CDC/IDSA COVID-19 Clinician Call

January 23, 2021

Welcome & Introductions

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- 51st in a series of weekly calls, initiated by CDC as a forum for information sharing among frontline clinicians caring for patients with COVID-19
- The views and opinions expressed here are those of the presenters and do not necessarily reflect the official policy or position of the CDC or IDSA. Involvement of CDC and IDSA should not be viewed as endorsement of any entity or individual involved.
- This webinar is being recorded and can be found online at www.idsociety.org/cliniciancalls.

Ask the Expert: Vaccine Q&A with the CDC

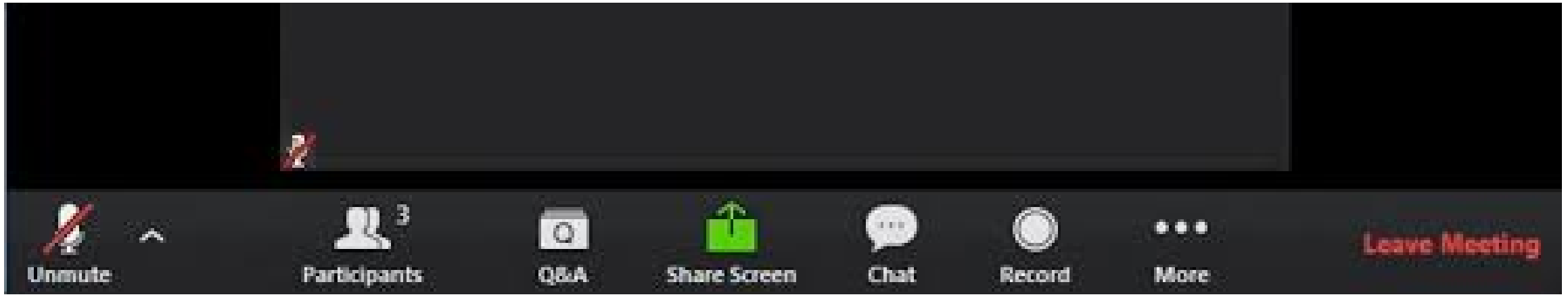
Sara Oliver, MD, MSPH
ACIP Work Group Co-Lead
CDC

Questions to be Addressed

- mRNA COVID-19 Vaccines Safety & Efficacy
- Clinical Considerations
  - Dosing & Administration– timing between doses, administration of different vaccine types
  - Persons with a History of SARS-CoV-2 Infection– timing to administer vaccine
  - Persons with Current Infection- protocol for those who receive diagnosis after first dose
  - Persons who previously received passive antibody therapy
  - Persons with underlying medical conditions
  - Pregnant women
- Contraindications & Precautions
- Anaphylaxis following Vaccination
- Patient Counseling- effect of vaccine on SARS-CoV-2 transmission; timing and durability of immune response; infection prevention/control recs for persons with post-vaccination symptoms
- Adenoviral Vector COVID-19 Vaccines

Question?
Use the “Q&A” Button

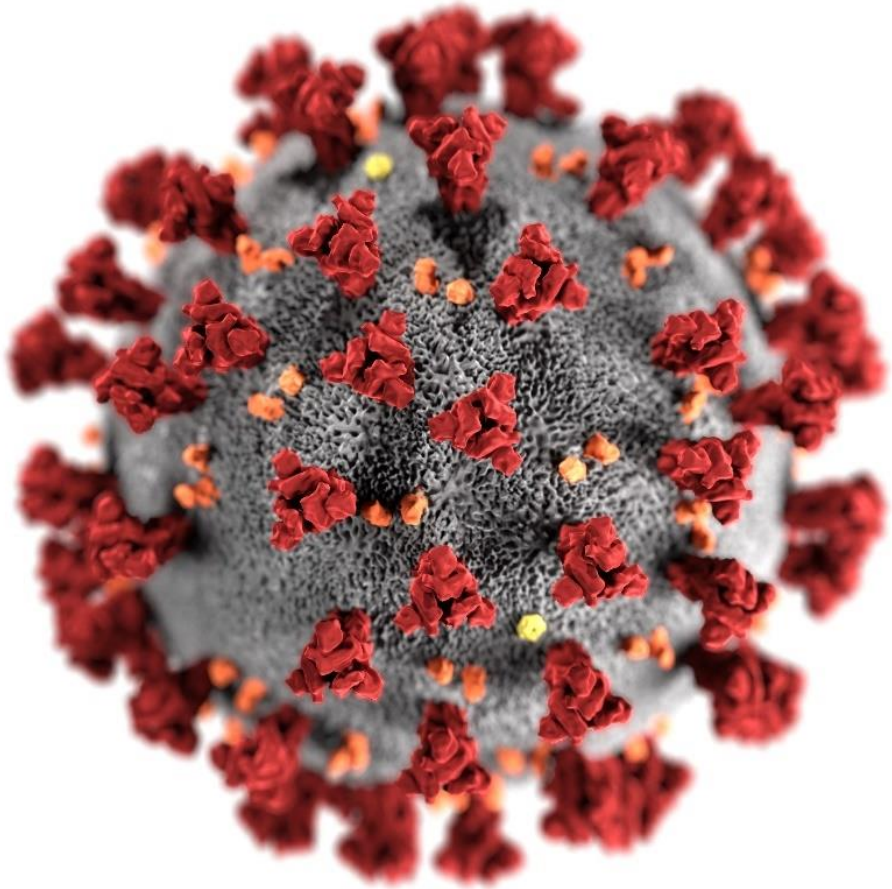
Comment?
Use the “Chat” Button



COVID-19 Vaccines

Sara Oliver, MD, MSPH
ACIP Work Group Co-Lead
CDC

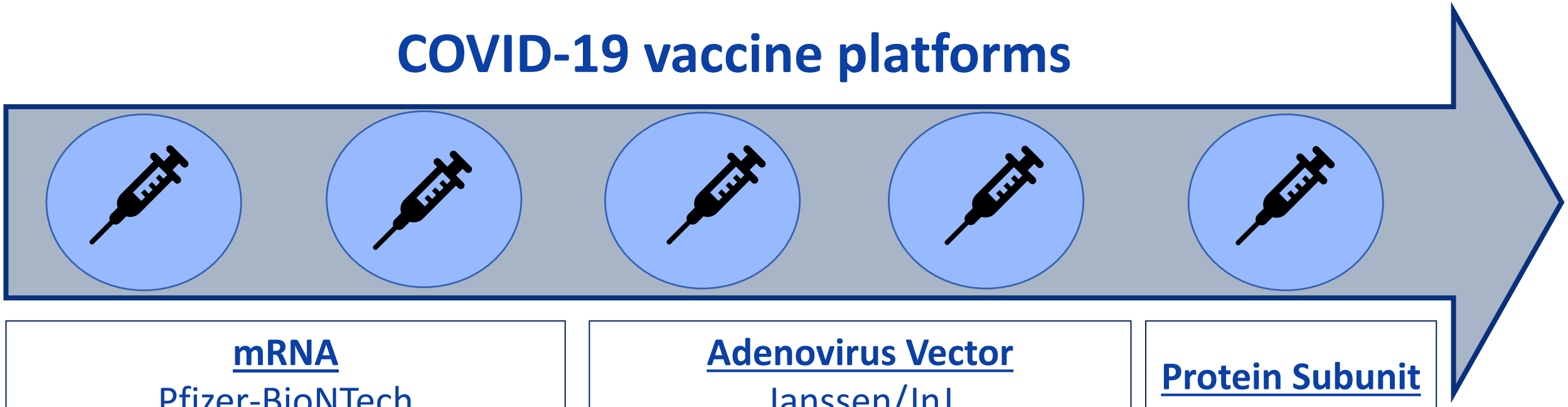
January 23, 2020



Disclosures

Dr. Oliver reports nothing to disclose

COVID-19 vaccine platforms



mRNA
Pfizer-BioNTech
Moderna

Adenovirus Vector
Janssen/JnJ
AstraZeneca

Protein Subunit
Novavax

Pfizer-BioNTech

– Two doses 3 weeks apart
– mRNA with lipid nanoparticle
– EUA issued Dec 2020
– Transported at -70°C
– High (~95%) VE

Moderna

– Two doses 4 weeks apart
– mRNA with lipid nanoparticle
– EUA issued Dec 2020
– Transported at -20°C
– High (~94%) VE

Janssen

– One dose
– Human adenovirus 26 vector
– Transported at 2-8°C
– Phase III trial ongoing

AstraZeneca

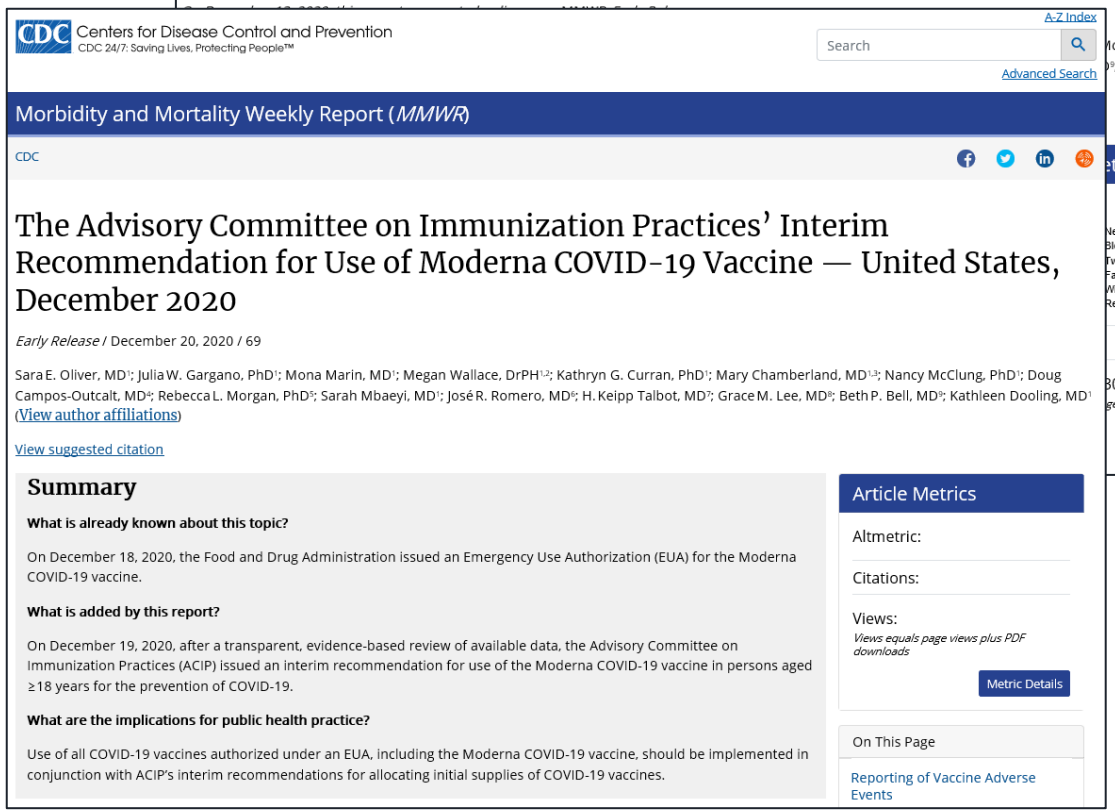
– Two doses 4 weeks apart
– Chimp adenovirus vector
– Transported at 2-8°C
– Phase III trial ongoing
– Approved in UK
– Prelim VE (SD/SD) ~62% pooled VE with LD/SD ~70%

Novavax

– Two doses 3 weeks apart
– Nanoparticle vaccine with Matrix-M1 adjuvant
– Transported at 2-8°C
– Phase III trial ongoing

ACIP recommendations for use of COVID-19 vaccines

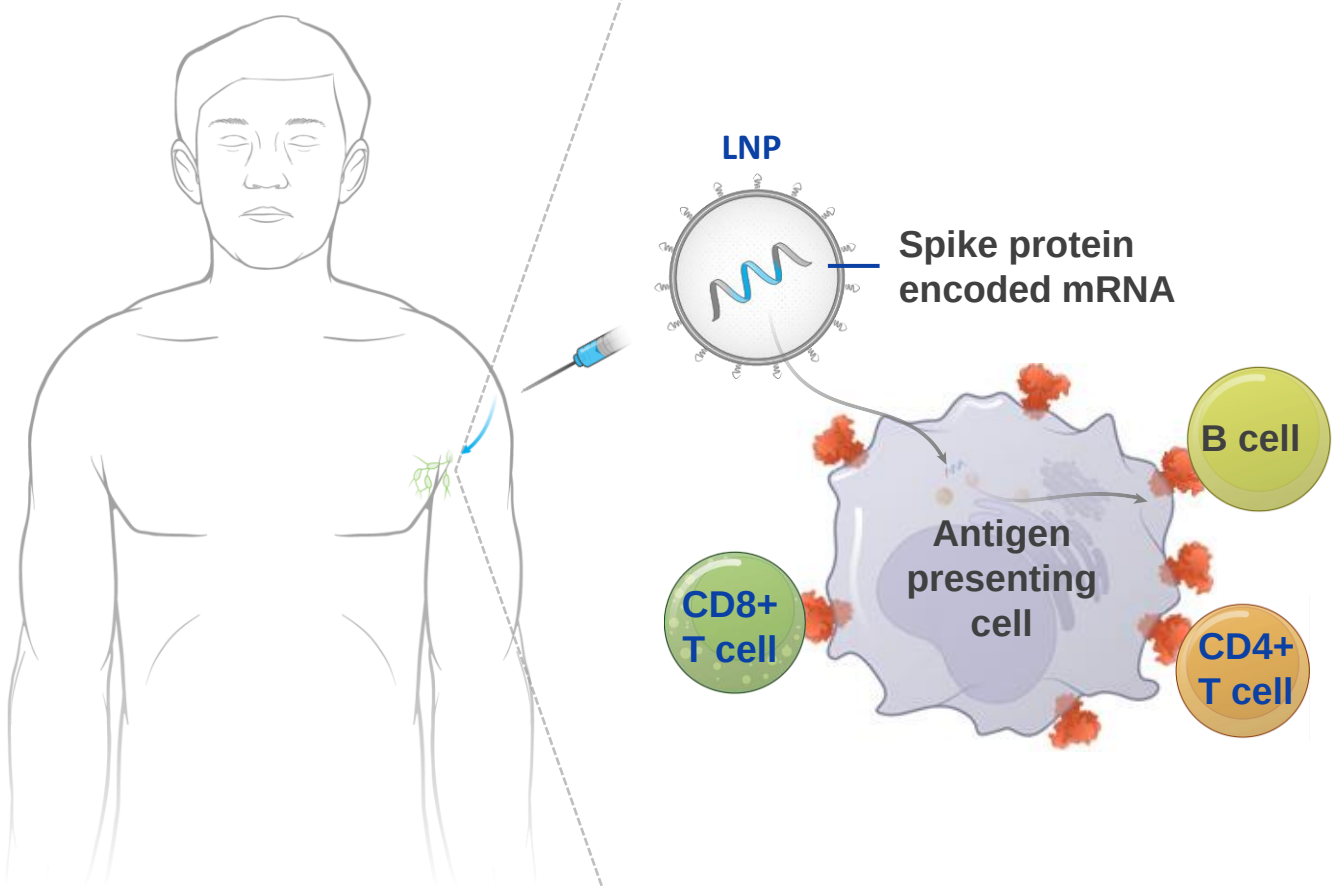
- Use of mRNA COVID-19 vaccines under FDA's Emergency Use Authorization
  - December 12, 2020: Pfizer-BioNTech
  - December 19, 2020: Moderna



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

mRNA COVID-19 vaccines
Safety and Efficacy

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

Efficacy data

Pfizer-BioNTech COVID-19 vaccine: Phase III data

- Primary efficacy endpoint: Symptomatic, laboratory-confirmed COVID-19 among subjects without evidence of prior infection
  - Efficacy: **95.0**% (90.3–97.6%)

- **High** efficacy (≥92%) for additional efficacy analysis: across age, sex, race, and ethnicity categories, and those with underlying medical conditions
  - Efficacy among adults ≥65 years of age: **94.7**% (66.7–99.9%)

Efficacy data

Pfizer-BioNTech COVID-19 vaccine: Phase III data

- Efficacy noted against severe disease as well
  - FDA definition*: **66.4**% (-124.8–96.3%)
  - CDC definition**: **100**% (-9.9–100%)

- Numbers of observed COVID-19 associated **hospitalization** or **death** are low
  - Five COVID-19 associated hospitalizations occurred, all in placebo recipients
  - No COVID-19 associated deaths occurred

*__FDA definition__: Respiratory Rate ≥ 30, Heart Rate ≥125, SpO2≤ 93% on room air at sea level or PaO2/FIO2< 300 mm Hg; OR Respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure <90mmHg, diastolic BP<60mmHg or requiring vasopressors); OR Significant acute renal, hepatic or neurologic dysfunction; OR Admission to an intensive care unit or death

**__CDC definition__: Hospitalization, admission to ICU, intubation or mechanical ventilation or death

Safety data

Pfizer-BioNTech COVID-19 vaccine: Phase III data

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (0.6% vs 0.5%).

- Severe reactions were more common in vaccine recipients; any grade ≥3 reaction was reported by 8.8% of vaccinated versus 2.1% of placebo group.

Safety data

Pfizer-BioNTech COVID-19 vaccine: Phase III data

- **Local** reactions occurring within 7 days were common
  - Pain at the injection site most common
- **Systemic** reactions within 7 days were common
  - Fatigue, headache and muscle pain most common
- Symptom onset was usually **1-2 days** post-vaccine receipt
- Most symptoms resolved after **1 day** (median duration)

Safety data

Pfizer-BioNTech COVID-19 vaccine: Local Reactogenicity

Select local reactions in persons aged 16-55 years

	Dose 1		Dose 2	
	Pfizer-BioNTech vaccine N=2291	**Placebo** N=2298	**Pfizer-BioNTech vaccine** N=2098	**Placebo N=2103**
Redness[a], n (%)				
Any	104 (4.5)	26 (1.1)	123 (5.9)	14 (0.7)
Severe (Grade 3)	6 (0.3)	4 (0.2	10 (0.5)	0 (0)
Pain at the injection site[b], n (%)				
Any	1904 (83.1)	322 (14.0)	1632 (77.8)	245 (11.7)
Severe (Grade 3)	24 (1.0)	2 (0.1)	25 (1.2)	0 (0)

Select local reactions in persons aged >55 years

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	**Placebo** N=1792	**Pfizer-BioNTech Vaccine** N=1660	**Placebo** N=1646
Redness[a], n (%)				
Any	85 (4.7)	19 (1.1)	120 (7.2)	12 (0.7)
Severe (Grade 3)	3 (0.2)	2 (0.1)	8 (0.5)	1 (0.1)
Pain at the injection site[b], n (%)				
Any	1282 (71.1)	166 (9.3)	1098 (66.1)	127 (7.7)
Severe (Grade 3)	4 (0.2)	0 (0)	8 (0.5)	0 (0)

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

Safety data

Pfizer-BioNTech COVID-19 vaccine: Systemic Reactogenicity

Select systemic reactions in persons aged 16-55 years

	Dose 1		Dose 2	
	Pfizer-BioNTech vaccine N=2291	**Placebo** N=2298	**Pfizer-BioNTech vaccine** N=2098	**Placebo** N=2103
Fever, n (%)				
≥38.0°C	85 (3.7)	20 (0.9)	331 (15.8)	10 (0.5)
≥38.0°C to 38.4°C	64 (2.8)	10 (0.4)	194 (9.2)	5 (0.2)
>38.4°C to 38.9°C	15 (0.7)	5 (0.2)	110 (5.2)	3 (0.1)
>38.9°C to 40.0°C	6 (0.3)	3 (0.1)	26 (1.2)	2 (0.1)
>40.0°C	0 (0)	2 (0.1)	1 (0)	0 (0)
Fatigue[a], n (%)				
Any	1085 (47.4)	767 (33.4)	1247 (59.4)	479 (22.8)

Select systemic reactions in persons aged >55 years

	Dose 1		Dose 2	
	Pfizer-BioNTech Vaccine N=1802	**Placebo** N=1792	**Pfizer-BioNTech Vaccine** N=1660	**Placebo** N=1646
Fever				
≥38.0°C	26 (1.4)	7 (0.4)	181 (10.9)	4 (0.2)
≥38.0°C to 38.4°C	23 (1.3)	2 (0.1)	131 (7.9)	2 (0.1)
>38.4°C to 38.9°C	1 (0.1)	3 (0.2)	45 (2.7)	1 (0.1)
>38.9°C to 40.0°C	1 (0.1)	2 (0.1)	5 (0.3)	1 (0.1)
>40.0°C	1 (0.1)	0 (0)	0 (0)	0 (0)
Fatigue[a], n (%)				
Any	615 (34.1)	405 (22.6)	839 (50.5)	277 (16.8)

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

Safety data

Pfizer-BioNTech COVID-19 vaccine: Phase III data

- **Lymphadenopathy**
  - Higher frequency in vaccine group (n=64), compared to placebo (n=6)
  - As localized lymph nodes are involved in the vaccine response, it is plausible this could be related to the vaccine
- **Bell's palsy**
  - Higher frequency in vaccine group (n=4), compared to placebo (n=0)
  - Incidence within vaccine group consistent with expected population rates
  - No known causal relationship

Efficacy data

Moderna COVID-19 vaccine: Phase III data

- Primary efficacy endpoint: Symptomatic, laboratory-confirmed COVID-19 among subjects without evidence of prior infection subjects without evidence of prior infection
  - Efficacy: **94.1**% (89.3%–96.8%)

- **High** efficacy for additional efficacy analysis, across age, sex, race, and ethnicity categories, and those with underlying medical conditions
  - Efficacy among adults 18-64 years of age: **95.6**% (90.6%–97.9%)
  - Efficacy among adults ≥65 years of age: **86.4**% (61.4%–95.5%)
    - Efficacy among adults ≥75 years of age: **100**%

Efficacy data

Moderna COVID-19 vaccine: Phase III data

- The ability of the vaccine series to prevent **asymptomatic SARS-CoV-2 infection** has not been assessed to date in a large, prospective clinical trial. However, it can be informed by PCR screening among trial participants returning for second dose.
- Four weeks after the first dose of the Moderna COVID-19 vaccine, 14 participants (**0.1**%) had a positive SARS-CoV-2 PCR without symptoms of COVID-19, compared to 38 (**0.3**%) of those receiving placebo.

Efficacy data

Moderna COVID-19 vaccine: Phase III data

- 30 cases of severe disease* noted in placebo group, 1 in vaccine group
  - VE estimate: **97**% (76%-100%)

- Numbers of observed COVID-19 associated **hospitalization** or **death** are low
  - Nine COVID-19 associated hospitalizations in placebo recipient, 1 in vaccine recipient
  - One COVID-19 associated death occurred in placebo recipient

*__Definition__: Respiratory Rate ≥ 30, Heart Rate ≥125, SpO2≤ 93% on room air at sea level or PaO2/FIO2< 300 mm Hg; OR respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure <90mmHg, diastolic BP<60mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death

Safety data

Moderna COVID-19 vaccine: Phase III data

- Serious adverse events were reported in a similar proportion among recipients of vaccine and placebo (1.0% vs 1.0%).

- Severe reactions were more common in vaccine recipients; any grade ≥3 reaction was reported by 21.5% of vaccinated versus 4.4% of placebo group.

Safety data

Moderna COVID-19 vaccine: Phase III data

- **Local** reactions occurring within 7 days were common
  - Pain at the injection site most common
- **Systemic** reactions within 7 days were common
  - Fatigue, headache, and myalgia most common
- Symptom onset was usually **1-2 days** post-vaccine receipt
- Most symptoms resolved after **2-3 days** (median duration)

Safety data

Moderna COVID-19 vaccine: Local reactogenicity

Select local reactions in persons aged 18-64 years

	Dose 1		Dose 2	
	Moderna vaccine N=11401	**Placebo** N=11404	**Moderna vaccine** N=10357	**Placebo** N=10317
Local Reaction				
Any	9960 (87.4)	2432 (21.3)	9371 (90.5)	2134 (20.7)
Severe (Grade 3)	452 (4.0)	39 (0.3)	766 (7.4)	41 (0.4)
Pain at the injection site				
Any	9908 (86.9)	2179 (19.1)	9335 (90.1)	1942 (18.8)
Severe (Grade 3)	367 (3.2)	23 (0.2)	479 (4.6)	21 (0.2)

Select local reactions in persons aged ≥65 years

	Dose 1		Dose 2	
	Moderna Vaccine N=3762	**Placebo** N=3746	**Moderna Vaccine** N=3587	**Placebo** N=3549
Local Reaction				
Any	2805 (74.6)	566 (15.1)	3010 (83.9)	473 (13.3)
Severe (Grade 3)	77 (2.0)	39 (1.0)	212 (5.9)	29 (0.8)
Pain at the injection site				
Any	2782 (74.0)	481(12.8)	2990 (83.4)	421 (11.9)
Severe (Grade 3)	50 (1.3)	32 (0.9)	96 (2.7)	17 (0.5)

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

Safety data

Moderna COVID-19 vaccine: Systemic reactogenicity

Select systemic reactions in persons aged 18-64 years

	Dose 1		Dose 2	
	Moderna vaccine N=11401	**Placebo** N=11404	**Moderna vaccine** N=10357	**Placebo** N=10317
Systemic Reaction				
Any	6503 (57.0)	5063 (44.4)	8484 (81.9)	3967 (38.4)
Grade 3 or 4	368 (3.2)	252 (2.2)	1811 (17.4)	217 (2.1)
Fever				
Any	105 (0.9)	39 (0.3)	1806 (17.4)	38 (0.4)
Grade 3	10 (<0.1)	1 (<0.1)	168 (1.6)	1 (<0.1)
Grade 4	4 (<0.1)	4 (<0.1)	10 (<0.1)	1 (<0.1)

Select systemic reactions in persons aged ≥65 years

	Dose 1		Dose 2	
	Moderna vaccine N=3761	**Placebo** N=3748	**Moderna vaccine** N=3589	**Placebo** N=10317
Systemic Reaction				
Any	1818 (48.3)	1335 (35.6)	2580 (71.9)	1102 (31.1)
Grade 3 or 4	84 (2.2)	63 (1.7)	389 (10.8)	59 (1.6)
Fever				
Any	10 (0.3)	7 (0.2)	366 (10.2)	5 (0.1)
Grade 3	1 (<0.1)	1 (<0.1)	18 (0.5)	0 (0)
Grade 4	0 (0)	2 (<0.1)	1 (<0.1)	1 (<0.1)

Grade 3 fever: 102.1–104.0°F
Grade 4 fever: >104.0°F

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

Safety data

Moderna COVID-19 vaccine: Phase III data

- **Lymphadenopathy**
  - Ipsilateral (same side) axillary swelling and tenderness was a **solicited** adverse event
  - More common among vaccine recipients <65 years of age

	Moderna vaccine	Placebo
Adults 18-64 years of age	21.4%	7.5%
Adults ≥65 years of age	12.4%	5.8%

  - Grade 3 axillary lymphadenopathy rare, but more common after second dose

	Moderna vaccine	Placebo
Dose 1	0.3%	0.2%
Dose 2	0.5%	0.1%

  - Duration after first dose: **1 day**. Duration after second dose: **2 days**

Grade 3 lymphadenopathy: Any use of prescription (narcotic) pain reliever or prevents daily activity

Safety data

Moderna COVID-19 vaccine: Phase III data

- **Bell's palsy**
  - Small imbalance between vaccine group (n=3) and placebo (n=1)
  - Currently available information is insufficient to determine a causal relationship with the vaccine
  - Post-authorization surveillance will help determine any possible causal relationship

mRNA COVID-19 vaccines
Clinical Considerations

Dosing and administration

- Authorized age groups:
  - Pfizer-BioNTech: ≥ 16 years
  - Moderna: ≥ 18 years
- Administration: two-dose series administered intramuscularly
  - Pfizer-BioNTech: three weeks apart
  - Moderna: four weeks 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.

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

Dosing and administration

- 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

- 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

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

Persons with a history of SARS-CoV-2 infection

- Data from clinical trials indicate that mRNA COVID-19 vaccines can **safely** be given to persons with evidence of prior SARS-CoV-2 infection
- Vaccination should be offered to persons regardless of history of prior symptomatic or asymptomatic SARS-CoV-2 infection
- Viral or serologic testing for acute or prior infection, respectively, is not recommended for the purpose of vaccine decision-making

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

Persons with a history of SARS-CoV-2 infection

- 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 by may increase with time due to waning immunity. Thus, **while vaccine supply remains limited**, persons with recent documented acute SARS-CoV-2 infection may chose to temporarily delay vaccination, if desired, recognizing that the risk of reinfection and therefore 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 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

- Prior receipt of an mRNA COVID-19 vaccine should not affect treatment decisions (including use of monoclonal antibodies, convalescent plasma, antiviral treatment, or corticosteroid administration)

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

Persons who previously received passive antibody therapy

- No data on the safety and efficacy of mRNA COVID-19 vaccines in persons who received monoclonal antibodies or convalescent plasma as part of COVID-19 treatment
- Based on estimated half-life of therapies as well as evidence suggesting reinfection is uncommon in the months after initial doses, vaccination should be deferred for at least **90 days**, to avoid potential interference of the antibody therapy with vaccine-induced immune responses
- There is no recommended minimum interval between other antibody therapies (i.e. those that are not specific to COVID-19 treatment) and mRNA COVID-19 vaccination

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

Persons with a history of dermal filler use

- Infrequently, persons who have received dermal fillers may develop swelling at or near the site of filler injection following administration of a dose of an mRNA COVID-19 vaccine.
- This appears 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.

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/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
  - 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/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html

Pregnant women

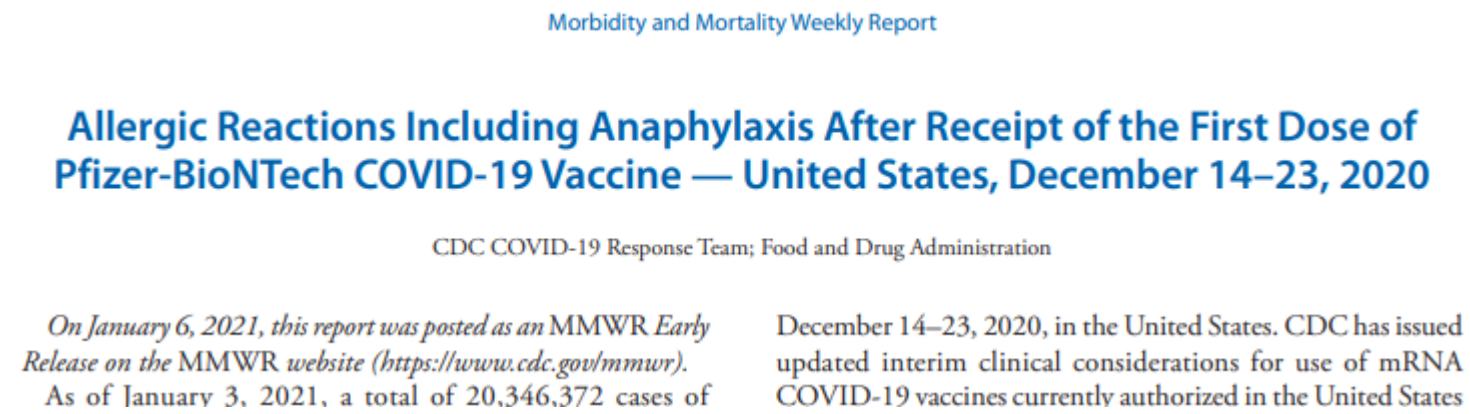
- Considerations for vaccination:
  - Level of COVID-19 community transmission (risk of acquisition)
  - Personal risk of contracting COVID-19 (by occupation or other activities)
  - Risks of COVID-19 to her and potential risks to the fetus
  - Efficacy of the vaccine
  - Known side effects of the vaccine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

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

mRNA vaccines
Contraindications and Precautions

Anaphylaxis in persons following Pfizer-BioNTech COVID-19 vaccination

- As of December 23, 2020 a reported 1,893,360 first doses of Pfizer-BioNTech COVID-19 vaccine administered in the United States
- 4,393 adverse events reported to VAERS, 175 possibly related to allergic reaction
- 21 cases determined to be anaphylaxis: **11.1 per million doses administered**
- 17 in persons with a documented history of allergies or allergic reactions
- Median interval from vaccine receipt to symptom onset: 13 minutes



Morbidity and Mortality Weekly Report

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

CDC COVID-19 Response Team; Food and Drug Administration

On January 6, 2021, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

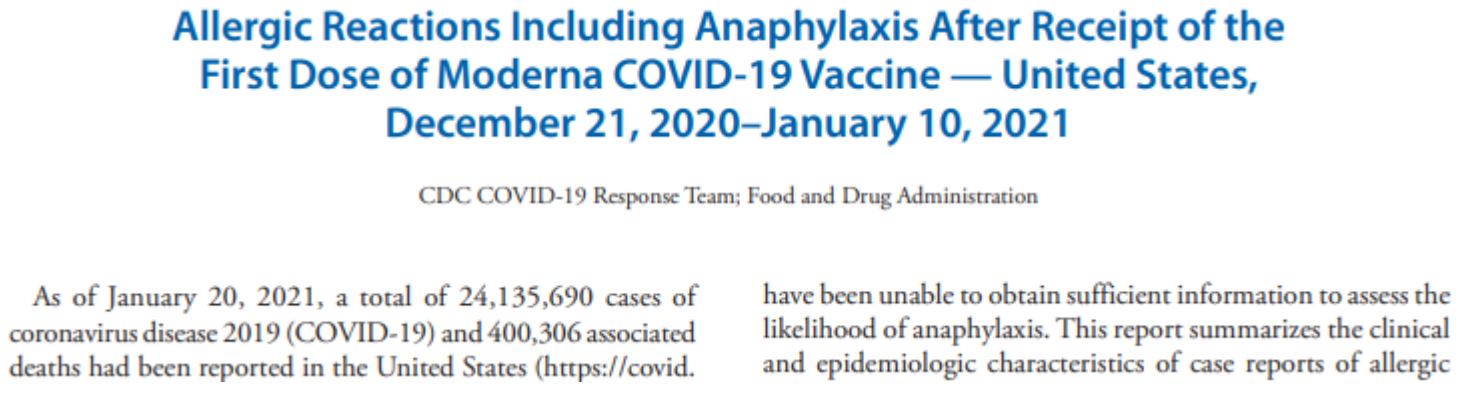
As of January 3, 2021, a total of 20,346,372 cases of

December 14–23, 2020, in the United States. CDC has issued updated interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States

https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm?s_cid=mm7002e1_w

Anaphylaxis in persons following Moderna COVID-19 vaccination

- As of January 10, 2021 a reported 4,041,396 first doses of Moderna COVID-19 vaccine administered in the United States
- 1,266 adverse events reported to VAERS, 108 possibly related to allergic reaction
- 10 cases determined to be anaphylaxis: **2.5 per million doses administered**
- 19 in persons with a documented history of allergies or allergic reactions
- Median interval from vaccine receipt to symptom onset: 7.5 minutes



Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021

CDC COVID-19 Response Team; Food and Drug Administration

As of January 20, 2021, a total of 24,135,690 cases of coronavirus disease 2019 (COVID-19) and 400,306 associated deaths had been reported in the United States (https://covid.

have been unable to obtain sufficient information to assess the likelihood of anaphylaxis. This report summarizes the clinical and epidemiologic characteristics of case reports of allergic

https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm?s_cid=mm7004e1_w

Contraindications to mRNA COVID-19 vaccination

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).

Precautions to mRNA COVID-19 vaccines

Pfizer-BioNTech and Moderna COVID-19 vaccines

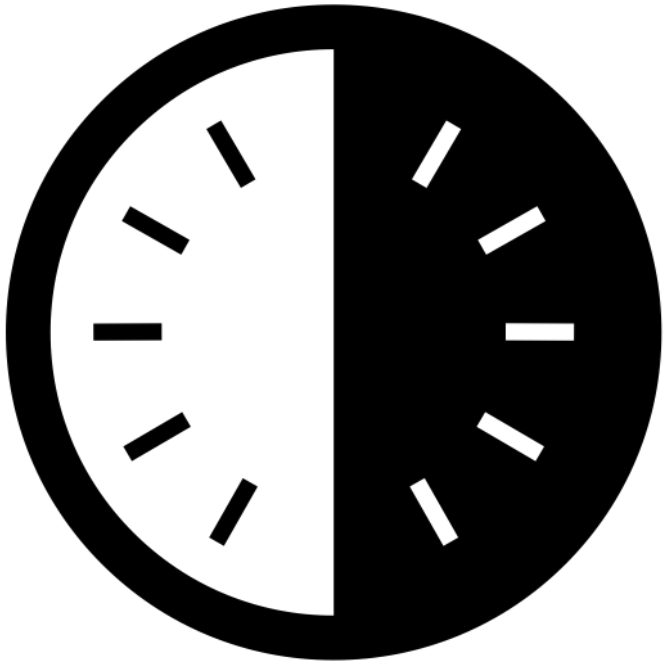
- Any immediate allergic reaction to any other vaccine or injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies not related to a component of mRNA COVID-19 vaccines or polysorbate)

- 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

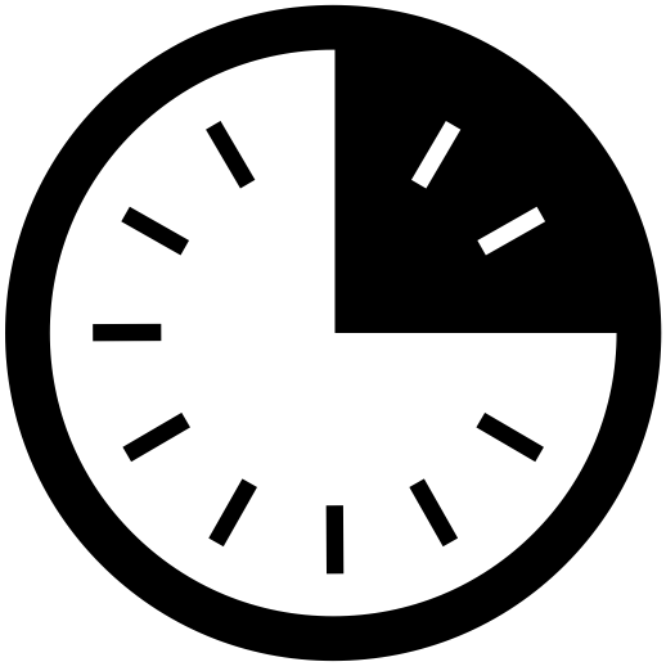
Observation period following vaccination

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



30 minutes

All other persons



15 minutes

Summary: Triage of persons presenting for mRNA COVID-19 vaccination

MAY PROCEED WITH VACCINATION	PRECAUTION TO VACCINATION	CONTRAINDICATION TO VACCINATION
ALLERGIES History of allergies that are unrelated to components of an mRNA COVID-19 vaccine†, other vaccines, or injectable therapies, 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

† 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 A 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.

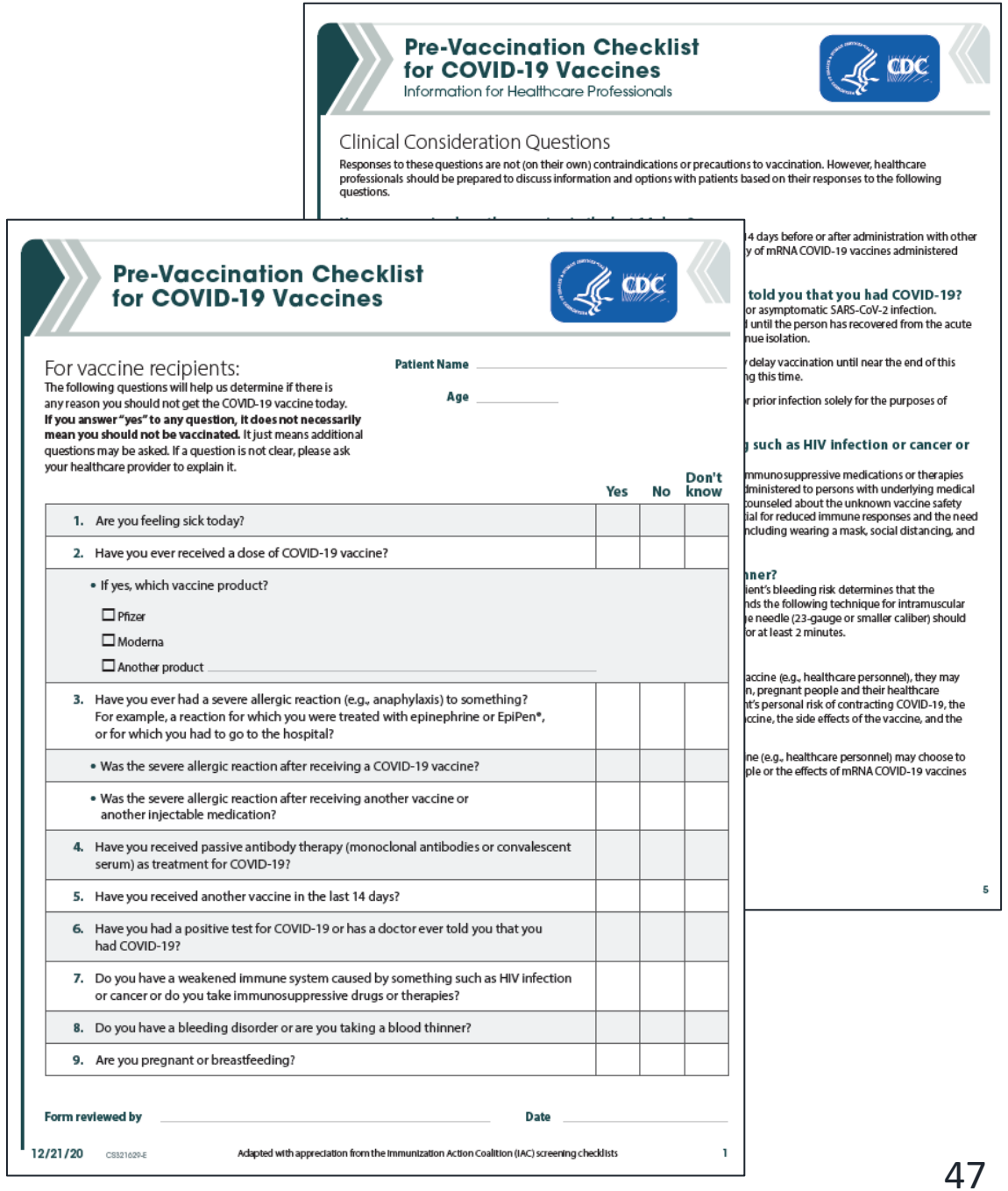
These persons should not receive mRNA COVID-19 vaccination at this time unless they have been evaluated by an allergist-immunologist and it is determined that the person can safely receive the vaccine (e.g., under observation, in a setting with advanced medical care available)

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

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.

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?			

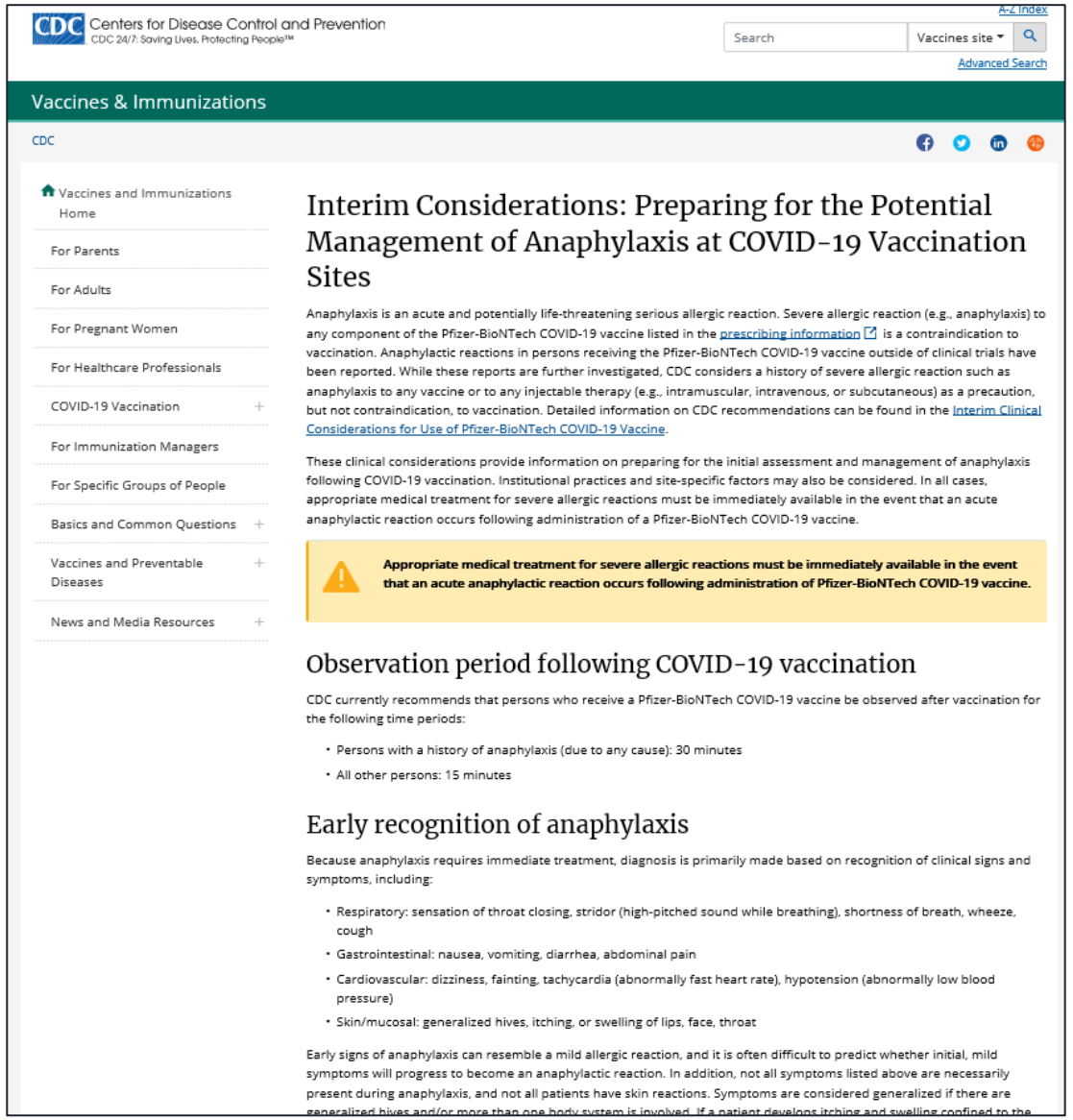
Form reviewed by _____ **Date** _____

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



CDC Centers for Disease Control and Prevention
CDC 24/7: Saving Lives, Protecting People™

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- News and Media Resources

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)
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 5 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.

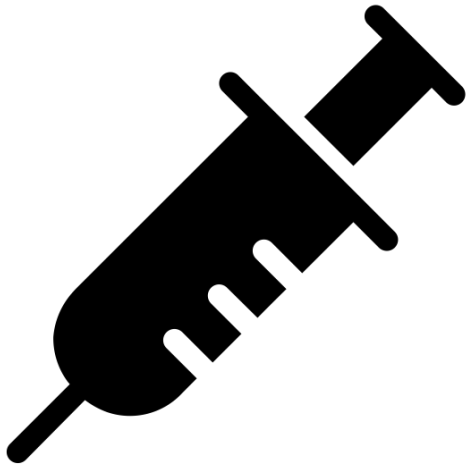
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

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

Patient Vaccine Counseling

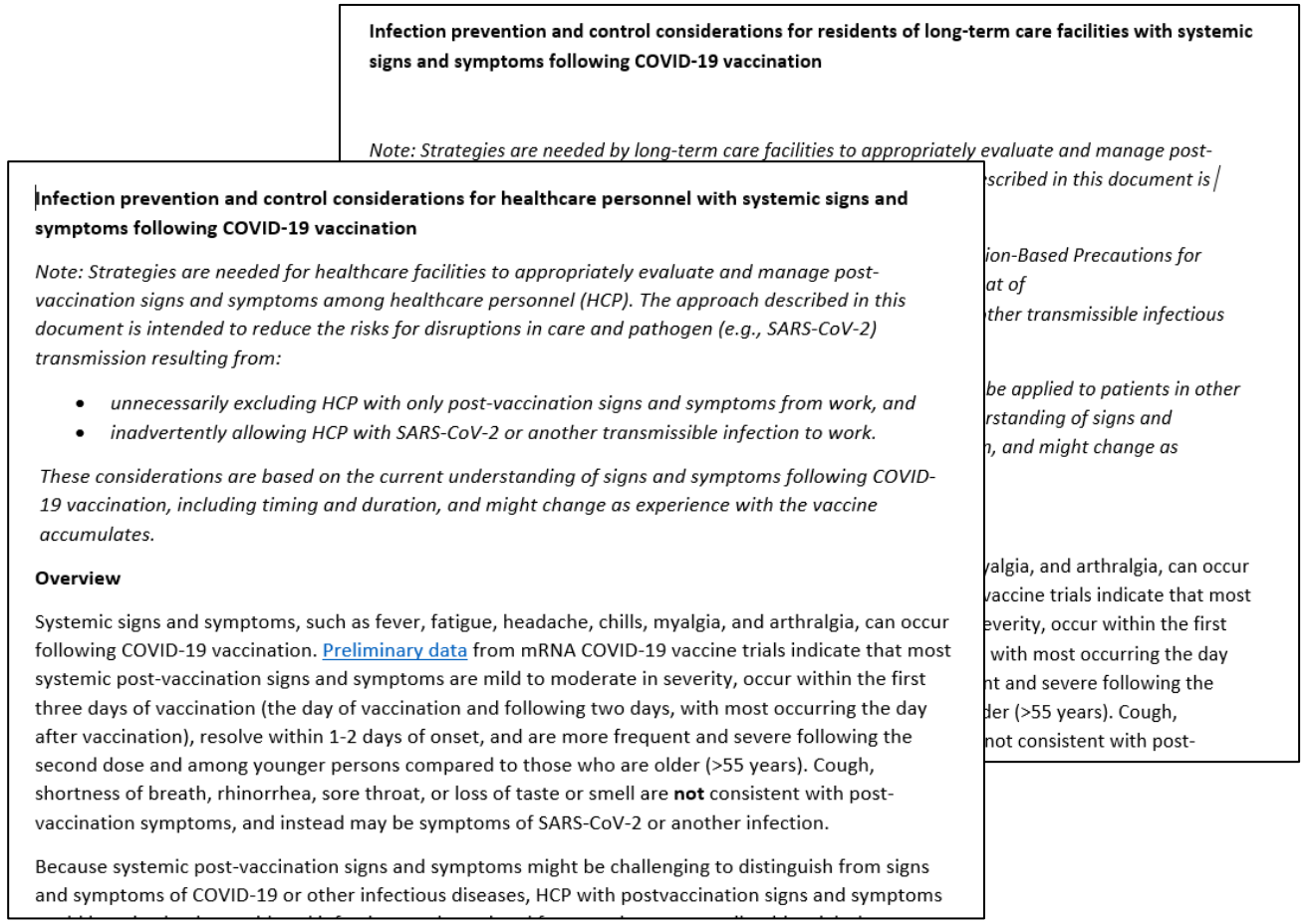
Public health recommendations for vaccinated persons

- Limited information regarding how much the vaccine may reduce transmission in the general population and how long protection will last.
- 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
- At this time, 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 any applicable workplace or school guidance

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

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-
scribed in this document is
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at of
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be applied to patients in other
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yalgia, and arthralgia, can occur
vaccine trials indicate that most
everity, occur within the first
with most occurring the day
nt and severe following the
der (>55 years). Cough,
not consistent with post-

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

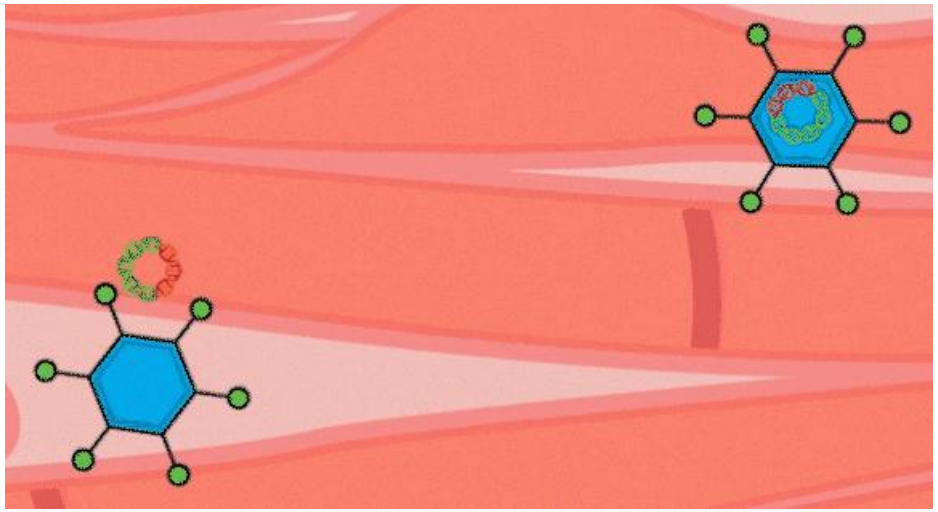
Systemic signs and symptoms, such as fever, fatigue, headache, chills, myalgia, and arthralgia, can occur following COVID-19 vaccination. Preliminary data from mRNA COVID-19 vaccine trials indicate that most systemic post-vaccination signs and symptoms are mild to moderate in severity, occur within the 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/coronavirus/2019-ncov/hcp/post-vaccine-considerations-healthcare-personnel.html
https://www.cdc.gov/coronavirus/2019-ncov/hcp/post-vaccine-considerations-residents.html

Adenoviral vector COVID-19 vaccines

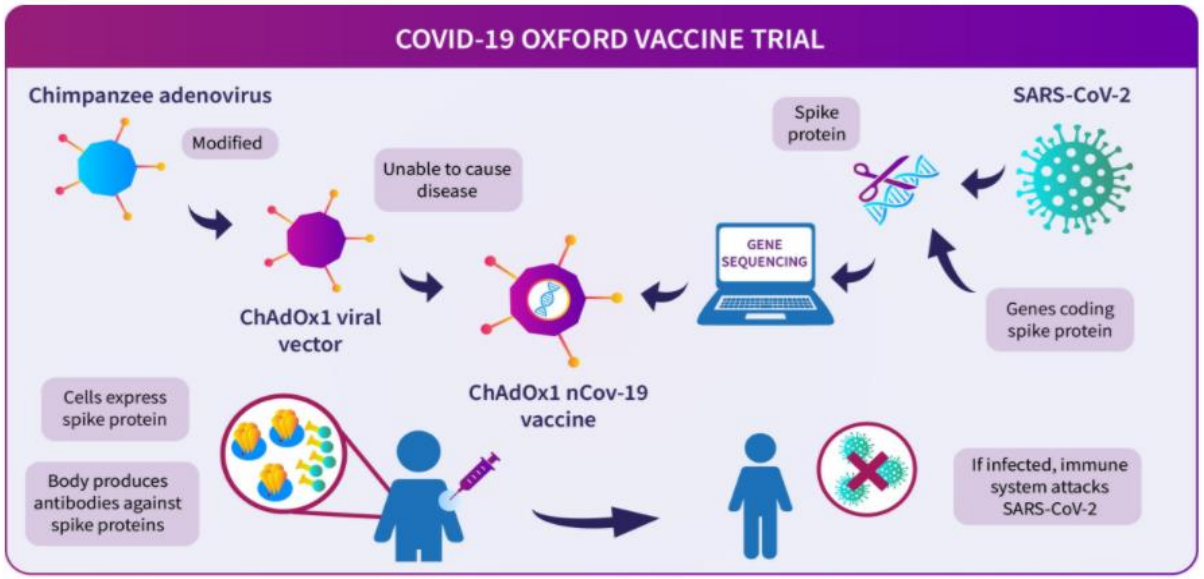
Adenovirus vector vaccines



Graphic source: https://www.janssen.com/infectious-diseases-and-vaccines/vaccine-technology

Human adenovirus 26 (Ad.26) vector

- Nonreplicating
- Used in other vaccines (Ebola vaccine)
- Ad.26 Ebola vaccine used in broad populations, including pregnant women and children
- Previous exposure to the vector could reduce effectiveness



Graphic source: https://www.research.ox.ac.uk/Article/2020-07-19-the-oxford-covid-19-vaccine

Chimpanzee adenovirus vector

- Nonreplicating
- Chimpanzee adenovirus vector circumvents preexisting immunity to human adenovirus

Vaccine safety

COVID-19 Vaccine Safety Strategy

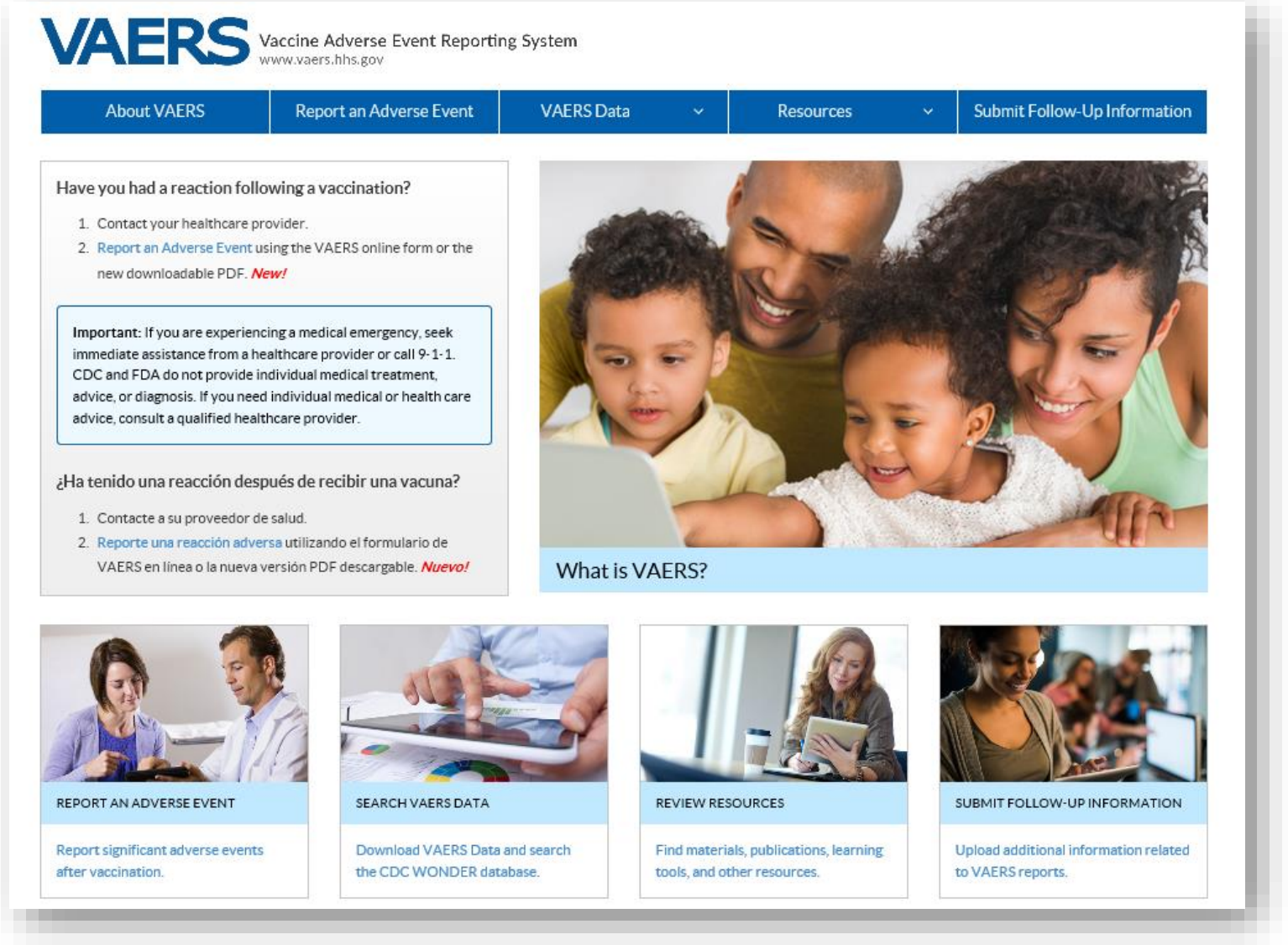
1. **Use established systems** to implement heightened safety monitoring for COVID-19 vaccines
2. **Develop new platforms** and leverage other federal data sources to complement existing systems
3. **Communicate clearly** on the vaccine safety process and systems now; provide COVID-19 vaccine safety data and monitoring results once available

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

Vaccine Adverse Event Reporting System

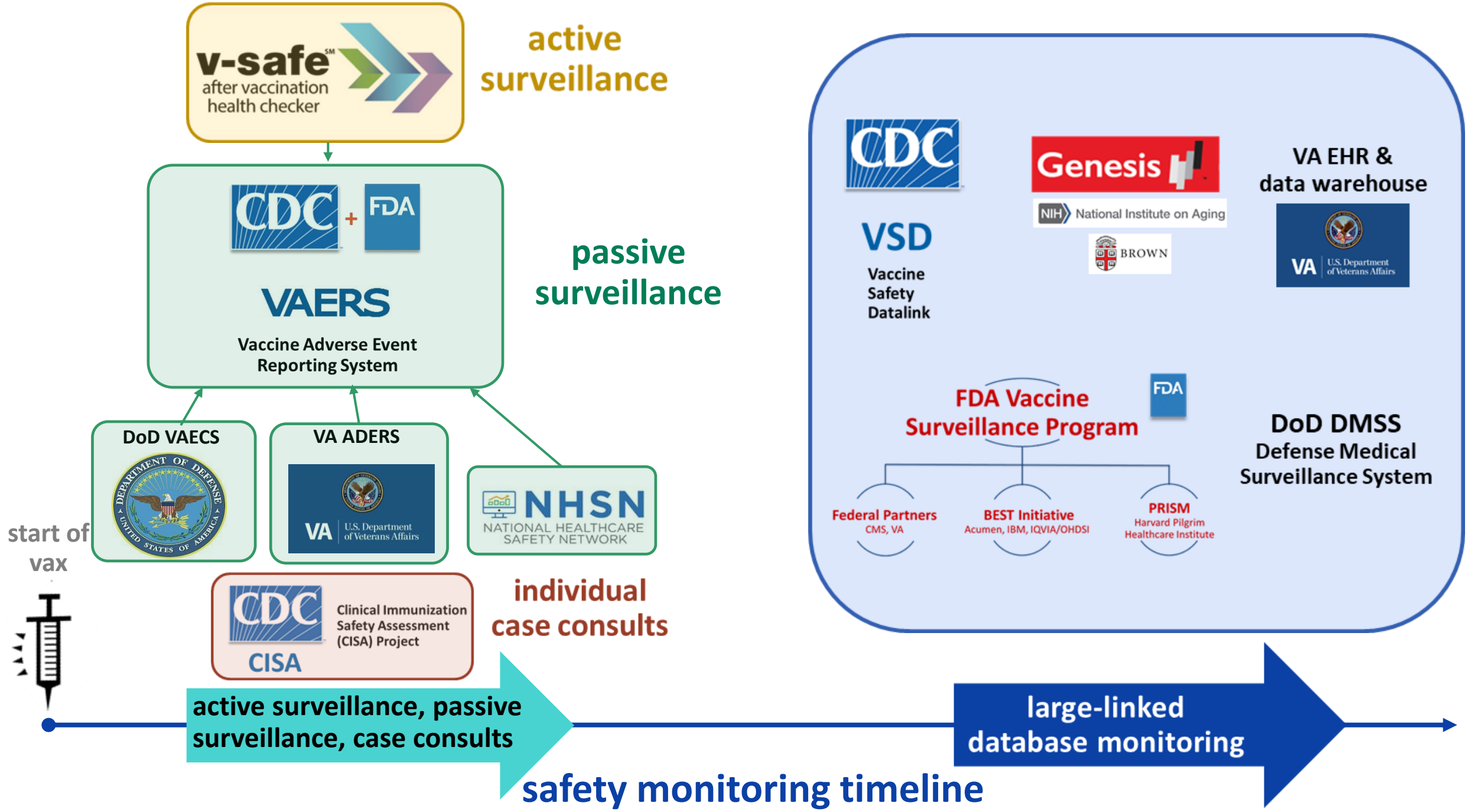
Co-managed by CDC and FDA

http://vaers.hhs.gov



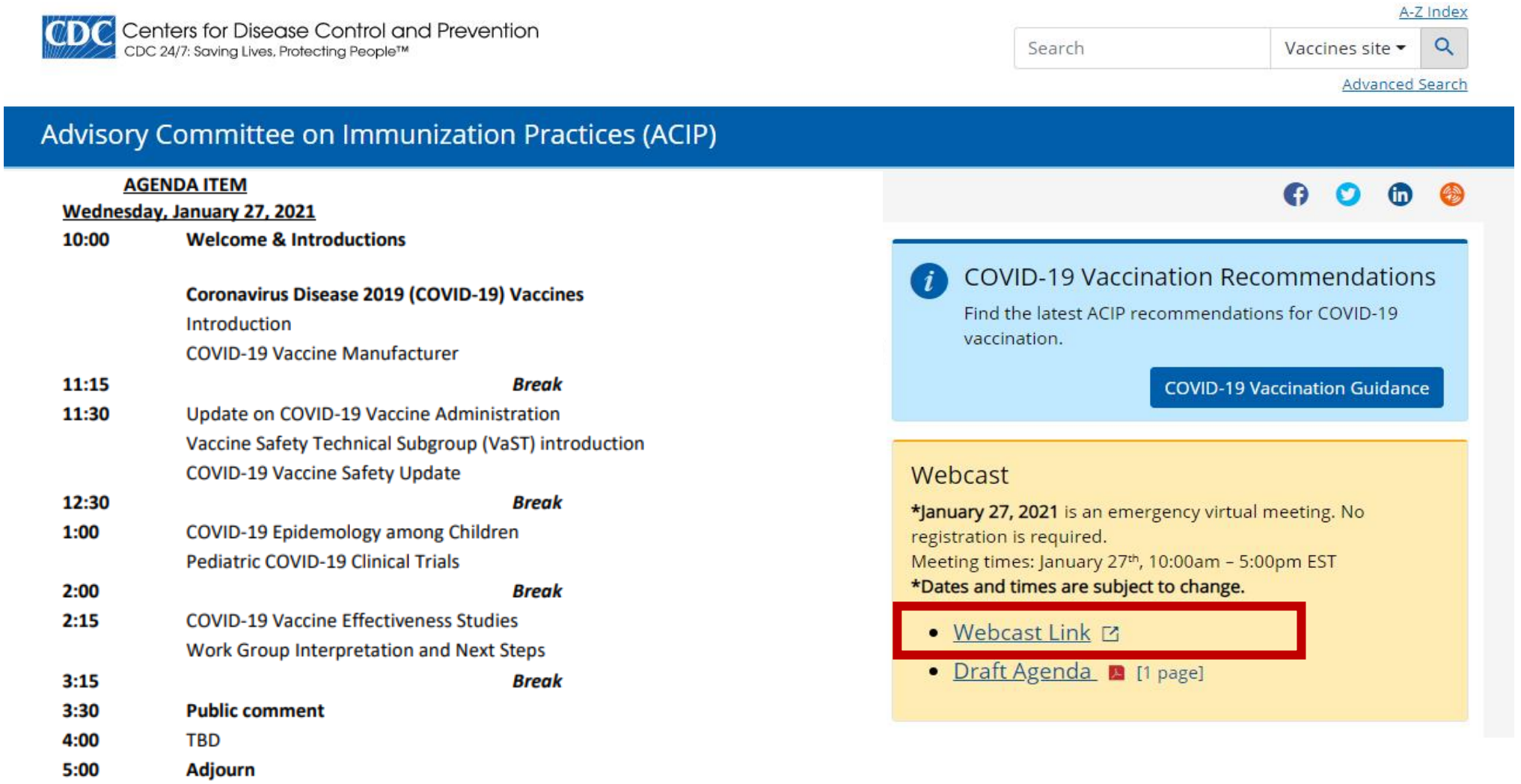
Active Safety Monitoring for COVID-19 Vaccines

- **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
  - Additional follow-up with patients who received the vaccine during pregnancy or within 30 days of becoming pregnant


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

Upcoming ACIP Meeting

January 27, 2021 10am-5pm EST



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Advisory Committee on Immunization Practices (ACIP)

AGENDA ITEM

Wednesday, January 27, 2021

10:00	**Welcome & Introductions**
	Coronavirus Disease 2019 (COVID-19) Vaccines
	Introduction
	COVID-19 Vaccine Manufacturer
11:15	***Break***
11:30	Update on COVID-19 Vaccine Administration
	Vaccine Safety Technical Subgroup (VaST) introduction
	COVID-19 Vaccine Safety Update
12:30	***Break***
1:00	COVID-19 Epidemology among Children
	Pediatric COVID-19 Clinical Trials
2:00	***Break***
2:15	COVID-19 Vaccine Effectiveness Studies
	Work Group Interpretation and Next Steps
3:15	***Break***
3:30	**Public comment**
4:00	TBD
5:00	**Adjourn**

COVID-19 Vaccination Recommendations

Find the latest ACIP recommendations for COVID-19 vaccination.

COVID-19 Vaccination Guidance

Webcast

***January 27, 2021** is an emergency virtual meeting. No registration is required.
Meeting times: January 27th, 10:00am – 5:00pm EST
***Dates and times are subject to change.**

- Webcast Link
- Draft Agenda [1 page]

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

Additional resources

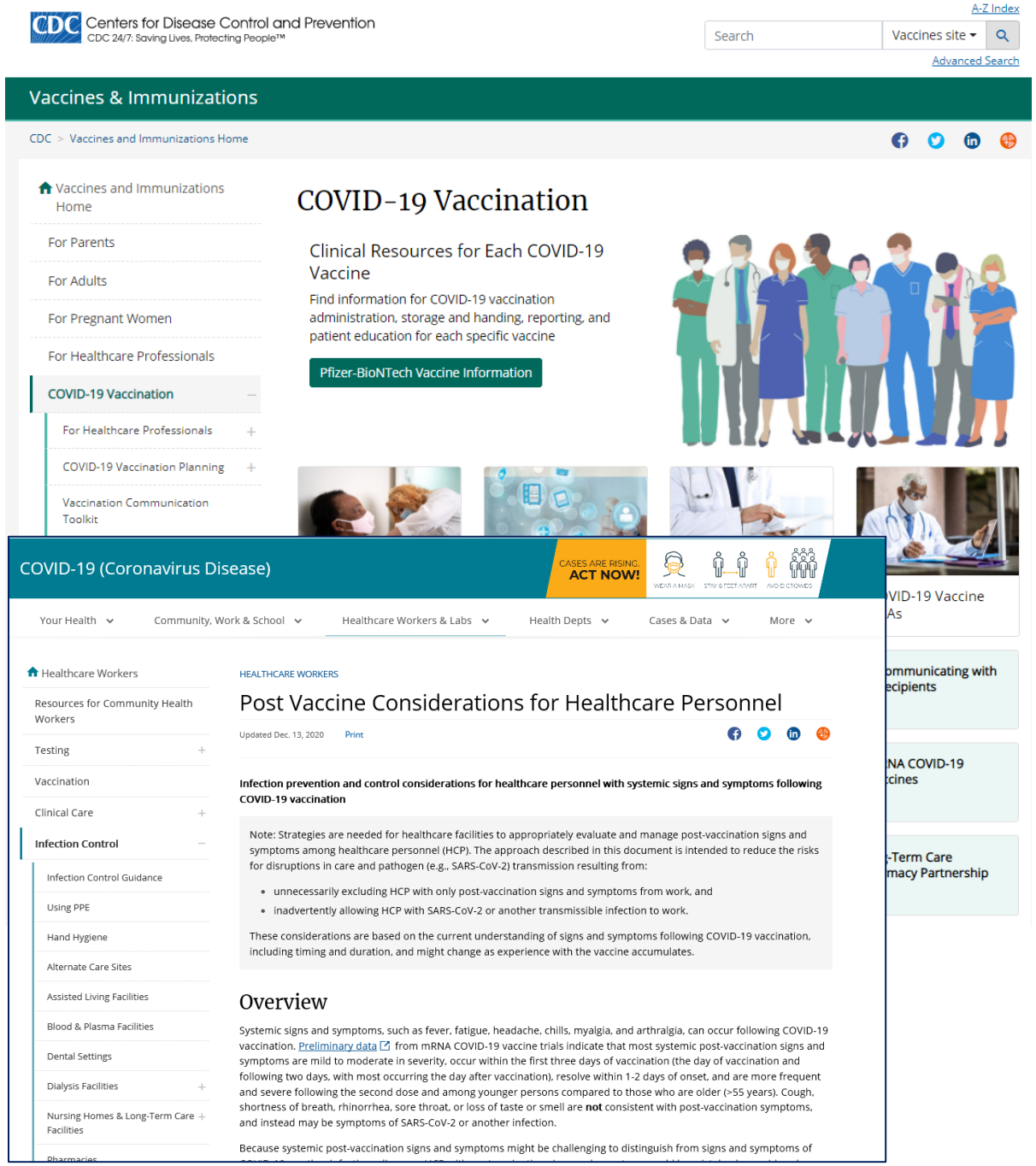
CDC Resources

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

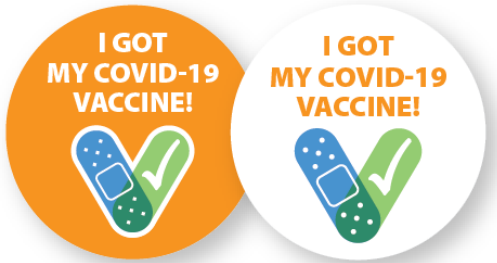
Infection prevention and control recommendations for persons with post-vaccination symptoms

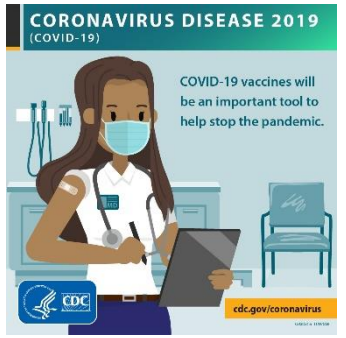
- Healthcare personnel
- Long-term care facility residents

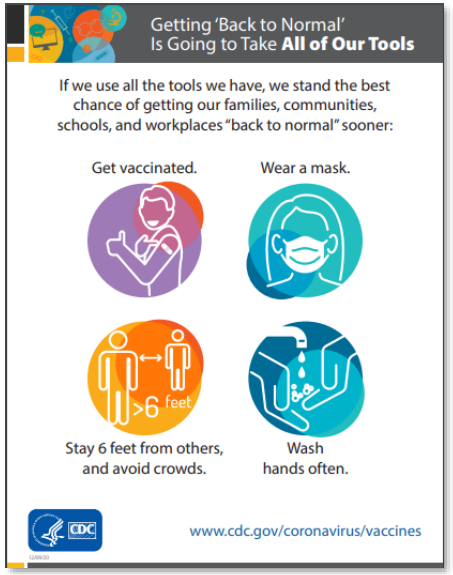


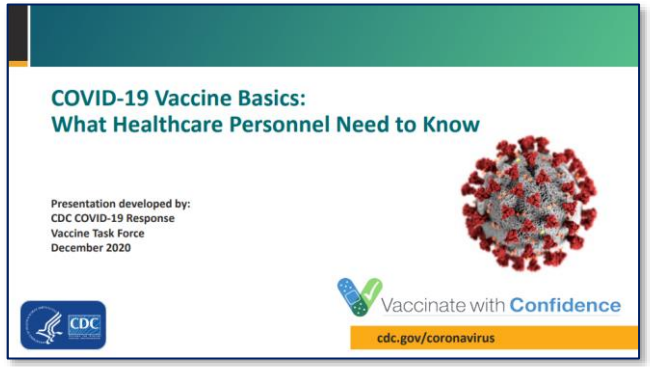
COVID-19 vaccine communication resources

- 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









Now Available: COVID-19 Vaccine FAQs

Go to www.COVID19LearningNetwork.org and click on “Vaccines FAQ”

Continue the conversation on Twitter

@RealTimeCOVID19
#RealTimeCOVID19

We want to hear from you! Please complete the post-call survey.

Next Call: **Saturday, January 30th**

A recording of this call will be posted at **www.idsociety.org/cliniciancalls**

-- library of all past calls now available --

Contact Us:

Dana Wollins (dwollins@idsociety.org)
Deirdre Lewis (dlewis@idsociety.org)