COVID-19 Vaccine Recommendations

Massachusetts Adult Immunization Coaltion

Immunize MA

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1-26-21
Updated 2-9-21
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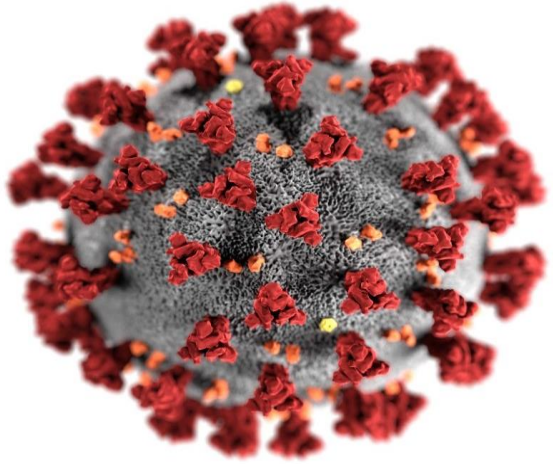


ACIP Meeting 1-27-21

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

	AGENDA ITEM	PRESIDER/PRESENTER(s)
Wednesday, 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
CMS	Centers for Medicare and Medicaid Services
COVID-19	Coronavirus disease 2019

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

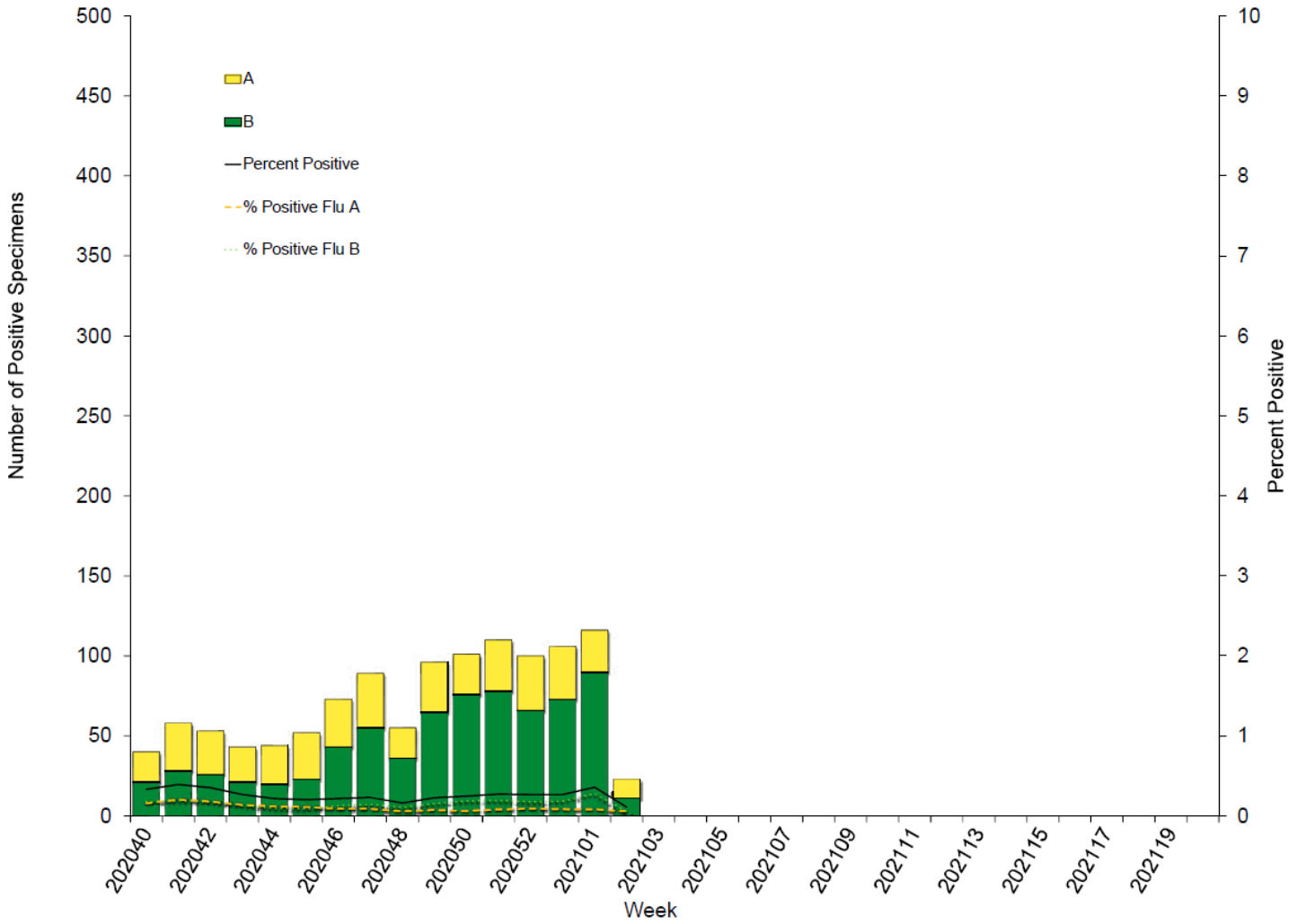
Outline

- **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



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

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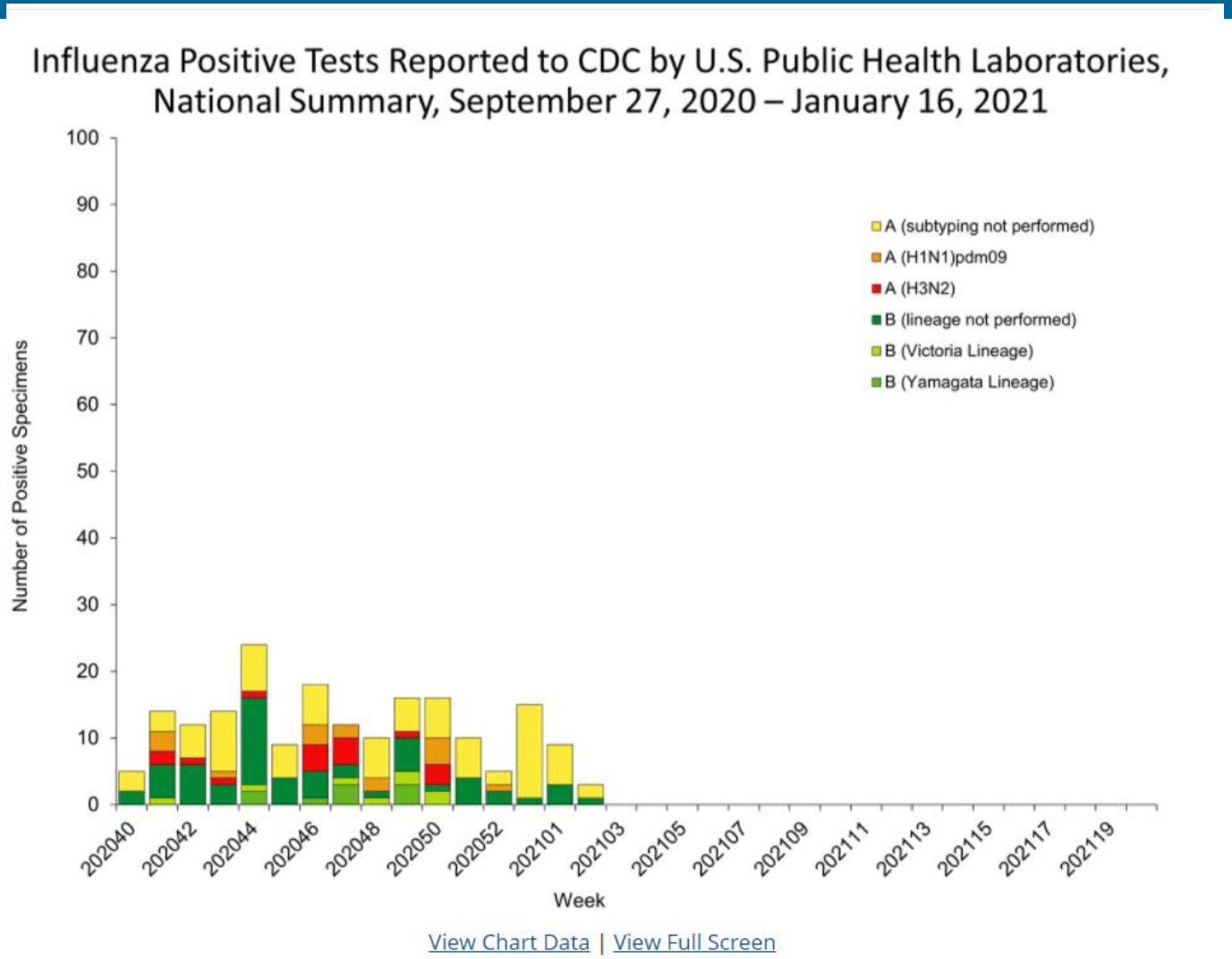
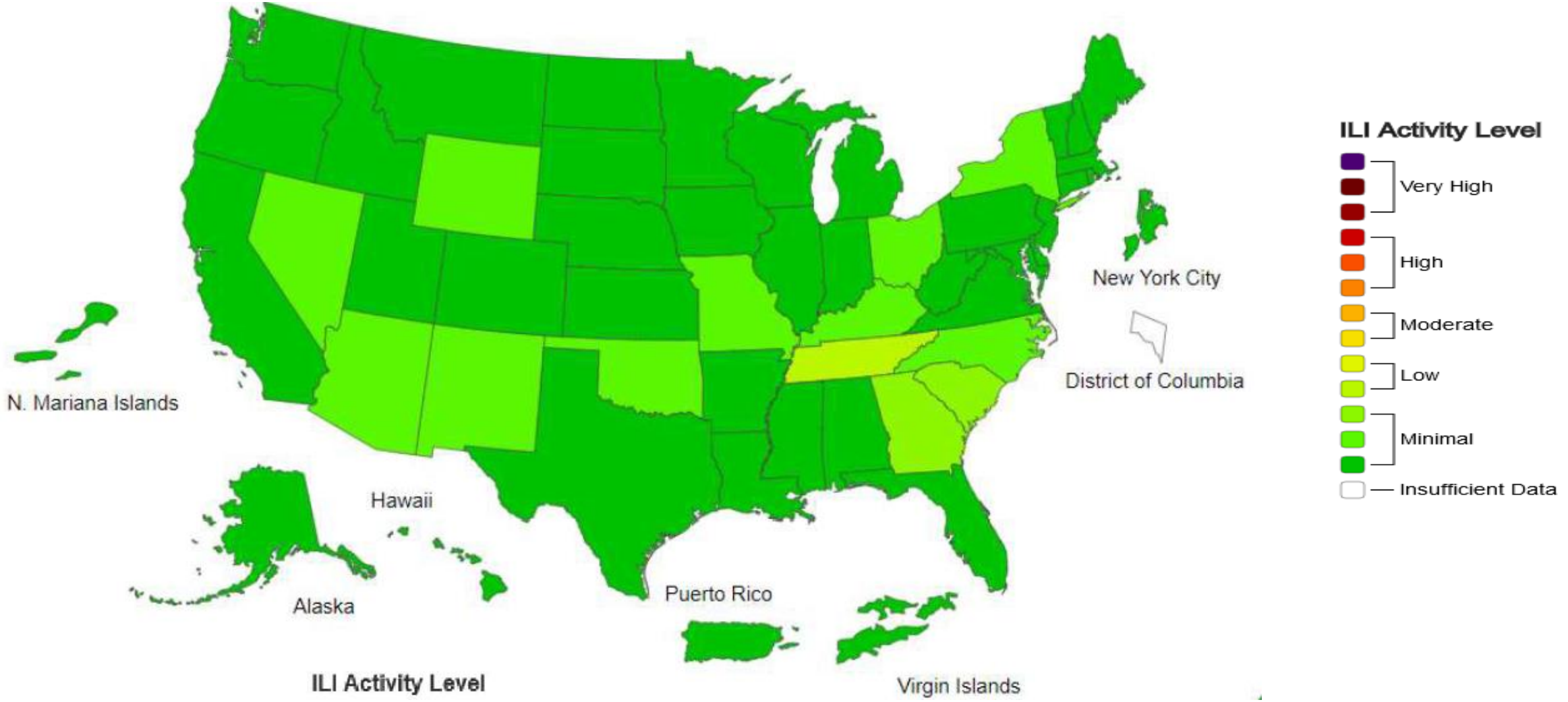


https://www.cdc.gov/flu/weekly/index.htm

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



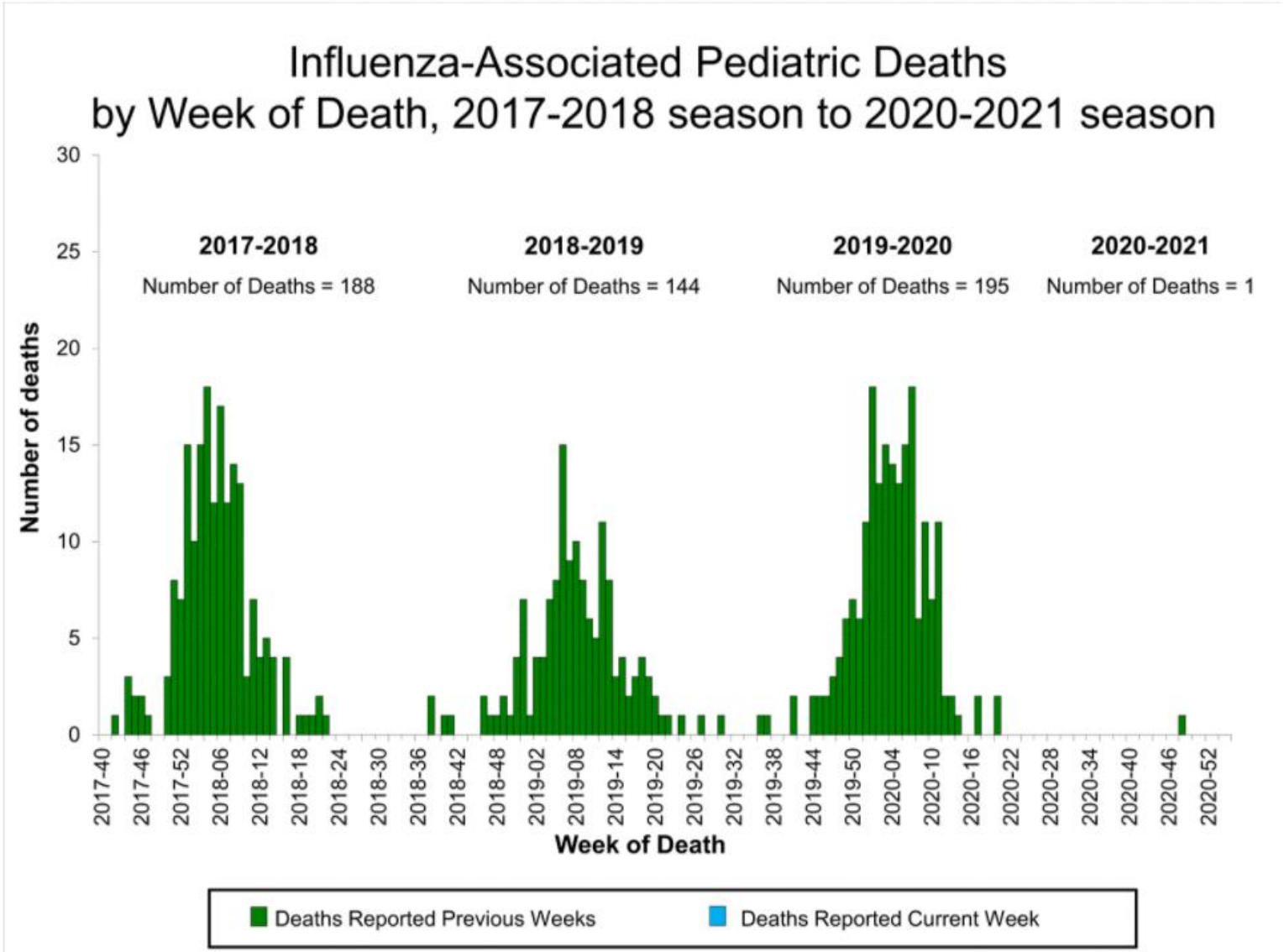
https://www.cdc.gov/flu/weekly/index.htm

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.

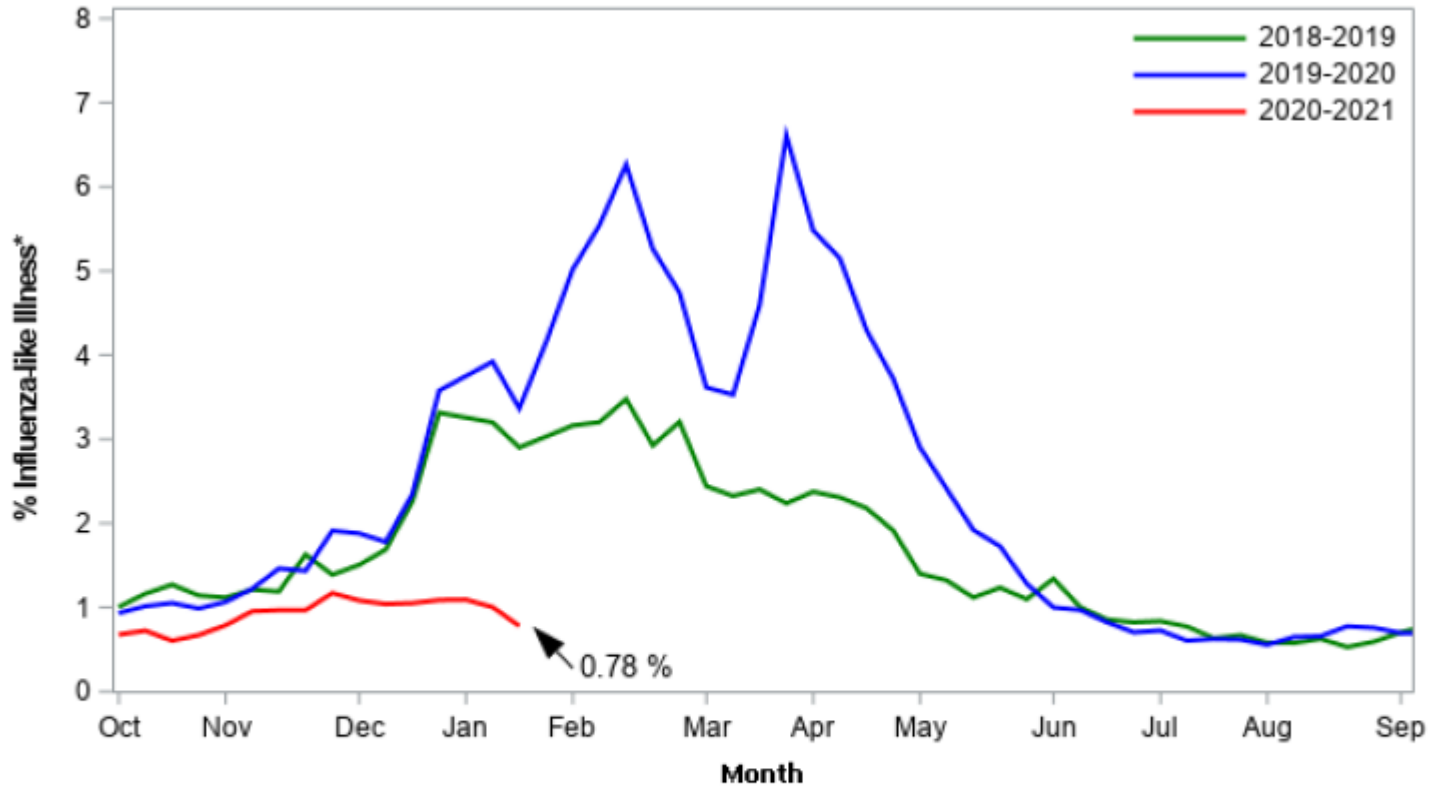


MDPH 2021

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

Massachusetts – Percent of ILI Visits 2020-2021

September 27, 2020-January 16, 2021 (reported by sentinel sites)



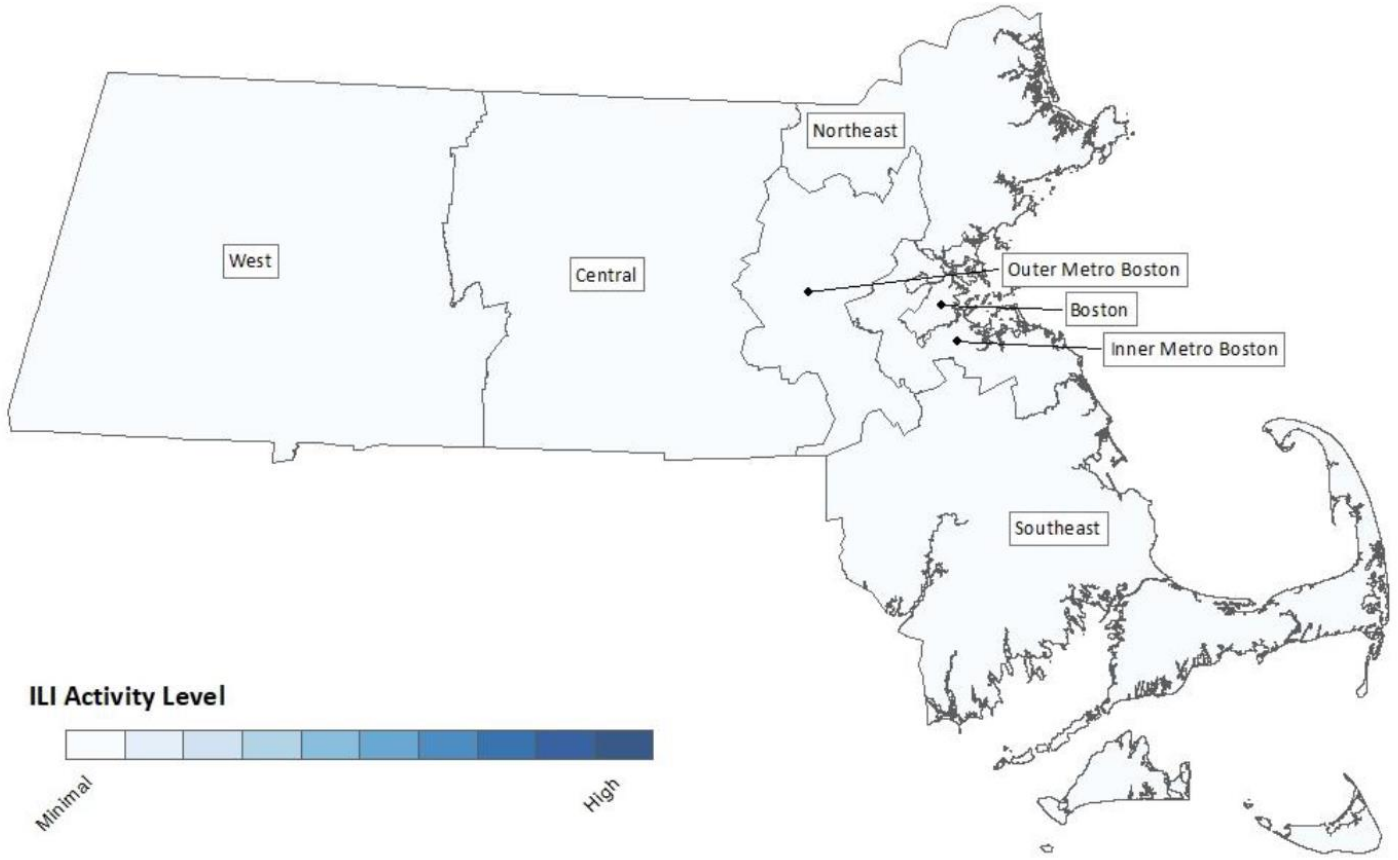
*Influenza-like illness (ILI, defined by fever >100F and cough and/or sore throat),as reported by Massachusetts sentinel surveillance sites. ILI reported by sentinel sites which report via ED syndromic surveillance include cases meeting the ILI definition and cases with a diagnosis indicating influenza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

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

Massachusetts by Region – ILI Activity 2020-2021

(reported by sentinel sites)

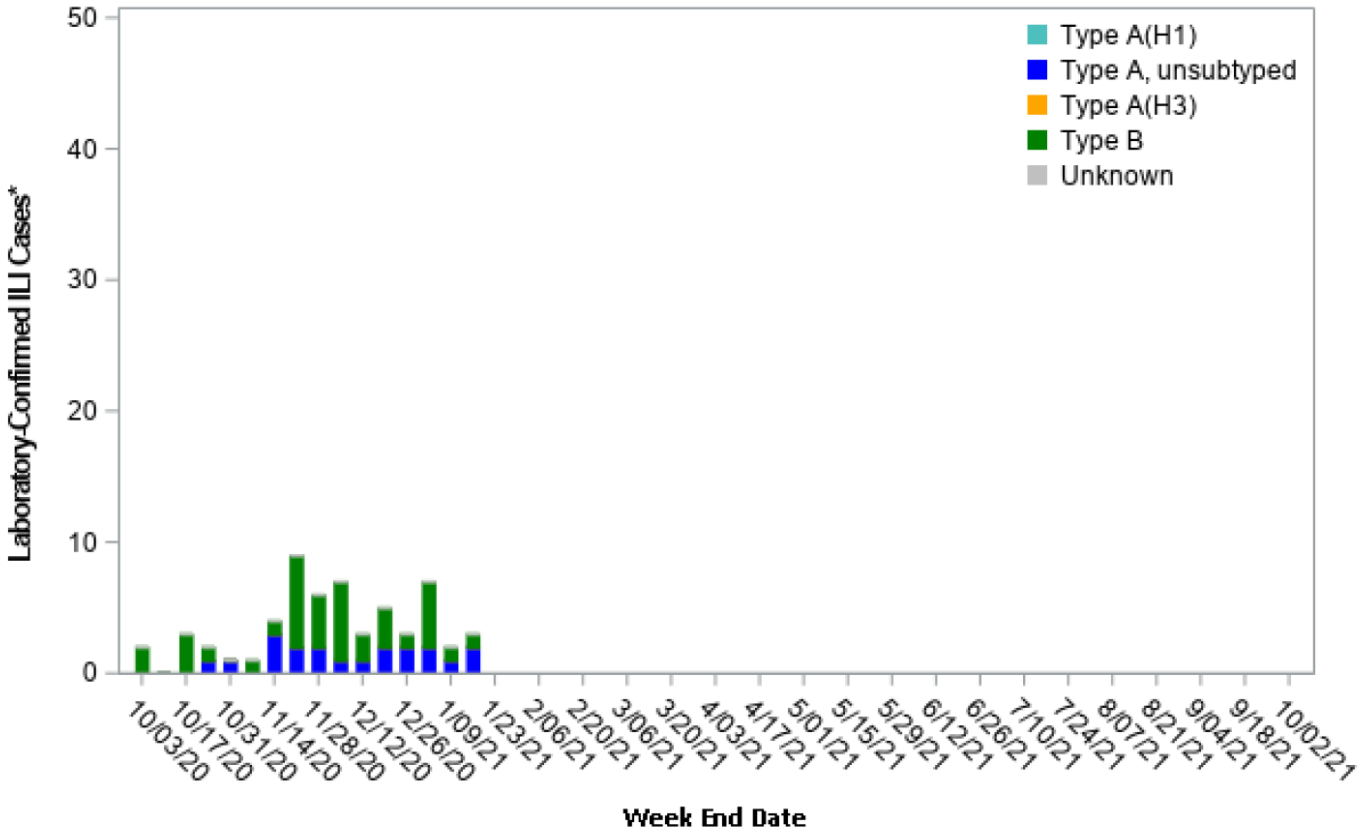
Figure 4: ILI Activity Reported Weekly by Massachusetts Sentinel Sites



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

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

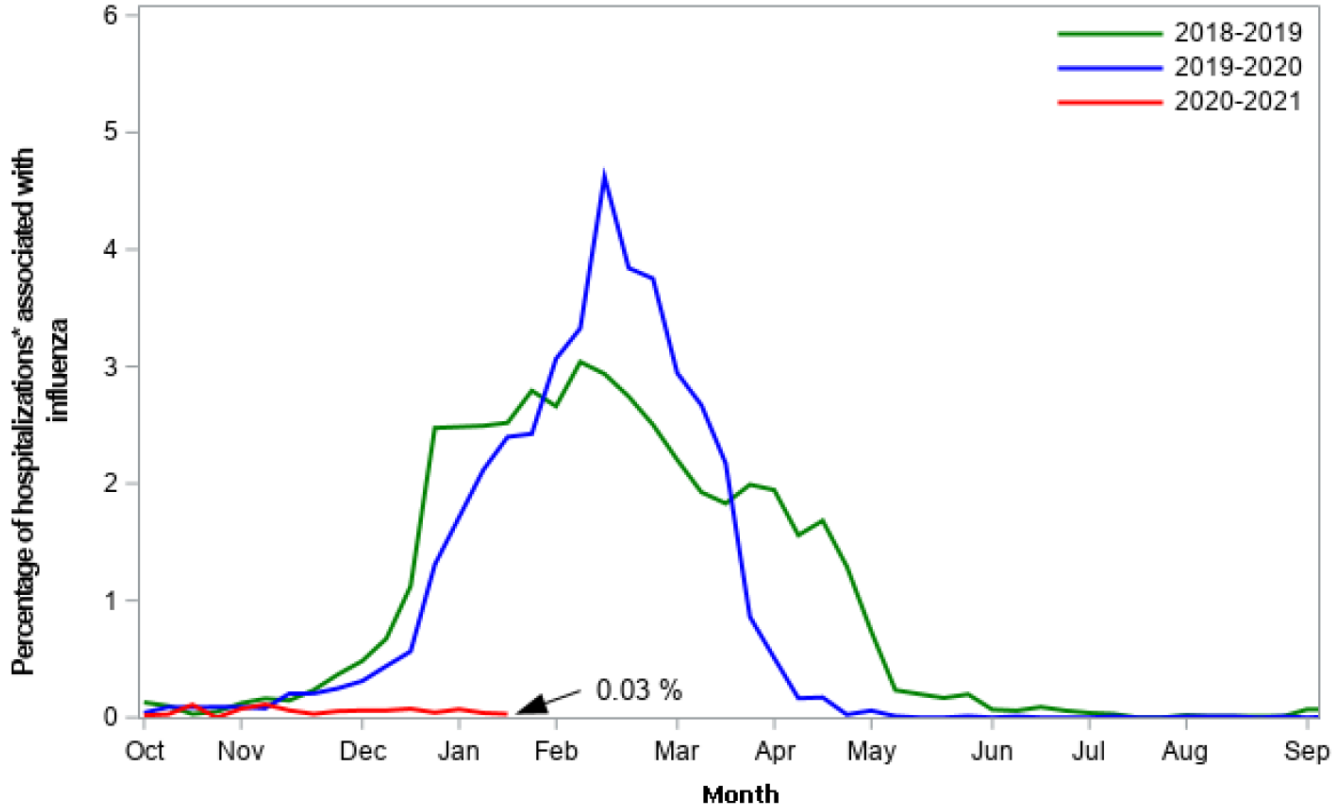


*Influenza cases confirmed via viral culture or PCR test by specimen collection date.

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

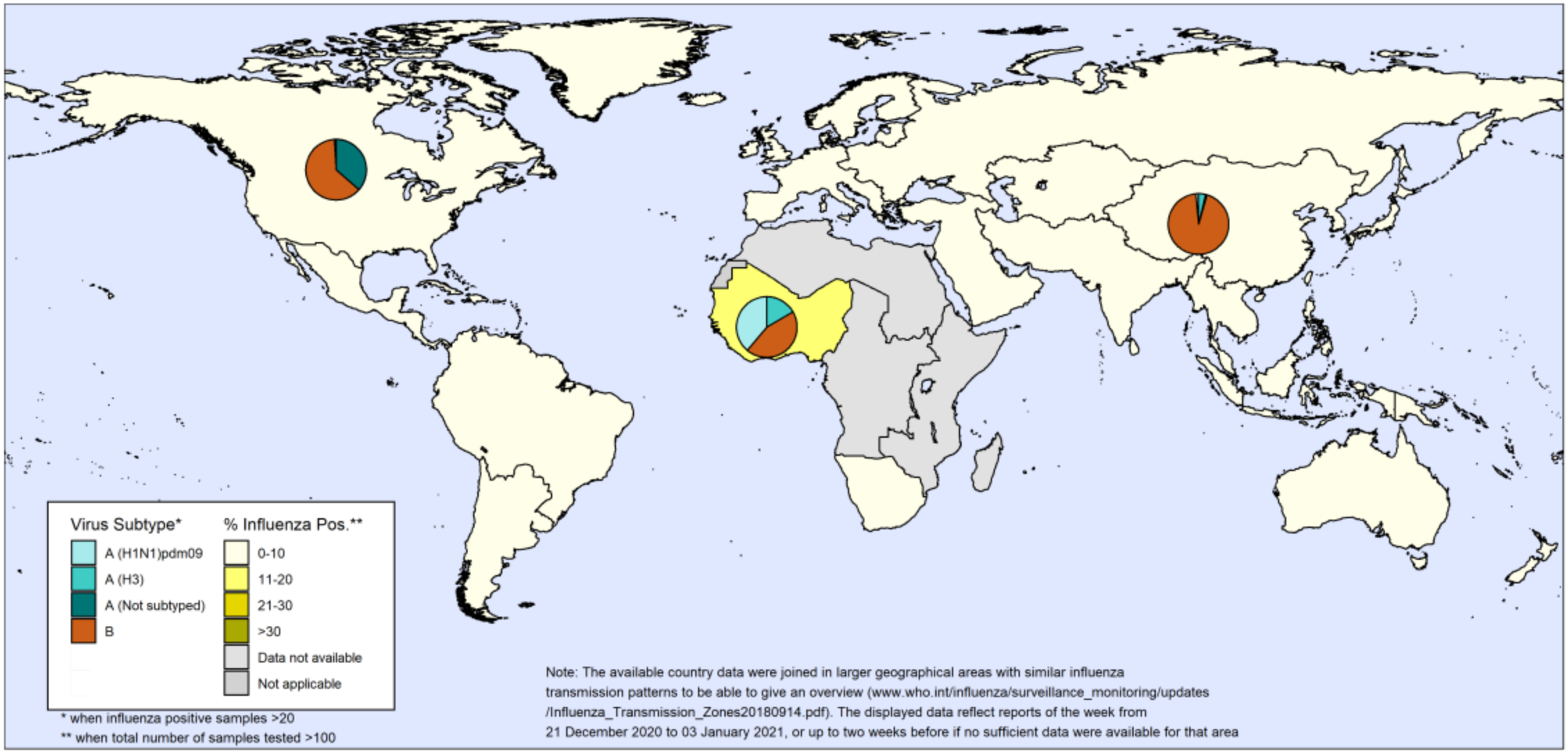


*All patients admitted through hospital emergency departments as captured by syndromic surveillance

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

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

Map generated on 15 January 2021

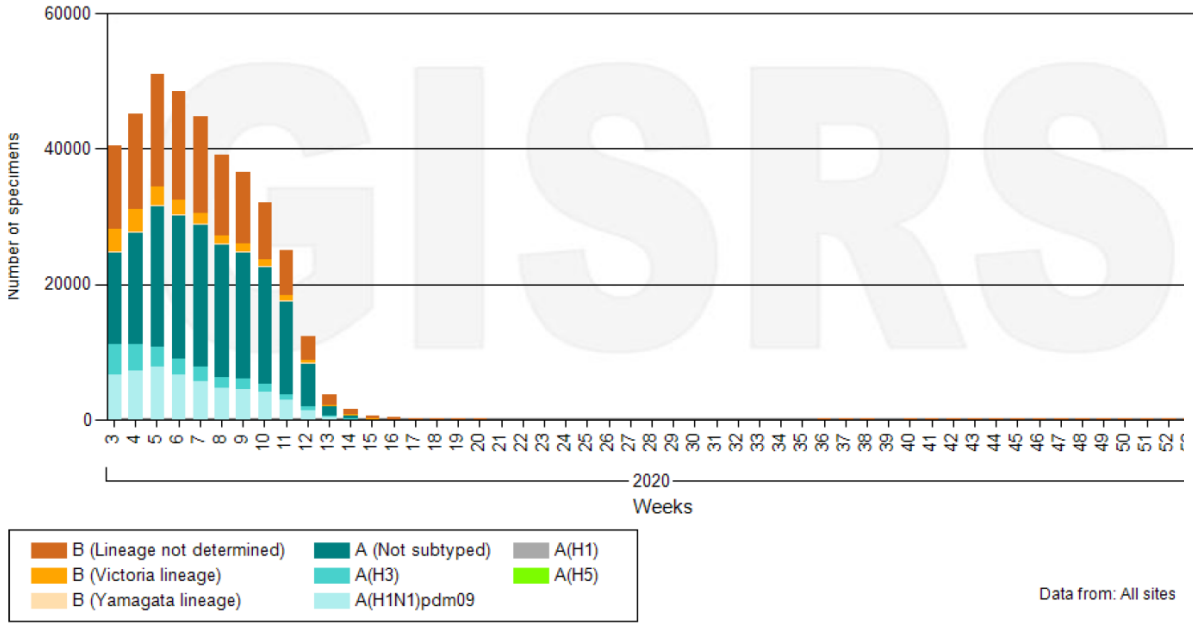


World Health Organization

Data source: Global Influenza Surveillance and Response System (GISRS), FluNet (www.who.int/flunet)

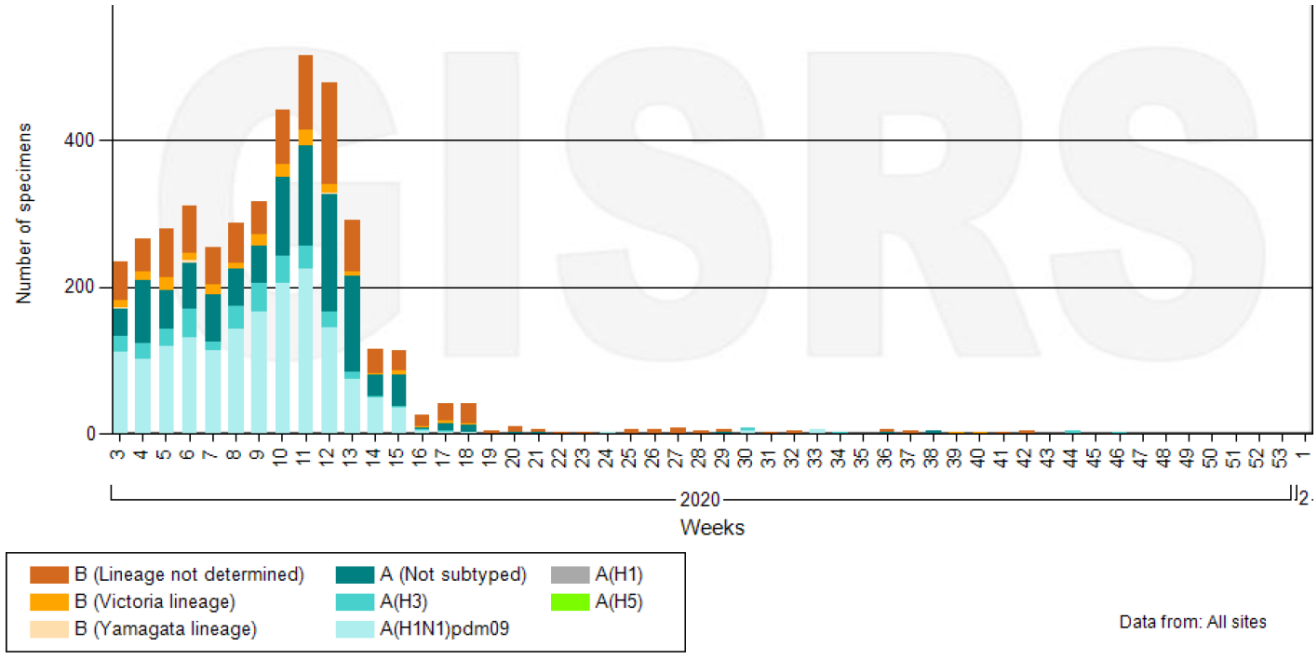
https://urldefense.com/v3/__https://www.who.int/influenza/surveillance_monitoring/updates/latest_update_GIP_surveillance/en/__;!!CUhgQOZgV7M!2hwVgDKefWxWpx-ifFPpxJV_NUQjxiPSz21i-wsh6ySMmpZw0hKTEAdScUJOhrjhqbY$

No of Specimens Positive for Influenza Northern Hemisphere



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

No of Specimens Positive for Influenza Southern Hemisphere



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

https://urldefense.com/v3/__https://www.who.int/influenza/surveillance_monitoring/updates/latest_update_GIP_surveillance/en/__;!!CUhgQOZqV7M!2hwVgDKefWxWpx-ifFPpxJV_NUQjxiPSz21i-wsh6ySMmpZw0hKTEAdScUJOhrjhqbY$

Recommendations are Rapidly Evolving…

Always check the websites
for the latest guidance and information.

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

COVID-19 Vaccination

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

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

General Vaccine Administration

Storage and Handling

Vaccination Toolkits

ACIP Recommendations

- V-safe
- Emergency Use Authorizations (EUAs)
- Clinical Considerations
- Recipient Education
- Training and Education
- Vaccination Provider Requirements & Support
- Planning and Partnerships
- Vaccination Data & Reporting Systems
- General Vaccine Safety

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

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

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

On This Page

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

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 contraindications to vaccination who receive an mRNA COVID-19 vaccine be observed after vaccination for the following time periods:

- 30 minutes: Persons with a history of an immediate allergic reaction of any severity to 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 needed for each specific COVID-19 vaccine that cover administration, storage and handling, safety, and reporting.

Pfizer-BioNTech

Moderna

Requirements, Trainings, and Resources

Vaccine Storage and Handling Toolkit

Provider Requirements and Support

Training and Education

COVID-19 Vaccine (Moderna) Administration Resources

Moderna COVID-19 Vaccine Standing Orders

Pre-Vaccination Screening Form

Preparation and Administration Summary

Vaccine administration training and clinical materials

Vaccine Expiration Date Tracking Tool

Moderna COVID-19 Vaccine

General Information:
Multidose vial: 10 doses per vial
Dosage: 0.5 mL

Do NOT mix with a diluent. Discard vial when there is not enough vaccine to obtain a complete dose. Do NOT combine residual vaccine from multiple vials to obtain a dose.

Age Indications:
18 years of age and older

Schedule:
2-dose series separated by 28 days
A series started with COVID-19 vaccine (Moderna) should be completed with this product.

Administer:
Intramuscular (IM) injection in the deltoid muscle

EUA

Interim Clinical Considerations

Moderna COVID-19 Vaccine FAQs

ACIP Recommendations

COVID-19 Vaccine (Moderna Storage and Handling Resources)

Storage and Handling Summary

Refrigerator Storage Temperature Log (Fahrenheit)

Moderna BUD Guidance and Labels

Freezer Storage Temperature Log (Celsius)

Storage and Handling Labels

Freezer Storage Temperature Log (Fahrenheit)

Refrigerator Storage Temperature Log (Celsius)

Vaccine Storage Troubleshooting Record for temperature excursions

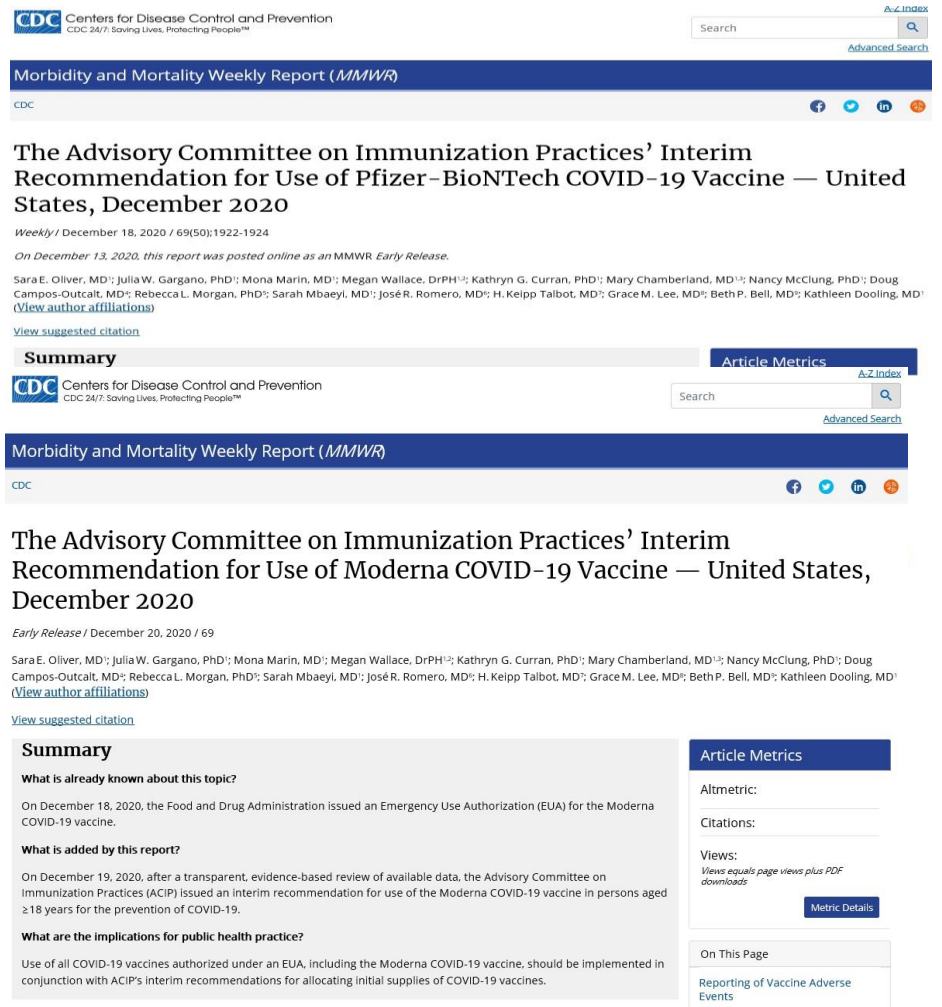
https://www.cdc.gov/vaccines/covid-19/info-by-product/index.html

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

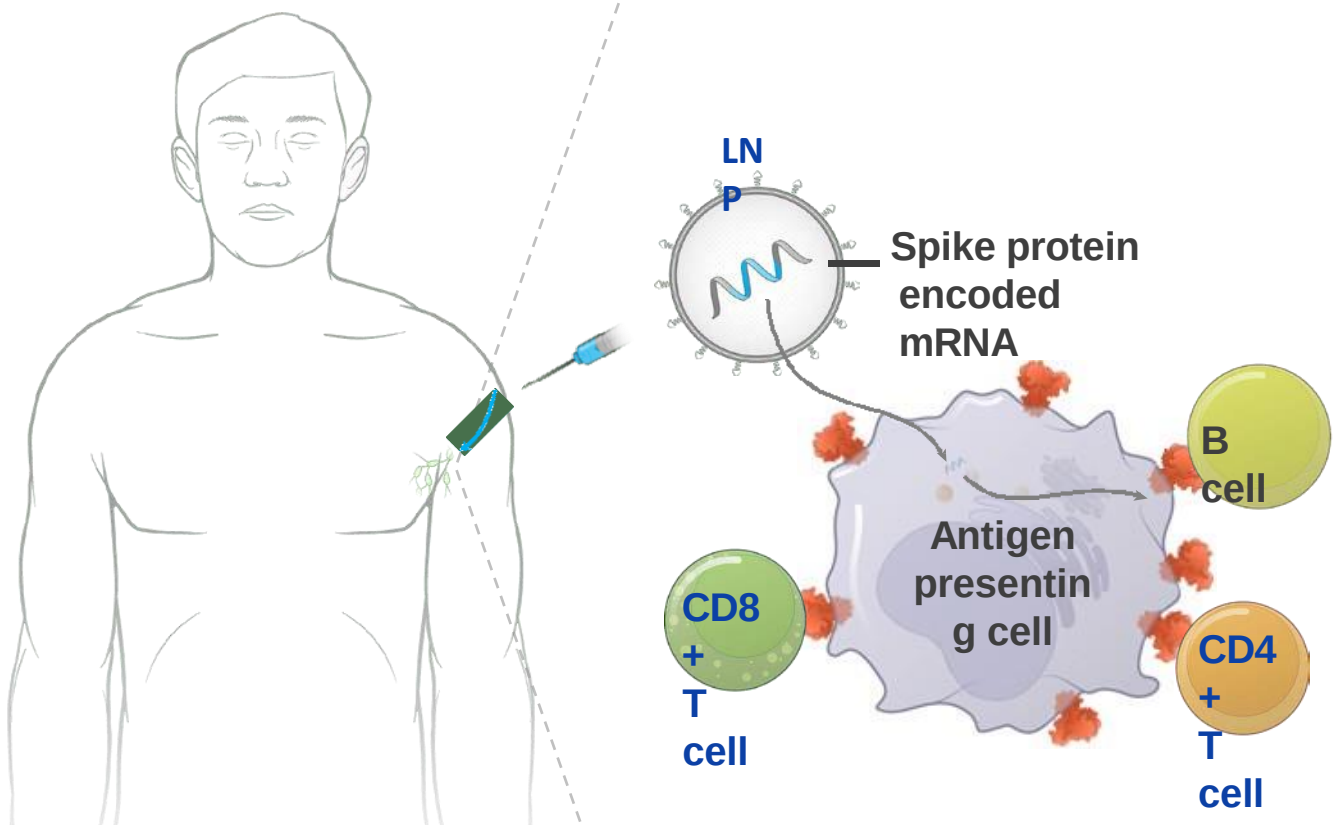
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html



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

Source: https://www.fda.gov/media/144583/download

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

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

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.

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

Oliver, Sarah. Work group interpretations of data. ACIP meeting 1-27-21

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).

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

Adapted from: Oliver, Sarah. Work group interpretations of data. ACIP meeting 1-27-21

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

- mRNA vaccines are recommended for a two-dose series administered intramuscularly
  - Pfizer-BioNTech: ≥16 years. Given **3 weeks (21 days)** apart
  - Moderna: ≥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.

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

Adapted from: Oliver, Sarah. Work group interpretations of data. ACIP meeting 1-27-21

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

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

Oliver, Sarah. Work group interpretations of data. ACIP meeting 1-27-21

Updated Strategies to help ensure patients receive 2nd 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 VaxText, a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- Encourage patients to enroll in V-safe 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.

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

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, current evidence suggests that the risk of SARS-CoV-2 reinfection is low in the months after initial infection but may increase with time due to waning immunity. **Thus, 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."

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

Persons with a known SARS-CoV-2 exposure

- **Residing in the Community:**
  - Defer vaccination until quarantine period has ended to avoid exposing healthcare personnel (HCP) or other persons during vaccination visit

- **Residents of congregate healthcare 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

https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html
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

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Immunocompromised persons

- Persons with HIV infection, other immunocompromising conditions, or who take immunosuppressive medications or therapies might be at increased risk for severe COVID-19

- 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

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.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

https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

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

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

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

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

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

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

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-A_FS_What_Expect_COVID-19_Vax_Final_12.13.20.pdf

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.

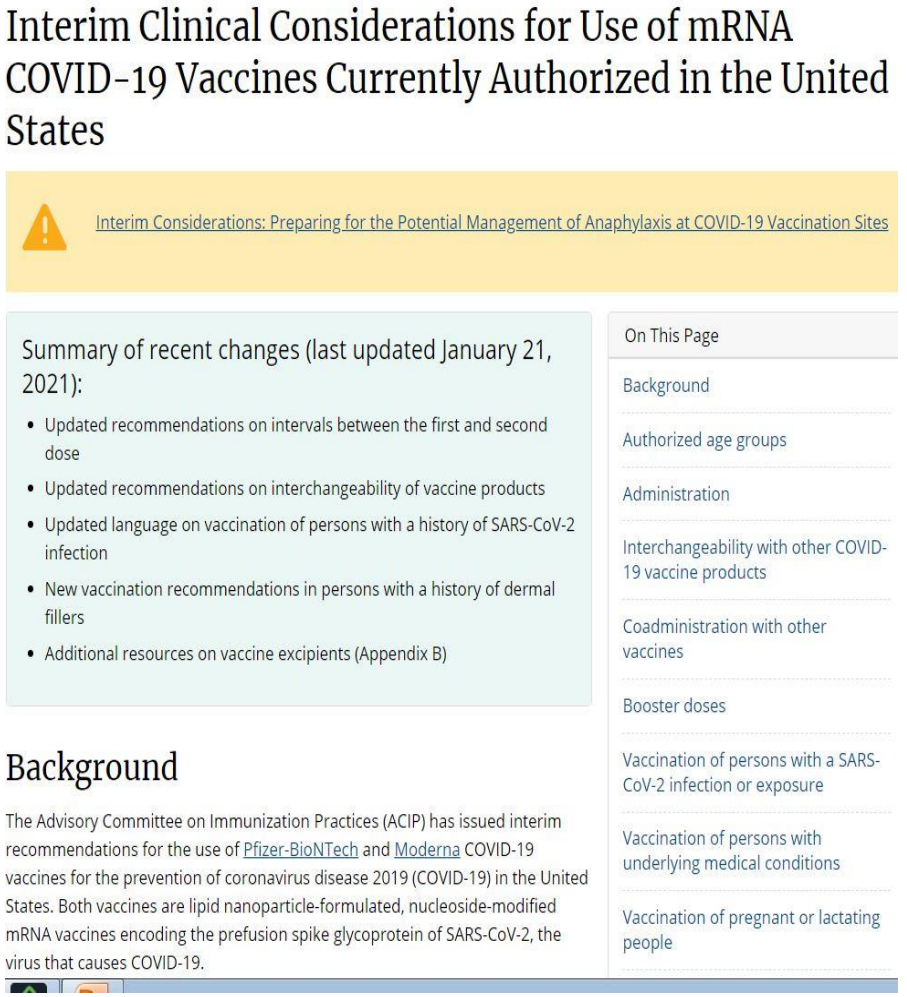
- **mRNA COVID-19 vaccines may be administered to persons who have received injectable dermal fillers who have no contraindications to vaccination.**
- No additional precautions are needed.
- **However, these persons should be advised to contact their healthcare provider for evaluation if they develop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

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

Contraindications and 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 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)

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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

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 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.

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

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 cross-reactive 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 allergist-immunologist 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, sugars, buffers	potassium chloride	Tromethamine
	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

NEW

Information on whether a medication contains PEG, a PEG derivative, or polysorbates can be found in the package insert. The NIH DailyMed database 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** CDC's vaccine excipient summary.pdf). 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. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6706272/pdf/nihms-1019221.pdf

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

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

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

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**

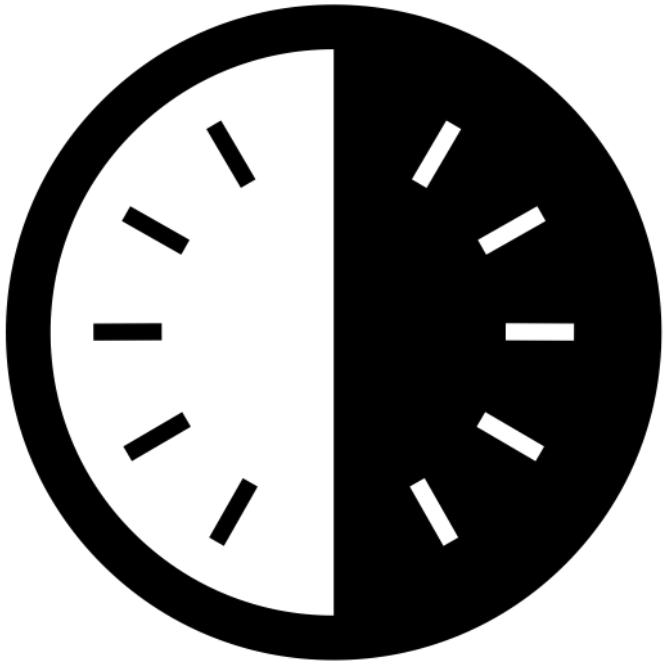
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html

Observation period following vaccination

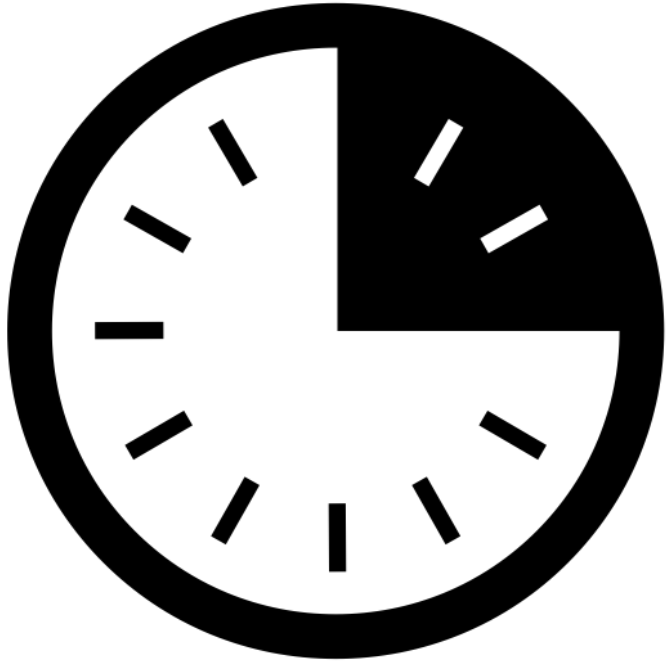
Persons with a history of either:

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

All other persons



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 recommendations			
Receive 2nd dose of mRNA COVID-19 vaccine?	No	Yes	Yes

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

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

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

* See Special Populations section for information on patient counseling in these groups

† 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.

^ 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 allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

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

Anaphylaxis

Centers for Disease Control and Prevention
MMWR
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 i
term sequalae of COVID-19 ov

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Early Release / Vol. 70
January 22, 2021

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

As of January 20, 2021, a to
coronavirus disease 2019 (COVI
deaths had been reported in the
cdc.gov/covid-data-tracker/#cas

JAMA Insights | CLINICAL UPDATE

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

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, adminis-

Following implementation of vaccination, reports of anaphylaxis after the first dose of the Pfizer-BioNTech COVID-19 vaccine emerged.[3] Anaphylaxis is a life-threatening allergic reaction that occurs rarely

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

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])†	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 (1st, 2nd, 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

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

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

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

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

- Total COVID-19 vaccine doses administered thru Jan 18 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)
  https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm
- Previously reported rate for Moderna vaccine: 2.5 per million doses admin (Dec 21-Jan 10)
  https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm

* Data through January 18, 2021

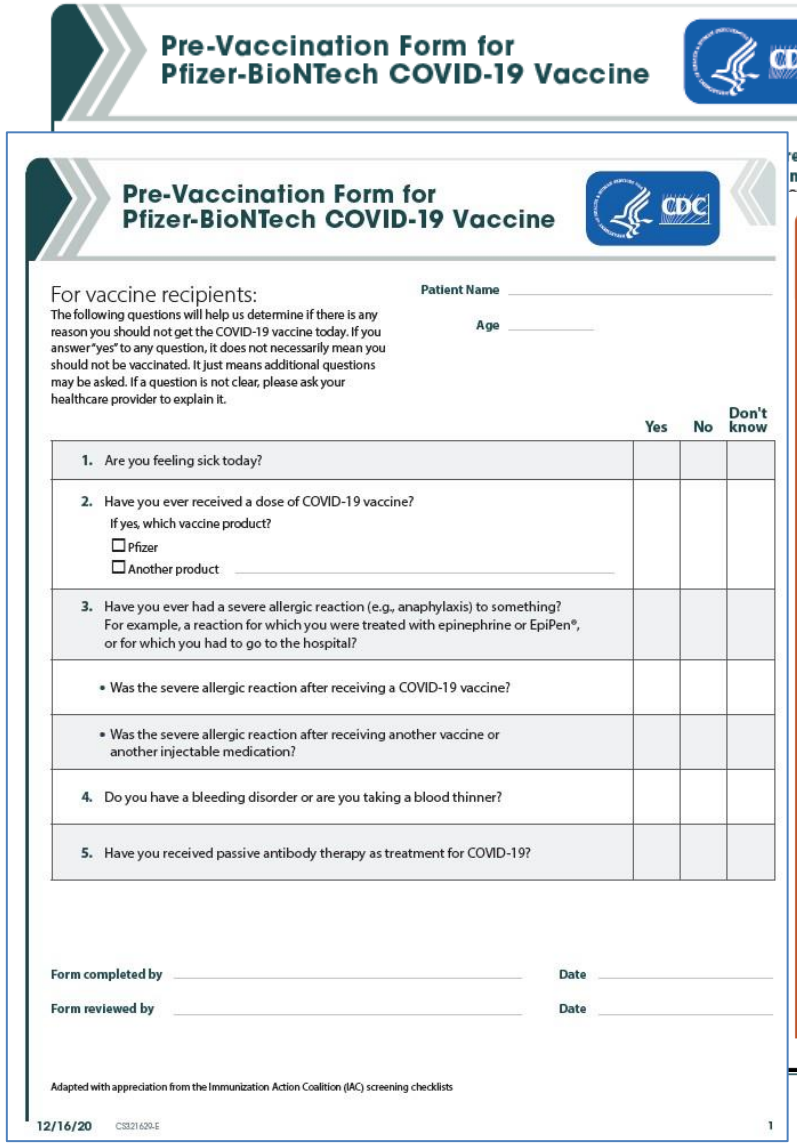
Shimabukuro, Tom. COVID-19 Vaccine safety Update. ACIP Meeting 1-21-21

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

Adapted from: Lee, Grace. Covid-19 Vaccine Safety Technical Subgroup: Discussion & Interpretation ACIP 1-27-21

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



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

CDC

For vaccine recipients:

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. If you answer "yes" to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions may be asked. If a question is not clear, please ask your healthcare provider to explain it.

Patient Name

Age

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine? If yes, which vaccine product? ☐ Pfizer ☐ Another product			
3. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something? For example, a reaction for which you were treated with epinephrine or EpiPen®, or for which you had to go to the hospital?			
• Was the severe allergic reaction after receiving a COVID-19 vaccine?			
• Was the severe allergic reaction after receiving another vaccine or another injectable medication?			
4. Do you have a bleeding disorder or are you taking a blood thinner?			
5. Have you received passive antibody therapy as treatment for COVID-19?			

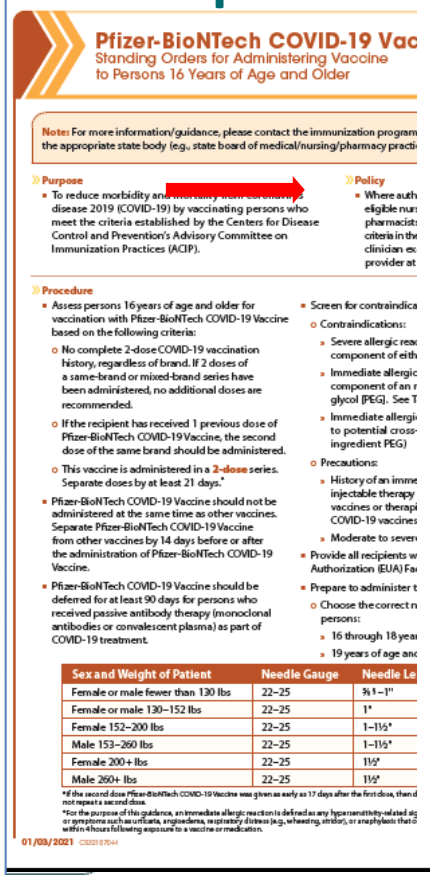
Form completed by _____ Date _____

Form reviewed by _____ Date _____

Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists

12/16/20 CS321629-E 1

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



Pfizer-BioNTech COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

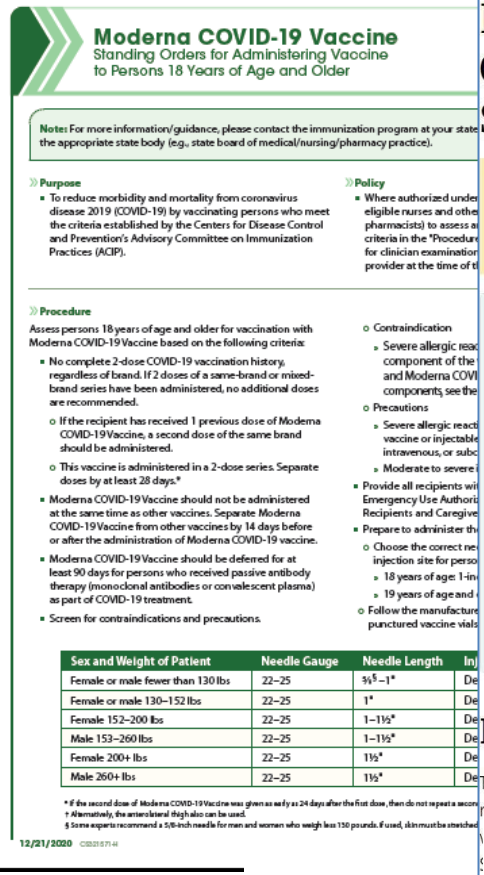
Policy
- Where authorized under eligible nurses and other pharmacists) to assess criteria in the "Procedure for clinician examination provider at the time of

Procedure
- Assess persons 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria:
  - No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
  - This vaccine is administered in a 2-dose series. Separate doses by at least 21 days.*
- Pfizer-BioNTech COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Pfizer-BioNTech COVID-19 Vaccine.
- Pfizer-BioNTech COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindications:
    - Severe allergic reaction (e.g., anaphylaxis) to any component of Pfizer-BioNTech COVID-19 Vaccine, including to any component of either
    - Immediate allergic reaction to any component of an mRNA COVID-19 vaccine, including to polyethylene glycol (PEG). See T
    - Immediate allergic reaction to polysorbate, including to potential cross-reactivity with this ingredient PEG)
  - Precautions:
    - History of an immediate allergic reaction to any other vaccine or injectable therapy (other than vaccines or therapeutics for treatment of COVID-19 vaccines
    - Moderate to severe
- Provide all recipients with Emergency Use Authorization (EUA) Fact Sheets.
- Prepare to administer the vaccine.
  - Choose the correct needle length and gauge for each person:
    - 16 through 18 years of age
    - 19 years of age and older

Sex and Weight of Patient	Needle Gauge	Needle Length
Female or male fewer than 130 lbs	22–25	⅝–1"
Female or male 130–152 lbs	22–25	1"
Female 152–200 lbs	22–25	1–1½"
Male 153–260 lbs	22–25	1–1½"
Female 200+ lbs	22–25	1½"
Male 260+ lbs	22–25	1½"

*If the second dose Pfizer-BioNTech COVID-19 Vaccine was given as early as 17 days after the first dose, then do not repeat a second dose.
*For the purpose of this guidance, an immediate allergic reaction is defined as any hypersensitivity-related sign or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occ within 4 hours following exposure to a vaccine or medication.

01/03/2021 CS321570-H



Moderna COVID-19 Vaccine
Standing Orders for Administering Vaccine to Persons 18 Years of Age and Older

Note: For more information/guidance, please contact the immunization program at your state the appropriate state body (e.g., state board of medical/nursing/pharmacy practice).

Purpose
- To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

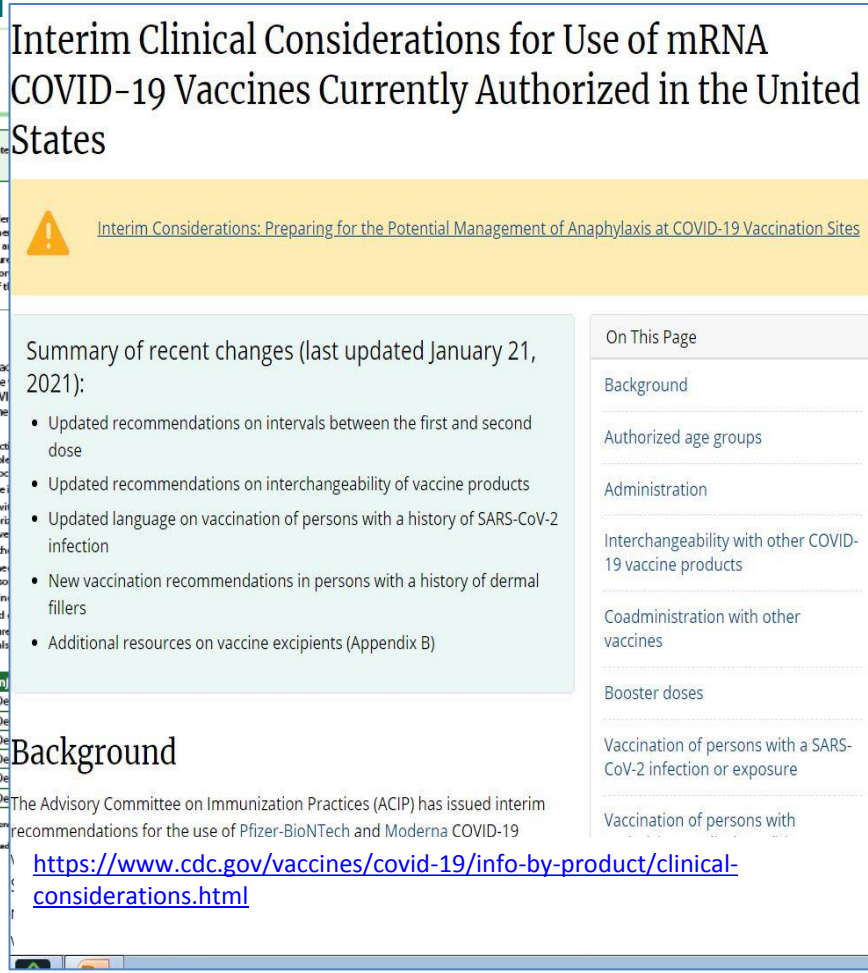
Policy
- Where authorized under eligible nurses and other pharmacists) to assess criteria in the "Procedure for clinician examination provider at the time of t

Procedure
Assess persons 18 years of age and older for vaccination with Moderna COVID-19 Vaccine based on the following criteria:
- No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Moderna COVID-19 Vaccine, a second dose of the same brand should be administered.
  - This vaccine is administered in a 2-dose series. Separate doses by at least 28 days.*
- Moderna COVID-19 Vaccine should not be administered at the same time as other vaccines. Separate Moderna COVID-19 Vaccine from other vaccines by 14 days before or after the administration of Moderna COVID-19 vaccine.
- Moderna COVID-19 Vaccine should be deferred for at least 90 days for persons who received passive antibody therapy (monoclonal antibodies or convalescent plasma) as part of COVID-19 treatment.
- Screen for contraindications and precautions.
  - Contraindication
    - Severe allergic reac component of the and Moderna COVI components, see the
  - Precautions
    - Severe allergic react vaccine or injectable intravenous, or subc
    - Moderate to severe
- Provide all recipients wi Emergency Use Authori Recipients and Caregive
- Prepare to administer th
  - Choose the correct ne injection site for perso
    - 18 years of age: 1-in
    - 19 years of age and
  - Follow the manufacture punctured vaccine vials

Sex and Weight of Patient	Needle Gauge	Needle Length	Inj
Female or male fewer than 130 lbs	22–25	⅝–1*	De
Female or male 130–152 lbs	22–25	1*	De
Female 152–200 lbs	22–25	1–1½*	De
Male 153–260 lbs	22–25	1–1½*	De
Female 200+ lbs	22–25	1½*	De
Male 260+ lbs	22–25	1½*	De

* If the second dose of Moderna COVID-19 Vaccine was given as early as 24 days after the first dose, then do not repeat a secon
† Alternatively, the anterolateral thigh also can be used.
§ Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched

12/21/2020 CS321571-H



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
- Vaccination of persons with a SARS-CoV-2 infection or exposure
- Vaccination of persons with

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19

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

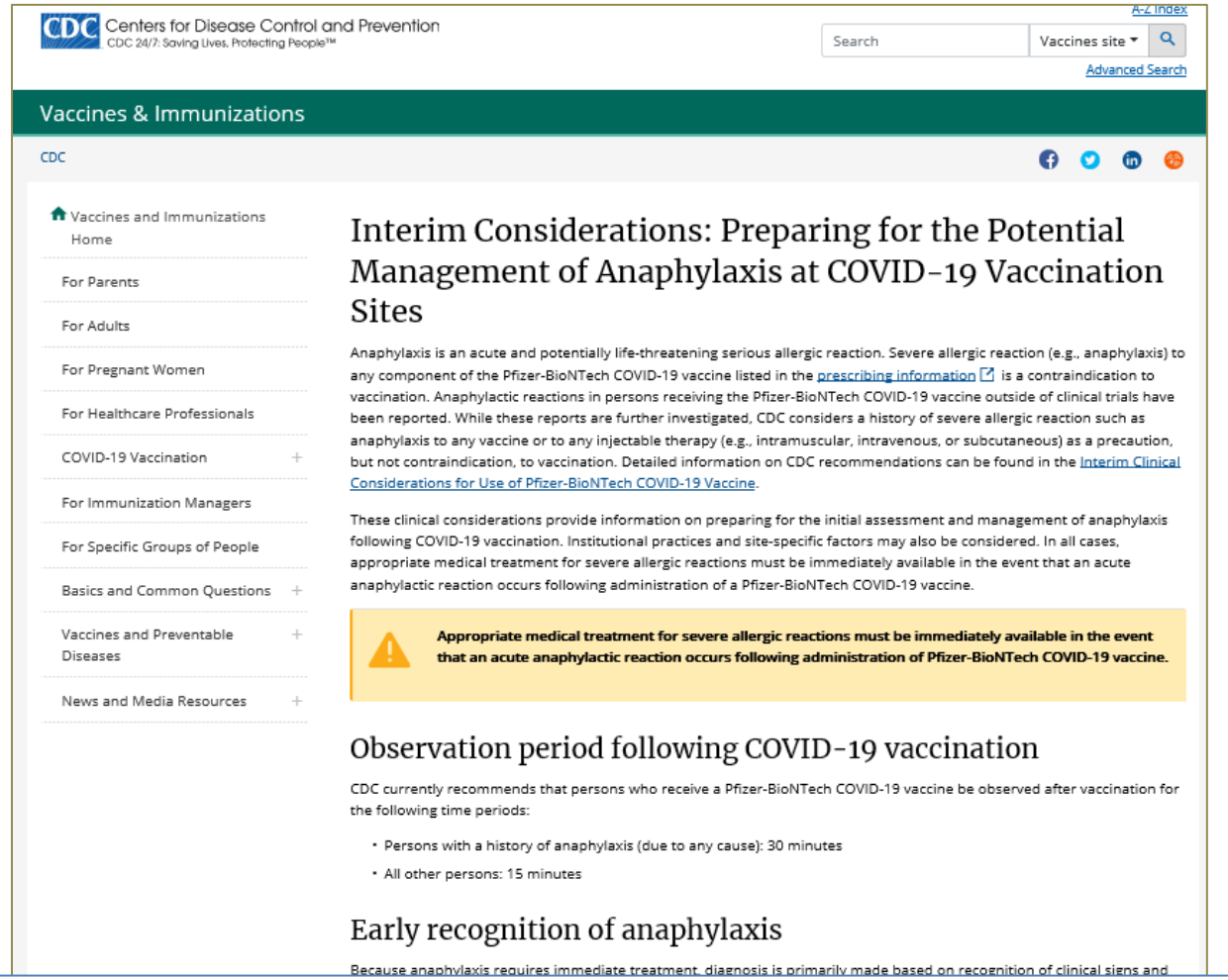
Testing after allergic reactions

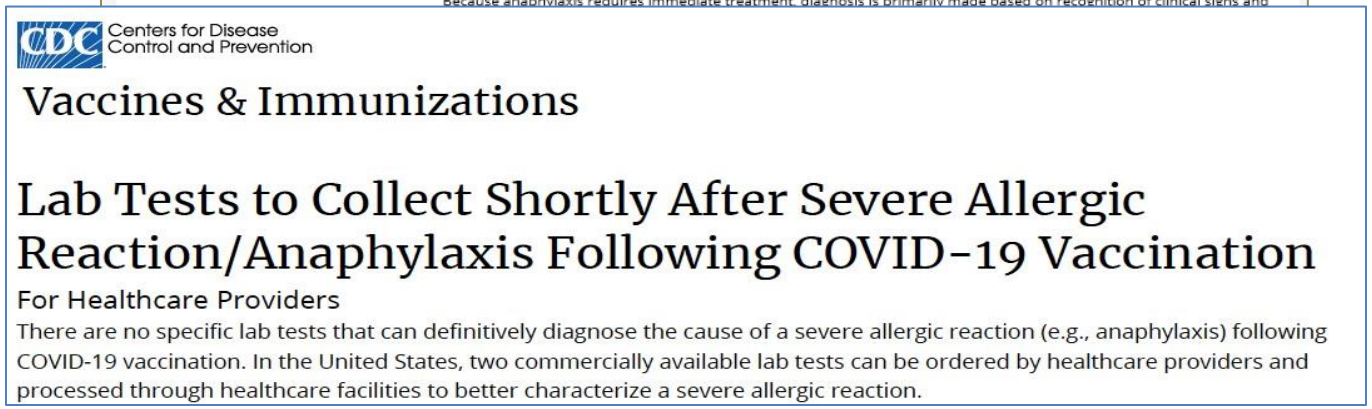
https:// https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

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

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

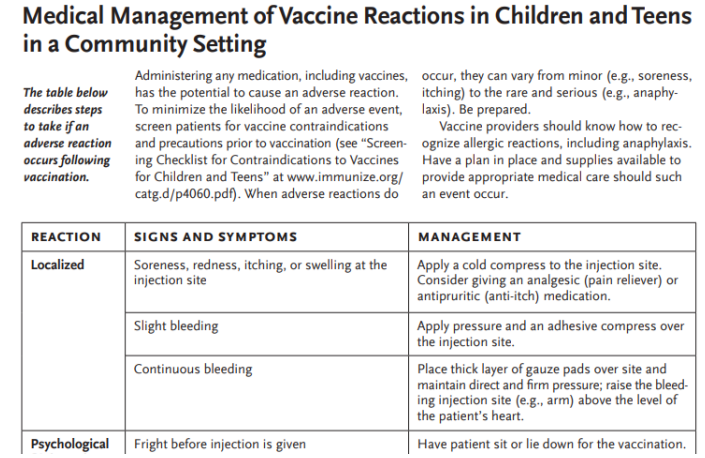




Managing Acute Vaccine Reactions

- 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



Medical Management of Vaccine Reactions in Children and Teens in a Community Setting

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Children and Teens" at www.immunize.org/catg.d/p4060.pdf). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

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 the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding 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

The table below describes steps to take if an adverse reaction occurs following vaccination.

Administering any medication, including vaccines, has the potential to cause an adverse reaction. To minimize the likelihood of an adverse event, screen patients for vaccine contraindications and precautions prior to vaccination (see "Screening Checklist for Contraindications to Vaccines for Adults" at www.immunize.org/catg.d/p4065.pdf). When adverse reactions do occur, they can vary from minor (e.g., soreness, itching) to the rare and serious (e.g., anaphylaxis). Be prepared.

Vaccine providers should know how to recognize allergic reactions, including anaphylaxis. Have a plan in place and supplies available to provide appropriate medical care should such an event occur.

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)†	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.

†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-by-product%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 https://vaers.hhs.gov/reportevent.html

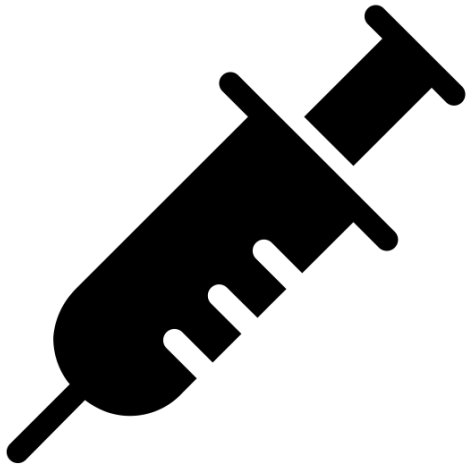
https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w
https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fpfizer%2Fanaphylaxis-management.html

Key messages

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-saf**e 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.

https://vaers.hhs.gov/faq.html

https://www.cdc.gov/vaccines/covid-19/vaccination-provider-support.html

Pfizer EUA: https://www.fda.gov/media/144413/download

Moderna EUA: https://www.fda.gov/media/144637/download

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

How to report an adverse event:

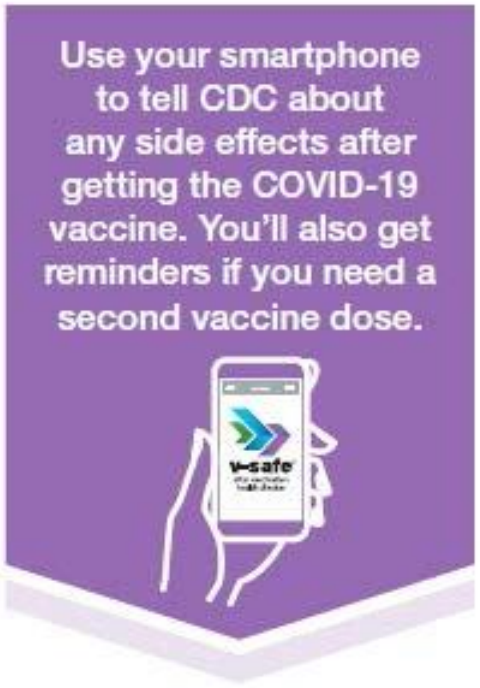
- Go to vaers.hhs.gov
- Submit a report online
- For help:
  - Call: 1-800-822-7967
  - Email: info@VAERS.org
  - Video instructions https://youtu.be/sbCWhcQADFE

- 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.

Pfizer EUA: https://www.fda.gov/media/144413/download

Moderna EUA: https://www.fda.gov/media/144637/download


v-safe
after vaccination
health checker


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 extent ***v-safe*** 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 sensitivity. 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 (HIPAA); the Federal Information Security Management Act, and the Freedom of Information Act.

12/01/20

v-safe after vaccination health checker

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 camera at this code

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:

Use your smartphone's browser to go to vsafe.cdc.gov

OR

Aim your smartphone's camera at this code

2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. 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**.
6. 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.gov/lists/additional-covid-19-vaccination-resources-for-providers#cdc:-tools-for-vaccine-providers-

CDC website

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

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

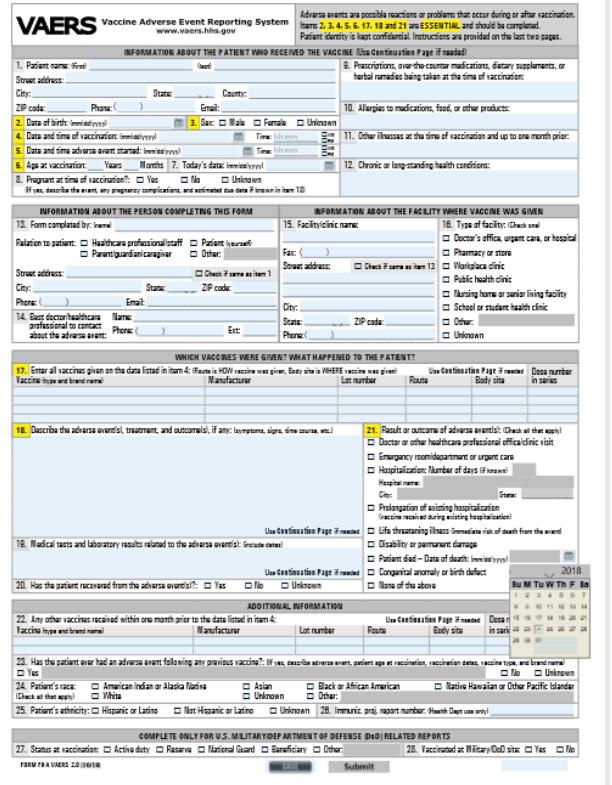
- Extension of CDC's CISA* Project's clinical consultation service for U.S. healthcare providers and health departments for complex COVID-19 vaccine safety questions/issues that are**
  - (1) about an individual patient(s) residing in the United States
  - (2) not readily addressed by CDC or ACIP guidelines
- 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 and submit a report online
- For help: call 1-800-822-7967, email info@VAERS.org
- Video instructions https://www.youtube.com/watch?v=sbCWhcQADFE


VAERS Vaccine Adverse Event Reporting System
www.vaers.hhs.gov

How to contact CDC at CDC-INFO

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

CDC-INFO
You have questions? We have answers.
CDC's national contact center and publications fulfillment system

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

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

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
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-A_FS_What_Expect_COVID-19_Vax_Final_12.13.20.pdf

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

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
https://www2.cdc.gov/vaccines/ed/covid19/

COVID-19 Vaccination Training Programs and Reference Materials for Healthcare Professionals
https://www.cdc.gov/vaccines/covid-19/downloads/COVID-19-Clinical-Training-and-Resources-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.gov%2Fvaccines%2Fed%2Fciinc%2Findex.html

GENERAL PUBLIC

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

- 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
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect.html
Available in Multiple languages

What to Expect after Getting a COVID-19 Vaccine – handout for recipients
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/pdfs/321466-A_FS_What_Expect_COVID-19_Vax_Final_12.13.20.pdf

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): https://www.modernatx.com/covid19vaccine-eua/providers/
Moderna COVID-19 Vaccine EUA for Providers:
https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-providers.pdf
Moderna COVID-19 Vaccine EUA for Recipients:
https://www.modernatx.com/covid19vaccine-eua/eua-fact-sheet-recipients.pdf

US FDA

Moderna COVID-19 Vaccine EUAs, in multiple languages:
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-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 https://www.cdc.gov/vaccines/covid-19/info-by-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/standing-orders.pdf

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

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

COVID-19 Vaccine Expiration Date Tracking Tool
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/expiration-tracker.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-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-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-by-product/pfizer/anaphylaxis-management.html
COVID-19 Vaccine Prevaccination Screening Form
https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf
Pfizer-BioNtech COVID-19 Vaccine Standing Order
https://www.cdc.gov/vaccines/covid-19/info-by-product/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/prep-and-admin-summary.pdf
Pfizer-BioNTech COVID-19 Vaccine Storage and Handling Summary:
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/storage-summary.pdf
Diluent poster
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/downloads/diluent-poster.pdf

Select Vaccination Clinic Planning Resources

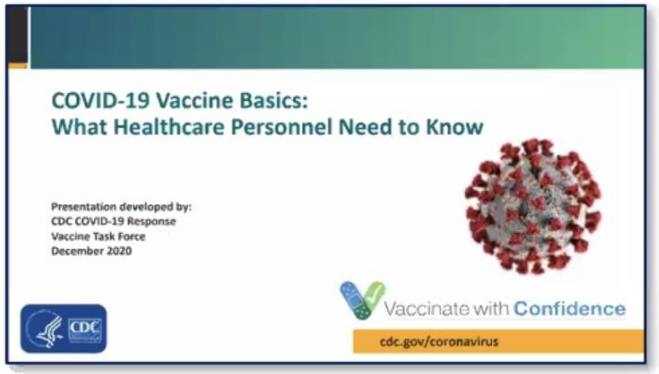
- CDC Vaccination Guidance During a Pandemic: https://www.cdc.gov/vaccines/pandemic-guidance/index.html
- CDC Guidance for Planning for Vaccination Clinics Held at Satellite, Temporary or Off-Site Locations: https://www.cdc.gov/vaccines/hcp/admin/mass-clinic-activities/index.html
- CDC Resources for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

CDC COVID-19 Vaccine Communication Resources

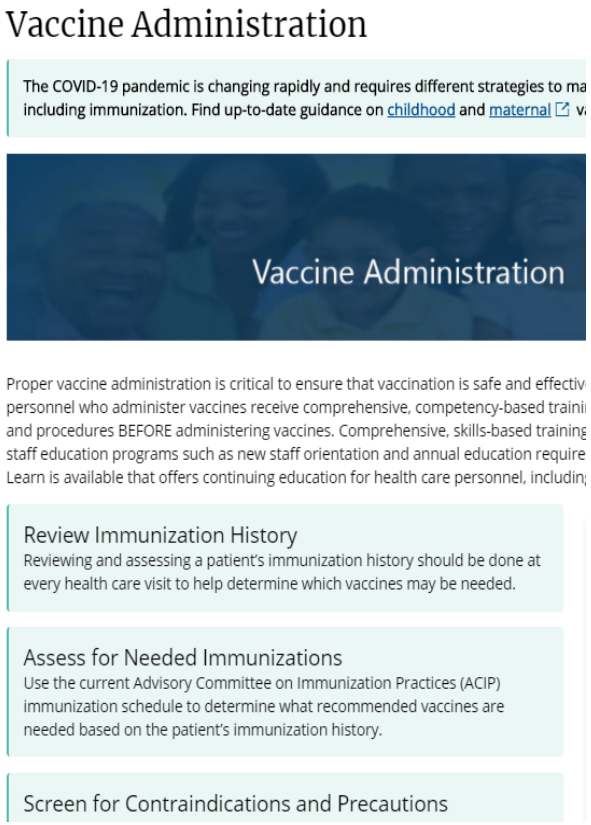
COVID-19 Vaccination Tool Kits

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

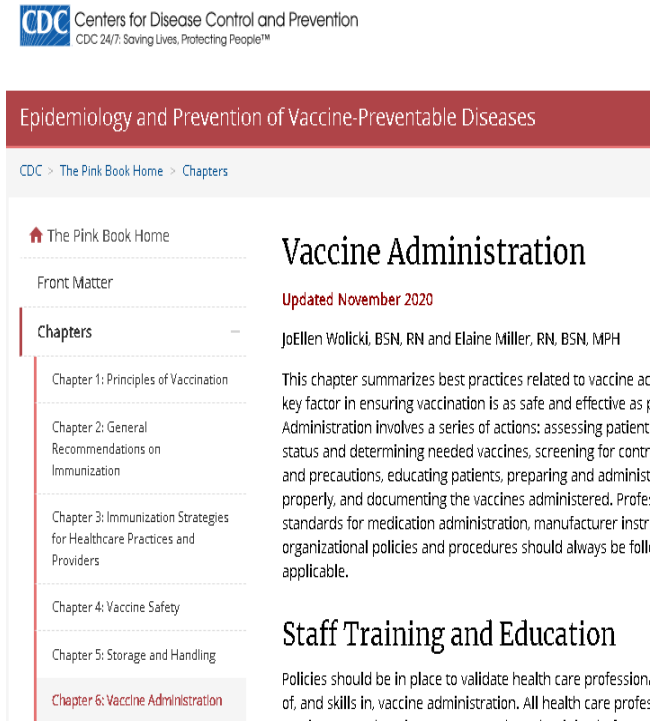
https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html



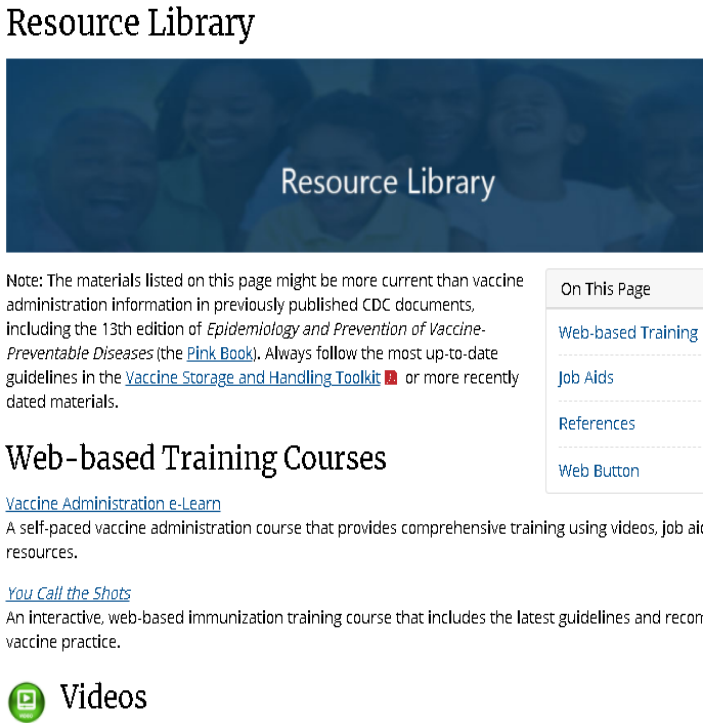
CDC Vaccine Administration Resources



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



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



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

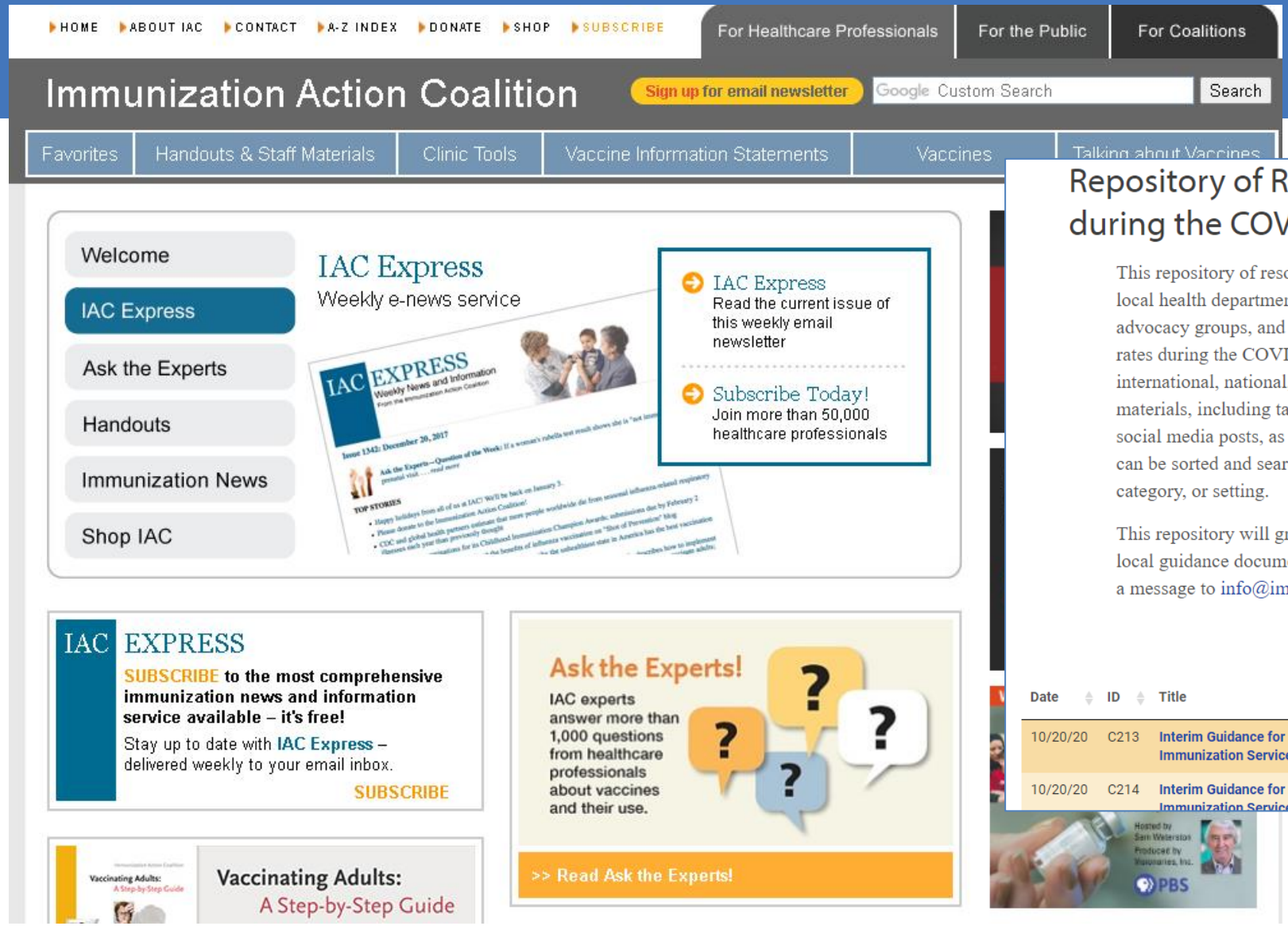
Clinical Resources for Proper Vaccine Administration

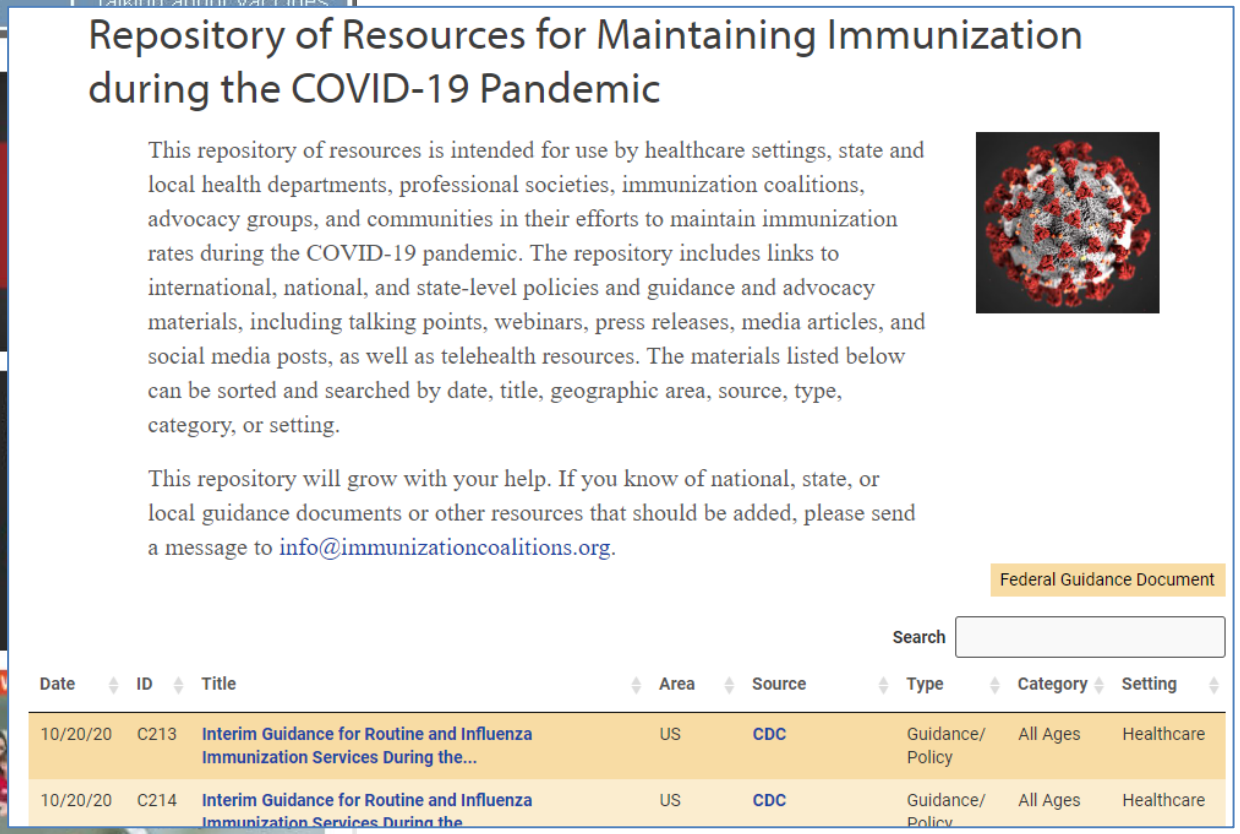
- CDC Vaccine administration & Resource Library webpages-- information and materials for health care personnel including:
  - IM demonstration video
  - Job aids and infographics

  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: https://www2.cdc.gov/vaccines/ed/vaxadmin/va/ce.asp

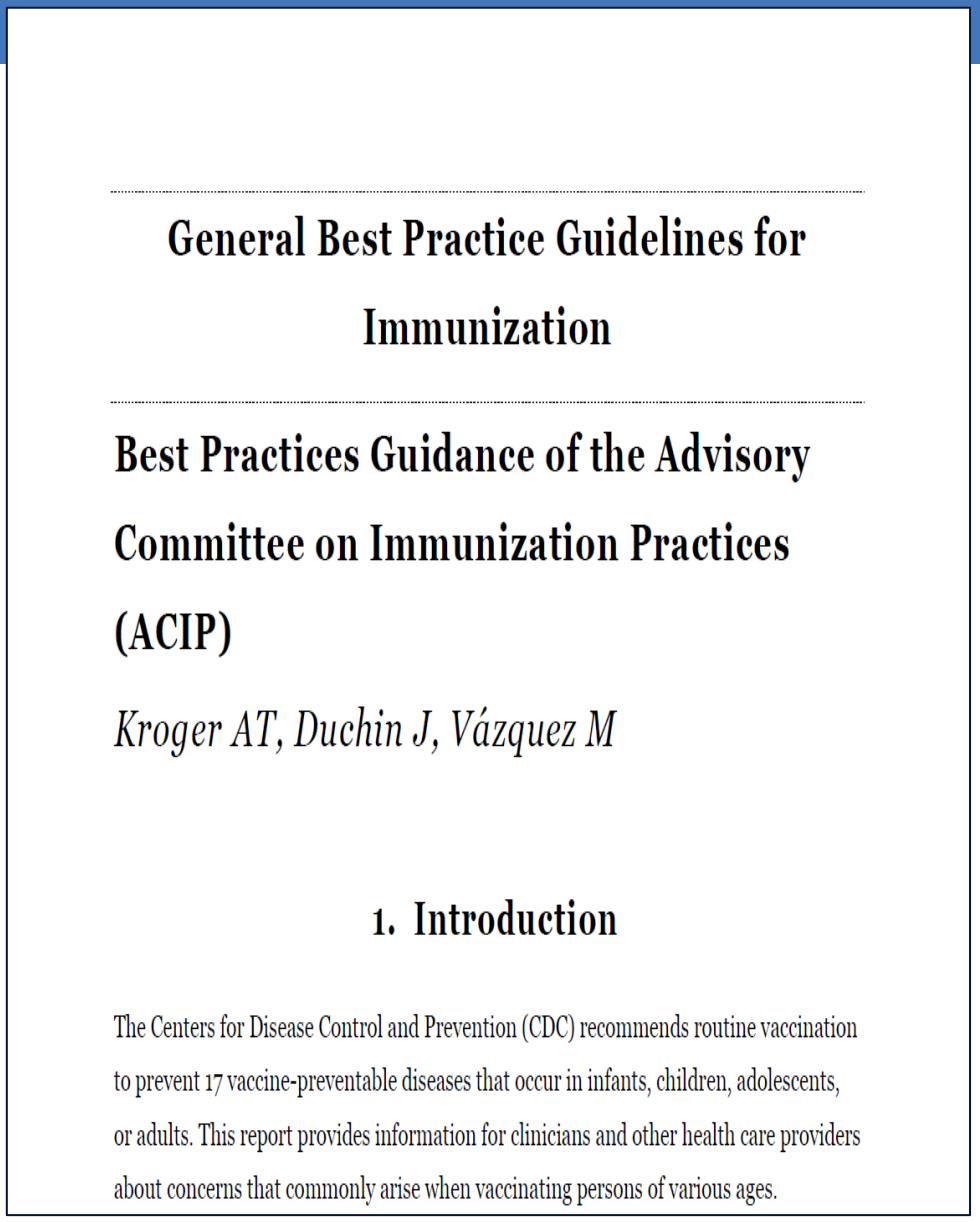




https://www.immunizationcoalitions.org/resource-repository/

https://immunize.org/

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

https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html

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

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Thank You For Being a COVID-19 Vaccinator !