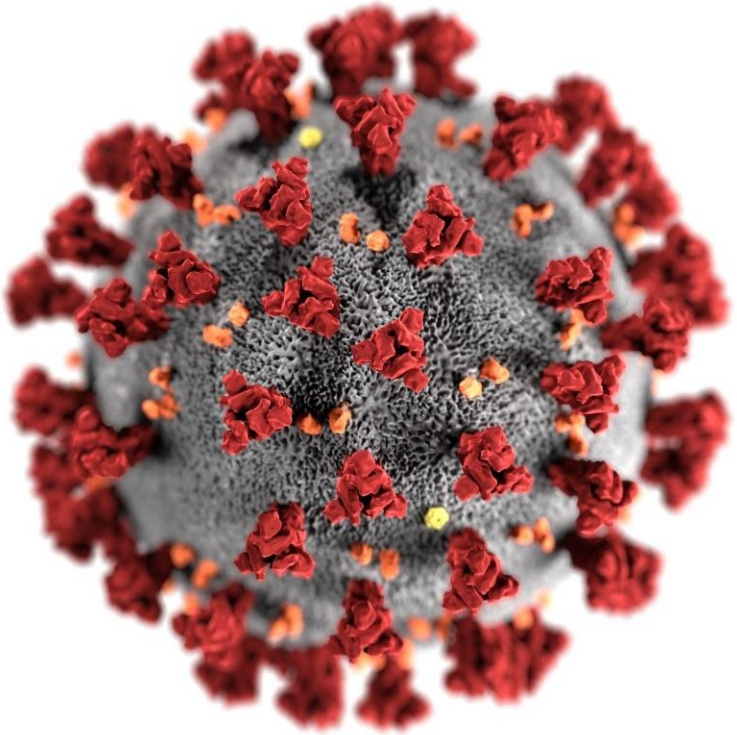
Clinical Considerations in COVID-19 Vaccinations with mRNA Vaccines



Adapted from CDC

Interim Clinical Considerations for mRNA COVID-19 Vaccines

COVID-19 Epidemiology

Current Epidemiology

Geography	Cases	Deaths
Global	112,000,000	2,470,000
US	28,200,000	500,159
NJ	769,109	22,874

Variants	US	NJ	# States
B.1.1.7 (UK)	1661	53	44
B.1.351 (S. Africa)	22	0	10
P.1 (Brazil)	5	0	4

COVID-19 Prevention

Preventive Measures

Non-pharmaceutical

1. Wearing a mask
2. Staying at least 6 feet away from others
3. Avoiding crowds
4. Avoiding poorly ventilated spaces
5. Covering coughs and sneezes
6. Washing hands often
7. Following travel guidance

Vaccines

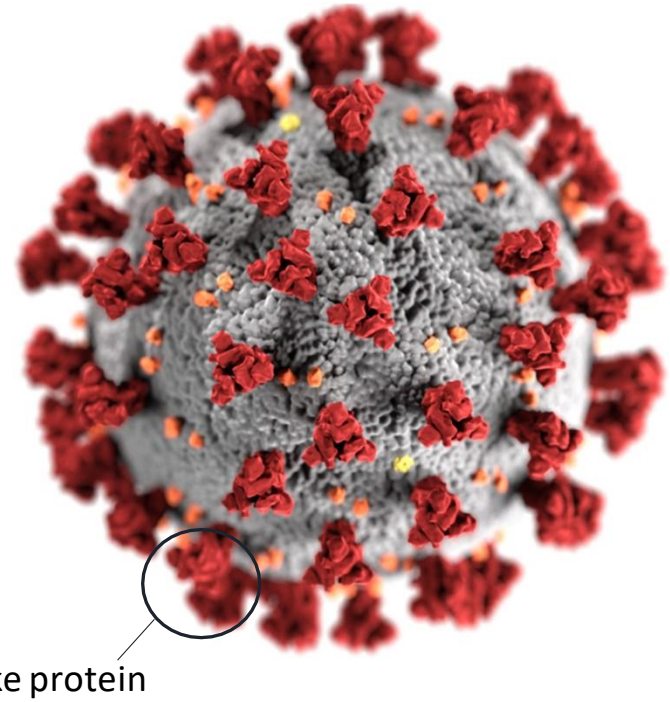
1. Currently FDA-authorized
    a. Pfizer mRNA
    b. Moderna mRNA

2. Pending FDA review (Public meeting 2/26)
    a. JnJ: Vector-based

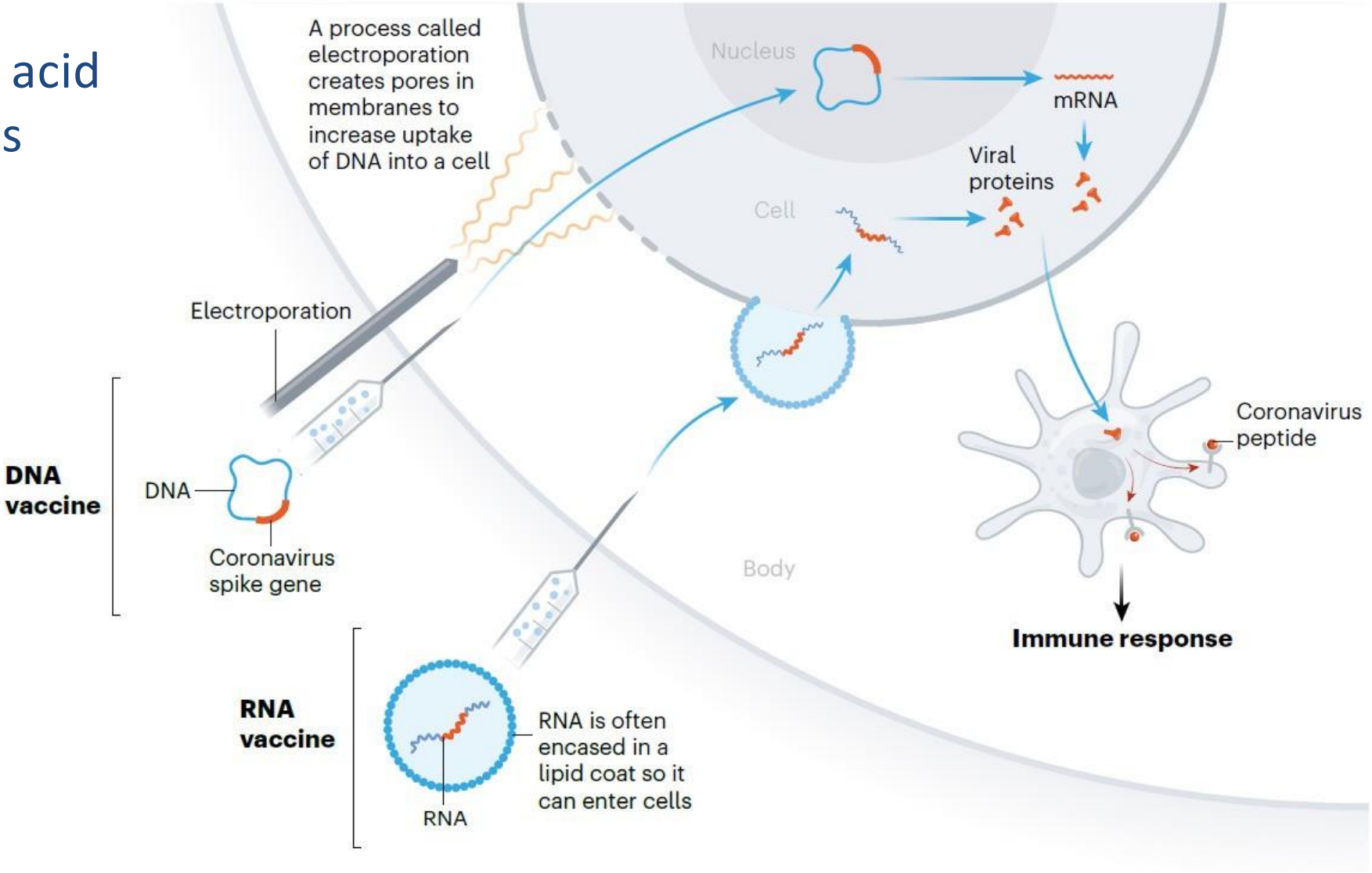
COVID-19 Vaccines

mRNA COVID-19 vaccines

- Lipid nanoparticle-formulated mRNA vaccine encoding the spike protein
  - Spike protein: facilitates entry of virus into cells
- Vaccination induces antibodies that can block entry of SARS-CoV-2 into cells, thereby preventing infection
- Additional immune responses (memory B and T-cells)



Nucleic acid vaccines



Nature. Vol 580. April 30, 2020. https://media.nature.com/original/magazine-assets/d41586-020-01221-y/d41586-020-01221-y.pdf

Explaining mRNA COVID-19 vaccines

- mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response

  - mRNA technology is new, but not unknown. They have been studied for more than a decade
  - mRNA vaccines do not contain a live virus and do not carry a risk of causing disease in the vaccinated person
  - mRNA from the vaccine never enters the nucleus of the cell and does not affect or interact with a person's DNA

COVID-19 mRNA Vaccines Characteristics

Vaccine Sponsors	BioNTech with Pfizer EUA 12/11/2020	ModernaTX, Inc. EUA (12/18/2020?)
Product Designator	BNT162b2, tozinameran	mRNA-1273
Dosing Regimen	Days 0 + 21	Days 0 + 28
Packaging	Frozen liquid. 5-dose vial, preservative-free	Frozen liquid. 10-dose vial, preservative-free
Handling	Dilute 0.45 mL of concentrate with 1.8 mL NaCl 0.9% to yield 30 mcg/0.3 mL. Gentle agitation	Dilution not required
Storage Conditions	Ship and store @ -70°C. Refrigerate @ 2° to 8°C ≤ 5 d. After diluting, use within 6 hours	Ship @ -20°C. Refrigerate @ 2° to 8°C ≤ 30 d. Room temp ≤ 12 h after thaw.
Chemistry-Manufacturing-Control (CMC) Data	FDA: Adequate information to ensure product quality and consistency	FDA: Adequate information to ensure product quality and consistency

Sources: FDA https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

Company reports, Wells Fargo Securities, LLC
EUA= Emergency Use Authroization

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	Polyethylene glycol (PEG) 2000 dimyristoyl glycerol (DMG)
	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
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

mRNA Vaccines Efficacy

Vaccine Sponsors	BioNTech with Pfizer (0+21 days)	ModernaTX, Inc. (0+28 days)
# in Phase-3 Trials	40,277	30,351
Ages studied	16 and over	18 and over
Efficacy, Overall	95.0% (95% CI: 90.0, 97.9%), starting 7 d after Dose 2 8 vaccinated vs. 162 control arm	94.1% (95% CI: 89.3, 96.8%), starting 14 d after Dose 2 11 vaccinated vs 185 control arm
Efficacy, Stratified	56+ y/o: 93.7% (80.6%, 98.8%) 16 to 55: 95.6% (89.4%, 98.6%) Similar efficacy findings across genders, racial and ethnic groups, and comorbidities. See VRBPAC documents	65+ y/o: 86.4% (61.4, 95.5%) 18 to 64: 95.6% (90.6, 97.9) Similar efficacy findings across genders, racial and ethnic groups, and comorbidities. See VRBPAC documents
Secondary Analyses (vaccinated vs control arms)	Severe disease: 1 vs 9 cases, 89% (20%, 99%) Between Doses 1-2: 52% (30%, 68%) (curves diverge Day ~ 12-15) Both with/without prior COVID-19 infection: 94.5% (89.6%, 97.6%), with no effect among those with prior infection	Severe disease: 0 vs 30 cases, 100% (95% CI not described) Between Doses 1-2: 80% (55, 92%) (curves diverge Day ~ 15) Both with/without prior COVID-19 infection: >93% (95% CI not described)

Sources: FDA https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

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mRNA Vaccines Tolerability and Safety Data-l

Vaccine Sponsors	BioNTech with Pfizer	ModernaTX, Inc.
All Volunteers	43,252 thru November 14	> 30,000
Volunteers with Median of 2+ Months of Follow-up	~ 38,000 thru November 14	~ 29,235 thru November 25, median 63 days of follow-up
Safety	Common Adverse Events (AEs): • injection-site reactions(84%) • fatigue (63%) • headache (55%) • muscle pain (38%) • chills (32%) • joint pain (24%) • fever (14%) Safety profile similar across age groups, genders, ethnic and racial groups, comorbidities, and prior SARS-CoV-2 infection.	Common Adverse Events (AEs): • injection-site pain (90%) • fatigue (69%) • headache (63%) • muscle pain (60%) • chills (43%) • joint pain (45%) • Fever (17%) Safety profile similar across age groups, genders, ethnic and racial groups, comorbidities, and prior SARS-CoV-2 infection.

Sources: FDA https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

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mRNA Vaccines Tolerability and Safety Data-ll

Vaccine Sponsors	BioNTech with Pfizer	ModernaTX, Inc.
Serious Adverse Events (AEs)	Serious AEs: 0.0% to 4.6%. More frequent after Dose 2 than Dose 1. Fewer SAEs if 56+ (≤2.8%) vs ≤55 (≤4.6%). No meaningful imbalances between study arms.	Severe AEs: 0.2% to 9.7%. More frequent after Dose 2 than Dose 1. Fewer SAEs if 65+ y/o No meaningful imbalances between study arms.
Deaths (vaccinated vs control arms)	2 vaccine arm vs 4 control arm	6 vaccine arm vs 7 control arm
Notable Findings	Bell's palsy: 4 vaccine vs 0 control, not clustered in time No meaningful imbalance with other neurologic, neuroinflammatory, or thrombotic events. Reports of anaphylactoid reactions from UK.	Bell's palsy: 3 vaccine vs 1 control, 22-32 d post vax, confounders No meaningful imbalance with other neurologic, neuroinflammatory, or thrombotic events. Hypersensitivity: 1.5% vaccine, 1.1% control, none severe

Sources: FDA https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines

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Advisory Committee on Immunization Practices (ACIP) Recommendations

MMWR: ACIP Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine (Dec. 13)

Interim Clinical Considerations for Use of Pfizer-BioNTech COVID-19 Vaccine (*Dec. 14*)

ACIP recommendations for use of COVID-19 vaccines

- On December 12, 2020, ACIP recommended use of the Pfizer-BioNTech COVID-19 vaccine in persons 16 years of age and older under the FDA's Emergency Use Authorization
- On December 18, 2020, ACIP recommended use of the Moderna COVID-19 vaccine in persons 18 years of age and older under the FDA's Emergency Use Authorization

https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19/clinical-considerations.html

Vaccine Administration

Administration of COVID-19 vaccines

- Pfizer-BioNTech: 2-dose series administered intramuscularly 3 weeks (21 days) apart
- Moderna: 2-dose series administered intramuscularly 1 month (28 days) apart
- Both doses are necessary for protection; efficacy of a single dose has not been systematically evaluated
- Second doses administered within a grace period of ≤4 days from the recommended date for the second dose are considered valid; however, doses administered earlier do not need to be repeated. The second dose should be administered as close to the recommended interval as possible. However, there is no maximum interval between the first and second dose for either vaccine.

Interchangeability of COVID-19 vaccine products

- Either of the currently authorized mRNA COVID-19 vaccines can be used when indicated. ACIP does not state a product preference.
- These mRNA COVID-19 vaccines are **not** interchangeable with each other or with other COVID-19 vaccine products.
- The safety and efficacy of a mixed-product series have not been evaluated. Both doses of the series should be completed with the same product.
- However, if two doses of different mRNA COVID-19 vaccine products are inadvertently administered, no additional doses of either product are recommended at this time. Recommendations may be updated as further information becomes available or other vaccine types (e.g., viral vector, protein subunit vaccines) are authorized.

Coadministration with other vaccines

- Both vaccines should be administered alone with a minimum interval of 14 days before or after administration with any other vaccines
  - Due to lack of data on safety and efficacy of the vaccine administered simultaneously with other vaccines

- If mRNA COVID-19 vaccines are inadvertently administered within 14 days of another vaccine, doses do not need to be repeated for either vaccine

Vaccination of Persons with Prior SARS-CoV-2 Infection or Exposure

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
  - Data from phase 2/3 clinical trials suggest vaccination safe and likely efficacious in these persons

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

Persons with known current SARS-CoV-2 infection

- Vaccination should be deferred until recovery from acute illness (if person had symptoms) *and* criteria have been met to discontinue isolation

- No minimal interval between infection and vaccination

- However, current evidence suggests reinfection uncommon in the 90 days after initial infection, and thus persons with documented acute infection in the preceding 90 days may defer vaccination until the end of this period, if desired

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-in-home-patients.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html

Persons who previously received passive antibody therapy for COVID-19

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

- Vaccination should be deferred for at least 90 days to avoid interference of the treatment with vaccine-induced immune responses
  - Based on estimated half-life of therapies and evidence suggesting reinfection is uncommon within 90 days of initial infection

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 other 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

Vaccination of Special Populations

Persons with underlying medical conditions

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

- Phase 2/3 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

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

- Persons with stable HIV infection were included in mRNA COVID-19 vaccine clinical trials, though data are limited.

- Immunocompromised individuals may still receive mRNA COVID-19 vaccines 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

Persons with autoimmune disorders

- No data are currently available on the safety and efficacy of mRNA COVID-19 vaccines in persons with autoimmune conditions, though these persons were eligible for enrollment in clinical trials.
- No imbalances were observed in the occurrence of symptoms consistent with autoimmune conditions or inflammatory disorders in clinical trial participants who received an mRNA COVID-19 vaccine compared to placebo.
- Persons with autoimmune conditions who have no contraindications to vaccination may receive an mRNA COVID-19 vaccine.

Persons with a history of Guillan-Barre syndrome

- To date, no cases of Guillain-Barré syndrome (GBS) have been reported following vaccination among participants in the Pfizer-BioNTech or Moderna COVID-19 vaccines clinical trials.
- With few exceptions, ACIP's general best practice guidelines for immunization does not include history of GBS as a contraindication or precaution to vaccination.
- Persons with a history of GBS may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination.
- Any occurrence of GBS following mRNA COVID-19 vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Persons with a history of Bell's palsy

- Cases of Bell's palsy were reported following vaccination in participants in both the Pfizer-BioNTech and Moderna COVID-19 vaccines clinical trials.
- However, the FDA does not consider these to be above the frequency expected in the general population and has not concluded that these cases were causally related to vaccination.
- Post-authorization safety surveillance will be important to further assess any possible causal association.
- In the absence of such evidence, persons with a history of Bell's palsy may receive an mRNA COVID-19 vaccine unless they have a contraindication to vaccination.
- Any occurrence of Bell's palsy following mRNA COVID-19 vaccination should be reported to VAERS

Pregnant women

- There are currently few data on the safety of COVID-19 vaccines in pregnant women
  - Limited animal (rats) developmental and reproductive toxicity (DART) data are available, with no safety concerns
  - Studies in humans are ongoing and more planned
  - Vaccine manufacturers are following outcomes in women in clinical trials who became pregnant
- mRNA vaccines and pregnancy
  - Not live vaccines
  - They are degraded quickly by normal cellular processes and don't enter the nucleus of the cell
- 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
- 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. A discussion with her healthcare provider can help her make an informed decision.

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)
  - her personal risk of contracting COVID-19 (by occupation or other activities)
  - the risks of COVID-19 to her and potential risks to the fetus
  - the efficacy of the vaccine
  - the known side effects of the vaccine
  - the lack of data about the vaccine during pregnancy

- Pregnant women who experience fever following vaccination should be counseled to take acetaminophen as fever has been associated with adverse pregnancy outcomes

- Routine testing for pregnancy prior to receipt of a COVID-19 vaccine is not recommended.

American College of Obstetricians and Gynecologists (ACOG) Practice Advisory-Pregnant Women

- ACOG recommends that COVID-19 vaccines should not be withheld from pregnant individuals who meet criteria for vaccination based on ACIP-recommended priority groups

- Individuals considering a COVID-19 vaccine should have access to available information about the safety and efficacy of the vaccine, including information about data that are not available. A conversation between the patient and their clinical team may assist with decisions regarding the use of vaccines approved under EUA for the prevention of COVID-19 by pregnant patients. Important considerations include:

  - the level of activity of the virus in the community
  - the potential efficacy of the vaccine
  - the risk and potential severity of maternal disease, including the effects of disease on the fetus and newborn
  - the safety of the vaccine for the pregnant patient and the fetus

https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

Breastfeeding/Lactating Women

- There are no data on the safety of COVID-19 vaccines in lactating women or the effects of mRNA vaccines on the breastfed infant or milk production/excretion

- mRNA vaccines are not considered live virus vaccines and are not thought to be a risk to the breastfeeding infant

- If a lactating woman is part of a group (e.g., healthcare personnel) who is recommended to receive a COVID-19 vaccine, she may choose to be vaccinated

American College of Obstetricians and Gynecologists (ACOG) Practice Advisory-Breastfeeding/Lactating Women

COVID-19 vaccines should be offered to lactating individuals similar to non-lactating individuals when they meet criteria for receipt of the vaccine based on prioritization groups outlined by the ACIP.

https://www.acog.org/en/clinical/clinical-guidance/practice-advisory/articles/2020/12/vaccinating-pregnant-and-lactating-patients-against-covid-19

Vaccination of children and adolescents

- Adolescents aged 16–17 years are included among persons eligible to receive the Pfizer-BioNTech COVID-19 vaccine under the EUA.
- While vaccine safety and efficacy data in this age group are limited, there are no biologically plausible reasons for safety and efficacy profiles to be different than those observed in persons 18 years of age and older.
- Adolescents aged 16–17 years who are part of a group recommended to receive a COVID-19 vaccine may be vaccinated with the Pfizer-BioNTech COVID-19 vaccine, with appropriate assent.
- Children and adolescents younger than 16 years of age are not authorized to receive the Pfizer-BioNTech COVID-19 vaccine at this time.
- Children and adolescents younger than 18 years of age are not authorized to receive the Moderna COVID-19 vaccine at this time

Patient Vaccine Counseling

Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- 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 symptoms
  - 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

Vaccine efficacy

- Preliminary data suggest high vaccine efficacy in preventing COVID-19 following receipt of two doses of mRNA COVID-19 vaccine
  - Pfizer-BioNTech: 95.0% [95% CI: 90.3%, 97.6%]
  - Moderna: 94.1% [95% CI: 89.3%, 96.8%].

- Limited data are currently available regarding the efficacy of a single dose.

- Patients should be counseled on the importance of completing the two-dose series (of the same vaccine product) to optimize protection.

Public Health Recommendations for Vaccinated People

Public health recommendations for vaccinated persons

- Protection from vaccine is not immediate; vaccine is a 2-dose series and will take 1 to 2 weeks following the second dose to be considered fully vaccinated
- No vaccine is 100% effective
- Given the currently limited information on how well the vaccine works in the general population; how much it may reduce disease, severity, or transmission; and how long protection lasts, vaccinated persons should continue to follow all current guidance to protect themselves and others, including:
  - Wearing a mask
  - Staying at least 6 feet away from others
  - Avoiding crowds
  - Washing hands often
  - Following CDC travel guidance
  - Following quarantine guidance after an exposure to someone with COVID-19
  - Following any applicable workplace or school guidance

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

Guidance on quarantine after vaccination

1. If exposed to someone with confirmed or suspected COVID-19, no need to quarantine if the individual meets all 3 of the following criteria :
   - Is fully vaccinated (i.e. $\geq$ 2 weeks following receipt of the second dose in 2-dose series, or $\geq$ 2 weeks following receipt of one dose of a single-dose series)
   - Is within 3 months following receipt of the last dose of the series
   - Has remained symptom free since the current COVID-19 exposure

2. Fully vaccinated persons who do not quarantine should still watch for symptoms of COVID-19 for 14 days following an exposure, and if they experience symptoms should be evaluated for COVID-19 infection, including SARS-CoV-2 testing

Vaccine Prioritization

NJ COVID-19 Vaccination Principles and Aims

Guiding Ethical Principles

The NJDOH COVID-19 Professional Advisory Committee (PAC) has adopted the overarching ethical principles adopted by the CDC's Advisory Committee on Immunization Practices (ACIP) for phased prioritization of COVID-19 vaccines. These serve as a foundation of the PAC's recommendations and include:

- Maximize benefits and minimize harms
- Equity
- Justice
- Transparency

Strategic Aims

As documented in the New Jersey Interim COVID-19 Vaccination Plan published publicly 10/26/20, the recommendations of the PAC are in service to the State of New Jersey's aims:

- To provide equitable access to COVID-19 vaccine to all who live, work, and/or are educated in New Jersey
- To achieve community protection, assuming vaccine efficacy, availability, and uptake
- To build sustainable trust in COVID-19 and other vaccines

Phases of Vaccination

1A

- Paid and unpaid persons serving in health care settings who have the potential for direct or indirect exposure to patients or infectious materials
- All residents and workers of long-term care and high-risk congregate care facilities

1B

- First responders
- Individuals aged 65 and older
- Individuals ages 16-64 with medical conditions, as defined by the Centers for Disease Control and Prevention, that increase the risk of severe illness from the virus.
- Individuals who are pregnant and those in an immunocompromised state (weakened immune system) from solid organ transplant are also eligible but should follow CDC guidance and first discuss vaccination with their medical provider before receiving the vaccine

Who is eligible for vaccination next?
Additional essential workers *(Phases 1B and/or 1C)*
Additional individuals at high risk *(Phases 1B and/or 1C)*
General population *(Phase 2)*

NOTE: Vaccination phases are tentative and subject to change. The movement between vaccination eligibility phases is fluid. One phase may overlap with another. Not all individuals in one phase will be vaccinated before opening to additional groups.

https://covid19.nj.gov/faqs/nj-information/slowing-the-spread/who-is-eligible-for-vaccination-in-new-jersey-who-is-included-in-the-vaccination-phases#direct-link

Contraindications and Precautions

Contraindications to vaccination

- Prescribing information for both Pfizer-BioNTech and Moderna COVID-19 vaccines:
  - Severe allergic reaction (e.g., anaphylaxis) to **any component of the vaccine** is a contraindication to vaccination
  - Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of the vaccine

Precautions to vaccination: Pfizer-BioNTech and Moderna COVID-19 vaccines

- History of severe allergic reaction (e.g., anaphylaxis) **to any other vaccine or injectable therapy** (e.g., intramuscular, intravenous, or subcutaneous)
  - Risk assessment should be conducted in persons who report history of severe allergic reaction (e.g., whether reaction required use of epinephrine [EpiPen®, etc.], resulted in hospitalization)

- These persons may still receive vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination

Allergies that do not constitute a contraindication or precaution to vaccination

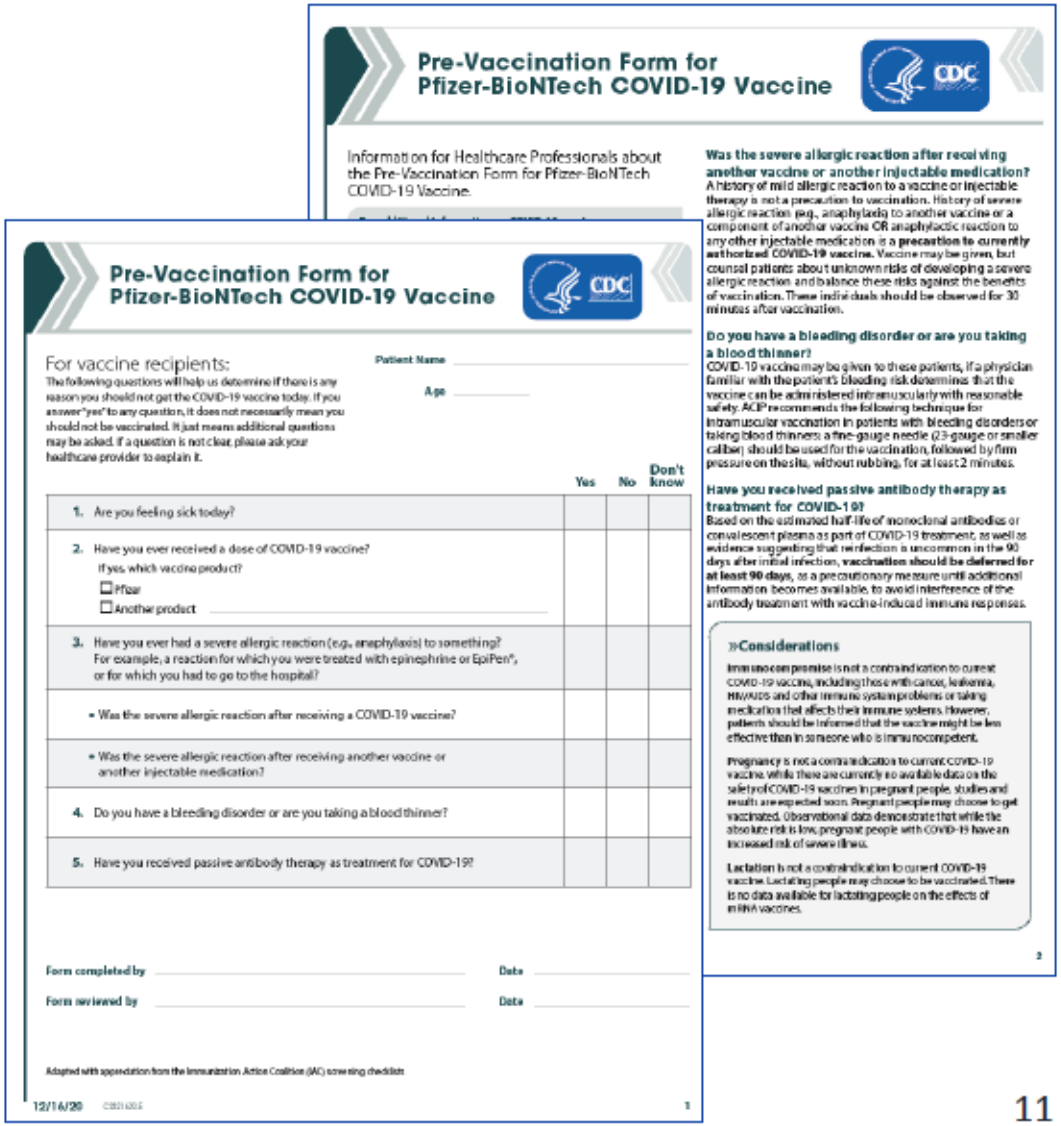
- Persons with the following allergies do not have a contraindication or precaution to vaccination:
  - History of food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies
  - History of allergy to oral medications (including the oral equivalent of an injectable medication)
  - Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis)
  - Family history of anaphylaxis
  - Any other history of anaphylaxis that is not related to a vaccine or injectable therapy

Algorithm for the 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 food, pet, insect, venom, environmental, latex, or other allergies not related to vaccines or injectable therapies • History of allergy to oral medications (including the oral equivalent of an injectable medication) • Non-serious allergy to vaccines or other injectables (e.g., no anaphylaxis) • Family history of anaphylaxis • Any other history of anaphylaxis that is not related to a vaccine or injectable therapy **ACTIONS** • 30 minute observation period: Persons with a history of severe allergic reaction (e.g., anaphylaxis) due to any cause • 15 minute observation period: Persons with allergic reaction, but not anaphylaxis	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not including mRNA COVID-19 vaccines†) • History of severe allergic reaction (e.g., anaphylaxis) to an injectable therapy **ACTIONS:** • Risk assessment • Potential deferral of vaccination • 30 minute observation period if vaccinated	**ALLERGIES** • History of severe allergic reaction (e.g., anaphylaxis) to any component of an mRNA COVID-19 vaccine† **ACTIONS** • Do not vaccinate

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

Additional tools to identify persons with contraindications and precautions to vaccination



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

Information for Healthcare Professionals about the Pre-Vaccination Form for Pfizer-BioNTech COVID-19 Vaccine.

Was the severe allergic reaction after receiving another vaccine or another injectable medication?
A history of mild allergic reaction to a vaccine or injectable therapy is not a precaution to vaccination. History of severe allergic reaction (e.g., anaphylaxis) to another vaccine or a component of another vaccine OR anaphylactic reaction to any other injectable medication is a **precaution to currently authorized COVID-19 vaccine.** Vaccine may be given, but counsel patients about unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination. These individuals should be observed for 30 minutes after vaccination.

Do you have a bleeding disorder or are you taking a blood thinner?
COVID-19 vaccine may be given to these patients, if a physician familiar with the patient's bleeding risk determines that the vaccine can be administered intramuscularly with reasonable safety. ACIP recommends the following technique for intramuscular vaccination in patients with bleeding disorders or taking blood thinners: a fine-gauge needle (23-gauge or smaller caliber) should be used for the vaccination, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Have you received passive antibody therapy as treatment for COVID-19?
Based on the estimated half-life of monoclonal antibodies or convalescent plasma as part of COVID-19 treatment, as well as evidence suggesting that reinfection is uncommon in the 90 days after initial infection, **vaccination should be deferred for at least 90 days**, as a precautionary measure until additional information becomes available, to avoid interference of the antibody treatment with vaccine-induced immune responses.

»Considerations

Immunocompromise is not a contraindication to current COVID-19 vaccine, including those with cancer, leukemia, HIV/AIDS and other immune system problems or taking medications that affects their immune systems. However, patients should be informed that the vaccine might be less effective than in someone who is immunocompetent.

Pregnancy is not a contraindication to current COVID-19 vaccine. While there are currently no available data on the safety of COVID-19 vaccines in pregnant people, studies and results are expected soon. Pregnant people may choose to get vaccinated. Observational data demonstrate that while the absolute risk is low, pregnant people with COVID-19 have an increased risk of severe illness.

Lactation is not a contraindication to current COVID-19 vaccine. Lactating people may choose to be vaccinated. There is no data available for lactating people on the effects of mRNA vaccines on the breastfed infant or on milk production/excretion.

2

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

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 checklist

12/14/20 CS321005

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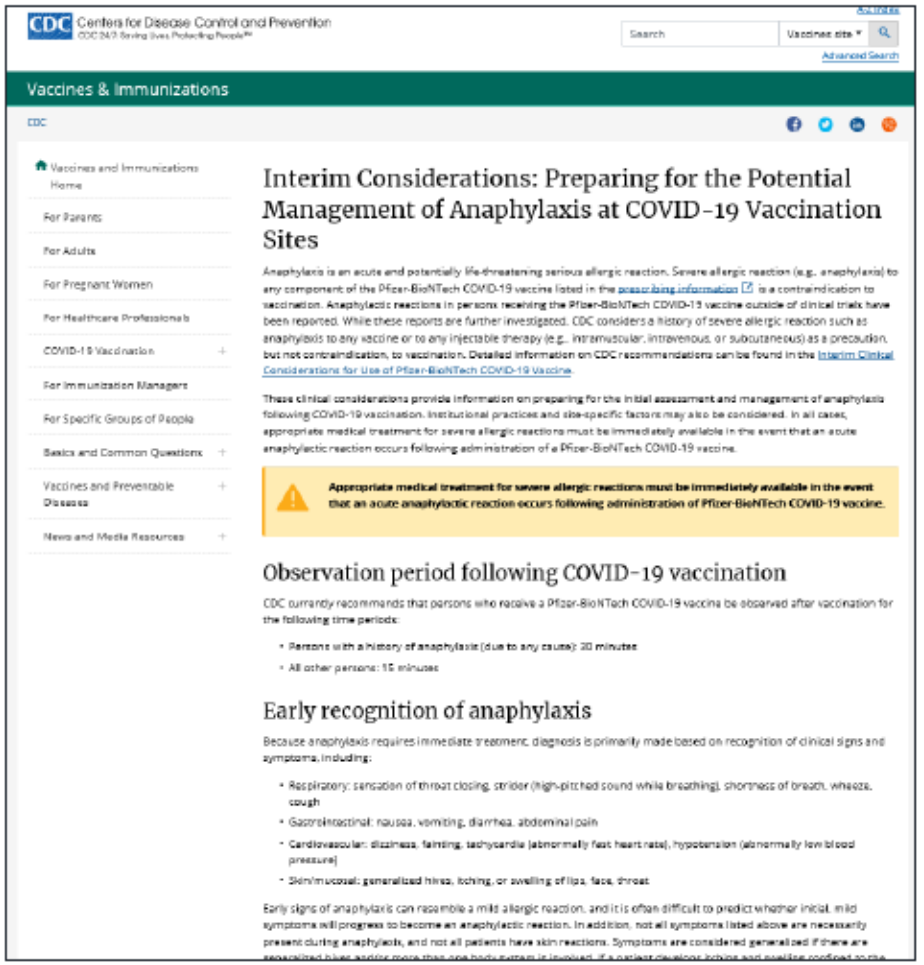
https://www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf

Interim considerations:

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

Fact sheets under development, including one tailored to long-term care facilities



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

Activate emergency medical services

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 sties

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)
Stethoscope	H2 antihistamine (e.g., famotidine, cimetidine)
Timing device to assess pulse	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.

Interpretation of SARS-CoV-2 Test Results in Vaccinated Persons

SARS-CoV-2 tests

- Viral tests: Prior receipt of an mRNA COVID-19 vaccine will not affect the results of SARS-CoV-2 nucleic acid amplification or antigen tests.

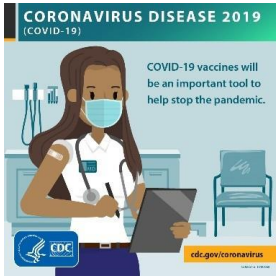
- Antibody tests:
  - Currently available antibody tests for SARS-CoV-2 assess IgM and/or IgG to spike or nucleocapsid proteins.
  - Both COVID-19 vaccines contain mRNA that encodes the spike protein; thus, a positive test for spike protein IgM/IgG could indicate either prior infection or vaccination.
  - To evaluate for evidence of prior infection in an individual with a history of mRNA COVID-19 vaccination, a test specifically evaluating IgM/IgG to the nucleocapsid protein should be used
  - Antibody testing is not currently recommended to assess for immunity to COVID-10 following mRNA COVID-19 vaccination or to assess the need for vaccination in an unvaccinated person.

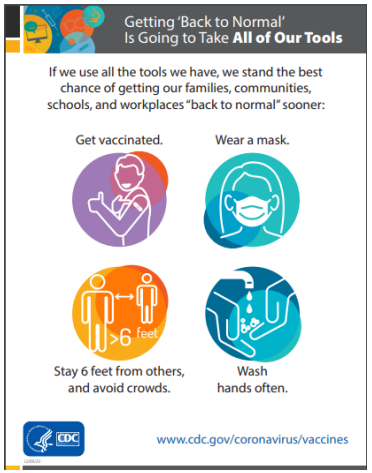
https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance

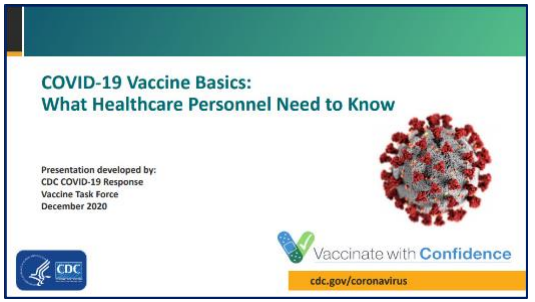
Clinical Resources

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

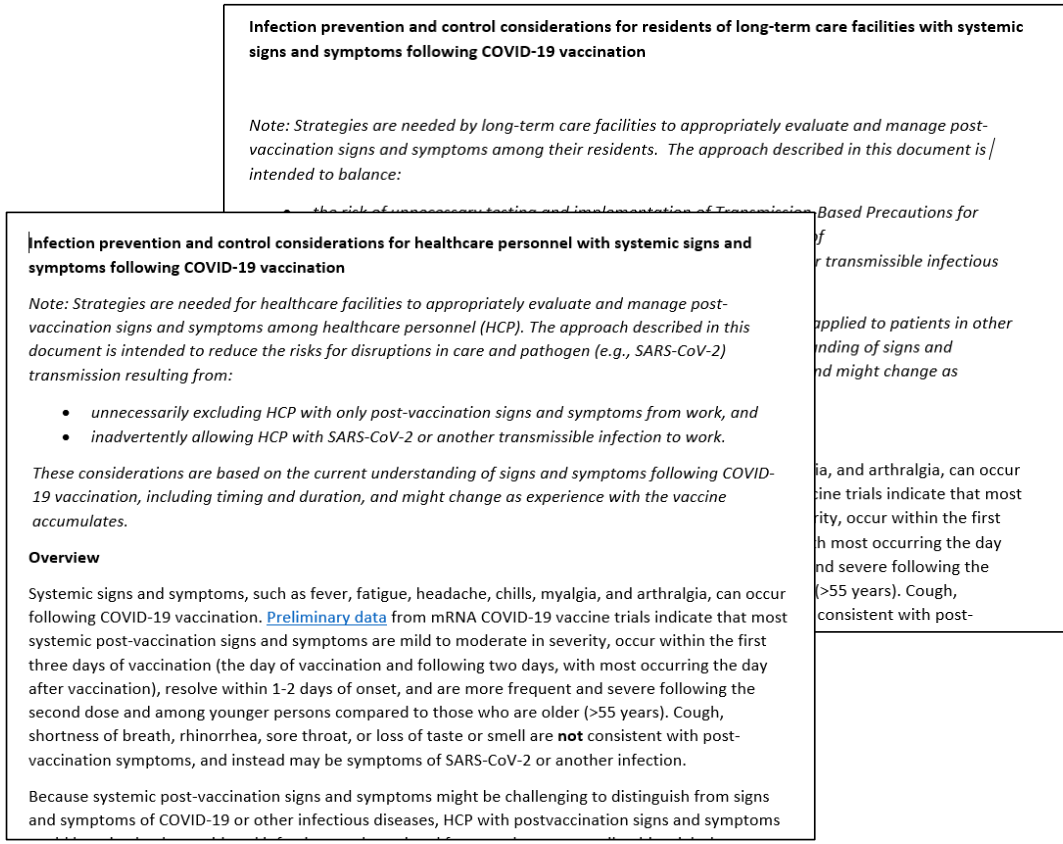






Infection prevention and control recommendations for persons with post-vaccination symptoms

- Healthcare personnel
- Long-term care facility residents



Infection prevention and control considerations for residents of long-term care facilities with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed by long-term care facilities to appropriately evaluate and manage post-vaccination signs and symptoms among their residents. The approach described in this document is intended to balance:

Infection prevention and control considerations for healthcare personnel with systemic signs and symptoms following COVID-19 vaccination

Note: Strategies are needed for healthcare facilities to appropriately evaluate and manage post-vaccination signs and symptoms among healthcare personnel (HCP). The approach described in this document is intended to reduce the risks for disruptions in care and pathogen (e.g., SARS-CoV-2) transmission resulting from:

- *unnecessarily excluding HCP with only post-vaccination signs and symptoms from work, and*
- *inadvertently allowing HCP with SARS-CoV-2 or another transmissible infection to work.*

These considerations are based on the current understanding of signs and symptoms following COVID-19 vaccination, including timing and duration, and might change as experience with the vaccine accumulates.

Overview

Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination. Preliminary data from mRNA COVID-19 vaccine trials indicate that most systemic post-vaccination signs and symptoms are mild to moderate in severity, occur within the first three days of vaccination (the day of vaccination and following two days, with most occurring the day after vaccination), resolve within 1-2 days of onset, and are more frequent and severe following the second dose and among younger persons compared to those who are older (>55 years). Cough, shortness of breath, rhinorrhea, sore throat, or loss of taste or smell are **not** consistent with post-vaccination symptoms, and instead may be symptoms of SARS-CoV-2 or another infection.

Because systemic post-vaccination signs and symptoms might be challenging to distinguish from signs and symptoms of COVID-19 or other infectious diseases, HCP with postvaccination signs and symptoms

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

FDA EUA resources

- FDA COVID-19 EUA
  - https://www.fda.gov/media/144412/download
- FDA COVID-19 Information
  - https://www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19
- FDA EUA Guidance
  - https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas