

Commonwealth of Massachusetts Department of Public Health

Helping People Lead Healthy Lives In Healthy Communities

# **COVID-19 Vaccine Recommendations**

### **Massachusetts Adult Immunization Coaltion**



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MDPH 2021

# ACIP Meeting 1-27-21 Clinical and Safety Updates –Stay Tuned!!!

Draft - December 4, 2020

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP) Centers for Disease Control and Prevention

Atlanta, Georgia 30329

January 27, 2021

#### PRESIDER/PRESENTER(s)

Wednesd	ay, January 27, 2021	
10:00	Welcome & Introductions	Dr. José Romero (ACIP Chair)
		Dr. Amanda Cohn (ACIP Executive Secretary, CDC)
	Coronavirus Disease 2019 (COVID-19) Vaccines	
	Introduction	Dr. Beth Bell (ACIP, WG Chair)
	COVID-19 Vaccine Manufacturer	TBD
11:15	Break	
11:30	Update on COVID-19 Vaccine Administration	Dr. Amanda Cohn (CDC/NCIRD)
	Vaccine Safety Technical Subgroup (VaST) introduction	Dr. Grace Lee (ACIP, VaST Co-chair)
	COVID-19 Vaccine Safety Update	Dr. Tom Shimabukuro (CDC/NCEZID)
12:30	Break	
1:00	COVID-19 Epidemology among Children	Dr. Angela Campbell (CDC/NCIRD)
	Pediatric COVID-19 Clinical Trials	Dr. Emily Erbelding (NIH)
2:00	Break	
2:15	COVID-19 Vaccine Effectiveness Studies	Dr. Katherine Fleming-Dutra (CDC/NCIRD)
	Work Group Interpretation and Next Steps	Dr. Sara Oliver (CDC/NCIRD)
3:15	Break	
3:30	Public comment	
4:00	TBD	TBD
5:00	Adjourn	
	Acronyms	
	CDC Centers for Disease Control and Prevention	

CDC Centers for Disease Control and Prevention CMS Centers for Medicare and Medicaid Services COVID-19 Coronavirus disease 2019

AGENDA ITEM

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

## Outline

- Brief Flu Update
- Vaccine Recommendations
  - Pfizer-BioNTech
  - Moderna
- Clinical Considerations for Use
- Anaphylaxis
- Resources



# Influenza Season 2020-2021

- Very little influenza has been seen this flu season
- Overall, hospitalization rates are much lower than in previous seasons
- There is extensive testing ongoing for influenza, but very few influenza virus infections are being detected in the United States at this time.
- Nationally, seasonal influenza activity remains unusually low for this time of year.



### Influenza Positive Tests Reported to CDC by U.S. Clinical Laboratories, National Summary September 27, 2020 – January 16, 2021





### Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary September 27, 2020 – January 16, 2021

Influenza Positive Tests Reported to CDC by U.S. Public Health Laboratories, National Summary, September 27, 2020 – January 16, 2021





### Outpatient Illness: ILINet Activity Map week 02 ending 1/16/21



https://www.cdc.gov/flu/weekly/index.htm

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https://www.cdc.gov/flu/weekly/index.htm#ILIActivityMap

### Influenza-Associated Pediatric Mortality

No influenza-associated pediatric deaths were reported to CDC during week 2.

One influenza-associated pediatric death occurring during the 2020-2021 season has been reported to CDC.





### Massachusetts – Percent of ILI Visits 2020-2021 September 27, 2020-January 16, 2021 (reported by sentinel sites)



\*Influenza-like illness (ILI, defined by fever >100F and cough and/or sore throat), as reported by Massachusetts sentinel surveillance sites. ILI reported by sentinel sites which report via ED syndromic surveillance include cases meeting the ILI definition and cases with a diagnosis indicating influenza infection.

### https://www.mass.gov/doc/weekly-flu-report-january-22-2021/download



### Massachusetts by Region – ILI Activity 2020-2021

(reported by sentinel sites)

Figure 4: ILI Activity Reported Weekly by Massachusetts Sentinel Sites





### Laboratory Confirmed Influenza Cases in Massachusetts September 27, 2020– January 16, 2021

### Figure 5: Laboratory-confirmed Influenza Cases in Massachusetts, September 27, 2020 – January 16, 2021



\*Influenza cases confirmed via viral culture or PCR test by specimen collection date.

https://www.mass.gov/doc/weekly-flu-report-january-22-2021/download



### Massachusetts - Influenza Activity 2020-2021 Hospitalizations

Figure 2: Influenza-associated Hospitalizations, Massachusetts September 27, 2020 – January 16, 2021



\*All patients admitted through hospital emergency departments as captured by syndromic surveillance

### Percentage of respiratory specimens that tested positive for influenza By influenza transmission zone

Map generated on 15 January 2021



The boundaries and names shown and the designations used on this map do not imply the expression of any opinion whatsoever on the part of the World Health Organization concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.



Data source: Global Influenza Surveillance and Response System (GISRS), FluNet (www.who.int/flunet) Copyright WHO 2021. All rights reserved.

https://urldefense.com/v3/ https://www.who.int/influenza/surveillance monitoring/updates/latest update GIP surveillance/en/ ;!!CUhgQOZqV7M!2hwVgDKefWxWpx-ifFPpxJV NUQixiPSz21i-wsh6ySMmpZw0hKTEAdScUJOhrjhqbY\$



### No of Specimens Positive for Influenza Northern Hemisphere

Data source: FluNet (<u>www.who.int/toolkits/flunet</u>). Global Influenza Surveillance and Response System (GISRS) Data generated on 15/01/2021

## **Recommendations are Rapidly Evolving...**







# Always check the websites for the latest guidance and information.

- CDC COVID-19 Vaccine Clinical Resources <u>https://www.cdc.gov/vaccines/covid-19/index.html</u>
- Interim Clinical Considerations for Use of COVID-19 Vaccine: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html</u>
- Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites: <u>https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html</u>
- COVID-19 Vaccine Product Information: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html</u>
- CDC Covid-Specific ACIP Recommendations: <u>https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html</u>

### COVID-19 Vaccination

	Product Info by US Vaccine	+
	Clinical Considerations	+
	Provider Requirements and Support	
	Training and Education	
	Recipient Education	+
	Planning & Partnerships	+
	Vaccination Toolkits	+
	COVID-19 Vaccination Reporting Data Systems	+
	Content Syndication	
	Vaccinate with Confidence	
https://w	ww.cdc.gov/vaccines/covid	-19/



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



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 at COVID-19 Vaccination Sites

Summary of recent changes (last updated January 21, 2021):

- Updated recommendations on intervals between the first and second dose
- Updated recommendations on interchangeability of vaccine products
- Updated language on vaccination of persons with a history of SARS-CoV-2 infection
- New vaccination recommendations in persons with a history of dermal fillers
- Additional resources on vaccine excipients (Appendix B)

On This Page

Background

Authorized age groups

Administration

Interchangeability with other COVID-19 vaccine products

Coadministration with other vaccines

Booster doses

Appendix A: Triage of persons presenting for mRNA COVID-19 vaccination Appendix B: Ingredients included in Pfizer-BioNTech and Moderna mRNA Covid-19 vaccines Appendix C: Potential characteristics of allergic reactions, vasovagal reactions and side effects following mRNA vaccines

On This Page Background Authorized age groups Administration Interchangeability with other COVID-19 vaccine products Coadministration with other vaccines Booster doses Vaccination of persons with a SARS-CoV-2 infection or exposure Vaccination of persons with underlying medical conditions Vaccination of pregnant or lactating people Vaccination of children and adolescents Patient counseling Contraindications and precautions Reporting of vaccine adverse events Laboratory testing

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

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

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported following COVID-19 vaccination. Detailed information on CDC recommendations for vaccination, including contraindications and precautions to vaccination, can be found in the <u>Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States</u>.

These interim considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination. Institutional practices and site-specific factors may also be considered. In all cases, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine.



Appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of an mRNA COVID-19 vaccine.

### Observation period following COVID-19 vaccination

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

- 30 minutes: Persons with a history of an <u>immediate allergic reaction</u> of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.
- 15 minutes: All other persons

### Early recognition of anaphylaxis

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and

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

- Screening
- Early recognition of symptoms
- Observation periods based on allergy history
- Medications and supplies for assessing and managing anaphylaxis
- Management of anaphylaxis at a COVID-19 vaccination site (Epinephrine)
- Considerations for anaphylaxis management in special populations
- Activation of Emergency Transport
- Patient counseling
- Reporting of anaphylaxis

U.S. COVID-19 Vaccine	Product Information			
Find a suite of information and materials that are storage and handling, safety, and reporting.	e needed for each specific COVID-19 vaccine that cover ad	dministration,		
Pfizer-BioNTech	Moderna	COVID-19 Vaccine (Moderna) Administra	ation Resources	
Requirements, Trainings, and Reso	urces	Moderna COVID-19 Vaccine Standing Orders 🖪	Pre-Vaccination Screening Form 🖪	
		Preparation and Administration Summary 🖪	Vaccine administration training and clinical materials	
Vaccine Storage and Handling Toolkit Training and Education	Provider Requirements and Support	Vaccine Expiration Date Tracking Tool		
Dosage: 0.5	Schedule:       vial: 10 doses per vial     2-dose series separated by 28       6 mL     days       A series started with COVID-19			
Discard vial	when there is not completed with this product.	COVID-19 Vaccine (Moderna Storage and Handling Resources)		
enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose. Administer: Intramuscular (IM) injection in the deltoid muscle Storage and Handling St	Storage and Handling Summary 🖪	Refrigerator Storage Temperature Log (Fahrenheit) 🖪		
Age Indications: 18 years of age and older		Moderna BUD Guidance and Labels 😕	Freezer Storage Temperature Log (Celsius) 🖪	
		Storage and Handling Labels 🖪	Freezer Storage Temperature Log (Fahrenheit) 📕	
EUA	Interim Clinical Considerations	Refrigerator Storage Temperature Log (Celsius) 📕	Vaccine Storage Troubleshooting Record for temperature excursions 🖪 🖸	
Moderna COVID-19 Vaccine FAQs	ACIP Recommendations	https://www.cdc.gov/vaccines/	<u>'covid-19/info-by-product/index.html</u>	

# **ACIP Recommendations for use of COVID-19 vaccines**

- Use of mRNA COVID-19 vaccines under FDA's Emergency Use Authorization
  - December 12, 2020: Pfizer-BioNTech
  - December 19, 2020: Moderna
- All current COVID-19 specific vaccines ACIP Guidance:
  - Recommendations
  - Evidence to Recommendations/Evidence Tables
  - Interim Clinical Considerations
  - Management of Anaphylaxis
  - Reactions

https://www.cdc.gov/vaccines/hcp/acip-recs/vaccspecific/covid-19.html



The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020

Weekly / December 18, 2020 / 69(50);1922-1924

On December 13, 2020, this report was posted online as an MMWR Early Release.

Sara E. Oliver, MD'; Julia W. Gargano, PhD'; Mona Marin, MD'; Megan Wallace, DrPH'?; Kathryn G. Curran, PhD'; Mary Chamberland, MD'?; Nancy McClung, PhD'; Doug Campos-Outcalt, MD'; Rebecca L. Morgan, PhD'; Sarah Mbaeyi, MD'; José R. Romero, MD'; H. Keipp Talbot, MD'; Grace M. Lee, MD'; Beil, MD'; Kathleen Dooling, MD '(<u>View author affiliations</u>)

Summary	Article Metrics	
Contary for Disagra Control and Provention		A-Z Inc
COC Centers for Disease Control and Prevention CDC 24/7: Saving Lives, Protecting People™	Search	0
		Advanced Sea
Morbidity and Mortality Weekly Report ( <i>MMWR</i> )		

#### The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Moderna COVID-19 Vaccine — United States, December 2020

Early Release / December 20, 2020 / 69

Sara E. Oliver, MD: Julia W. Gargano, PhD'; Mona Marin, MD'; Megan Wallace, DrPH<sup>12</sup>; Kathryn G. Curran, PhD'; Mary Chamberland, MD<sup>12</sup>; Nancy McClung, PhD'; Doug Campos-Outcalt, MD: Rebecca L. Morgan, PhD'; Sarah Mbaeyi, MD'; José R. Romero, MD'; H. Kelpp Talbot, MD'; Grace M. Lee, MD'; Beth P. Bell, MD'; Kathileen Dooling, MD' (<u>Videw author affiliations</u>)

#### View suggested citation

Summary	Article Metrics
What is already known about this topic?	Altmetric:
On December 18, 2020, the Food and Drug Administration issued an Emergency Use Authorization (EUA) for the Moderna COVID-19 vaccine.	Citations:
What is added by this report?	
	Views: Views equals page views plus PDF
On December 19, 2020, after a transparent, evidence-based review of available data, the Advisory Committee on	downloads
Immunization Practices (ACIP) issued an interim recommendation for use of the Moderna COVID-19 vaccine in persons aged	Construction of Academic
≥18 years for the prevention of COVID-19.	Metric Details
What are the implications for public health practice?	
Use of all COVID-19 vaccines authorized under an EUA, including the Moderna COVID-19 vaccine, should be implemented in	On This Page
conjunction with ACIP's interim recommendations for allocating initial supplies of COVID-19 vaccines.	Reporting of Vaccine Adverse Events

https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s\_cid=mm6950e2\_w https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s\_cid=mm695152e1\_w

# ACIP recommendations for mRNA COVID-19 vaccines and

# **Clinical considerations**

### **Messenger RNA vaccines**



- Provides instruction directly to the immune system (Spike protein)
- Efficiently creates specific immune memory
- mRNA can neither interact with nor integrate into DNA

### mRNA COVID-19 vaccines

- Two mRNA COVID-19 vaccines authorized under Emergency Use
  - Pfizer-BioNTech
  - Moderna
- Both products demonstrate vaccine efficacy >90%
  - Efficacy demonstrated across age groups, racial and ethnic groups

- Vaccine safety profile of both products acceptable
  - Imbalance of Bell's Palsy but still within expected range
  - Local and systemic reactogenicity, particularly after second dose

# Updated Dosing and administration (1) (1-21-21)

- mRNA vaccines are not interchangeable with each other or other COVID-19 vaccines
  - Either vaccine series may be used; ACIP does not state a product preference
  - Every effort should be made to determine which vaccine product was received as the first dose
  - In exceptional situations in which the first-dose vaccine product cannot be determined or is no longer available, any available mRNA COVID-19 vaccine may be administered at a minimum interval of 28 days between doses.

# Updated Dosing and administration (2) (1-21-21)

- mRNA vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines
  - However, mRNA COVID-19 vaccines and other vaccines may be administered within a shorter period in situations where benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration\*
  - If mRNA COVID-19 vaccines are administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

\* However, mRNA COVID-19 and other vaccines may be administered within a shorter period in situations where the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine co-administration (e.g., tetanus toxoid-containing vaccination as part of wound management, measles or hepatitis A vaccination during an outbreak) or to avoid barriers or delays to mRNA COVID-19 vaccination (e.g., in long-term care facility residents or healthcare personnel who received influenza or other vaccinations prior to/upon admission or onboarding).

# Updated Dosing and administration (3) (1-21-21)

- mRNA vaccines are recommended for a two-dose series administered intramuscularly
  - Pfizer-BioNTech: <a>216</a> years. Given **3 weeks (21 days)** apart
  - Moderna: <u>></u>18 years. Given 4 weeks (28 days) apart
- Persons should not be scheduled to receive the second dose earlier than the recommended intervals
  - However, doses administered earlier should not be repeated
- The second dose should be administered as close to the recommended interval as possible. However, if it is not feasible to adhere to the recommended interval, the second dose of Pfizer-BioNTech and Moderna COVID-19 vaccines may be scheduled for administration up to 6 weeks (42 days) after the first dose, and there is no need to start the series.

# Updated Alternative Dosing/Schedules (4) (1-21-21)

- Currently, recommended schedule and doses from Phase III trials where safety and high efficacy were demonstrated
- If data become available for alternative schedules or doses, ACIP can review data and consider new recommendations
- However, in the absence of additional data to support alternative schedules or doses, the current recommendations will remain

# Updated Strategies to help ensure patients receive 2<sup>nd</sup> dose with the appropriate product and interval (1-21-21)

- Provide COVID-19 vaccination record cards to vaccine recipients, asking recipients to bring their card to their appointment for the second dose, and encouraging recipients to make a backup copy (e.g., by taking a picture of the card of their phone).
- Encourage vaccine recipients to enroll in <u>VaxText</u>, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- Encourage patients to enroll in <u>V-safe</u> for vaccine safety check-ins.
- Record each recipient's vaccination in the immunization information system (IIS)
- Record vaccine administration information in the patient's medical record.
- Make an appointment for the second dose before the vaccine recipient leaves, to increase the likelihood that patients will present at the same vaccination site for the second dose.

# Updated language on vaccination of persons with a history of SARs-Cov2 infection (1-21-21)

Updated language includes:

"Data from clinical trials indicate that mRNA COVID-19 vaccines can safely be given to persons with evidence of a prior SARS-CoV-2 infection."

"Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection for the purposes of vaccine decision-making is not recommended."

"While there is no recommended minimum interval between infection and vaccination, <u>current evidence</u> suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. **Thus, while vaccine supply remains limited, persons with recent documented acute SARS-CoV-2 infection may choose to temporarily delay vaccination, if desired,** recognizing that the risk of reinfection, and therefore the need for vaccination, may increase with time following initial infection."

# Persons with a known SARS-CoV-2 exposure

### Residing in the Community:

- Defer vaccination until <u>quarantine period</u> has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit
- Residents of congregate <u>healthcare</u> settings (e.g., long-term care facilities):
  - May be vaccinated, as likely would not result in additional exposures. HCP are already in close contact with residents and should employ appropriate infection prevention and control procedures
- Residents of congregate settings (e.g., correctional facilities, homeless shelters)
  - May be vaccinated, in order to avoid delays and missed opportunities for vaccination
  - Where feasible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff

<u>https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html</u> <u>https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html</u> https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

### Persons with underlying medical conditions

- Vaccine may be administered to persons with underlying medical conditions who have no contraindications to vaccination
- 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

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

# Immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take <u>immunosuppressive medications or therapies might be at increased risk for severe</u> <u>COVID-19</u>
- Data not currently available to establish safety and efficacy of vaccine in these groups
- These individuals may still receive COVID-19 vaccine unless otherwise contraindicated
- 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

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

# **Pregnant women**

### COVID-19 and pregnancy

- Increased risk of severe illness (ICU admission, mechanical ventilation and death)
- Might be an increased risk of adverse pregnancy outcomes, such as preterm birth
- There are currently few data on the safety of COVID-19 vaccines in pregnant women
  - Limited animal developmental and reproductive toxicity (DART) data
  - Studies in humans are ongoing and more planned
- If a woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine and is pregnant, she may choose to be vaccinated.

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

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# **Pregnant women**

- Considerations for vaccination:
  - Level of COVID-19 community transmission (risk of acquisition)
  - Personal risk of contracting COVID-19 (by occupation or other activities)
  - -Risks of COVID-19 to her and potential risks to the fetus
  - Efficacy of the vaccine
  - Known side effects of the vaccine
  - Lack of data about the vaccine during pregnancy

# **Breastfeeding/Lactating**

- There are no data on the safety of COVID-19 vaccines in lactating people or the effects of mRNA vaccines on the breastfed infant or milk production/excretion
- mRNA vaccines are not thought to be a risk to the breastfeeding infant
- A lactating person who is part of a group recommended to receive a COVID-19 vaccine (e.g., healthcare personnel) may choose to be vaccinated

# **Post-Vaccination Symptoms- Reactogenicity**

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- Depending on vaccine product, age group, and dose:
  - 80-89% of clinical trial participants reported ≥1 local reaction (e.g., pain or swelling at injection site; swollen lymph nodes on same side as vaccinated arm)
  - 55-83% of clinical trial participants reported ≥1 systemic reaction (e.g., fever, fatigue, muscle aches, headache, chills)
  - Most are mild-moderate in severity, occur within first 3 days of vaccination, and resolve within 1-2 days
    of onset
  - More frequent and severe following the second dose and among younger age groups
- Unless a person develops a contraindication to vaccination, they should be encouraged to complete the series even if they develop post-vaccination symptoms in order to optimize protection against COVID-19
- Antipyretic or analgesic medications may be taken for treatment of post-vaccination symptom
  - Routine prophylaxis for the purposes of preventing symptoms is not recommended at this time, due to lack of information on impact of use on vaccine-induced antibody responses
## New Vaccination Recommendations for those with a History of Dermal fillers (1-21-21)

Added language states "Infrequently, persons who have received dermal fillers may develop selling at or near the site of filler injection (usually face or lips) following administration of a dose of an mRNA COVID-19 vaccine. This appears to be temporary and can resolve with medical treatment, including corticosteroid therapy.

- mRNA COVID-19 vaccines may be administered to persons who have received injectable dermal fillers who have no contraindications to vaccination.
- No additional precautions are needed.
- However, these persons should be advised to contact their healthcare provider for evaluation if they develop swelling at or near the site of dermal filler following vaccination."

### Contraindications



### Precautions

### **Contraindications and precautions to COVID-19vaccination**

- Recommendations apply to both Pfizer-BioNTech and Moderna COVID-19 vaccines
- Guidance may change as further information becomes available
- Definition of immediate allergic reaction to vaccine or medication:
  - Any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration

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

Interim Considerations: Preparing for the Potential Management of Ar	naphylaxis at COVID-19 Vaccination Sit
Summary of recent changes (last updated January 21,	On This Page
2021):	Background
<ul> <li>Updated recommendations on intervals between the first and second dose</li> </ul>	Authorized age groups
Updated recommendations on interchangeability of vaccine products	Administration
Updated language on vaccination of persons with a history of SARS-CoV-2 infection	Interchangeability with other COVI 19 vaccine products
<ul> <li>New vaccination recommendations in persons with a history of dermal fillers</li> </ul>	
Additional resources on vaccine excipients (Appendix B)	Coadministration with other vaccines
	Booster doses
Background	Vaccination of persons with a SARS CoV-2 infection or exposure
he Advisory Committee on Immunization Practices (ACIP) has issued interim ecommendations for the use of <u>Pfizer-BioNTech</u> and <u>Moderna</u> COVID-19	Vaccination of persons with underlying medical conditions
vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. Both vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2, the virus that causes COVID-19	Vaccination of pregnant or lactatin people

### **Contraindications to mRNA COVID-19vaccination**

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Contraindications to either of the mRNA COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or to any of its components
  - Immediate allergic reaction of any severity to a previous dose of an mRNA COVID-19 vaccine or
    - any of its components (including polyethylene glycol [PEG])\*
  - Immediate allergic reaction of any severity to polysorbate (due to potential crossreactive hypersensitivity with the vaccine ingredient PEG)\*
- Persons with an immediate allergic reaction to the first dose of an mRNA vaccine should not receive additional doses of either of the mRNA COVID-19 vaccines

\* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergistimmunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available).

### Ingredients\* included in mRNA COVID-19 vaccines

Description	Pfizer-BioNTech	Moderna
mRNA	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2	nucleoside-modified mRNA encoding the viral spike (S) glycoprotein of SARS-CoV-2
Lipids	2[(polyethylene glycol)-2000]- N,N- ditetradecylacetamide	PEG2000-DMG: 1,2-dimyristoyl-rac- glycerol, methoxypolyethylene glycol
	1,2-distearoyl-sn-glycero-3-phosphocholine	1,2-distearoyl-sn-glycero-3-phosphocholine
	cholesterol	cholesterol
	(4-hydroxybutyl)azanediyl)bis(hexane-6,1- diyl)bis(2-hexyldecanoate)	SM-102: heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts,	potassium chloride	Tromethamine
sugars, buffers	monobasic potassium phosphate	Tromethamine hydrochloride
	sodium chloride	Acetic acid
	dibasic sodium phosphate dihydrate	Sodium acetate
	sucrose	sucrose

\*As reported in the prescribing information

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

### Polyethylene glycol (PEG)

- Primary ingredient in osmotic laxatives and oral bowel preparations for colonoscopy procedures
- Inactive ingredient or excipient in medications
- Used in a process called pegylation to improve therapeutic activity of some medications
- Cross-reactive hypersensitivity between PEG and polysorbates can occur
  - Polysorbates are included as an excipient in some vaccines and other therapeutic agents

Information on whether a medication contains PEG, a PEG derivative, or polysorbates can be found in the package insert. The NIH <u>DailyMed database</u> may also be used as a resource. **As of January 21, 2021, mRNA COVID-19 vaccines are the only currently available vaccines in the United States that contain PEG, though several vaccines contain polysorbate (more information can be found in <u>CDC's vaccine excipient summary.pdf</u>). Medications that contain PEG and/or polysorbate are described in the supplemental materials of Stone CA, et al. "Immediate hypersensitivity to polyethylene glycols and polysorbates: more common than we have recognized."** *The Journal of Allergy and Clinical Immunology: In Practice* **7.5 (2019): 1533-1540. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf</u>** 

NEW

### **Precautions to mRNA COVID-19 vaccines**

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)
- Unknown risks of developing a severe allergic reaction should be balanced against the benefits of vaccination
- Deferral of vaccination and/or consultation with an allergist-immunologist may be considered

## Considerations for risk assessment for mRNA COVID-19 vaccination in persons with a precaution to vaccination

- Risk of exposure to SARS-CoV-2
  - e.g., residence in a congregate setting such as a long-term care facility, occupation
- Risk of severe disease or death due to COVID-19
  - e.g., age, underlying medical conditions
- Previous infection with SARS-CoV-2
  - Vaccination is recommended for persons with a history of COVID-19; persons with a precaution to vaccination and recent COVID-19 may choose to defer vaccination until further information is available
- The unknown risk of anaphylaxis following mRNA COVID-19 vaccination persons with a history of an immediate allergic reaction to other vaccines or injectable therapies
- Ability of the patient to be vaccinated in a setting where appropriate medical care is immediately available for anaphylaxis

### **Observation period following vaccination**

Persons with a history of either:

- immediate allergic reaction of any severity to a vaccine or injectable (precaution)
- anaphylaxis due to any cause







#### **30 minutes**

15 minutes

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

### Distinguishing allergic reactions from other types of reactions

Characteristic	Immediate allergic reactions (including anaphylaxis)	Vasovagal reaction	Vaccine side effects (local and systemic)
	Most occur within 15-30 minutes of vaccination	Most occur within 15 minutes	Median of 1 to 3 days after vaccination (with most occurring day after vaccination)
Signs and symptoms			
Constitutional	Feeling of impending doom	Feeling warm or cold	Fever, chills, fatigue
Cutaneous	Skin symptoms present in ~90% of people with anaphylaxis, including pruritus, urticaria, flushing, angioedema	Pallor, diaphoresis, clammy skin, sensation of facial warmth	Pain, erythema or swelling at injection site; lymphadenopathy in same arm as vaccination
Neurologic	Confusion, disorientation, dizziness, lightheadedness, weakness, loss of consciousness	Dizziness, lightheadedness, syncope (often after prodromal symptoms for a few seconds or minutes), weakness, changes in vision (such as spots of flickering lights, tunnel vision), changes in hearing	Headache
Respiratory	Shortness of breath, wheezing, bronchospasm, stridor, hypoxia	Variable; if accompanied by anxiety, may have an elevated respiratory rate	N/A
Cardiovascular	Hypotension, tachycardia	Variable; may have hypotension or bradycardia during syncopal event	N/A
Gastrointestinal	Nausea, vomiting, abdominal cramps, diarrhea	Nausea, vomiting	Vomiting or diarrhea may occur
Musculoskeletal	N/A	N/A	Myalgia, arthralgia
Vaccine recommendation	IS		
Receive 2 <sup>nd</sup> dose of mRN/ COVID-19 vaccine?	A No	Yes ø-by-product/clinical-considerations.html	Yes

	MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
CONDITIONS	CONDITIONS <ul> <li>Immunocompromising conditions</li> <li>Pregnancy</li> <li>Lactation</li> </ul> <li>ACTIONS <ul> <li>Additional information provided*</li> <li>15 minute observation period</li> </ul> </li>	CONDITIONS • Moderate/severe acute illness ACTIONS • Risk assessment • Potential deferral of vaccination • 15-minute observation period if vaccinated	CONDITIONS • None ACTIONS • N/A
ALLERGIES	<ul> <li>ALLERGIES</li> <li>History of allergies that are unrelated to components of an mRNA COVID-19 vaccine', other vaccines, injectable therapies, or polysorbate, such as: <ul> <li>Allergy to oral medications (including the oral equivalent of an injectable medication)</li> <li>History of food, pet, insect, venom, environmental, latex, etc., allergies</li> <li>Family history of allergies</li> </ul> </li> <li>ACTIONS <ul> <li>30-minute observation period: Persons with a history of anaphylaxis (due to any cause)</li> <li>15-minute observation period: All other persons</li> </ul> </li> </ul>	<ul> <li>ALLERGIES         <ul> <li>History of any immediate allergic reaction<sup>±</sup> to vaccines or injectable therapies (except those related to component of mRNA COVID-19 vaccines<sup>+</sup> or polysorbate, as these are contraindicated)</li> </ul> </li> <li>ACTIONS:         <ul> <li>Risk assessment</li> <li>Consider deferral of vaccination and/or referral to allergist-immunologist</li> <li>30-minute observation period if vaccinated</li> </ul> </li> </ul>	<ul> <li>ALLERGIES History of the following are contraindication to receiving either of the mRNA COVID-19 vaccines': <ul> <li>Severe allergic reaction (e.g., anaphylaxis) after a previous dose of an mRNA COVID-19 vaccine or any of its components</li> <li>Immediate allergic reaction<sup>1</sup> of any severity to a previous dose of an mRN COVID-19 vaccine or any of its components^ (including polyethylene glycol)<sup>#</sup></li> <li>Immediate allergic reaction of any severity to polysorbate<sup>*#</sup></li> </ul> ACTIONS <ul> <li>Do not vaccinate<sup>#</sup></li> <li>Consider referral to allergist- immunologist</li> </ul></li></ul>

<sup>+</sup> Refers only to mRNA COVID-19 vaccines currently authorized in the United States (i.e., Pfizer-BioNTech, Moderna COVID-19 vaccines)

\*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.

<sup>^</sup> See Appendix B for a list of ingredients. Note: Polyethylene glycol (PEG), an ingredient in both mRNA COVID-19 vaccines, is structurally related to polysorbate and cross-reactive hypersensitivity between these compounds may occur. Information on ingredients of a vaccine or medication (including PEG, a PEG derivative, or polysorbates) can be found in the package insert.

\* These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergistimmunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

#### Appendix A: Triage of persons presenting for mRNA COVID-19 vaccine

### Anaphylaxis



Morbidity and Mortality Weekly Report

Early Release / Vol. 70

January 6, 2021

Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020

As of January 3, 2021, a tota coronavirus disease 2019 (COVI) ated deaths have been reported in term sequalae of COVID-19 over



Morbidity and Mortality Weekly Report

January 22, 2021

#### Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States,

JAMA Insights | CLINICAL UPDATE

#### Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine

As of January 20, 2021, a to

coronavirus disease 2019 (COVIE deaths had been reported in the

cdc.gov/covid-data-tracker/#cas

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s cid=mm7002e1 w

https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm

https://jamanetwork.com/journals/jama/fullarticle/2775646

Tom Shimabukuro, MD, MPH, MBA; Narayan Nair, MD

On December 11, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the Pfizer-BioNTech coronavirus disease 2019 (COVID-19) vaccine, adminisFollowing implementation of vaccination, reports of anaphylaxis after the first dose of the Pfizer-BioNTech COVID-19 vaccine emerged.<sup>3</sup> Anaphylaxis is a life-threatening allergic reaction that occurs rarely

### Anaphylaxis reports to VAERS following COVID-19 vaccines\*

Characteristics	Pfizer-BioNTech (N = 50)	Moderna (N = 21)
Median age, years (range)	38.5 (26–63)	39 (24–63)
Female (%)	47 (94)	21 (100)
Minutes to symptom onset, median (range)	10 (<1-1200 [20 hr]) <sup>+</sup>	10 (<1-45)
Symptom onset ≤15 minutes (%)	37 (74)	18 (86)
Symptom onset ≤30 minutes (%)	45 (90)	19 (90)
Documented h/o of allergies or allergic rxns (%)	40 (80)	18 (86)
Documented h/o of prior anaphylaxis (%)	12 (24)	5 (24)
Dose number (1 <sup>st</sup> , 2 <sup>nd</sup> , unknown)	42, 3, 5	19, 1, 1

Common allergies and allergic reactions included to drugs and foods

Anaphylaxis cases occurred following drugs, foods, contrast media, vaccines, insect stings, unspecified

<sup>\*</sup> Reports received through January 18, 2021; Includes case reports that met Brighton Collaboration case definition criteria for anaphylaxis at Levels 1, 2, or 3 <sup>†</sup>20 hour onset was an outlier, the remaining onset for cases with onset >30 minutes were 34, 54, 90, and 150 minutes

Estimated anaphylaxis reporting rates following COVID-19 vaccines based on VAERS reports and reported doses administered\*

Reported vaccine doses administered	Anaphylaxis cases	<b>Reporting rate</b> (analytic period Dec 14-Jan 18)
Pfizer-BioNTech: <b>9,943,247</b>	50	5.0 per million doses admin.
Moderna: <b>7,581,429</b>	21	2.8 per million doses admin.

- Total COVID-19 vaccine doses administered <u>thru Jan 18</u> by sex: Female 61%, Male 36%, Unk 3%
- Previously reported rate for Pfizer-BioNTech vaccine: 11.1 per million doses admin (Dec 14-Dec 23) <u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm</u>
- Previously reported rate for Moderna vaccine: 2.5 per million doses admin (Dec 21-Jan 10) <u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm</u>

\* Data through January 18, 2021

### **COVID-19 Vaccine Safety Technical Subgroup (VaST) Discussion and Interpretation**

- Anaphylaxis following COVID-19 vaccination is being closely monitored
  - Estimated rates currently range from 2.8 to 5.0 per million doses (using Brighton Collaboration case definition)
- In response, CDC has recommended risk mitigation strategies, including:
  - Screening for risk prior to vaccination
  - Monitoring for symptoms post-vaccination
  - Early recognition and management of anaphylaxis on-site
- Provider and patient education ongoing by CDC and partners

**Pre-Vaccination Form for** Pfizer-BioNTech COVID-19 Vaccine



CDC

e cei vi ng

medication?

To reduce morbidity an

recommended

Procedure

Vaccine

COVID-19 treatment.

Female 152-200 lbs

Male 153-260 lbs

Female 200+lbs

Male 260+ lbs

"If the second dose Pficer-I not repeat a second dose.

01/03/2021 05301575

**Pre-Vaccination Form for** Pfizer-BioNTech COVID-19 Vaccine

		Don
Yes	No	know
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ccine?		
ie or		
iner?		
OVID-19?		
Date		
Date		
	to something? shrine or EpiPen%, ccine? ee or ner? OVID-19?	ohrine or EpiPen®,

https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccinationscreening-form.pdf

Screening, standing orders, clinical considerations, and other tools to identify persons with contraindications and

#### precautions to vaccination Interim Clinical Considerations for Use of mRNA Moderna COVID-19 Vaccine Pfizer-BioNTech COVID-19 Vac Standing Orders for Administering Vaccine Standing Orders for Administering Vaccine COVID-19 Vaccines Currently Authorized in the United to Persons 18 Years of Age and Older to Persons 16 Years of Age and Older States Note: For more information/guidance, please contact the immunization program at you Note: For more information/quidance, please contact the immunization progra the appropriate state body (e.g., state board of medical/nursing/pharmacy pract the appropriate state body (e.g., state board of medical/nursing/pharmacy practice) Policy Purpos Where auth To reduce morbidity and mortality from coronavirus Where authorized under Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites disease 2019 (COVID-19) by vaccinating persons who eligible nu disease 2019 (COVID-19) by vaccinating persons who meet eligible nurses and othe meet the criteria established by the Centers for Disease pharmacist the criteria established by the Centers for Disease Control pharmacists) to assess a Control and Prevention's Advisory Committee on criteria in th and Prevention's Advisory Committee on Immunization criteria in the "Procedur Immunization Practices (ACIP). dinician e Practices (ACIP). for clinician examination provider at provider at the time of Assess persons 16 years of age and older for Screen for contraindic Procedure On This Page vaccination with Pfizer-BioNTech COVID-19 Vaccine Contraindications: Summary of recent changes (last updated January 21, o Contraindication Assess persons 18 years of age and older for vaccination with based on the following criteria: Severe allergic read Moderna COVID-19 Vaccine based on the following criteria » Severe allergic n o No complete 2-dose COVID-19 vaccination component of eit 2021): history, regardless of brand. If 2 doses of No complete 2-dose COVID-19 vaccination history. component of the Background Immediate allergic regardless of brand. If 2 doses of a same-brand or mixedand Moderna COVI a same-brand or mixed-brand series have component of an been administered, no additional doses are brand series have been administered, no additional doses components, see the glycol [PEG]. See T · Updated recommendations on intervals between the first and second are recommended. o Precautions Immediate allergi Authorized age groups o If the recipient has received 1 previous dose of Moderna o If the recipient has received 1 previous dose of Severe allergic real to potential cross dose Pfizer-BioNTech COVID-19 Vaccine, the second COMD-19Vaccine, a second dose of the same brand vaccine or injectable ingredient PEG) dose of the same brand should be administered should be administered. intravenous, or sul Updated recommendations on interchangeability of vaccine products Precautions: o This vaccine is administered in a 2-dose series. Separate Administration This vaccine is administered in a 2-dose series Moderate to sever History of an imm doses by at least 28 days.\* Separate doses by at least 21 days." Provide all recipients injectable therapy Updated language on vaccination of persons with a history of SARS-CoV-2 Moderna COVID-19 Vaccine should not be administered Emergency Use Authori Pfizer-RioNTech COVID-19 Vaccine should not be vaccines or therai administered at the same time as other vaccines at the same time as other vaccines. Separate Modern Recipients and Caregi Interchangeability with other COVID COVID-19 vaccines Separate Pfizer-BioNTech COVID-19 Vaccine infection COVID-19 Vaccine from other vaccines by 14 days before Prepare to administer the prepare to administer to administer the prepare to administer the prepare to administer the prepare to administer the prepare to administer to administer the prepare to administer to administer to administer the prepare to administer to admini Moderate to sever from other vaccines by 14 days before or after or after the administration of Moderna COVID-19 vaccine 19 vaccine products o Choose the correct r the administration of Pfizer-BioNTech COVID-19 Provide all recipients v Moderna COVID-19 Vaccine should be deferred for at New vaccination recommendations in persons with a history of dermal injection site for perso Authorization (EUA) Fa least 90 days for persons who received passive antibody » 18 years of age: 1-in Pfizer-BioNTech COVID-19 Vaccine should be therapy (monocional antibodies or convalescent plasma) fillers Prepare to administer » 19 years of age and Coadministration with other as part of COVID-19 treatment. deferred for at least 90 days for persons who o Choose the correct in the corre o Follow the manufactu received passive antibody therapy (monoclonal Screen for contraindications and precautions vaccines Additional resources on vaccine excipients (Appendix B) punctured vaccine via antibodies or convalescent plasma) as part of 16 through 18 year 19 years of age an Sex and Weight of Patient Needle Lengt Booster doses Sex and Weight of Patient Needle L 365-1\* Female or male fewer than 130 lbs 22-25 Female or male fewer than 130 lbs 22-25 915-1" Female or male 130-152 lbs 1\* 22-25 Female or male 130-152 lbs 22-25 12 1-11/2\* Background Female 152-200 lbs 22-25 Vaccination of persons with a SARS-1-115" 22-25 Male 153-260 lbs 22-25 1-11/2\* 22-25 1-132\* CoV-2 infection or exposure Female 200+ lbs 22-25 132 22-25 11/2\* Male 260+ lbs 22-25 132 22-25 11/5\* De The Advisory Committee on Immunization Practices (ACIP) has issued interim was given as early as the first dose, then Vaccination of persons with • If the second dose of Moderna COMD-19 Vacine was give ecommendations for the use of Pfizer-BioNTech and Moderna COVID-19 te allergic reaction is defined as For the purpose of this guidance, an im r symptome such as unficaria, angloede Alternatively, the enterplateral think also can be used https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-12/21/2020 considerations.html

COVID-19 Vaccine Standing orders and other clinical tools:

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

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/standing-orders.pdf

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standing-orders.pdf

**Emergency Standing Orders** 

https://www.immunize.org/catg.d/p3082a.pdf

https://www.immunize.org/catg.d/p3082.pdf

#### **Interim considerations:**

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

and

### **Testing after allergic reactions**

https:// https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html https://www.cdc.gov/vaccines/covid-19/clinical-considerations/testing-after-allergic-reaction.html

COVID-19 Vaccine Standing orders and other clinical tools can be found at: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html</u>

Emergency Standing Orders https://www.immunize.org/catg.d/p3082a.pdf https://www.immunize.org/catg.d/p3082.pdf

#### CDC Centers for Disease Control and Prevention Q CDC 24/7: Saving Lives, Protecting People\*\* Search Vaccines site 🔻 Advanced Search Vaccines & Immunizations CDC G 🖸 🔞 Vaccines and Immunizations Interim Considerations: Preparing for the Potential Home Management of Anaphylaxis at COVID-19 Vaccination For Parents Sites For Adults Anaphylaxis is an acute and potentially life-threatening serious allergic reaction. Severe allergic reaction (e.g., anaphylaxis) to For Pregnant Women any component of the Pfizer-BioNTech COVID-19 vaccine listed in the prescribing information 2 is a contraindication to vaccination. Anaphylactic reactions in persons receiving the Pfizer-BioNTech COVID-19 vaccine outside of clinical trials have For Healthcare Professionals been reported. While these reports are further investigated, CDC considers a history of severe allergic reaction such as anaphylaxis to any vaccine or to any injectable therapy (e.g., intramuscular, intravenous, or subcutaneous) as a precaution, COVID-19 Vaccination but not contraindication, to vaccination. Detailed information on CDC recommendations can be found in the Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine. For Immunization Managers These clinical considerations provide information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination. Institutional practices and site-specific factors may also be considered. In all cases, For Specific Groups of People appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a Pfizer-BioNTech COVID-19 vaccine. Basics and Common Questions Vaccines and Preventable Appropriate medical treatment for severe allergic reactions must be immediately available in the event Diseases that an acute anaphylactic reaction occurs following administration of Pfizer-BioNTech COVID-19 vaccine News and Media Resources Observation period following COVID-19 vaccination CDC currently recommends that persons who receive a Pfizer-BioNTech COVID-19 vaccine be observed after vaccination for the following time periods: · Persons with a history of anaphylaxis (due to any cause): 30 minutes

All other persons: 15 minutes

#### Early recognition of anaphylaxis

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and

Centers for Disease Control and Prevention

#### Vaccines & Immunizations

#### Lab Tests to Collect Shortly After Severe Allergic Reaction/Anaphylaxis Following COVID-19 Vaccination

#### For Healthcare Providers

There are no specific lab tests that can definitively diagnose the cause of a severe allergic reaction (e.g., anaphylaxis) following COVID-19 vaccination. In the United States, two commercially available lab tests can be ordered by healthcare providers and processed through healthcare facilities to better characterize a severe allergic reaction.

### **Managing Acute Vaccine Reactions**

- Severe reactions are rare
- Screening can help prevent reactions
- Staff should be familiar with signs and symptoms of hypersensitivity/anaphylaxis
- There must be a clinic emergency plan for dealing with reactions and you need to ensure that all staff are familiar with that plan.
- Have Emergency Treatment Standing Orders signed before the clinic
- Staff must have had appropriate training and equipment to manage reactions
- All vaccination providers should be currently certified in CPR

https://www.immunize.org/catg.d/p3082a.pdf https://www.immunize.org/catg.d/p3082.pdf https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html The table below has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, describes steps screen patients for vaccine contraindications to take if an adverse reaction occurs following ing Checklist for Contraindications to Vaccines vaccination. catg.d/p4060.pdf). When adverse reactions do

Administering any medication, including vaccines, occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

and precautions prior to vaccination (see "Screenfor Children and Teens" at www.immunize.org/ provide appropriate medical care should such an event occur

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to

REACTION SIGNS AND SYMPTOMS MANAGEMENT Localized Soreness, redness, itching, or swelling at the Apply a cold compress to the injection site. injection site Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication Slight bleeding Apply pressure and an adhesive compress over the injection site Continuous bleeding Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleed ing injection site (e.g., arm) above the level of the patient's heart. Psychological Fright before injection is given Have patient sit or lie down for the vaccination.

#### Medical Management of Vaccine Reactions in Adults in a Community Setting

	Administering any medication, including vaccines,	they can vary from minor (e.g., soreness, itching)
The table below	has the potential to cause an adverse reaction.	to the rare and serious (e.g., anaphylaxis). Be
describes steps	To minimize the likelihood of an adverse event,	prepared.
to take if an	screen patients for vaccine contraindications	Vaccine providers should know how to rec-
adverse reaction	and precautions prior to vaccination (see "Screen-	ognize allergic reactions, including anaphylaxis.
occurs following	ing Checklist for Contraindications to Vaccines	Have a plan in place and supplies available
vaccination.	for Adults" at www.immunize.org/catg.d/	to provide appropriate medical care should such
	p4065.pdf). When adverse reactions do occur,	an event occur.

REACTION	SIGNS AND SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply pressure and an adhesive compress over

#### Emergency medical protocol for management of anaphylactic reactions in adults in a community setting

- 1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- 2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway. breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.
- **3** DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
- a First-line treatment: EPINEPHRINE is the first-line treatment for anaphylaxis, and there is no known equivalent substitute. Use epinephrine in a 1.0 mg/mL

## Recommended medications and supplies for the management of anaphylaxis at COVID-19 vaccination sites

Should be available at all sites	Include at sites where feasible
Epinephrine prefilled syringe or autoinjector*	Pulse oximeter
H1 antihistamine (e.g., diphenhydramine) <sup>+</sup>	Oxygen
Blood pressure monitor	Bronchodilator (e.g., albuterol)
Timing device to assess pulse	H2 antihistamine (e.g., famotidine, cimetidine)
	Intravenous fluids
	Intubation kit
	Adult-sized pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)

\*COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.

<sup>+</sup>Antihistamines may be given as adjunctive treatment and should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

### CDC guidance for use of COVID-19 vaccines and management of anaphylaxis (1)

- Ensure necessary supplies available to manage anaphylaxis, especially sufficient quantities of epinephrine in prefilled syringes or autoinjectors;
- Screen potential vaccine recipients to identify persons with contraindications and precautions
- Implement recommended post-vaccination observation periods, either 15 or 30 minutes depending on each patient's previous history of allergic reactions
- Ensure that health care providers can recognize the signs and symptoms of anaphylaxis early

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s\_cid=mm7002e1\_w\_ https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-byproduct%2Fpfizer%2Fanaphylaxis-management.html

### CDC guidance for use of COVID-19 vaccines and management of anaphylaxis (2)

- Immediately treat suspected anaphylaxis with intramuscular epinephrine; because of the acute, life-threatening nature of anaphylaxis
  - There are no contraindications to epinephrine administration.
- Patients experiencing anaphylaxis should be transported to facilities where they can receive appropriate medical care.
- All patients should be instructed to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination location.
- Health care providers can play an important role in vaccine safety by being vigilant in recognizing and reporting adverse events after immunization to VAERS at <u>https://vaers.hhs.gov/reportevent.html</u>

MDPH 2021

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s\_cid=mm7002e1\_w https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-byproduct%2Fpfizer%2Fanaphylaxis-management.html 58



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

Early recognition of anaphylaxis symptoms

Prompt treatment with epinephrine

Activation of emergency medical services







https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

## Your Role

- 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-safe program yourself when you get vaccinated and encourage patients to participate in v-safe
- Communicate with patients on vaccine safety

### **COVID-19 Vaccine Adverse Event Reporting**

- Healthcare providers are required to report to VAERS the following adverse events after COVID-19 vaccination, under Emergency Use Authorization (EUA), and other adverse events if later revised by CDC:
  - Vaccine administration errors, whether or not associated with an adverse event (AE)
  - Serious AEs regardless of causality. Serious AEs per FDA are defined as:
    - 1. Death;
    - 2. A life-threatening AE;
    - 3. Inpatient hospitalization or prolongation of existing hospitalization;
    - 4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - 5. A congenital anomaly/birth defect;
    - 6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.
  - Cases of Multisystem Inflammatory Syndrome (MIS)
  - Cases of COVID-19 that result in hospitalization or death
- Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.
- Also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an EUA
- To the extent feasible, adverse events should be reported to Pfizer and Moderna as well.

### VAERS is the nation's early warning system for vaccine safety

### How to report an adverse event:

- Go to <u>vaers.hhs.gov</u>
- Submit a report online
- For help:
  - Call: 1-800-822-7967
  - Email: info@VAERS.org
  - Video instructions
     <u>https://youtu.be/sbCWh</u>
     <u>cQADFE</u>

- VAERS Vaccine Adverse Event Reporting System About VAERS Report an Adverse Event VAERS Data Submit Follow-Up Information Resources Have you had a reaction following a vaccination? 1 Contact your healthcare provider 2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. New! mportant: If you are experiencing a medical emergency, seel immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment advice, or diagnosis. If you need individual medical or health care advice consult a qualified healthcare provide ¿Ha tenido una reacción después de recibir una vacuna? 1. Contacte a su proveedor de salud. 2 Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. Nuevo! What is VAERS? REPORT AN ADVERSE EVENT SEARCH VAERS DATA REVIEW RESOURCES SUBMIT FOLLOW-UP INFORMATION Upload additional information related Report significant adverse events Download VAERS Data and search Find materials publications learning after vaccination the CDC WONDER database tools, and other resources to VAERS reports
- For COVID-19 vaccines, when filling out the form:
  - Put "Pfizer COVID- 19 Vaccine EUA" in the description box.
  - Put "Moderna COVID- 19 Vaccine EUA" in the description box.





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 vaccine dose.





Get vaccinated. Get your smartphone. Get started with v-safe.

#### What is v-safe?

V-safe is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through v-safe, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And v-safe will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's *v-safe* makes a difference — it helps keep COVID-19 vaccines safe.

#### How can I participate?

Once you get a COVID-19 vaccine, you can enroll in **v-safe** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from **v-safe** around 2pm local time. To opt out, simply text "STOP" when **v-safe** sends you a text message. You can also start **v-safe** again by texting "START."

#### How long do v-safe check-ins last?

During the first week after you get your vaccine, **v-safe** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions **v-safe** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, **v-safe** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

#### Is my health information safe?

Yes. Your personal information in v-safe is protected so that it stays confidential and private.\*

To the eatent v-zafe uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of semitivity. These measures comply, where applicable, with the following federal laws, including the Privacy Act of 1974; standards enacted that are consistent with the Health insurance Portability and Accountability Act of 1996 (HEPA); the Federal Information Security Management Act, and the Freedom of Information Act.



#### 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 vaccine dose.



Sign up with your smartphone's browser at vsafe.cdc.gov

OR Aim your smartphone's



#### How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

#### Register

1. Go to the v-safe website using one of the two options below:





- 2. Read the instructions. Click Get Started.
- 3. Enter your name, mobile number, and other requested information. Click Register.
- You will receive a text message with a verification code on your smartphone. Enter the code in v-safe and click Verify.
- 5. At the top of the screen, click Enter your COVID-19 vaccine information.
- Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click Next.
- 7. Review your vaccine information. If correct, click Submit. If not, click Go Back.
- 8. Congrats! You're all set! If you complete your registration before 2pm local time, v-safe will start your initial health check-in around 2pm that day. If you register after 2pm, v-safe will start your initial health check-in immediately after you register just follow the instructions.
  - You will receive a reminder text message from v-safe when it's time for the next check-in around 2pm local time. Just click the link in the text message to start the check-in.

#### Complete a v-safe health check-in

- 1. When you receive a v-safe check-in text message on your smartphone, click the link when ready.
- 2. Follow the instructions to complete the check-in.

#### Troubleshooting

#### How can I come back and finish a check-in later if I'm interrupted?

 Click the link in the text message reminder to restart and complete your check-in.

#### How do I update my vaccine information after my second COVID-19 vaccine dose?

 V-safe will automatically ask you to update your second dose information. Just follow the instructions. Need help with v-safe? Call 800-CDC-INFO (800-232-4636) TTY 888-232-6348 Open 24 hours, 7 days a week Visit www.cdc.gov/vsafe



#### Mass.gov website

https://www.mass.g ov/lists/additionalcovid-19vaccinationresources-forproviders#cdc:-toolsfor-vaccineproviders-

**CDC** website

https://www.cdc. gov/coronavirus/2 019ncov/vaccines/saf ety/vsafe.html

12/01/20

### 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 <u>ACIP</u> 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)

\*\*Advice from CDC and CISA is meant to assist in decision-making, rather than provide direct patient management

<sup>\* &</sup>lt;u>https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html</u>

### How to report an adverse event to VAERS

- Go to <u>vaers.hhs.gov</u> and submit a report online
- For help: call 1-800-822-7967, email info@VAERS.org
- Video instructions <u>https://www.youtube.com/watch?v=sbCWhcQADFE</u>

### How to contact CDC at CDC-INFO

- Go to <u>https://www.cdc.gov/cdc-info/index.html</u>
- Call 1-800-CDC-INFO (800-232-4636)



### **Safety information resources**

- https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html
- https://www.cdc.gov/v accinesafety/ensuringsafety/monitoring/vaers/index.html

### CISA

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

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### **CDC COVID-19 Vaccine Resources**

#### **HEALTHCARE PROVIDERS / PUBLIC HEALTH:**

COVID-19 Vaccination - Clinical Resources for Each COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/index.html

Interim Clinical Considerations for Use of COVID-19 Vaccine https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

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

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

What to Expect after Getting a COVID-19 Vaccine – handout for recipients <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-</u> A FS What Expect COVID-19 Vax Final 12.13.20.pdf

COVID-19 Vaccination - Clinical Resources for Each COVID-19 Vaccine <u>https://www.cdc.gov/vaccines/covid-19/index.html</u>

Recipient Education https://www.cdc.gov/vaccines/covid-19/hcp/index.html

Understanding and Explaining mRNA COVID-19 Vaccines https://www.cdc.gov/vaccines/covid-19/hcp/mrna-vaccine-basics.html

Talking to Patients about Covid-19 Vaccines https://www.cdc.gov/vaccines/covid-19/hcp/talking-to-patients.html

Answering Patients' Questions

https://www.cdc.gov/vaccines/covid-19/hcp/answering-questions.html

Frequently Asked Questions about COVID-19 Vaccination https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

#### ACIP

Main page https://www.cdc.gov/vaccines/acip/index.html

COVID-19 Recommendations (MMWRs) https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

#### V-SAFE and VaxText:

V-Safe After Vaccination Health Checker: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

FAQ's About V-Safe: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/faq.html

Vax Text: https://www.cdc.gov/vaccines/covid-19/reporting/vaxtext/

#### **COVID-19 Vaccination Tool Kits**

- Communication
- Recipient Education
- LTCF
- Special Populations (Essential Workers, Community Based Organizations) https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html

#### **VACCINE STORAGE & HANDLING TOOLKIT**

with Covid-19 Vaccine Addendum https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/index.html

### **COVID-19 Vaccine Resources**

#### TRAINING & RESOURCES: CDC Training Education

https://www.cdc.gov/vaccines/ed/index.html

COVID-19 Vaccine Training Module for Health Care Providers <a href="https://www2.cdc.gov/vaccines/ed/covid19/">https://www2.cdc.gov/vaccines/ed/covid19/</a>

COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals <u>https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-</u>for-HCPs.pdf

- Vaccine Storage and Handling
- Vaccine Administration
- Communicating with Patients about Vaccines
- COVID-19 Vaccine Training and Clinical Materials

COCA Calls/Webinars: https://emergency.cdc.gov/coca/calls/index.asp

#### **CIINC Webinars:**

https://www.cdc.gov/vaccines/ed/ciiw/index.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.g ov%2Fvaccines%2Fed%2Fciinc%2Findex.html

#### **GENERAL PUBLIC**

COVID-19 Vaccine information <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html</u>

- Frequently Asked Questions
- Benefits of Getting a COVID-19 Vaccine
- Ensuring Safety of COVID-19 Vaccines
- Ensuring COVID-19 Vaccines Work
- How CDC is Making COVID-19 Vaccine Recommendations
- How COVID-19 Vaccines Work
- Understanding and Explaining mRNA Vaccines

What to Expect about Your Appointment <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect.html</u> Available in Multiple languages

What to Expect after Getting a COVID-19 Vaccine – handout for recipients <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-A\_FS\_What\_Expect\_COVID-19\_Vax\_Final\_12.13.20.pdf</u>

### **Moderna COVID-19 Vaccine Resources**

#### MODERNA

Moderna Call Center: 1-866-MODERNA (1-866-663-3762) Moderna COVID-19 Vaccine Website:

https://www.modernatx.com/covid19vaccine-eua/

Moderna COVID-19 Vaccine EUA Website (EUA's and exp date look-

up): <u>https://www.modernatx.com/covid19vaccine-eua/providers/</u> Moderna COVID-19 Vaccine EUA for Providers:

https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheetproviders.pdf

Moderna COVID-19 Vaccine EUA for Recipients:

https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheetrecipients.pdf

#### US FDA

Moderna COVID-19 Vaccine EUAs, in multiple languages: https://www.fda.gov/emergency-preparedness-and-response/coronavirusdisease-2019-covid-19/moderna-covid-19-vaccine#additional EUA Letter, December 18, 2020 https://www.fda.gov/media/144636/download MODERNA EUA Factsheet for Providers: https://www.fda.gov/media/144637/download MODERNA EUA Factsheet for Caregivers: https://www.fda.gov/media/144638/download

#### CDC

COVID-19 Vaccination – Clinical Resources https://www.cdc.gov/vaccines/covid-19/index.html

Moderna COVID-19 Vaccine (general info, how to administer instructions, links to FAQs, EUAs, interim clinical considerations, storage and handling resources, screening form): https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/index.html

Interim Considerations: Preparing for the Potential Management of **Anaphylaxis** at COVID-19 Vaccination Sites <u>https://www.cdc.gov/vaccines/covid-19/info-by-</u>product/pfizer/anaphylaxis-management.html

COVID-19 Vaccine Prevaccination Screening Form https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Moderna COVID-19 Vaccine Standing Order:

https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/standingorders.pdf

Moderna COVID-19 Vaccine Preparation and Administration Summary Sheet: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/prep-and-admin-summary.pdf</u>

Moderna COVID-19 Vaccine Storage and Handling Summary: <u>https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/downloads/storage-summary.pdf</u>

COVID-19 Vaccine Expiration Date Tracking Tool https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expirationtracker.pdf

### **Pfizer-BioNTech COVID-19 Vaccine Resources**

#### **PFIZER BIONTECH**

Pfizer Customer Service: 1-800-TRY-FIRST (1-800-879-3477) Pfizer-BioNTech COVID-19 Vaccine Website:

https://www.cvdvaccine.com/

Pfizer BioNTech COVID-19 Vaccine EUA for Providers: http://labeling.pfizer.com/ShowLabeling.aspx?id=14471 Pfizer BioNTech COVID-19 Vaccine EUA for Recipients: http://labeling.pfizer.com/ShowLabeling.aspx?id=14472

#### **US FDA**

Pfizer-BioNTech COVID-19 Vaccine EUAs, in Multiple Languages: https://www.fda.gov/emergency-preparedness-andresponse/coronavirus-disease-2019-covid-19/pfizer-biontechcovid-19-vaccine EUA Letter, Dec 11, 2020: https://www.fda.gov/media/144412/download PFIZER-BIONTECH EUA Factsheet for Providers: https://www.fda.gov/media/144413/download PFIZER-BIONTECH EUA Factsheet for Recipients: https://www.fda.gov/media/144414/download

#### CDC

COVID-19 Vaccination - Clinical Resources https://www.cdc.gov/vaccines/covid-19/index.html Pfizer-BioNTech COVID-19 Vaccine (general info, screening form, standing orders, vaccine prep and administration summary, mixing diluent, and more) https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/index.html Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites https://www.cdc.gov/vaccines/covid-19/info-byproduct/pfizer/anaphylaxis-management.html **COVID-19 Vaccine Prevaccination Screening Form** https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screeningform.pdf Pfizer-BioNtech COVID-19 Vaccine Standing Order https://www.cdc.gov/vaccines/covid-19/info-byproduct/pfizer/downloads/standing-orders.pdf Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary Sheet https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/prepand-admin-summarv.pdf Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary: https://www.cdc.gov/vaccines/covid-19/info-byproduct/pfizer/downloads/storage-summary.pdf Diluent poster https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/diluentposter.pdf

### **Select Vaccination Clinic Planning Resources**

- CDC Vaccination Guidance During a Pandemic: <u>https://www.cdc.gov/vaccines/pandemic-guidance/index.html</u>
- CDC Guidance for Planning for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations: <u>https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html</u>
- CDC Resources for Hosting a Vaccination Clinic (including a Best Practices Checklist): <u>https://www.cdc.gov/flu/business/hosting-vaccination-clinic.htm</u>
- CDC Clinic Supplies Check List: <u>https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/vaccination-clinic-supply-checklist.html</u> <u>https://www.cdc.gov/vaccines/hcp/admin/downloads/2020-vaccine-clinic-supply-checklist-508.pdf</u>
- CDC Infection Control Guidance: <a href="https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control.html">https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html</a>
- CDC Considerations for Planning Curbside/Drive-Through Vaccination Clinics: <u>https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/curbside-vaccination-clinics.html</u>
- IAC Protective Measures for Vaccinating During a Pandemic: <u>https://www.immunize.org/catg.d/p2009.pdf</u>
- IAC COVID Repository of Resources for Maintaining Immunizations during the COVID-19 Pandemic: <u>https://www.immunizationcoalitions.org/resource-repository/</u>

### **CDC COVID-19 Vaccine Communication Resources**

Get vaccinated

Stay 6 feet from others,

and avoid crowds.

www.cdc.gov/coronavirus/vaccines

### **COVID-19 Vaccination Tool Kits**

- Communication
- Recipient Education
- LTCF
- Special Populations (Essential Workers, Community Based **Organizations**)

https://www.cdc.gov/vaccines/c ovid-19/health-systemscommunication-toolkit.html





### **CDC Vaccine Administration Resources**

#### Vaccine Administration

The COVID-19 pandemic is changing rapidly and requires different strategies to ma including immunization. Find up-to-date guidance on childhood and maternal 🗹 va



Proper vaccine administration is critical to ensure that vaccination is safe and effectiv personnel who administer vaccines receive comprehensive, competency-based training and procedures BEFORE administering vaccines. Comprehensive, skills-based training staff education programs such as new staff orientation and annual education require Learn is available that offers continuing education for health care personnel, including

Review Immunization History Reviewing and assessing a patient's immunization history should be done at every health care visit to help determine which vaccines may be needed.

Assess for Needed Immunizations Use the current Advisory Committee on Immunization Practices (ACIP) immunization schedule to determine what recommended vaccines are needed based on the patient's immunization history.

Screen for Contraindications and Precautions

https://www.cdc.gov/vaccin es/hcp/admin/adminprotocols.html



#### Epidemiology and Prevention of Vaccine-Preventable Diseases

#### CDC > The Pink Book Home > Chapters

#### of The Pink Book Home

#### Front Matter Chapter 2: General Recommendations on Immunization

Chapter 3: Immunization Strategies for Healthcare Practices and

Providers

Chapter 4: Vaccine Safety Chapter 5: Storage and Handling

Chapter 6: Vaccine Administration

https://www.cdc.gov/vaccines/ pubs/pinkbook/vac-admin.html

#### Resource Library

## **Resource Library**

On This Page

lob Aids

References

Web Button

Web-based Training

Note: The materials listed on this page might be more current than vaccine administration information in previously published CDC documents, including the 13th edition of Epidemiology and Prevention of Vaccine-Preventable Diseases (the Pink Book). Always follow the most up-to-date guidelines in the <u>Vaccine Storage and Handling Toolkit</u> D or more recently dated materials.

#### Web-based Training Courses

#### Vaccine Administration e-Learn

A self-paced vaccine administration course that provides comprehensive training using videos, job aid resources.

#### You Call the Shots

An interactive, web-based immunization training course that includes the latest guidelines and recon vaccine practice.



https://www.cdc.gov/vaccine s/hcp/admin/resourcelibrary.html

Updated November 2020 Chapters IoEllen Wolicki, BSN, RN and Elaine Miller, RN, BSN, MPH Chapter 1: Principles of Vaccination This chapter summarizes best practices related to vaccine ac

key factor in ensuring vaccination is as safe and effective as r Administration involves a series of actions: assessing patient status and determining needed vaccines, screening for contr and precautions, educating patients, preparing and administ properly, and documenting the vaccines administered. Profe: standards for medication administration, manufacturer instr organizational policies and procedures should always be follapplicable.

Vaccine Administration

#### Staff Training and Education Policies should be in place to validate health care profession.

of, and skills in, vaccine administration. All health care profes

### **Clinical Resources for Proper Vaccine Administration**

 CDC Vaccine administration & Resource Library webpages-- information and materials for health care personnel including:

- IM demonstration video
- Job aids and infographics

www.cdc.gov/vaccines/hcp/admin/admin-protocols.html

https://www.cdc.gov/vaccines/hcp/admin/resource-library.html

 CDC Vaccine Admin E-Learn module: <u>https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp</u>



### Repository of Resources for Maintaining Immunization during the COVID-19 Pandemic

This repository of resources is intended for use by healthcare settings, state and local health departments, professional societies, immunization coalitions, advocacy groups, and communities in their efforts to maintain immunization rates during the COVID-19 pandemic. The repository includes links to international, national, and state-level policies and guidance and advocacy materials, including talking points, webinars, press releases, media articles, and social media posts, as well as telehealth resources. The materials listed below can be sorted and searched by date, title, geographic area, source, type, category, or setting.



Federal Guidance Document

This repository will grow with your help. If you know of national, state, or local guidance documents or other resources that should be added, please send a message to info@immunizationcoalitions.org.

							\$	Search		
Date 🍦	ID 🍦	Title	$\stackrel{\mathbb{A}}{\nabla}$	Area	÷	Source	÷	Туре 🍦	Category	Setting 🍦
10/20/20	C213	Interim Guidance for Routine and Influenza Immunization Services During the		US		CDC		Guidance/ Policy	All Ages	Healthcare
10/20/20	C214	Interim Guidance for Routine and Influenza		US		CDC		Guidance/	All Ages	Healthcare



#### https://immunize.org/

faccinating Adults:

Vaccinating Adults:

A Step-by-Step Guide

### **ACIP Best Practice Guidelines for Immunization**

**General Best Practice Guidelines for** 

Immunization

Best Practices Guidance of the Advisory Committee on Immunization Practices

(ACIP)

Kroger AT, Duchin J, Vázquez M

#### 1. Introduction

The Centers for Disease Control and Prevention (CDC) recommends routine vaccination to prevent 17 vaccine-preventable diseases that occur in infants, children, adolescents, or adults. This report provides information for clinicians and other health care providers about concerns that commonly arise when vaccinating persons of various ages.

- Describes the ACIPs recommendations and guidelines on vaccination practice
- Updated as needed online

### **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: <a href="https://www.mass.gov/topics/immunization">https://www.mass.gov/topics/immunization</a>

#### **MIIS Help Desk**

Phone: 617-983-4335

Fax: 617-983-4301

Email: miishelpdesk@state.ma.us

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

#### **MDPH Vaccine Unit**

Phone: 617-983-6828

Fax: 617-983-6924

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



### **Connect with DPH**







### Massachusetts Department of Public Health



### DPH blog

https://blog.mass.gov/publichealth



www.mass.gov/dph



### Massachusetts Department of Public Health





# Thank You For Being a COVID-19 Vaccinator !