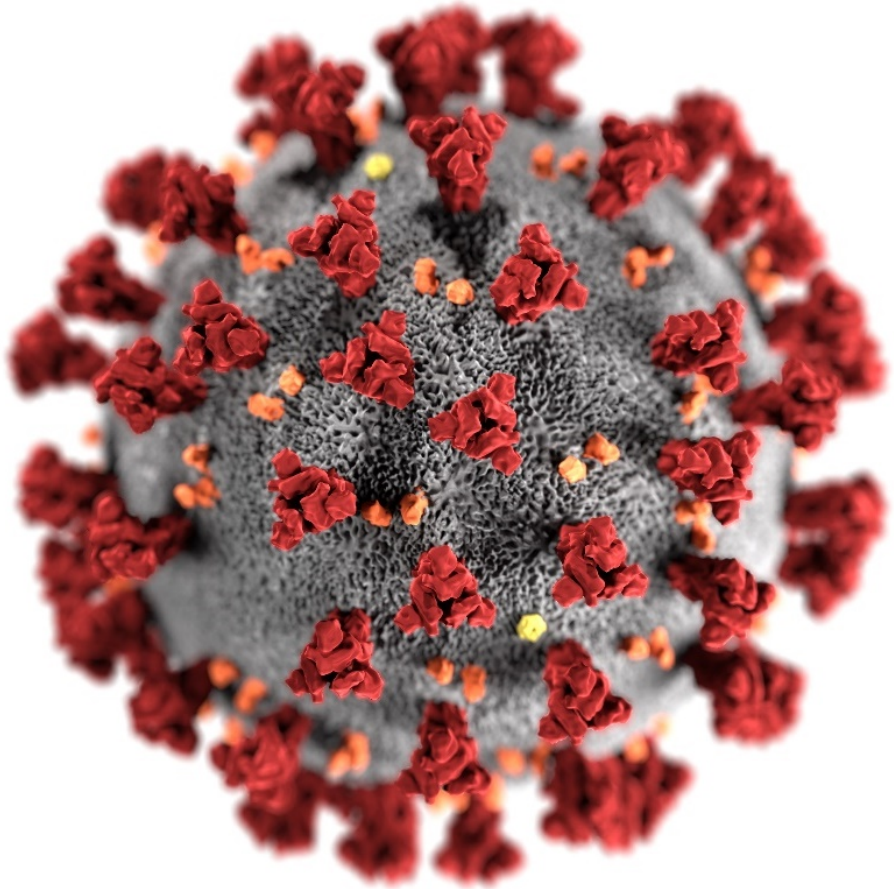
COVID-19 Vaccination Clinical Considerations

April 13, 2021

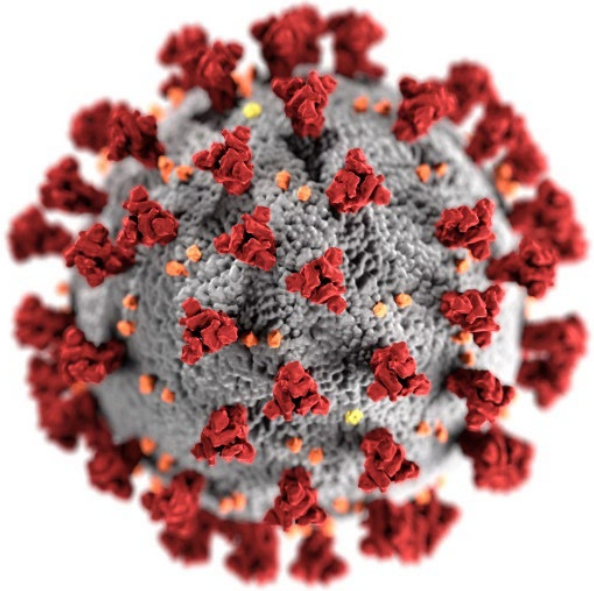


I, Andrew Kroger, have been asked to disclose any significant relationships with commercial entities that are either providing financial support for this program or whose products or services are mentioned during this presentation.

I have no relationships to disclose.

I may discuss the use of vaccines in a manner not approved by the U.S. Food and Drug Administration, but in accordance with ACIP recommendations.

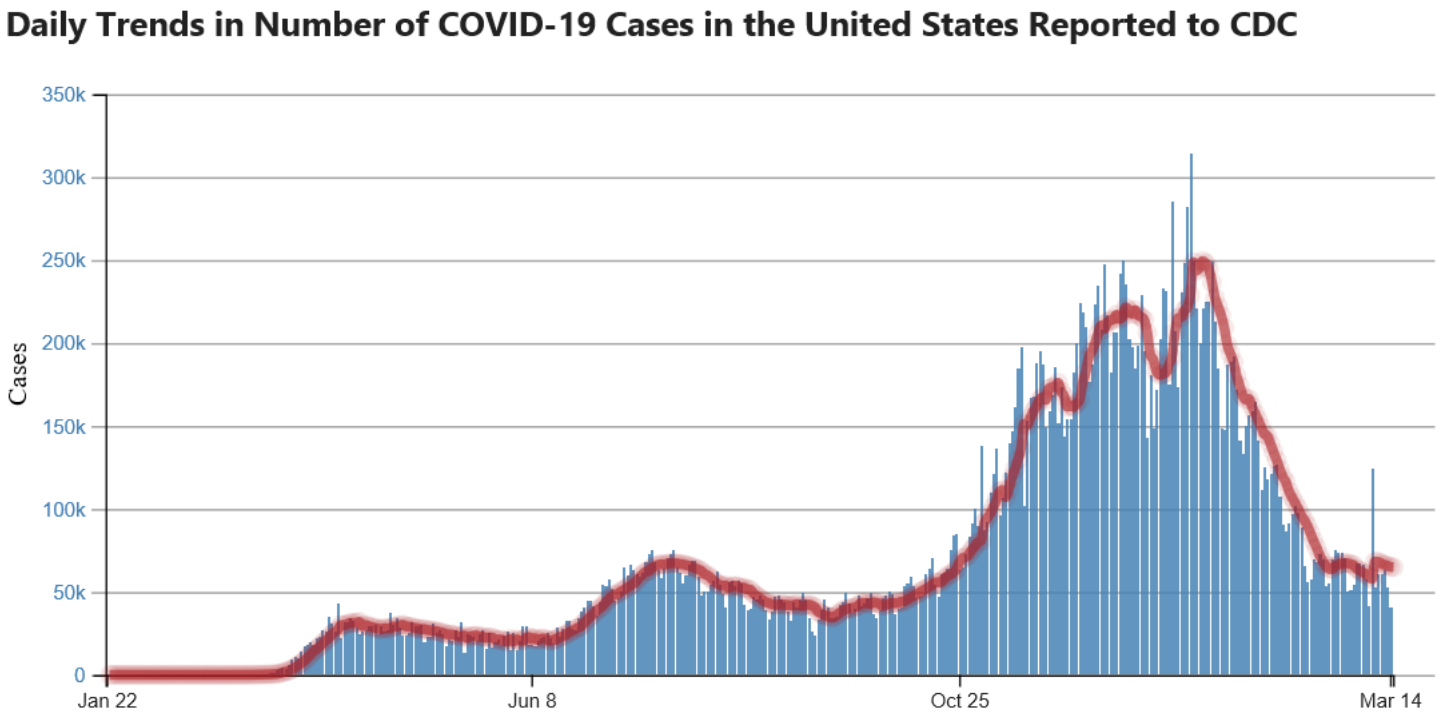
COVID-19: Emergence



- Identified in Wuhan, China in December 2019
- Caused by the virus SARS-CoV-2
- Early on, many patients were reported to have a link to a large seafood and live animal market.
- Later patients did not have exposure to animal markets.
  - Indicated person-to-person spread
- Travel-related exportation of cases reported
  - First U.S. case: January 20, 2020 https://www.cdc.gov/mmwr/volumes/69/wr/mm6924e2.htm?s_cid=mm6924e2_w
- CDC is reporting confirmed COVID-19 cases in the U.S. online. at www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html

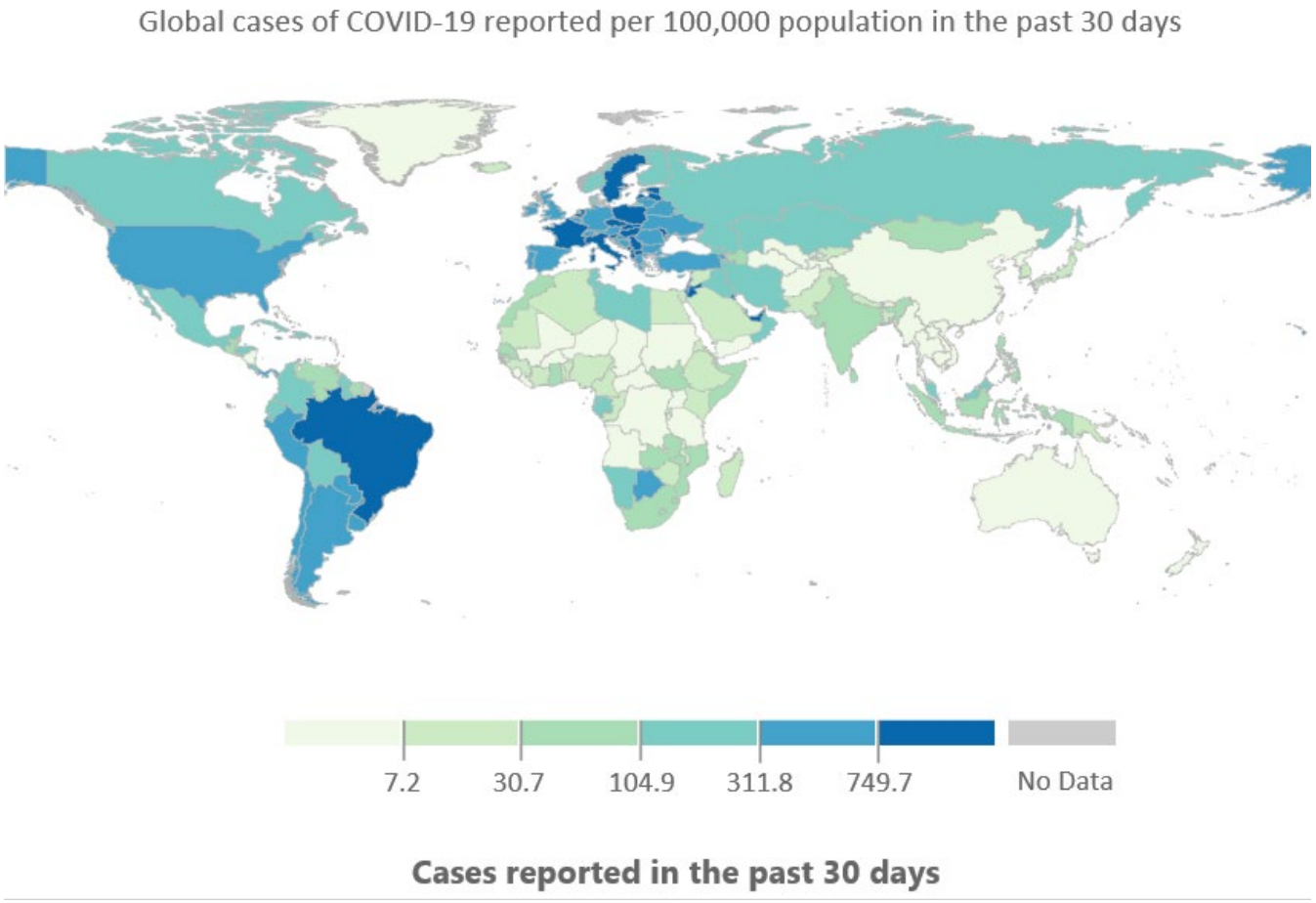
COVID-19: Epidemiology

- https://covid.cdc.gov/covid-data-tracker/#trends_dailytrendscases (March 15, 2021)



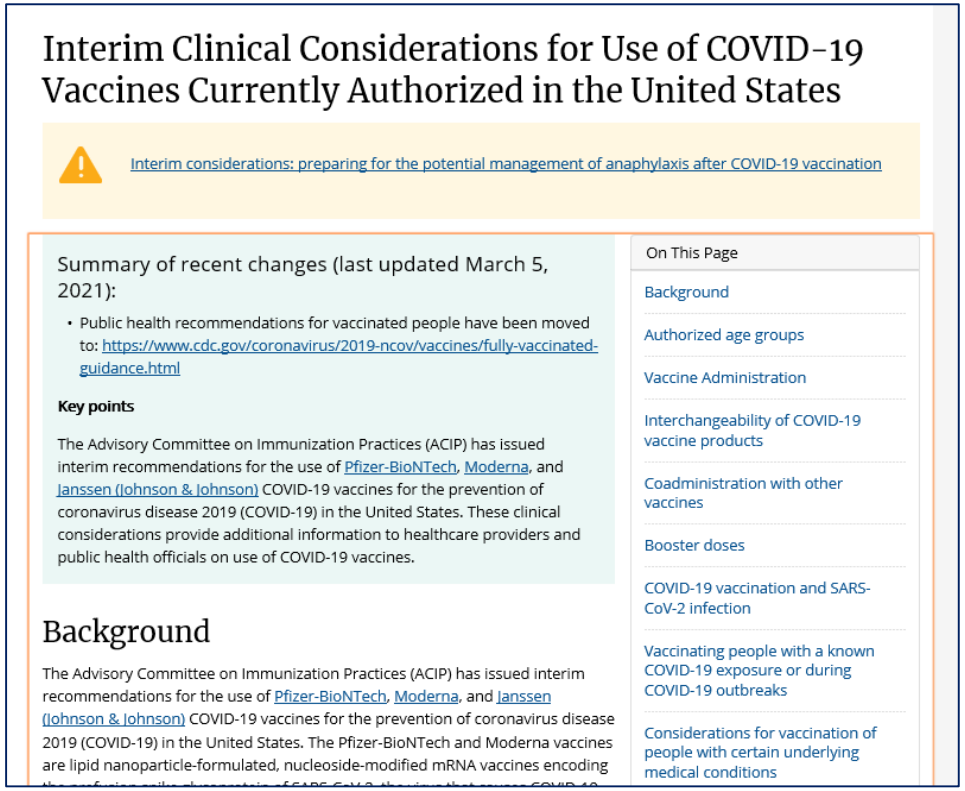
COVID-19: Epidemiology

- https://covid.cdc.gov/covid-data-tracker/#global-counts-rates (March 15, 2021)



Clinical Considerations for COVID-19 Vaccines

- Recommendations apply to both Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines.
- Guidance may change as further information becomes available.



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

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

Summary of recent changes (last updated March 5, 2021):

- Public health recommendations for vaccinated people have been moved to: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

Key points

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. These clinical considerations provide additional information to healthcare providers and public health officials on use of COVID-19 vaccines.

On This Page

Background
Authorized age groups
Vaccine Administration
Interchangeability of COVID-19 vaccine products
Coadministration with other vaccines
Booster doses
COVID-19 vaccination and SARS-CoV-2 infection
Vaccinating people with a known COVID-19 exposure or during COVID-19 outbreaks
Considerations for vaccination of people with certain underlying medical conditions

Background

The Advisory Committee on Immunization Practices (ACIP) has issued interim recommendations for the use of Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines for the prevention of coronavirus disease 2019 (COVID-19) in the United States. The Pfizer-BioNTech and Moderna vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding

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

Dosing and Administration

	Pfizer-BioNTech	Moderna	Janssen
Authorized age groups	≥ 16 years	≥ 18 years	≥ 18 years
Number of doses in series	2 doses	2 doses	1 dose
Interval between 1st and 2nd doses*	3 weeks	1 month	NA
Dose volume	0.3 ml	0.5 ml	0.5 ml
Route	Intramuscular	Intramuscular	Intramuscular

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

Strategies to Improve 2nd Dose Compliance for mRNA COVID-19 Vaccines

- Providing 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
- Encouraging vaccine recipients to enroll in VaxText[SM], a free text message-based platform to receive COVID-19 vaccination second-dose reminders.
- Recording each recipient's vaccination in the immunization information system (IIS)
- Recording vaccine administration information in the patient's medical record
- Making an appointment for the second dose before the vaccine recipient leaves

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

Vaccine Coadministration and Interchangeability

- COVID-19 vaccines are not interchangeable with each other.
  - In exceptional situations where the mRNA vaccine used for first dose cannot be determined or is no longer available, any mRNA COVID-19 vaccine may be used for 2nd dose.

- Vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines.
  - Shorter period acceptable if the benefits of vaccination are deemed to outweigh the potential unknown risks of vaccine coadministration or to avoid vaccination barriers or delays

Persons with a History of SARS-CoV-2 Infection

- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection.

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation.
  - No 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.

- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making.

Persons who Previously Received Passive Antibody Therapy for COVID-19

- Currently no data on safety or efficacy of COVID-19 vaccination in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment

- Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses
  - Recommendation also applies to persons who receive passive antibody therapy after receiving first mRNA COVID-19 vaccine dose

Persons with a Known SARS-CoV-2 Exposure

- **Community or outpatient setting:**
  - 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/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/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

TB Testing and COVID-19 Vaccination

- COVID-19 vaccine should not be delayed because of TB testing
  - Neither the tuberculin skin testing (TST) or interferon release assay (IGRA) is expected to have an effect on vaccine safety or effectiveness
  - Reliability of a positive TST or IGRA result after vaccination is expected to be the same as without vaccination (i.e., vaccine not expected to cause false-positives)
  - Reliability of a negative TST or IGRA result after COVID-19 vaccination has not been studied

- TB testing with TST or interferon IGRA can be done before or on same day as COVID-19 vaccination
  - If not possible, should be delayed at least 4 weeks after completion of COVID-19 vaccination but generally should not be cancelled

- Patients with active TB or who are being evaluated for active TB can receive vaccine
  - Note: presence of a moderate or severe acute illness is a precaution to administration of all vaccines

Fully Vaccinated* People Can:

- Visit with other fully vaccinated people indoors, no masks or distancing
- Visit with other unvaccinated people from a single household, if low risk, indoors, no masks, no distancing
- Refrain from quarantine and testing following a known exposure to COVID-19 if asymptomatic

* ≥2 weeks after the second dose in a 2-dose series (Pfizer-BioNTech or Moderna), or ≥2 weeks after a single-dose vaccine (Johnson and Johnson [J&J]/Janssen)

Visits Between Fully Vaccinated People & Unvaccinated People

- Recommendation for prevention measures depends on:
  - Underlying risks for severe COVID-19 among unvaccinated people and members of their households
  - Number of households with unvaccinated persons

No Prevention Measures Needed

- Unvaccinated people are from a *single* household & are at *low risk* of severe COVID-19

Prevention Measures Needed

- Unvaccinated people are from a *single* household & at *high risk* for severe COVID-19
- Unvaccinated people are from *multiple* households

For Now, Fully Vaccinated People Should Continue To:

- Take precautions in public, mask and distancing
- Avoid medium- and large-sized in-person gatherings
- Get tested if experiencing COVID-19 symptoms
- Follow guidance issued by individual employers
- Follow CDC and health department travel requirements and recommendations

Supporting Scientific Evidence

- Fully vaccinated people are at low risk of symptomatic & severe COVID-19
- Fully vaccinated people are less likely to have asymptomatic infection and potentially less likely to transmit SARS-CoV-2 to others
- COVID-19 vaccines will likely be effective against a variety of emerging variants, however continued monitoring of emerging variants is critical
  - Reduced neutralizing antibody activity and efficacy observed for B.1.351 variant

- Further information on evidence and considerations related to these recommendations is available in the new Science Brief

Web Links

- Interim Public Health Recommendations for Fully Vaccinated People
  - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html
- Science Brief: Background Rationale and Evidence for Public Health Recommendations for Fully Vaccinated People
  - https://www.cdc.gov/coronavirus/2019-ncov/more/fully-vaccinated-people.html
- When You've Been Fully Vaccinated: How to Protect Yourself and Others
  - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html
- Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination-Updated Healthcare Infection Prevention and Control Recommendations in Response to COVID-19 Vaccination | CDC

Contraindications to COVID-19 Vaccination

Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine
- Immediate allergic reaction* of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine
- Note: People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna)

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

Precautions to COVID-19 Vaccines

Pfizer-BioNTech, Moderna, and Janssen COVID-19 vaccines

- Severe or moderate acute illness
- Any immediate allergic reaction to any other vaccine or injectable therapy
  - 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
- Note: Persons with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa

Potential Cross-reactivity Between COVID-19 Vaccines: Polyethylene Glycol (PEG) and Polysorbate

- Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines
- Polysorbate 80 is an ingredient in Janssen COVID-19 vaccine
- PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur

Potential Cross-reactivity Between COVID-19 Vaccines

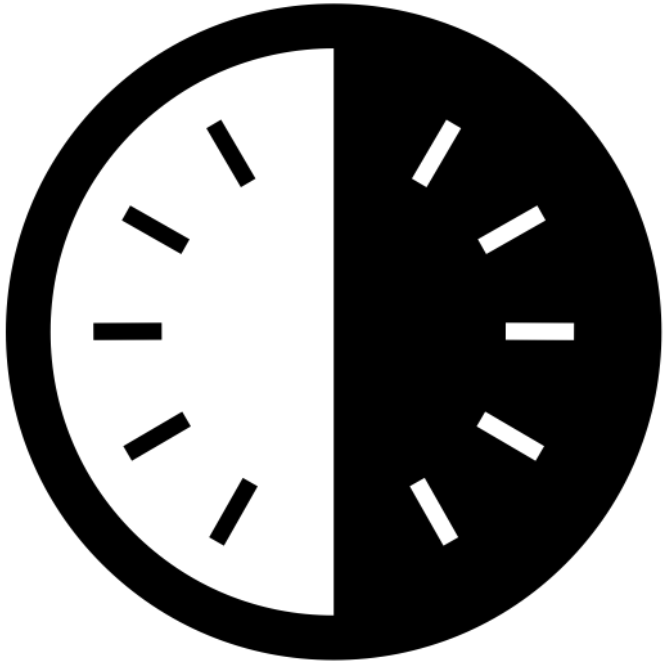
- **People with a contraindication to one of the mRNA COVID-19 vaccines** (including due to known PEG allergy)
  - Should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna)
  - Have a **precaution** to Janssen COVID-19 vaccine

- **People with a contraindication to Janssen COVID-19 vaccine** (including due to a known allergy to polysorbate)
  - Have a **precaution** to mRNA COVID-19 vaccines

- For people with these precautions for either of these reasons
  - Referral to an allergist-immunologist should be considered
  - Vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions

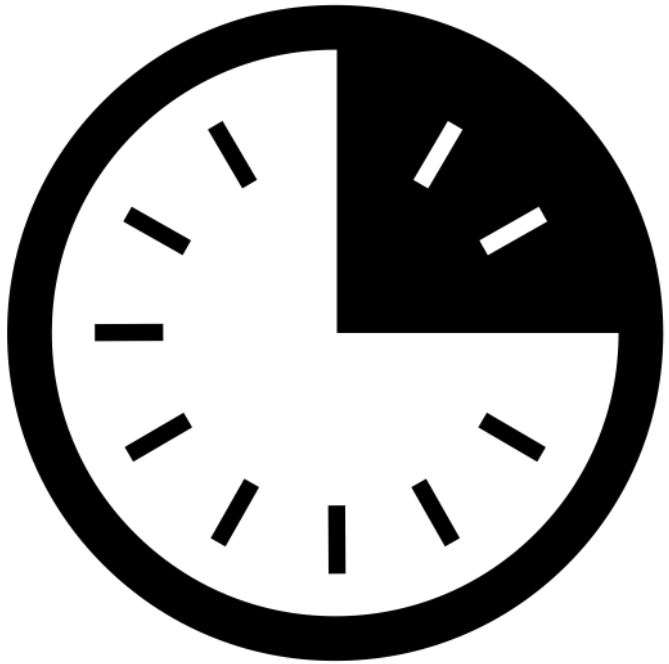
Observation Period Following Vaccination

Persons with a precaution to vaccination or a history of anaphylaxis (due to any cause)



30 minutes

All other persons



15 minutes

Triage of Persons Presenting for COVID-19 Vaccination

CONTRAINDICATION TO VACCINATION

ALLERGIES

History of the following:

- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine
- Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine

ACTIONS

- Do not vaccinate.
- Consider referral to allergist-immunologist.
- Consider other vaccine alternative.

PRECAUTION TO VACCINATION

ALLERGIES

Among people without a contraindication, a history of:

- Any immediate allergic reaction* to other vaccines or injectable therapies‡

Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#

ACTIONS

- Risk assessment
- Consider referral to allergist-immunologist
- 30-minute observation period if vaccinated

SEVERE OR MODERATE ACUTE ILLNESS

MAY PROCEED WITH VACCINATION

ALLERGIES

Among persons without a contraindication or precaution, a history of:

- 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

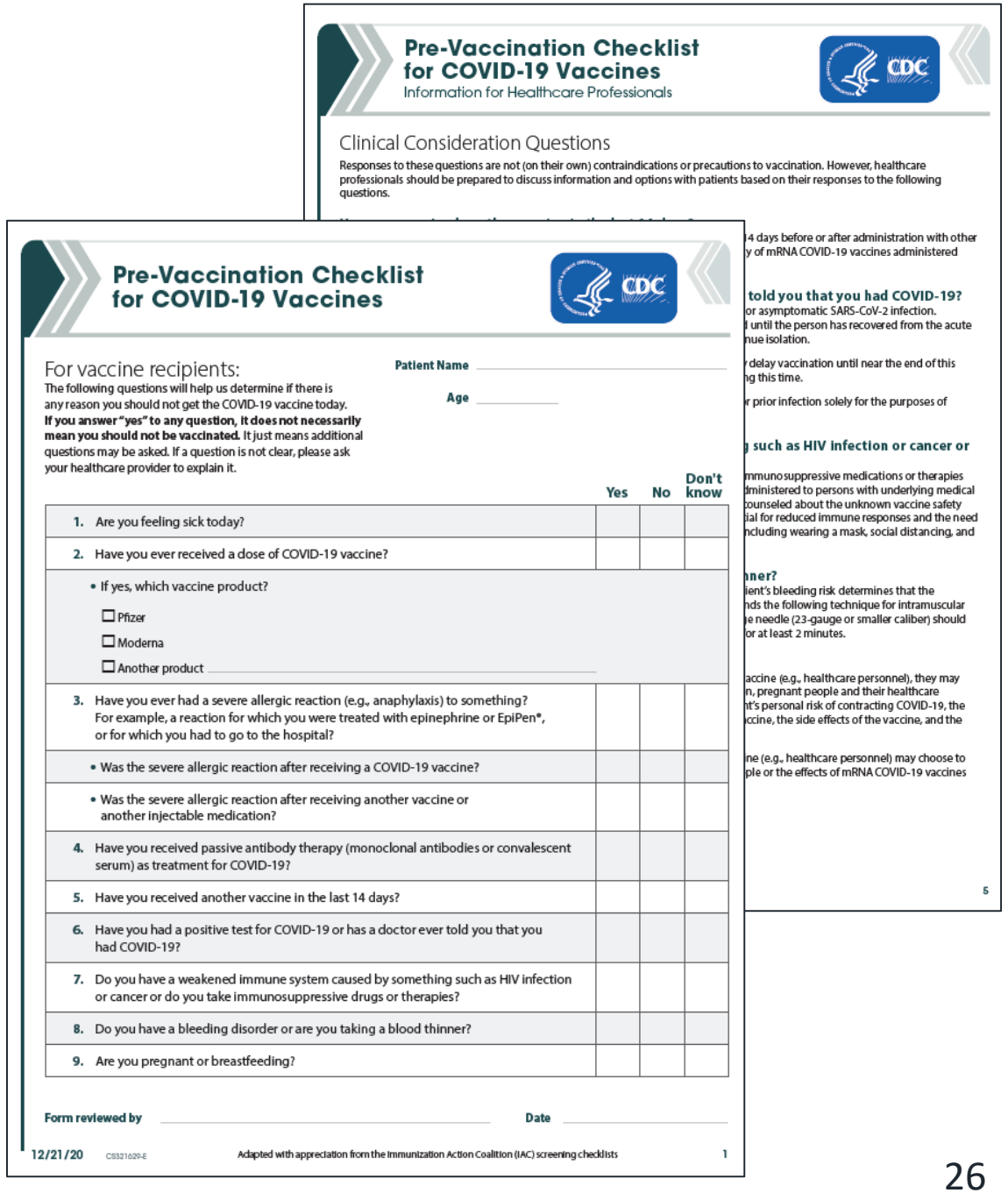
- 30-minute observation period: Persons with a history of anaphylaxis (due to any cause)
- 15-minute observation period: All other persons

* 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.

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

#Polyethylene glycol (PEG) is an ingredient in both mRNA COVID-19 vaccines, and polysorbate 80 is an ingredient in Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and cross-reactive hypersensitivity between these compounds may occur. People with a contraindication to mRNA COVID-19 vaccines (including due to a known allergy to PEG) have a precaution to Janssen COVID-19 vaccine. Among people who received one mRNA COVID-19 dose but for whom the second dose is contraindicated, consideration may be given to vaccination with Janssen COVID-19 vaccine (administered at least 28 days after the mRNA COVID-19 dose). People with a contraindication to Janssen COVID-19 vaccine (including due to a known allergy to polysorbate) have a precaution to mRNA COVID-19 vaccines. In patients with these precautions, vaccination should only be undertaken in an appropriate setting under the supervision of a health care provider experienced in the management of severe allergic reactions.

Additional tools to identify persons with contraindications and precautions to vaccination



Pre-Vaccination Checklist for COVID-19 Vaccines
Information for Healthcare Professionals

Clinical Consideration Questions

Responses to these questions are not (on their own) contraindications or precautions to vaccination. However, healthcare professionals should be prepared to discuss information and options with patients based on their responses to the following questions.

4 days before or after administration with other
y of mRNA COVID-19 vaccines administered

told you that you had COVID-19?
or asymptomatic SARS-CoV-2 infection.
l until the person has recovered from the acute
nue isolation.

delay vaccination until near the end of this
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ccine, the side effects of the vaccine, and the

ne (e.g., healthcare personnel) may choose to
ple or the effects of mRNA COVID-19 vaccines

5

Pre-Vaccination Checklist for COVID-19 Vaccines

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 ☐ Moderna ☐ 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. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
5. Have you received another vaccine in the last 14 days?			
6. Have you had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
7. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
8. Do you have a bleeding disorder or are you taking a blood thinner?			
9. Are you pregnant or breastfeeding?			

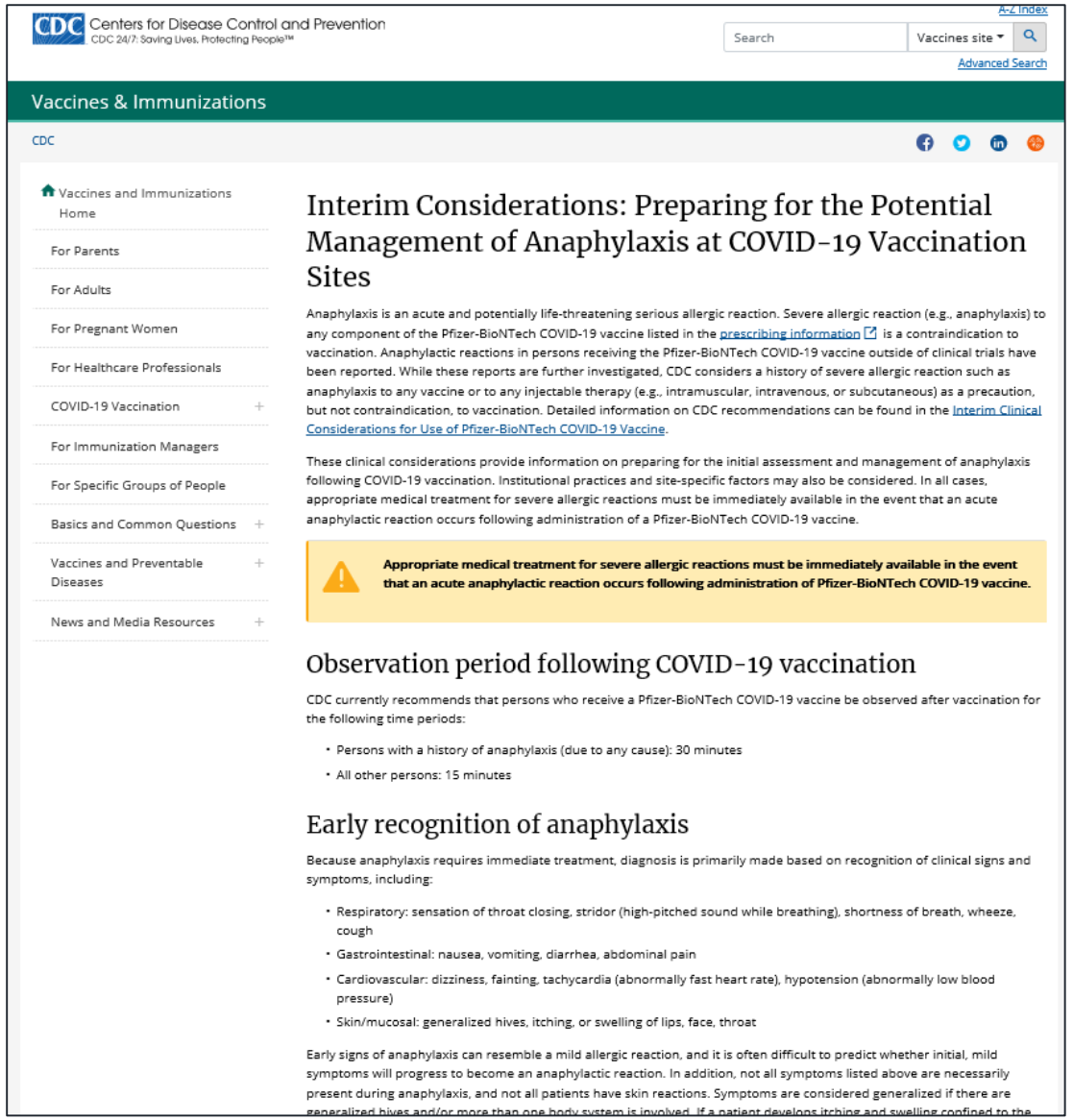
Form reviewed by _____ **Date** _____

12/21/20 CS321629-E Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists 1

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

Interim considerations:

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



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- For Pregnant Women
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- COVID-19 Vaccination
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- For Specific Groups of People
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- Vaccines and Preventable Diseases
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Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites

Anaphylaxis is an acute and potentially life-threatening serious allergic reaction. Severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech COVID-19 vaccine listed in the prescribing information is a contraindication to vaccination. Anaphylactic reactions in persons receiving the Pfizer-BioNTech COVID-19 vaccine outside of clinical trials have 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, 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.

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, 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.

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

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 symptoms, including:

- Respiratory: sensation of throat closing, stridor (high-pitched sound while breathing), shortness of breath, wheeze, cough
- Gastrointestinal: nausea, vomiting, diarrhea, abdominal pain
- Cardiovascular: dizziness, fainting, tachycardia (abnormally fast heart rate), hypotension (abnormally low blood pressure)
- Skin/mucosal: generalized hives, itching, or swelling of lips, face, throat

Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, not all symptoms listed above are necessarily present during anaphylaxis, and not all patients have skin reactions. Symptoms are considered generalized if there are generalized hives and/or more than one body system is involved. If a patient develops itching and swelling confined to the

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

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 cuff	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.

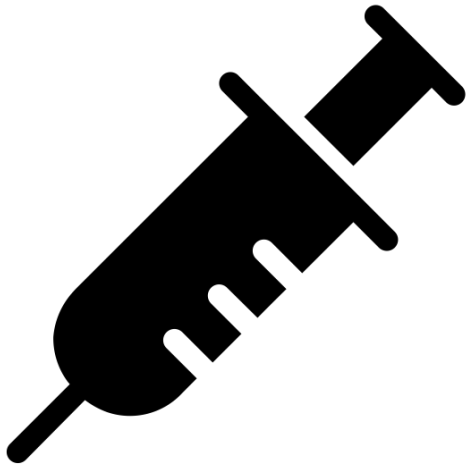
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

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

Conditions that are Neither Contraindications Nor Precautions

- Immunocompromise
- Pregnancy
- History of local reaction after the first dose
- Dermal fillers

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/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 limited data on the safety of COVID-19 vaccines in pregnant women
- 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/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

Delayed-onset Local Reactions to First Dose

Pfizer-BioNTech and Moderna COVID-19 vaccines

- Delayed-onset local reactions (e.g., erythema, induration, pruritus around the injection site area), are **not** a contraindication or precaution to receiving 2nd dose

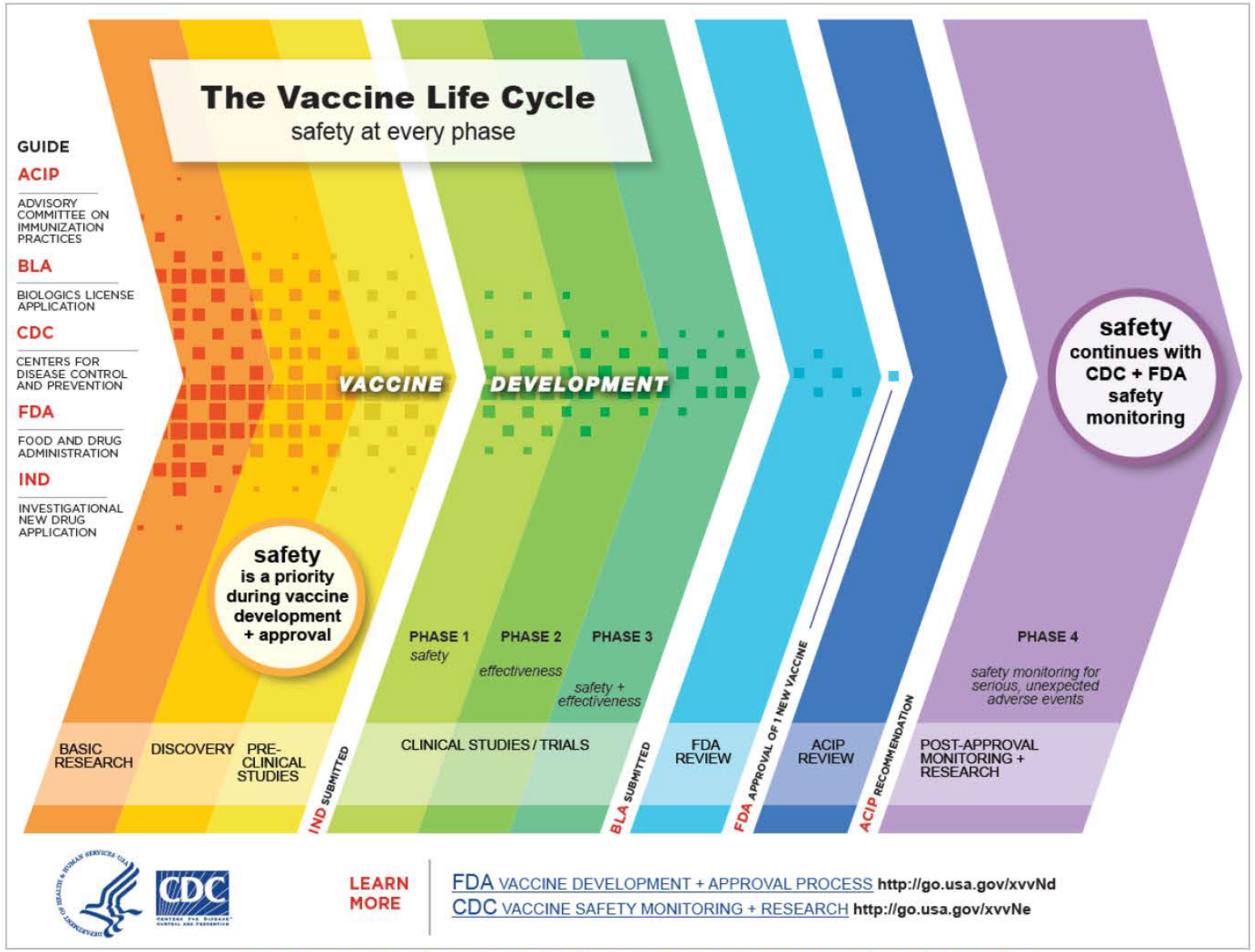
- Not known whether persons who experienced a delayed-onset injection site reaction after the first dose will experience a similar reaction after the second dose
  - These reactions are not felt to represent a risk for anaphylaxis upon receipt of the second dose

- Persons with such delayed injection site reactions after the first mRNA COVID-19 vaccine dose should receive the second dose using the same vaccine product as the first dose and at the recommended interval, and **preferably in the opposite arm**.

Persons with a History of Dermal Filler Use

- Swelling at or near the site of filler injection (usually face or lips) has been reported following administration of mRNA COVID-19 vaccine.
  - Temporary, resolves with medical treatment (e.g., corticosteroid therapy)
- mRNA COVID-19 vaccines can be administered to persons who have received injectable dermal fillers
- Persons should be advised to contact their healthcare provider for evaluation if they experience swelling at or near the site of dermal filler following vaccination.

- Safety is a priority during all phases of vaccine development, approval, and use
- Post-licensure (post-authorization) safety monitoring is an established part of the vaccine life cycle
- Monitoring COVID-19 vaccine safety will be a coordinated effort by multiple federal agencies



https://www.cdc.gov/vaccinesafety/ensuringsafety/history/index.html#anchor_1593624850886

Post-Vaccination Symptoms – Adverse Reactions

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- Depending on vaccine product, age group, and dose:
  - **35-91%** 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)
  - **45-83%** 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

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

Reporting Adverse Events

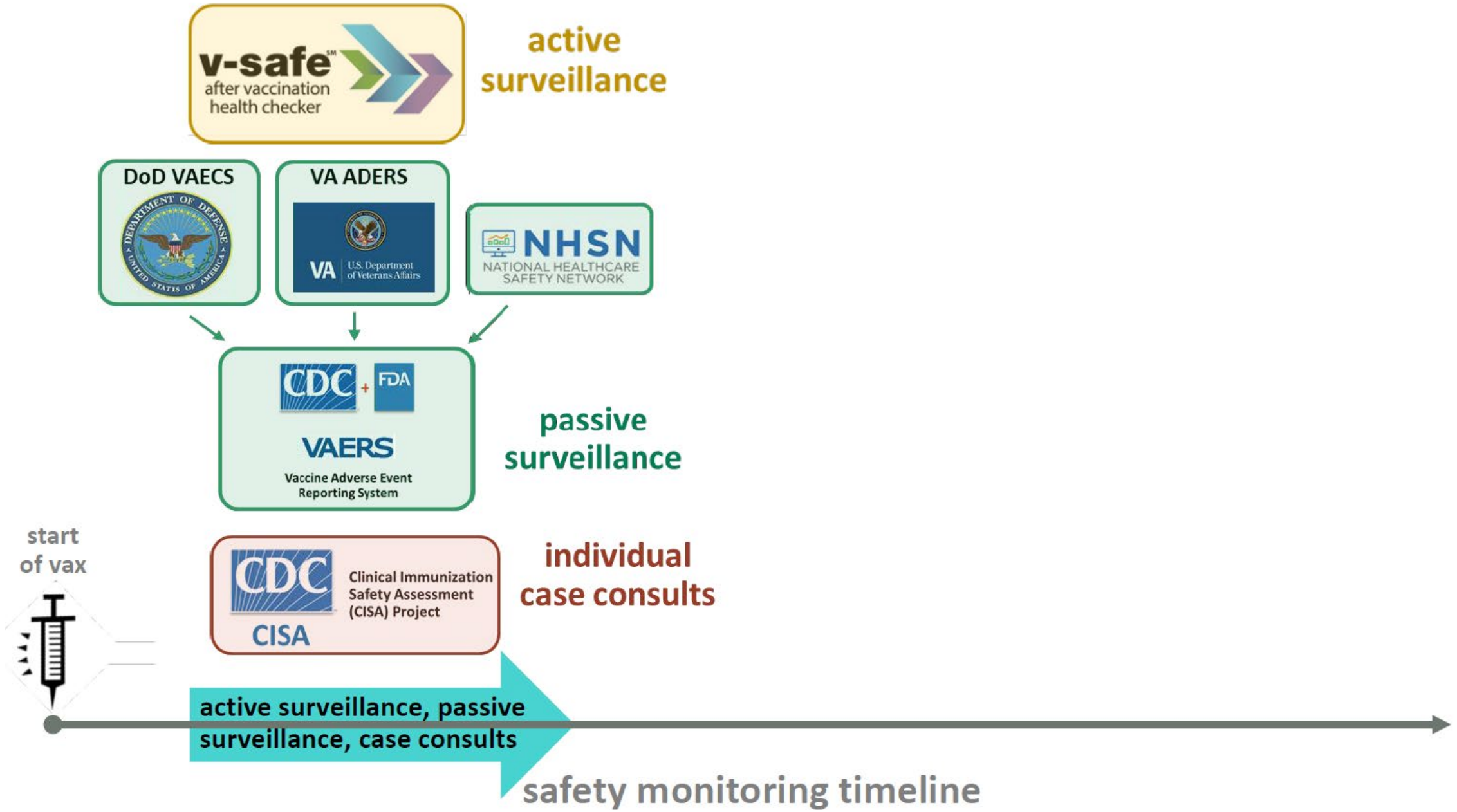
- Adverse events, whether or not they are adverse reactions or not, should be reported if concerning
- Report to Vaccine Adverse Event Reporting System www.vaers.hhs.gov
- V-safe is an active surveillance system – related to VAERS

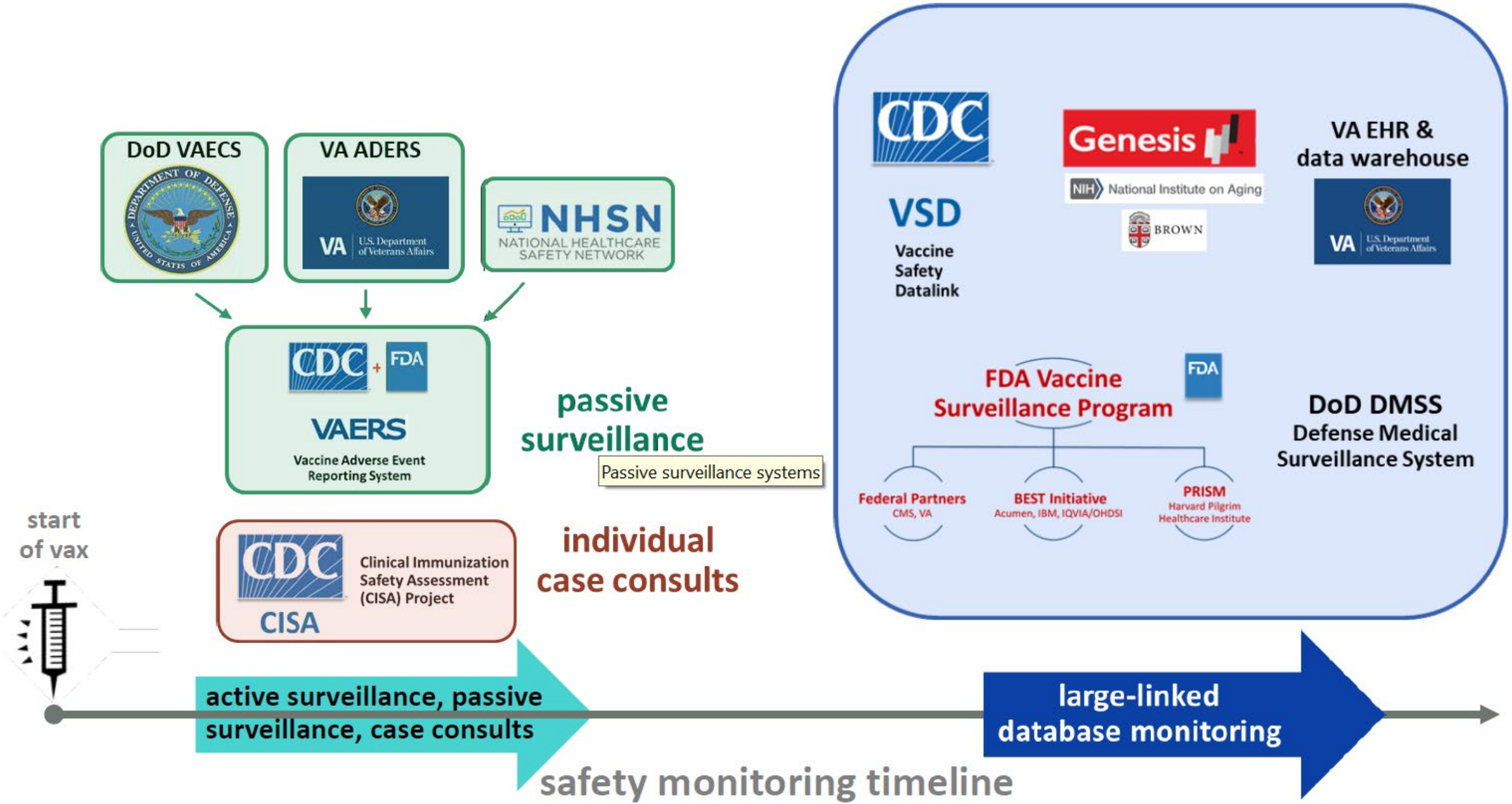
- Clinical Immunization Safety Assessment (provider reporting) https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html

Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
  - Uses text messaging and web surveys to check-in with vaccine recipients after vaccination
  - Participants can report any side effects or health problems after COVID-19 vaccination
  - Includes active telephone follow-up by CDC for reports of significant health impact

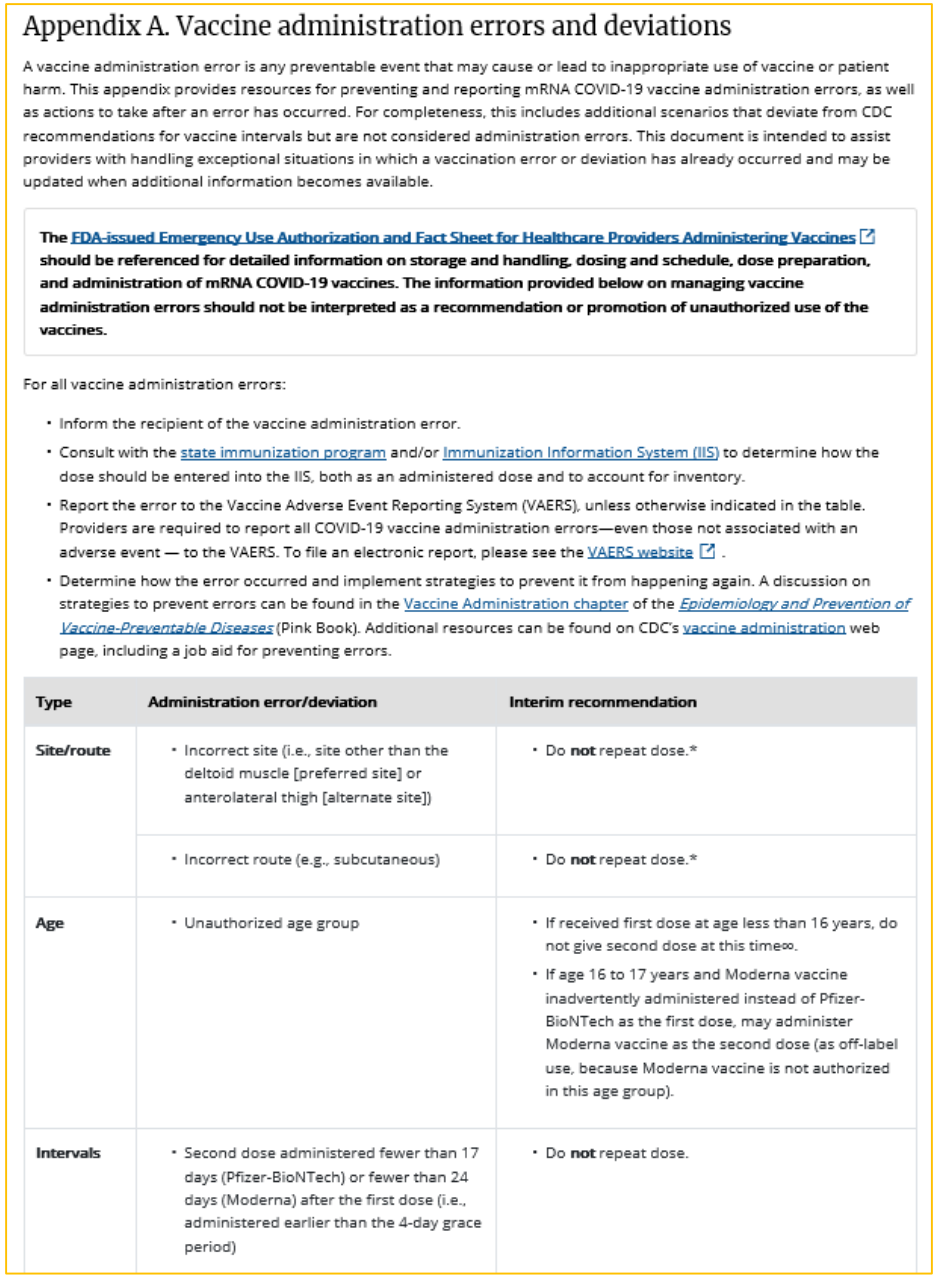
https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html


v-safe
after vaccination health checker
active surveillance
DoD VAECS
VA ADERS
VA U.S. Department of Veterans Affairs
NHSN
NATIONAL HEALTHCARE SAFETY NETWORK
CDC + FDA
VAERS
Vaccine Adverse Event Reporting System
passive surveillance
start of vax
CDC
Clinical Immunization Safety Assessment (CISA) Project
CISA
individual case consults
active surveillance, passive surveillance, case consults
safety monitoring timeline


DoD VAECS
VA ADERS
NHSN
NATIONAL HEALTHCARE SAFETY NETWORK
CDC + FDA
VAERS
Vaccine Adverse Event Reporting System
passive surveillance
Passive surveillance systems
CDC
Clinical Immunization Safety Assessment (CISA) Project
CISA
individual case consults
start of vax
active surveillance, passive surveillance, case consults
large-linked database monitoring
safety monitoring timeline
CDC
VSD
Vaccine Safety Datalink
Genesis
NIH National Institute on Aging
BROWN
VA EHR & data warehouse
VA U.S. Department of Veterans Affairs
FDA Vaccine Surveillance Program
FDA
Federal Partners
CMS, VA
BEST Initiative
Acumen, IBM, IQVIA/OHDSI
PRISM
Harvard Pilgrim Healthcare Institute
DoD DMSS
Defense Medical Surveillance System

Appendix A:

How to manage vaccine administration errors and deviations



Appendix A. Vaccine administration errors and deviations

A vaccine administration error is any preventable event that may cause or lead to inappropriate use of vaccine or patient harm. This appendix provides resources for preventing and reporting mRNA COVID-19 vaccine administration errors, as well as actions to take after an error has occurred. For completeness, this includes additional scenarios that deviate from CDC recommendations for vaccine intervals but are not considered administration errors. This document is intended to assist providers with handling exceptional situations in which a vaccination error or deviation has already occurred and may be updated when additional information becomes available.

The FDA-issued Emergency Use Authorization and Fact Sheet for Healthcare Providers Administering Vaccines should be referenced for detailed information on storage and handling, dosing and schedule, dose preparation, and administration of mRNA COVID-19 vaccines. The information provided below on managing vaccine administration errors should not be interpreted as a recommendation or promotion of unauthorized use of the vaccines.

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Consult with the state immunization program and/or Immunization Information System (IIS) to determine how the dose should be entered into the IIS, both as an administered dose and to account for inventory.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the table. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event — to the VAERS. To file an electronic report, please see the VAERS website .
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the Vaccine Administration chapter of the *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

Type	Administration error/deviation	Interim recommendation
Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.*
	• Incorrect route (e.g., subcutaneous)	• Do **not** repeat dose.*
Age	• Unauthorized age group	• If received first dose at age less than 16 years, do not give second dose at this time∞. • If age 16 to 17 years and Moderna vaccine inadvertently administered instead of Pfizer-BioNTech as the first dose, may administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is not authorized in this age group).
Intervals	• Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)	• Do **not** repeat dose.

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

Additional resources

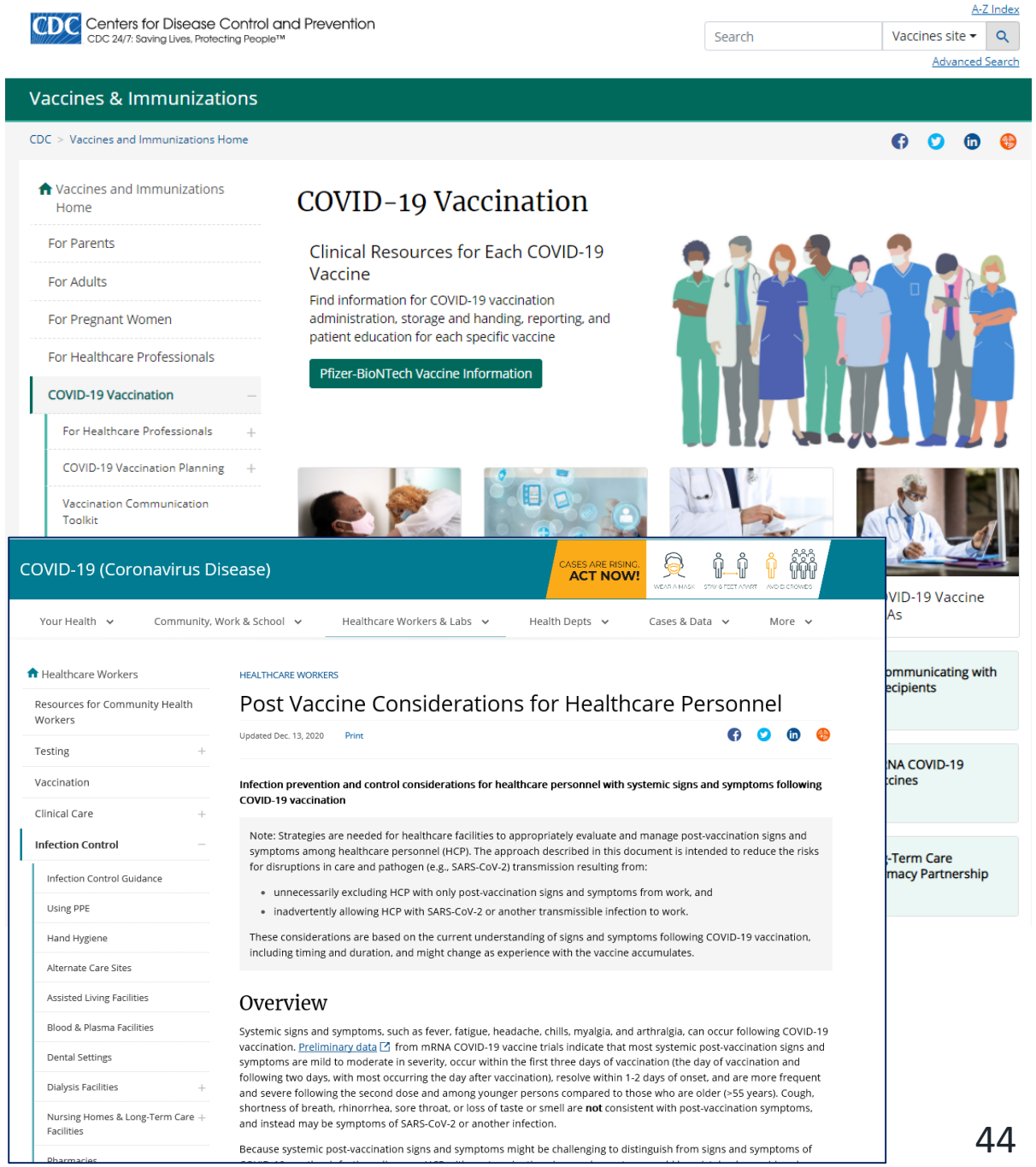
CDC Resources

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

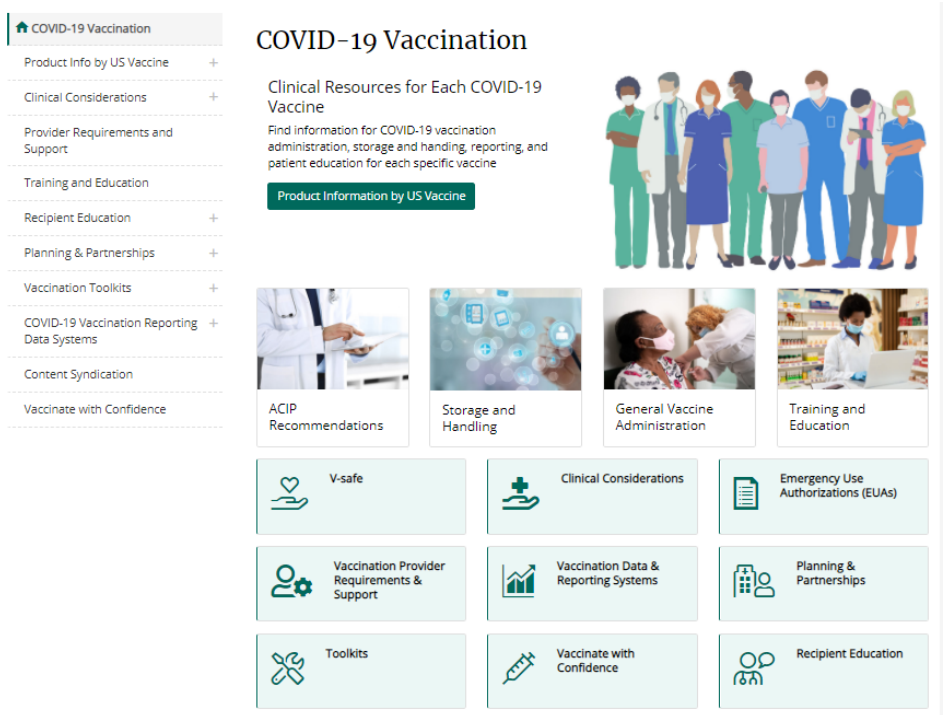
- COVID-19 Vaccination: https://www.cdc.gov/vaccines/covid-19/index.html
- For health care professionals, guidance for recipient education: https://www.cdc.gov/vaccines/covid-19/hcp/index.html

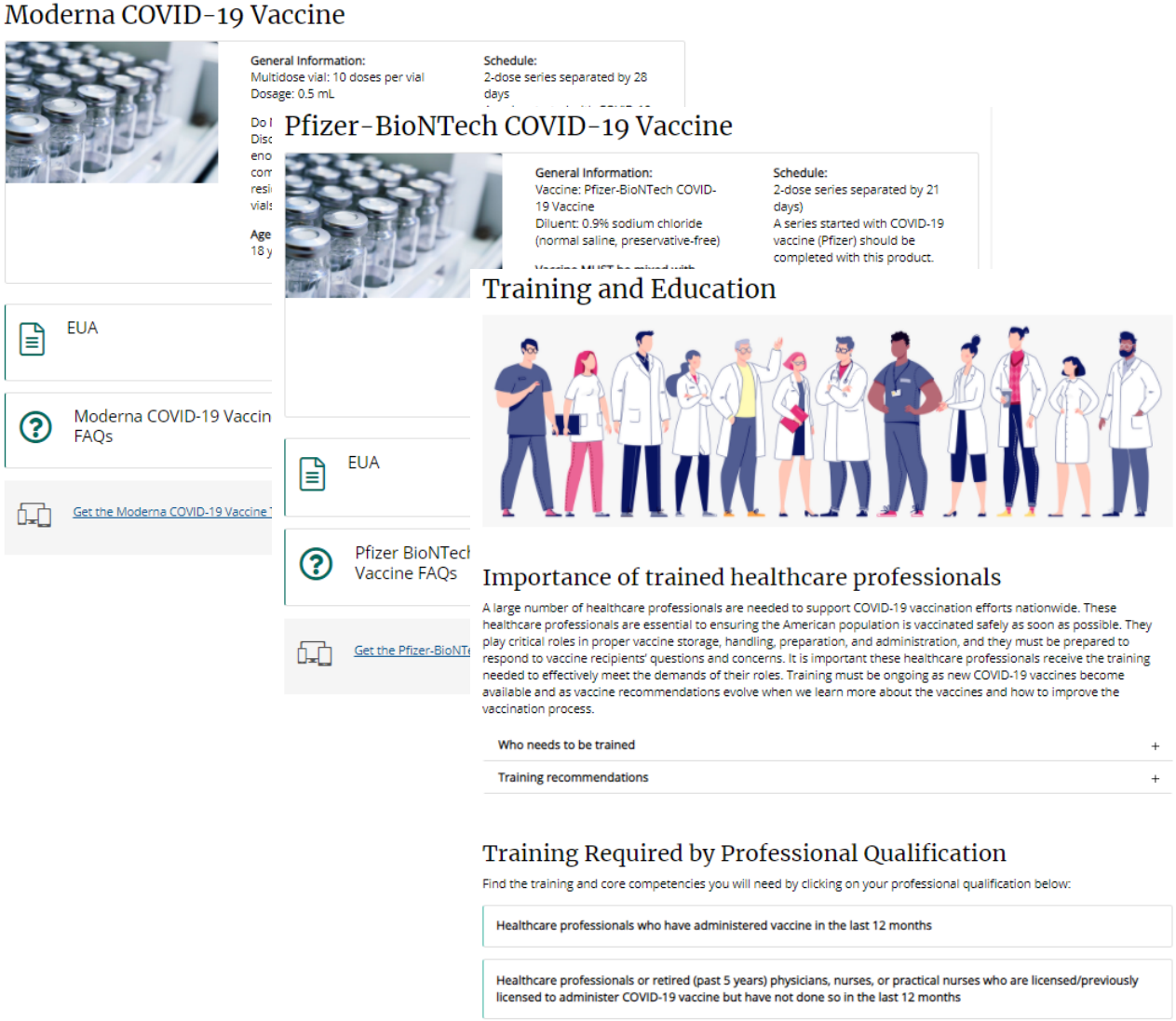
Infection prevention and control recommendations for persons with post-vaccination symptoms

- Health care providers
- Long-term care facility residents



CDC COVID-19 Vaccine Clinical Trainings and Materials

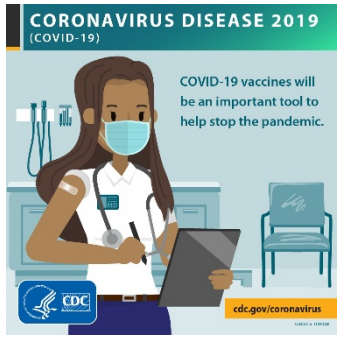


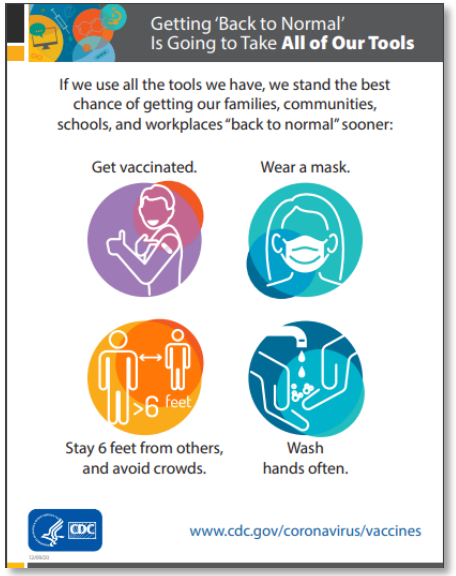


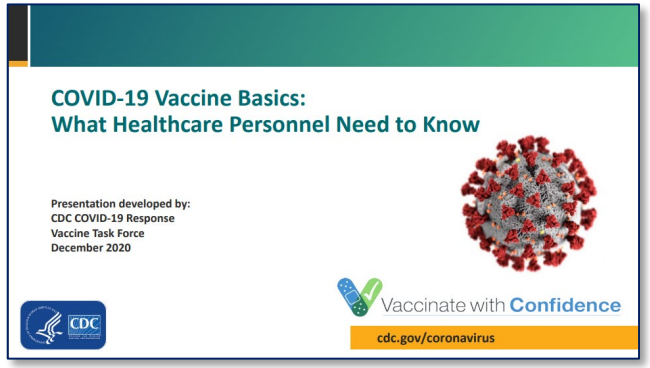
[COVID-19 Vaccination | CDC]
[Pfizer-BioNTech COVID-19 Vaccine Information | CDC]
[Moderna COVID-19 Vaccine Information | CDC]
[Training and Education | COVID-19 Vaccination | CDC]

COVID-19 Vaccine Communication Resources

- Engaging in Effective COVID-19 Vaccine Conversations
  - https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.htm
- Toolkit for Medical Centers, Clinics, and Clinicians
  - https://www.cdc.gov/vaccines/covid-19/health-systems-communication-toolkit.html
- More toolkits coming soon
  - Long-term care facilities
  - Health departments
  - Community-based organizations
  - Employers of essential workers







COVID-19 Vaccine Communication Resources: Safety Webpage

Vaccine Safety

CDC > Vaccine Safety

- Vaccine Safety
- Safety Information by Vaccine +
- Questions and Concerns +
- Information for Healthcare Providers +
- Information for Parents and Caregivers +
- Research +
- Ensuring Safety –

Ensuring Vaccine Safety

The United States has the safest, most effective vaccine supply in its history. The nation's longstanding vaccine safety system ensures that vaccines are as safe as possible. As new information and science become available, the system is updated and improved.

As part of these vaccine safety efforts, scientists ensure the safety of vaccines by conducting different types of studies:

- Clinical trials are done before a vaccine is made available. Vaccine manufacturers conduct these studies as part of the development, testing, and approval process. The Food and Drug

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

Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov