021)**
    https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html
  - **Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites**
    https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html
  - **Myocarditis (New 5/28/21)**
    https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html
  - **Homebound Vaccination Guidance**
    https://www.cdc.gov/vaccines/covid-19/clinical-considerations/homebound-persons.html
- **COVID-19 Vaccine Product Information: (updated 5/28/21)**
  For screening forms, standing orders, vaccine preparation/administration summaries, storage and handling guidance, EUA fact sheets and more
  https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html
- **Healthcare Professionals Training and Education: (updated 6/4/21)**
  https://www.cdc.gov/vaccines/covid-19/training.html
- **CDC Covid-Specific ACIP Recommendations: (updated 5/14/21)**

CDC COVID-19 Gateway Page Takes You To…..

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

Recommendations Rapidly Evolving

For the most current guidance, check the CDC Gateway for COVID-19 Vaccination information on administration, storage and handling, reporting and patient education for each specific vaccine:

- COVID-19 Vaccination
- Product Info by US Vaccine +
- Clinical Care +
- Provider Requirements and Support +
- Training and Education +
- Vaccine Recipient Education +
- Health Departments +
- Planning & Partnerships +
- Vaccine Effectiveness Research
- Vaccination Toolkits +
- COVID-19 Vaccine Data Systems +
- Content Syndication
- Vaccinate with Confidence +

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

ACIP Recommendations

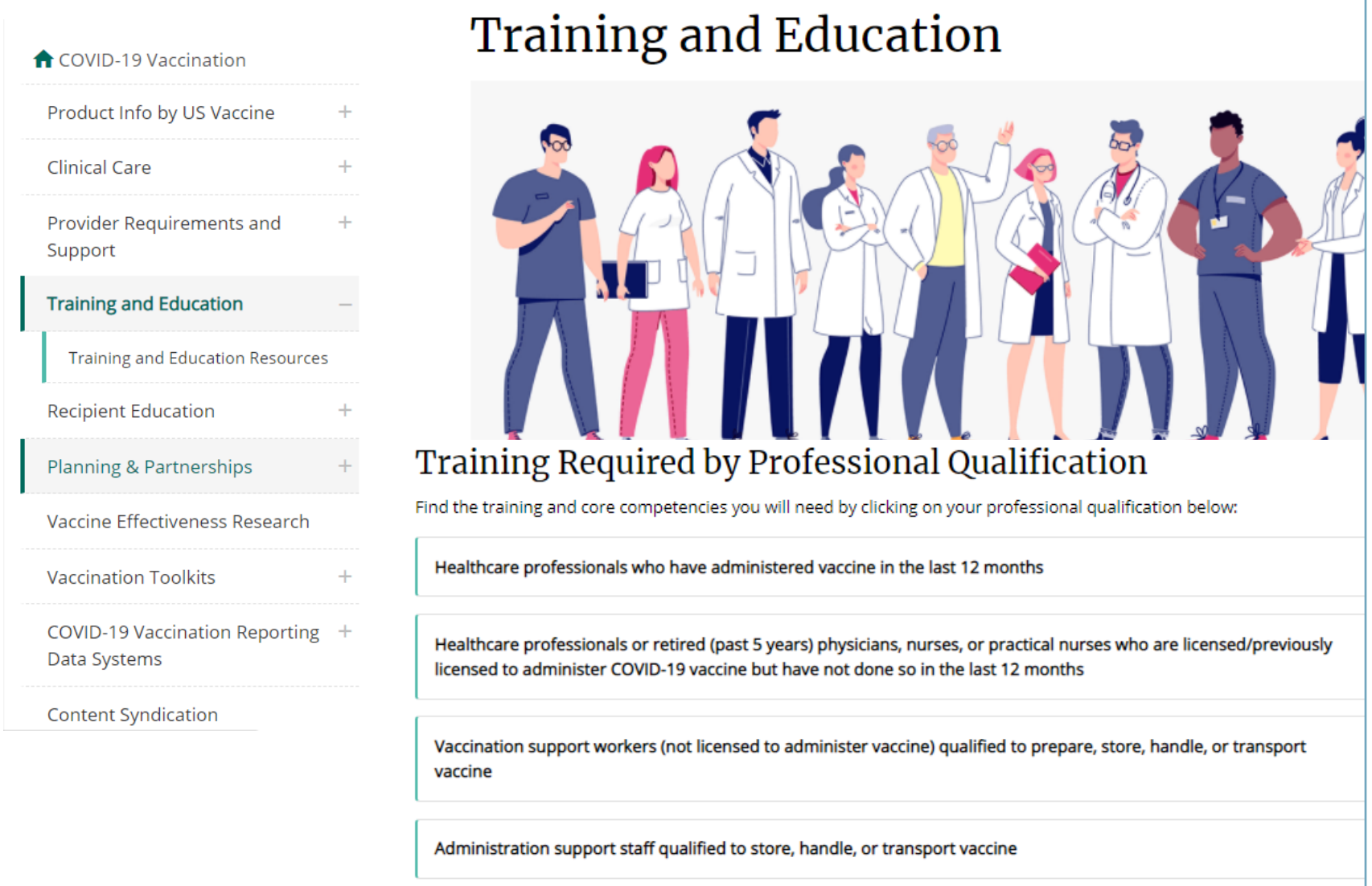
Storage and Handling

General Vaccine Administration

Training and Education

https://www.cdc.gov/vaccines/COVID-19/index.html

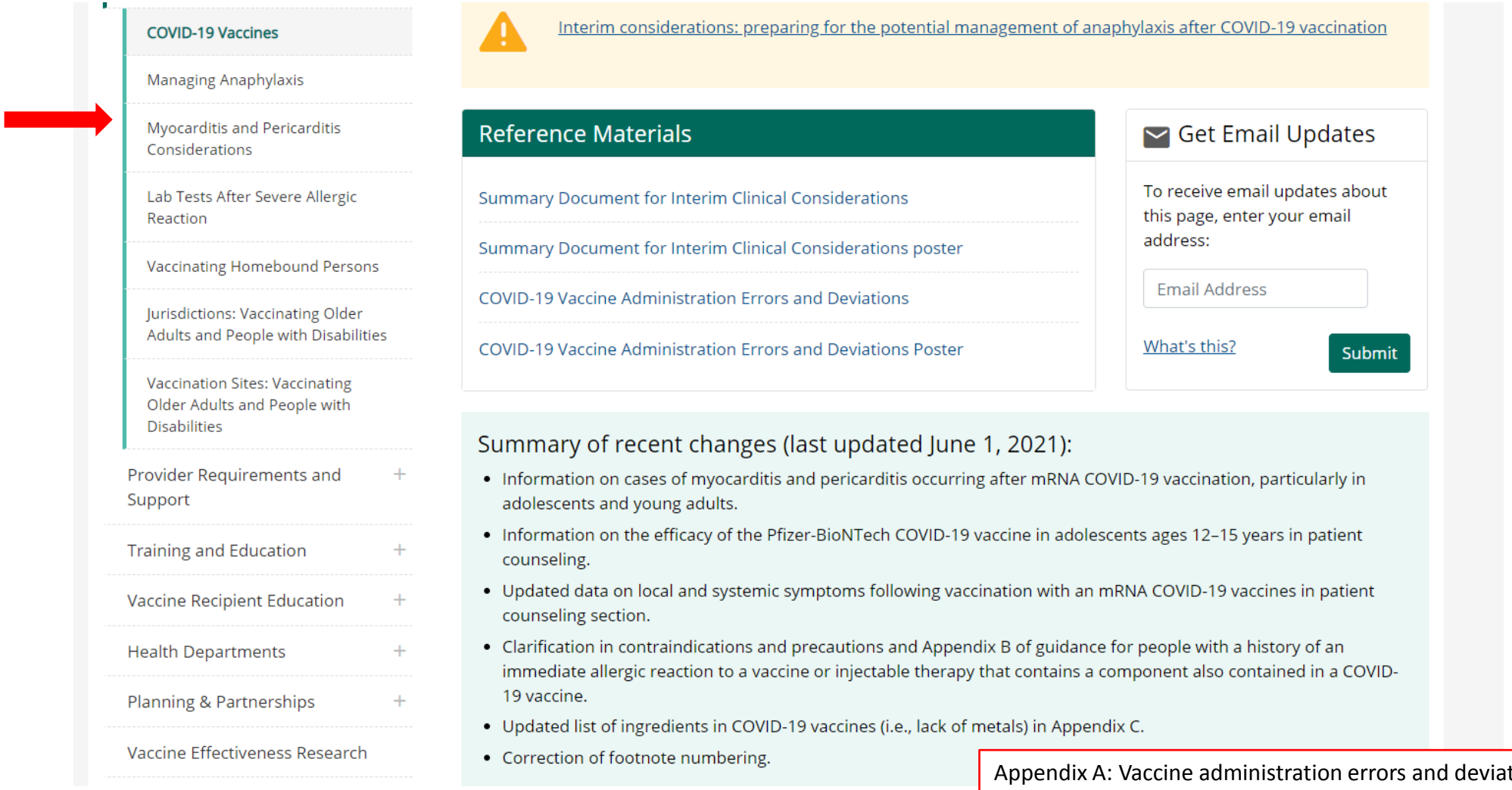
CDC Healthcare Provider Training and Education Landing Page



- Core Competencies
  - Relevant information contained in EUA Fact Sheet(s) for Healthcare Providers for the vaccine product(s) in your facility
  - Clinical considerations
  - Storage and handling requirements
  - Preparation requirements
  - Administration requirements
  - Anaphylaxis guidance
  - Vaccination documentation and reporting requirements
  - Required and additional information for vaccine recipients
  - COVID-19 Vaccine Administration Competency Assessment Form
- Based on Role
- Trainings
- Competencies Assessment Form

https://www.cdc.gov/vaccines/covid-19/training.html

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

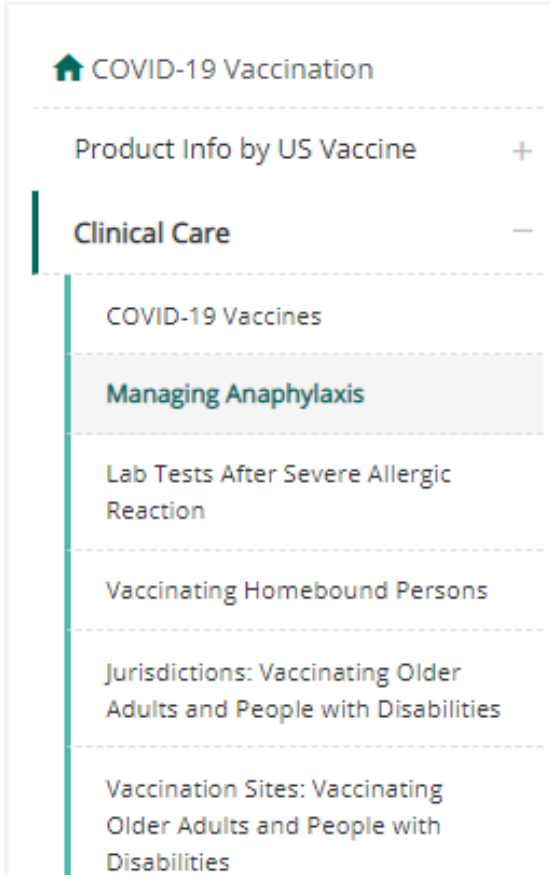


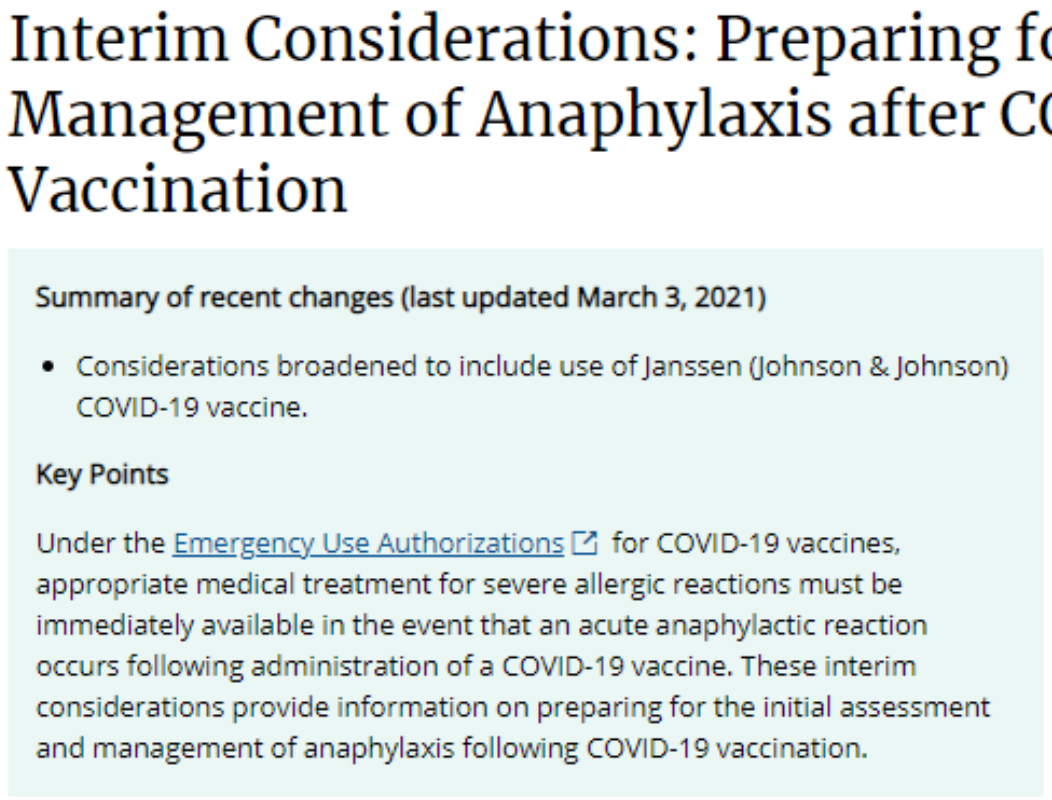
Updates include Adolescents, TTS and myocarditis

Appendix A: Vaccine administration errors and deviations
Appendix B: Triage of people presenting for COVID-19 vaccination
Appendix C: Ingredients included in COVID-19 vaccines
Appendix D: Potential characteristics of allergic reactions, vasovagal reactions, and vaccine side effects following COVID-19 vacation

Sign up to receive email updates when clinical considerations are updated:
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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





Includes:

- Overview
- Personnel, medications, and supplies for assessing and managing anaphylaxis
- Routine observation periods following COVID-19 vaccination
- Early recognition of anaphylaxis
- Management of anaphylaxis at a COVID-19 vaccination location
- Considerations for anaphylaxis management in special populations
- Patient counseling
- Reporting anaphylaxis

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

COVID Vaccine Update

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
May 14, 2021

The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Aged 12–15 Years — United States, May 2021

Megan Wallace, DrPH[1,2]; Kate R. Woodworth, MD[1]; Julia W. Gargano, PhD[1]; Heather M. Scobie, PhD[1]; Amy E. Blain, MPH[1]; Danielle Moulia, MPH[1]; Mary Chamberland, MD[1]; Nicole Reisman, MPH[1]; Stephen C. Hadler, MD[1]; Jessica R. MacNeil, MPH[1]; Doug Campos-Outcalt, MD[3]; Rebecca L. Morgan, PhD[4]; Matthew F. Daley, MD[5]; José R. Romero, MD[6]; H. Keipp Talbot, MD[7]; Grace M. Lee, MD[8]; Beth P. Bell, MD[9]; Sara E. Oliver, MD[1]

The Pfizer-BioNTech COVID-19 (BNT162b2) vaccine is a lipid nanoparticle–formulated, nucleoside-modified mRNA vaccine encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19. Vaccination with the Pfizer-BioNTech COVID-19 vaccine consists of 2 intramuscular doses (30 μg, 0.3 mL each) administered 3 weeks apart. On December 11, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for use of the Pfizer-BioNTech COVID-19 vaccine (Pfizer, Inc; Philadelphia, Pennsylvania) in persons aged ≥16 years (*1*); on December 12, 2020, the Advisory Committee on Immunization Practices (ACIP) issued an interim recommendation for use of the vaccine in the same age group (*2*). As of May 12, 2021, approximately 141.6 million doses of the Pfizer-BioNTech COVID-19 vaccine had been administered to persons aged ≥16 years.* On May 10, 2021, FDA expanded the EUA for the Pfizer-BioNTech COVID-19 vaccine to include adolescents aged 12–15 years (*1*). On May 12, 2021, ACIP issued an interim recommendation† for use of the Pfizer-BioNTech COVID-19 vaccine in adolescents aged 12–15 years for the prevention of COVID-19. To guide its deliberations regarding the vaccine, ACIP used the Evidence to Recommendation (EtR) Framework,§ using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.¶ The ACIP recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine in persons aged ≥12 years under an EUA is interim and will be updated as additional information becomes available.

Since June 2020, ACIP has convened 14 public meetings to review data on the epidemiology of COVID-19 and the potential use of COVID-19 vaccines, including the Pfizer-BioNTech COVID-19 vaccine (*3*). The ACIP COVID-19 Vaccines Work Group, comprising experts in infectious diseases, vaccinology, vaccine safety, public health, and ethics, has held weekly meetings to review COVID-19 surveillance data, evidence for vaccine efficacy and safety, and implementation considerations for COVID-19 vaccines. Within the EtR Framework for the Pfizer-BioNTech COVID-19 vaccine for adolescents aged 12–15 years, ACIP considered the importance of COVID-19 as a public health problem, as well as issues of resource use, benefits and harms, patients' and parents' values and preferences, acceptability, feasibility, and equity for use of the vaccine among adolescents. After a systematic review of published and unpublished evidence for benefits and harms, the Work Group used the GRADE approach to assess the certainty of evidence for outcomes related to the vaccine, rated on a scale of 1 (high certainty) to 4 (very low certainty) (*4*). Work Group conclusions regarding the evidence for the Pfizer-BioNTech COVID-19 vaccine were presented to ACIP at a public meeting on May 12, 2021.

The body of evidence for the Pfizer-BioNTech COVID-19 vaccine was primarily guided by one randomized, double-blind, placebo-controlled Phase II/III clinical trial that was expanded

* Accessed May 12, 2021. https://covid.cdc.gov/covid-data-tracker/#vaccinations

† On May 12, 2021, ACIP voted 14–0 (one recusal) in favor of the interim recommendation for use of Pfizer BioNTech COVID-19 vaccine for persons aged 12–15 years. One ACIP member recused herself because of participation in clinical trials and other studies involving companies producing COVID-19 vaccines.

§ https://www.cdc.gov/vaccines/acip/recs/grade/downloads/ACIP-evidence-rec-frame-508.pdf

¶ https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Administration of COVID-19 vaccines

- COVID-19 vaccines are administered intramuscularly as either a two-dose series or single dose
- One valid vaccination series should be completed.

Vaccine	Authorized age group	Dose	Dose volume	Number doses/series	Interval between doses
Pfizer-BioNTech	≥12 years	30 µg	0.3 ml	2	3 weeks (21 days)
Moderna	≥18 years	100 µg	0.5 ml	2	1 month (28 days)
Janssen	≥18 years	5×10^{10} virus particles	0.5 ml	1	N/A

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

Interchangeability of COVID-19 vaccine products

- COVID-19 vaccines are **not** interchangeable[1]

- mRNA COVID-19 vaccines (Pfizer-BioNTech and Moderna)
  - Preferable to delay the 2nd dose (up to 6 weeks) to receive the same product than to receive a mixed series using a different product
  - In exceptional situations where the mRNA vaccine used for the 1st dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine may be used for the 2nd dose

- Janssen COVID-19 vaccine administration after an mRNA COVID-19 vaccine
  - In exceptional situations where a patient but is unable complete the series with either the same or a different m-RNA vaccine (e.g., due to a contraindication), a single dose of Janssen may be considered at a minimum interval of 28 days from the m-RNA dose[2]

1 Safety and efficacy of a mixed series has not been evaluated

2 People are considered fully vaccinated against COVID-19 ≥2 weeks after receipt of the 2nd dose of an mRNA vaccine; or ≥2 weeks after a single dose of Janssen vaccine .

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

Coadministration

- COVID-19 vaccines were previously recommended to be administered alone, with a minimum interval of 14 days before or after administration of any other vaccines. This was out of an abundance of caution and not due to any known safety or immunogenicity concerns.
- However, substantial data have now been collected regarding the safety of COVID-19 vaccines currently authorized for use by FDA for use under EUA.
- Although data are not available for COVID-19 vaccines administered simultaneously with other vaccines, extensive experience with non-COVID-19 vaccines has demonstrated that immunogenicity and adverse event profiles are generally similar when vaccines are administered simultaneously as when they are administered alone.

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

Coadministration of COVID-19 Vaccine with Other Vaccines

- 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.

- 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
  - Administer COVID-19 vaccine and vaccine that may be locally reactogenic (tetanus-toxoid containing vaccine and adjuvanted vaccines) in separate limbs if possible

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

Syncope (fainting)

- 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

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

Janssen/J&J COVID-19 vaccine:
HAN released April 13, 2021

Cases of Cerebral Venous Sinus Thrombosis with Thrombocytopenia after Receipt of the Johnson & Johnson COVID-19 Vaccine

HAN HEALTH ALERT NETWORK

This is an official CDC HEALTH ALERT

- Recommendations for Clinicians: diagnosis and treatment
  - Evaluate patients with a screening **PF4 enzyme-linked immunosorbent (ELISA) assay** as would be performed for autoimmune HIT. Consultation with a hematologist is strongly recommended.
  - **Do not treat with heparin**, unless HIT testing is negative
- Recommendations for Public Health: case reporting through VAERS
  - Encourage healthcare providers and the public to report all serious and life-threatening adverse events and deaths following receipt of COVID-19 vaccines to VAERS
- Recommendations for the Public: clinical signs and symptoms to monitor
  - Contact healthcare provider, or seek medical care if you develop severe headache, abdominal pain, leg pain, or shortness of breath within three weeks after vaccination with the J&J COVID-19 vaccine

HAN Archive - 00442 | Health Alert Network (HAN) (cdc.gov)

Centers for Disease Control and Prevention

MMWR

Morbidity and Mortality Weekly Report

Early Release / Vol. 70 April 27, 2021

Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021

Jessica R. MacNeil, MPH[1]; John R. Su, MD, PhD[1]; Karen R. Broder, MD[1]; Alice Y. Guh, MD[1]; Julia W. Gargano, PhD[1]; Megan Wallace, DrPH[1]; Stephen C. Hadler, MD[1]; Heather M. Scobie, PhD[1]; Amy E. Blain, MPH[1]; Danielle Moulia, MPH[1]; Matthew F. Daley, MD[2]; Veronica V. McNally, JD[3]; José R. Romero, MD[4]; H. Keipp Talbot, MD[5]; Grace M. Lee, MD[6]; Beth P. Bell, MD[7]; Sara E. Oliver, MD[1]

"ACIP reaffirmed its interim recommendations for use of the Janssen COVID-19 vaccine in all persons aged ≥18 years under FDA's EUA, which now includes a **warning** that **rare clotting events** might occur after vaccination, primarily among **women aged 18-49 years**.

Patient and provider education about the risk for TTS with the Janssen COVID-19 vaccine, especially among women aged <50 years, as well as the **availability of alternative COVID-19 vaccines**, is required to guide vaccine decision making and ensure early recognition and clinical management of TTS."

https://www.cdc.gov/mmwr/volumes/70/wr/mm7017e4.htm?s_cid=mm7017e4_w

https://www.fda.gov/media/146304/download

https://www.cdc.gov/coronavirus/2019-ncov/downloads/talking-patients-jj-vaccine-html.pdf

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.htm

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

FACT SHEET FOR HEALTHCARE PROVIDERS ADMINISTERING VACCINE (VACCINATION PROVIDERS)

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN 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, Janssen COVID-19 Vaccine, for active immunization to prevent COVID-19 in individuals 18 years of age and older.

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Talking to Patients
about Safety of the Janssen COVID-19 Vaccine

Effective April 23, 2021, CDC and FDA recommend use of the Janssen COVID-19 Vaccine (Johnson & Johnson) resume in the United States. **The available data show that the vaccine's known and potential benefits outweigh its known and potential risks.** You can offer the Janssen COVID-19 Vaccine to people 18 years and older who want to get vaccinated against COVID-19.

As a clinician, your answers to patient questions matter. Your strong recommendation can help them make an informed decision and feel confident about getting vaccinated against COVID-19.

If your patient has questions about the safety of the Janssen COVID-19 Vaccine:

- Discuss the possibility of a **rare but increased risk** of blood clots with low platelets seen after receipt of the Janssen COVID-19 Vaccine.
- To date, most of these reports have been in adult women younger than 50 years old, but there have been reports in men and older women.
- The reporting rate for this event in women 18 to 49 years old is about 7 per 1 million women vaccinated, so this event is rare.
- The reporting rate for both women 50 years and older and men is less than 1 per 1 million people vaccinated.

- Explain that that there are other COVID-19 vaccine options available for which this specific risk has not been seen.
- Consider and discuss if the patient will be able and willing to complete a two-dose mRNA vaccine series.
- CDC and FDA will continue to monitor the safety of all COVID-19 vaccines.

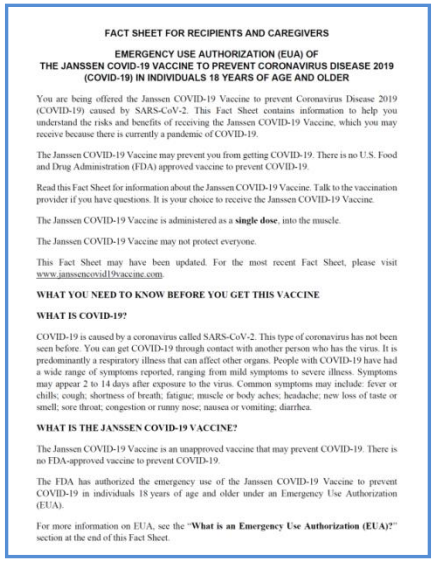
If they have questions, you can send them to:
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

Adapted and updated form: Lee, Advisory Committee on Immunization Practices (ACIP) May 12, 2021

https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/08-COVID-Lee-508.pdf https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Thrombotic Thrombocytopenic Syndrome (TTS)

- TTS is rare syndrome that involves acute venous or arterial thrombosis and new onset thrombocytopenia in patients with no recent exposure to heparin
- TTS after Janssen vaccine had clots located in the cerebral venous sinuses and also other unusual locations including the portal vein, the splenic vein and included a combination of venous and arterial thromboses
- FDA had added a warning to the Janssen COVID-019 EUA fact sheets and prescribing information
- The EUA Fact Sheets should be provided to all recipients and caregivers
- To date, most of the reports have been in women younger than 50 years, but there have been reports in men and older women.
- Women younger than 50 years especially should be aware of the rare but increased risk of this adverse event and that there are other COIV-19 vaccine options available for which this risk has not been seen.



FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF
THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019
(COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

https://www.fda.gov/media/146305/download

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

Considerations for use of the Janssen COVID-19 vaccine

Women aged <50 years

- Women aged <50 years can receive any FDA-authorized COVID-19 vaccine
- However, they should be aware of the rare risk of TTS after receipt of the Janssen COVID-19 vaccine, and the availability of other FDA-authorized COVID-19 vaccines (i.e. mRNA vaccines).
- The highest rates of TTS per vaccine doses administered were identified in women <50 years of age

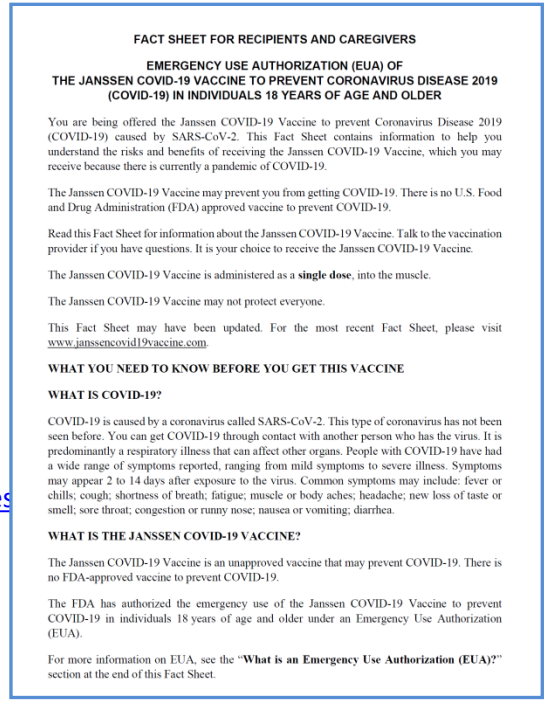
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Educating Recipients about Potential Symptoms of a Blood Clot

Should give EUA Fact Sheet to Recipients and Caregivers

Shortness of breath
Chest pain
Leg swelling
Persistent abdominal pain
Severe headache
Blurred vision
New or easy bruising
Tiny blood spots under the skin (petechiae)

- These symptoms are most likely to develop within **three weeks** of getting the Janssen COVID-19 vaccine.
- These symptoms are **distinct from the mild, commonly reported side effects** (headache, fatigue, muscle aches) in the first few days after vaccination, lasting only 1-2 days.
- **Educate** recipients of the Janssen COVID-19 vaccine about these possible symptoms.
- **Direct recipients to seek medical care right away if ANY of these symptoms develop.**



FACT SHEET FOR RECIPIENTS AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF THE JANSSEN COVID-19 VACCINE TO PREVENT CORONAVIRUS DISEASE 2019 (COVID-19) IN INDIVIDUALS 18 YEARS OF AGE AND OLDER

You are being offered the Janssen COVID-19 Vaccine to prevent Coronavirus Disease 2019 (COVID-19) caused by SARS-CoV-2. This Fact Sheet contains information to help you understand the risks and benefits of receiving the Janssen COVID-19 Vaccine, which you may receive because there is currently a pandemic of COVID-19.

The Janssen COVID-19 Vaccine may prevent you from getting COVID-19. There is no U.S. Food and Drug Administration (FDA) approved vaccine to prevent COVID-19.

Read this Fact Sheet for information about the Janssen COVID-19 Vaccine. Talk to the vaccination provider if you have questions. It is your choice to receive the Janssen COVID-19 Vaccine.

The Janssen COVID-19 Vaccine is administered as a **single dose**, into the muscle.

The Janssen COVID-19 Vaccine may not protect everyone.

This Fact Sheet may have been updated. For the most recent Fact Sheet, please visit www.janssencovid19vaccine.com.

WHAT YOU NEED TO KNOW BEFORE YOU GET THIS VACCINE

WHAT IS COVID-19?

COVID-19 is caused by a coronavirus called SARS-CoV-2. This type of coronavirus has not been seen before. You can get COVID-19 through contact with another person who has the virus. It is predominantly a respiratory illness that can affect other organs. People with COVID-19 have had a wide range of symptoms reported, ranging from mild symptoms to severe illness. Symptoms may appear 2 to 14 days after exposure to the virus. Common symptoms may include: fever or chills; cough; shortness of breath; fatigue; muscle or body aches; headache; new loss of taste or smell; sore throat; congestion or runny nose; nausea or vomiting; diarrhea.

WHAT IS THE JANSSEN COVID-19 VACCINE?

The Janssen COVID-19 Vaccine is an unapproved vaccine that may prevent COVID-19. There is no FDA-approved vaccine to prevent COVID-19.

The FDA has authorized the emergency use of the Janssen COVID-19 Vaccine to prevent COVID-19 in individuals 18 years of age and older under an Emergency Use Authorization (EUA).

For more information on EUA, see the "**What is an Emergency Use Authorization (EUA)?**" section at the end of this Fact Sheet.

What do I need to know about Johnson & Johnson's Janssen COVID-19 Vaccine (J&J/Janssen) now?

There is a risk of a rare but serious condition involving blood clots and low platelets in people after receiving the J&J/Janssen COVID-19 Vaccine. **This risk is very low.**

This problem is rare and happened in about 7 per 1 million vaccinated women between 18 and 49 years old.

For women 50 years and older and men of any age, this problem is even more rare.

This problem has not been linked to the other two COVID-19 vaccines (Pfizer-BioNTech and Moderna).

SHOULD I STILL GET VACCINATED with this or other vaccines to protect against COVID-19?

YES, experts agree that all COVID-19 vaccines help prevent COVID-19 disease, especially severe illness and death.

The known and potential benefits of all COVID-19 vaccines outweigh the known and potential risks. You need only one dose of the J&J/Janssen vaccine. You need two doses of the other two vaccines (Pfizer-BioNTech and Moderna).

What if I already got the J&J/Janssen COVID-19 Vaccine?

For three weeks after getting the J&J/Janssen vaccine, you should watch for possible symptoms of a blood clot with low platelets, like:

- Severe headache or blurred vision
- Shortness of breath
- Chest pain
- Leg swelling
- Gut pain that does not go away
- Easy bruising or tiny blood spots under the skin

Get medical care right away if you develop any of these symptoms.

CDC

Learn more by talking with your doctor, nurse, or pharmacist, or visit the CDC website: www.cdc.gov.

cdc.gov/coronavirus

https://www.fda.gov/media/146305/download

https://www.cdc.gov/coronavirus/2019-ncov/downloads/vaccines/324167-a-consumer-facing-three-vaccines

www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html#symptoms-list-question

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

People at Higher Risk for Thrombosis

- Although the etiology of TTS is unclear, it appears to be similar to another rare immune-mediated syndrome **heparin-induced thrombocytopenia (HIT),** a rare reaction to heparin treatment.
- Until more information, experts advise people with a history of an episode of an immune-mediated syndrome characterized by thrombosis and low platelet counts, like HIT, should be offered another FDA-authorized COVID-19 vaccine (i.e. mRNA vaccine) if it has been 90 days or less since resolution of their illness.
  - After 90 days, persons may be vaccinated with any FDA-authorized COVID vaccine.
- This recommendation may change as more information becomes available.

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

Considerations for use of the Janssen COVID-19 vaccine

People with a history of thrombosis or risk factors for thrombosis

- The biologic mechanisms for venous thromboembolism (VTE) and arterial thrombi differ from the underlying immune-mediated mechanism for HIT
- Based on current knowledge, experts believe that people with risk factors for VTE (e.g., inherited or acquired thrombophilia including Factor V Leiden; prothrombin gene 20210A mutation; antiphospholipid syndrome; protein C, protein S or antithrombin deficiency), or a prior history of thromboses **not** associated with thrombocytopenia are **unlikely** to be at increased risk for TTS
- Although the risk of thrombosis is increased during pregnancy and the postpartum period, and with some hormonal contraceptives, experts believe that these factors **do not** make people more susceptible to TTS after receipt of the Janssen COVID-19 vaccine
  - Individuals can receive any FDA-authorized vaccine, including Janssen COVID-19 vaccine

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

Considerations for use of the Janssen COVID-19 vaccine

Use of anticoagulants

- People who take aspirin or anticoagulants as a part of their routine medications do **not** need to **stop** taking these medications prior to receipt of the Janssen COVID-19 vaccine
- It is **not** recommended that people take aspirin or anticoagulants before vaccination with the Janssen COVID-19 vaccine or any other FDA-authorized COVID-19 vaccine (i.e., m-RNA vaccines, unless they take these medications as part of their routine medications

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

Reporting rates of TTS after Janssen COVID-19 vaccine

(ACIP meeting 5-12-21)

8.73 million total Janssen COVID-19 vaccine doses administered*

	Females			Males		
Age group	TTS cases	Doses admin	Reporting rate† (per million)	TTS cases	Doses admin	Reporting rate† (per million)
18-29 yrs old	**3**	641,510	4.7	**2**	714,458	2.8
30-39 yrs old	**8**	642,745	12.4	**1**	728,699	1.4
40-49 yrs old	**7**	743,256	9.4	**1**	775,390	1.3
50-64 yrs old	**4**	1,463,416	2.7	**2**	1,505,505	1.3
65+ yrs old	**0**	814,947	0	**0**	697,925	0

* Source of doses administered: https://covid.cdc.gov/covid-data-tracker/#vaccinations; † Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

Tom Shimabukuro. COVID-19 Safety Updates ACIP meeting 5-12-21 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf

Summary (ACIP meeting 5-12-21)

- TTS is a rare, clinically serious and potentially life-threatening condition; current evidence suggests a potential causal association with the Janssen COVID-19 vaccine
- Symptom onset appears to occur at least several days after vaccination, typically around 1–2 weeks after vaccination; most cases are in women, with most aged 18-49 years old
- The clinical features of TTS following Janssen COVID-19 vaccine appear similar to what is being observed following the AstraZeneca COVID-19 vaccine in Europe
- It is important to recognize TTS early and initiate appropriate treatment
  - Do not treat thrombosis with thrombocytopenia cases with heparin unless heparin-PF4 ELISA HIT antibody testing is negative
- TTS does not appear to be associated with mRNA COVID-19 vaccines
- The U.S. vaccine safety monitoring system is able to rapidly detect rare adverse events following immunization and quickly assess safety signals
- Safety surveillance and research on TTS continues
- CDC is committed to open and transparent communication of vaccine safety information

Tom Shimabukuro. COVID-19 Safety Updates ACIP meeting 5-12-21 https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf

TTS Update - CDC Select Adverse Events after COVID Vaccine (Updated June 11, 2021)

- As of June 7, 2021, more than 11.2 million doses of the J&J/Janssen COVID-19 Vaccine have been given in the United States. CDC and FDA identified 35 confirmed reports of people who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. There is a plausible causal relationship between J&J/Janssen COVID-19 Vaccine and TTS. Women younger than 50 years old especially should be aware of the rare but increased risk of this adverse event. There are other COVID-19 vaccine options available for which this risk has not been seen. See: about J&J/Janssen COVID-19 Vaccine and TTS: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
  - To date, one confirmed case of TTS following mRNA COVID-19 vaccination (Moderna) has been reported to VAERS after more than 292 million doses of mRNA COVID-19 vaccines administered in the United States. Based on available data, there is not an increased risk for TTS after mRNA COVID-19 vaccination.

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

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

Resources for Janssen and TTS

- CDC Clinical Considerations
  - https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html
- CDC Recommends J&J Vaccination Resume
  https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
- Janssen EUA fact sheet Providers:
  - https://www.fda.gov/media/146304/download
- Janssen EUA Factsheet Recipient or care giver:
  - https://www.fda.gov/media/146305/download
- American Society of Hematologists
  Published considerations relevant to the diagnosis and treatment of thrombosis with thrombocytopenia following the Janssen COVID-19 Vaccine.
  Their website includes FAQs, webinar links and slide set
  - https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia

Myocarditis and Pericarditis after mRNA COVID-19 Vaccines

- Reports of myocarditis and pericarditis after mRNA vaccines
- CDC clinical guidance for providers: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html
- Consider myocarditis and pericarditis when evaluating chest pain, dyspnea, or palpitations
  - Ask about a prior COVID-19 vaccination , potential exposure to COVID-19, as well as relevant medical, travel and social history
- Report cases of myocarditis, pericarditis and other serious events after vaccination to VAERS: https://vaers.hhs.gov/reportevent.html
- CDC information for patients can be found at: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
- Update at Vaccines and Related Biologic Product Advisory Committee 6-10-21 (see next slide)

ACIP Vaccine Safety Technical Work Group report 5/17/2021: https://www.cdc.gov/vaccines/acip/work-groups-vast/technical-report-2021-05-17.html
CDC's Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

Summary (as of May 31, 2021) (VRBPAC 6-10-21)

- Initial safety findings from Pfizer-BioNTech COVID-19 vaccination of 12-15-year-olds from v-safe and VAERS surveillance are consistent with results from pre-authorization clinical trials
- Analysis of VAERS preliminary reports of myocarditis/pericarditis is in progress, including follow-up to obtain medical records, complete reviews, apply CDC working case definition, and adjudicate cases
- Preliminary findings suggest:
  - Median age of reported patients is younger and median time to symptom onset is shorter among those who developed symptoms after dose 2 vs. dose 1
  - Predominance of male patients in younger age groups, especially after dose 2
  - Observed reports > expected cases after dose 2 (16–24 years of age)
  - Limited outcome data suggest most patients (at least 81%) had full recovery of symptoms
- Early VSD data also suggest more cases after dose 2 vs. dose 1; rate ~16 cases per million 2nd doses
- ACIP meeting scheduled for June 18, 2021: update data, further evaluate myocarditis following mRNA COVID-19 vaccination, and assess benefit-risk balance

Shimabukuro. COVID-19 Vaccine Safety Updates. VRBPAC 6-10-21 https://www.fda.gov/media/150054/download

Myocarditis Pericarditis Update - CDC Select Adverse Events after Vaccination (6-14-21)

- As of June 9, 2021, VAERS has received 623 reports of myocarditis or pericarditis among people ages 30 and younger who received COVID-19 vaccine. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults.
- Through follow-up, including medical record reviews, CDC and FDA have confirmed 268 reports of myocarditis or pericarditis. CDC and its partners are investigating these reports to assess whether there is a relationship to COVID-19 vaccination. Learn more about myocarditis, see:
  https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

Stay tuned for ACIP meeting taking place on June 23-25, 2021

The ACIP Covid-19 vaccine discussion originally planned for June 18 has been rescheduled to be part of the June 23-25 ACIP meeting
https://www.cdc.gov/vaccines/acip/index.html

Final agenda not yet available. Will be posted at:
https://www.cdc.gov/vaccines/acip/meetings/index.html

CDC educational materials*

Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination

Updated May 27, 2021 Languages Print

What You Need to Know

- More than 165 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 increased 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 (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.
- Most patients who received care responded well to medicine and rest and quickly felt better.

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.

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

YOUR ROLE in Safety

- Recognize, respond, and report anaphylaxis and other adverse events following COVID-19 vaccination to **VAERS** ✓
- Report adverse events to **VAERS** in accordance with FDA EUA reporting requirements and CDC guidance ✓
- Participate in CDC's **v-saf**e program yourself when you get vaccinated and encourage patients to participate in **v-safe** ✓
- **Communicate** with patients on vaccine safety ✓
- **Clinical Immunization Safety Assessment (CISA) Project COVID-Vax** ✓

V-safe

- Smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccine
- Parents and guardians can enroll adolescents and complete health check-ins on their behalf
- All v-safe communications will be sent to the parent or guardian's smartphone.

ttps://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html
ttps://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html
ttps://www.mass.gov/lists/additional-covid-19-vaccination-resources-for-providers#cdc:-tools-for-vaccine-providers-

CDC's Clinical Immunization Safety & Assessment (CISA) Project COVIDvax

- Extension of CDC's CISA* Project's clinical consultation service for U.S. healthcare providers and health departments for complex COVID-19 vaccine safety questions/issues that are**
  - (1) about an individual patient(s) residing in the United States
  - (2) not readily addressed by CDC or ACIP guidelines
- Vaccine safety subject matter expertise in multiple specialties (e.g., infectious diseases, allergy/immunology, neurology, OB/GYN, pediatrics, geriatrics)
- Requests for a CISA consult about COVID-19 vaccine safety:
  - Contact CDC-INFO: 800-CDC-INFO (800-232-4636) or webform
  - Indicate the request is for a "CDC CISA"* consult (no patient identifiers)

* https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html
**Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management

Shimabukuro, Tom. COVID-19 Vaccine safety Update. ACIP Meeting 1-21-21

How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online
- For help:

  Call 1-800-822-7967

  Email info@VAERS.org

  video instructions
  https://youtu.be/sbCWhcQADFE

- Please send records to VAERS ASAP if contacted and asked
  - HIPAA permits reporting of protected health information to public health authorities including CDC and FDA

COCA Products & Services

COCA Call Announcements contain all information subscribers need to participate in COCA Calls. COCA Calls are held as needed.

Monthly newsletter that provides information on CDC training opportunities, conference and training resources, the COCA Partner Spotlight, and the Clinician Corner.

As-needed messages that provide specific, immediate action clinicians should take. Contains comprehensive CDC guidance so clinicians can easily follow recommended actions.

https://emergency.cdc.gov/coca/calls/index.asp

MDPH Immunization Division Contact Information

Immunization Division Main Number

For questions about immunization recommendations, disease reporting, etc.

Phone: 617-983-6800 (24/7 MDPH Epidemiology line)

Fax: 617-983-6840

Website: https://www.mass.gov/topics/immunization

MIIS Help Desk

Phone: 617-983-4335

Fax: 617-983-4301

Email: miishelpdesk@state.ma.us

Website: https://www.mass.gov/service-details/massachusetts-immunization-information-system-miis

MDPH Vaccine Unit

Phone: 617-983-6828

Fax: 617-983-6924

Website: https://www.mass.gov/service-details/vaccine-management

EXTRAS