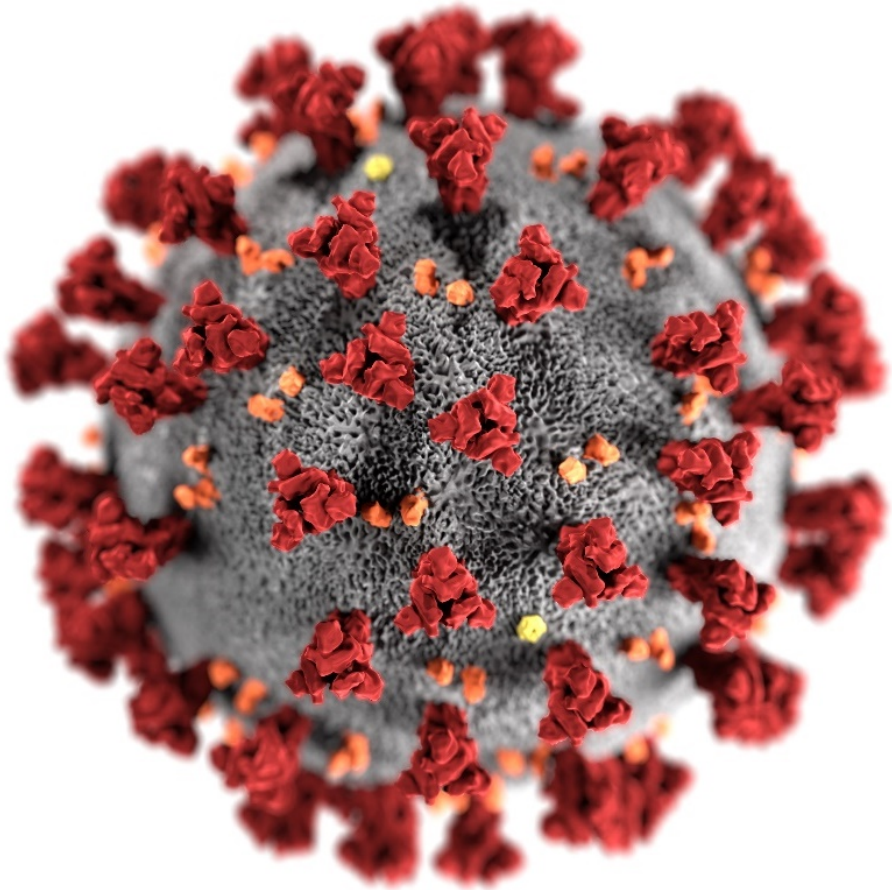
COVID-19 Vaccine Recommendations

Kathleen Dooling, MD, MPH

January 6, 2020



Objectives

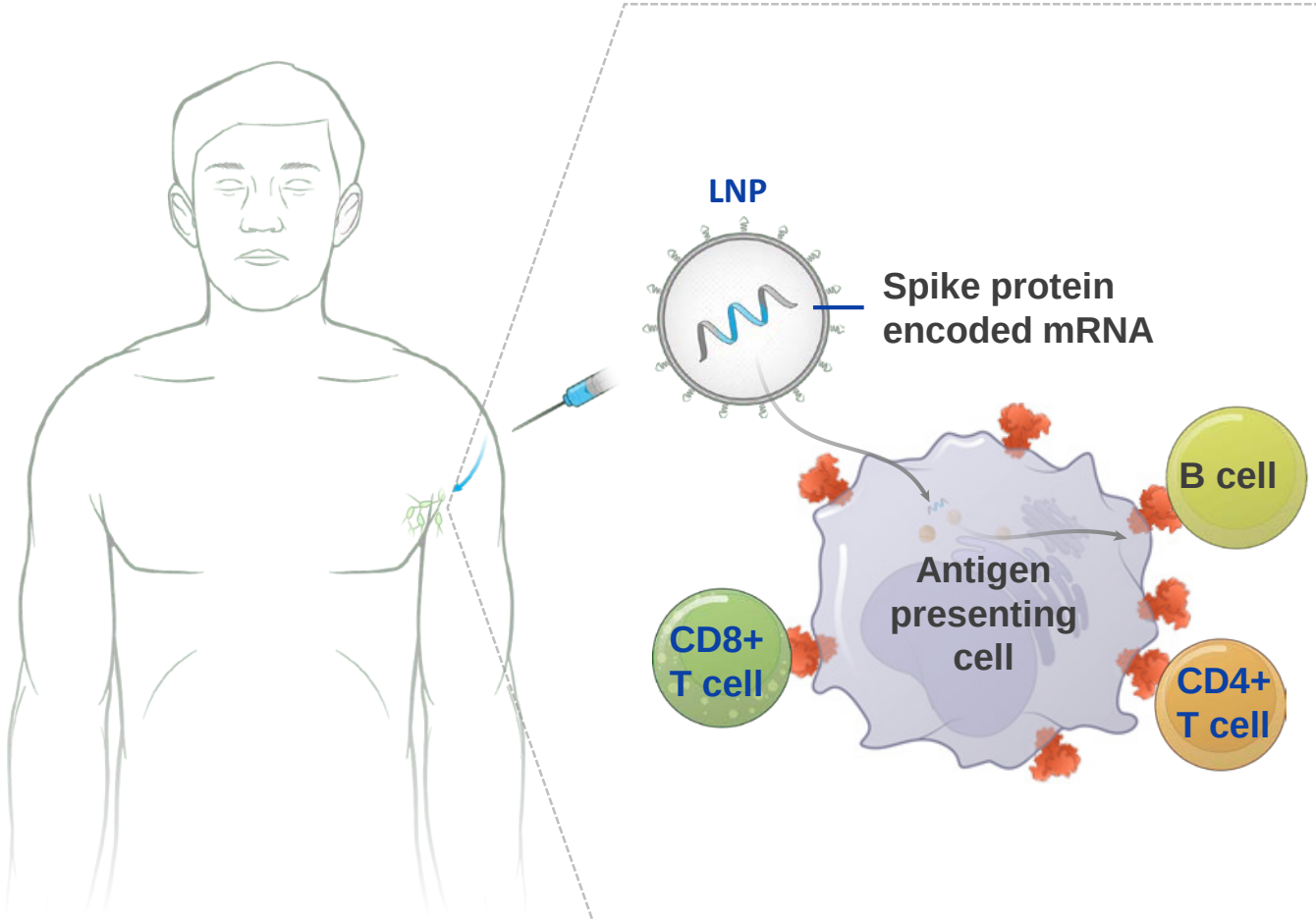
- **Vaccine Recommendations**
  - Pfizer-BioNTech
  - Moderna
- **Clinical considerations for use**
- **Anaphylaxis**

- **Allocation**
- **Considerations for implementation**

- **Summary & What's on the Horizon**

ACIP recommendations for mRNA COVID-19 vaccines

Messenger RNA vaccines

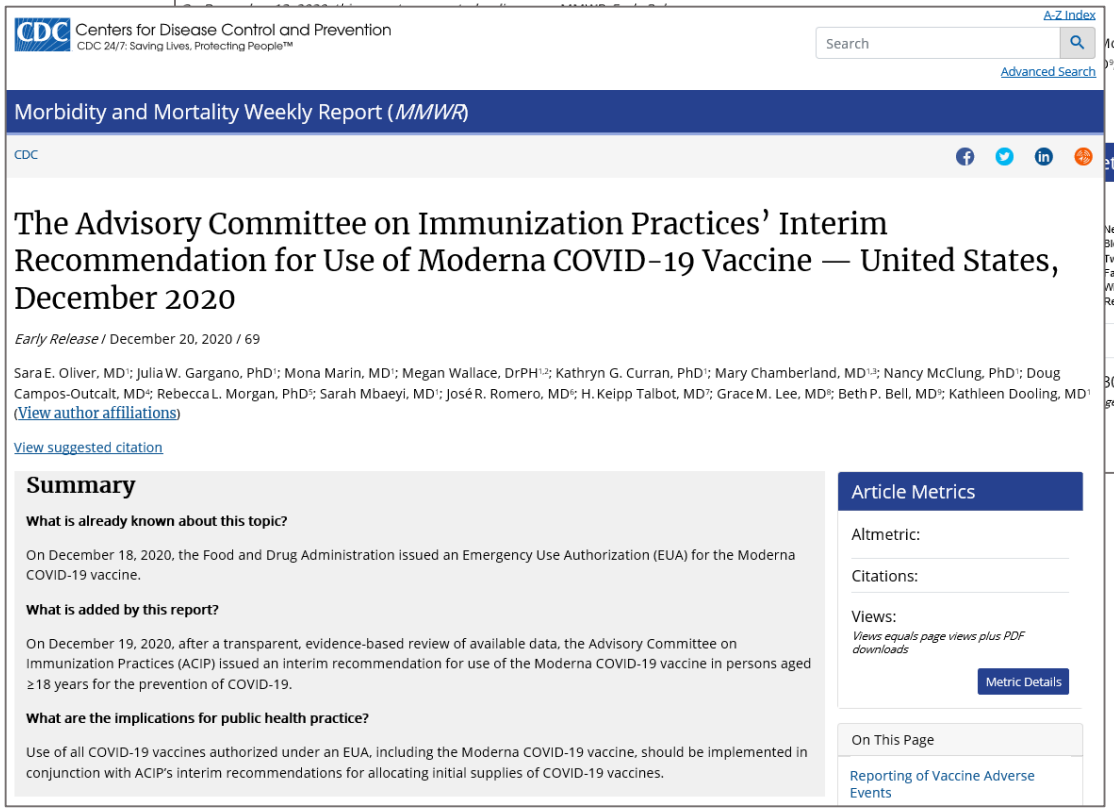


- Provides instruction directly to the immune system (Spike protein)
- Efficiently creates specific immune memory
- mRNA can neither interact with nor integrate into DNA

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

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

- Two mRNA COVID-19 vaccines authorized under Emergency Use
  - Pfizer-BioNTech
  - Moderna
- Both products demonstrate vaccine efficacy >90%
  - Efficacy demonstrated across age groups, racial and ethnic groups
- Vaccine safety profile of both products acceptable
  - Imbalance of Bell's Palsy but still within expected range
  - Local and systemic reactogenicity, particularly after second dose

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
- 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
- mRNA vaccines should be administered alone, with a minimum interval of 14 days before or after administration with any other vaccines

Dosing and administration

- Persons should not be prospectively scheduled to receive the second dose earlier than recommended (Pfizer-BioNTech= 3 weeks, Moderna=4 weeks)
  - Second doses administered within a "**grace period"** of ≤4 days from the recommended date are considered valid
  - There is no maximum interval between the first and second dose for either vaccine.

- If minimum intervals (between COVID-19 doses or between COVID-19 and other vaccines) are violated, still consider the COVID-19 dose VALID
  - COVID-19 vaccine supply is constrained
  - We don't have data on 3 doses of COVID-19 or doses given with shorter inter-dose intervals

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 clinical trials suggest vaccination safe 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 with a known SARS-CoV-2 exposure

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

- **Residents of congregate healthcare settings (e.g., long-term care facilities):**
  - May be vaccinated, as likely would not result in additional exposures. HCP are already in close contact with residents and should employ appropriate infection prevention and control procedures

- **Residents of congregate settings (e.g., correctional facilities, homeless shelters)**
  - May be vaccinated, in order to avoid delays and missed opportunities for vaccination
  - Where feasible, precautions should be taken to limit mixing of these individuals with other residents or non-essential staff

https://www.cdc.gov/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

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

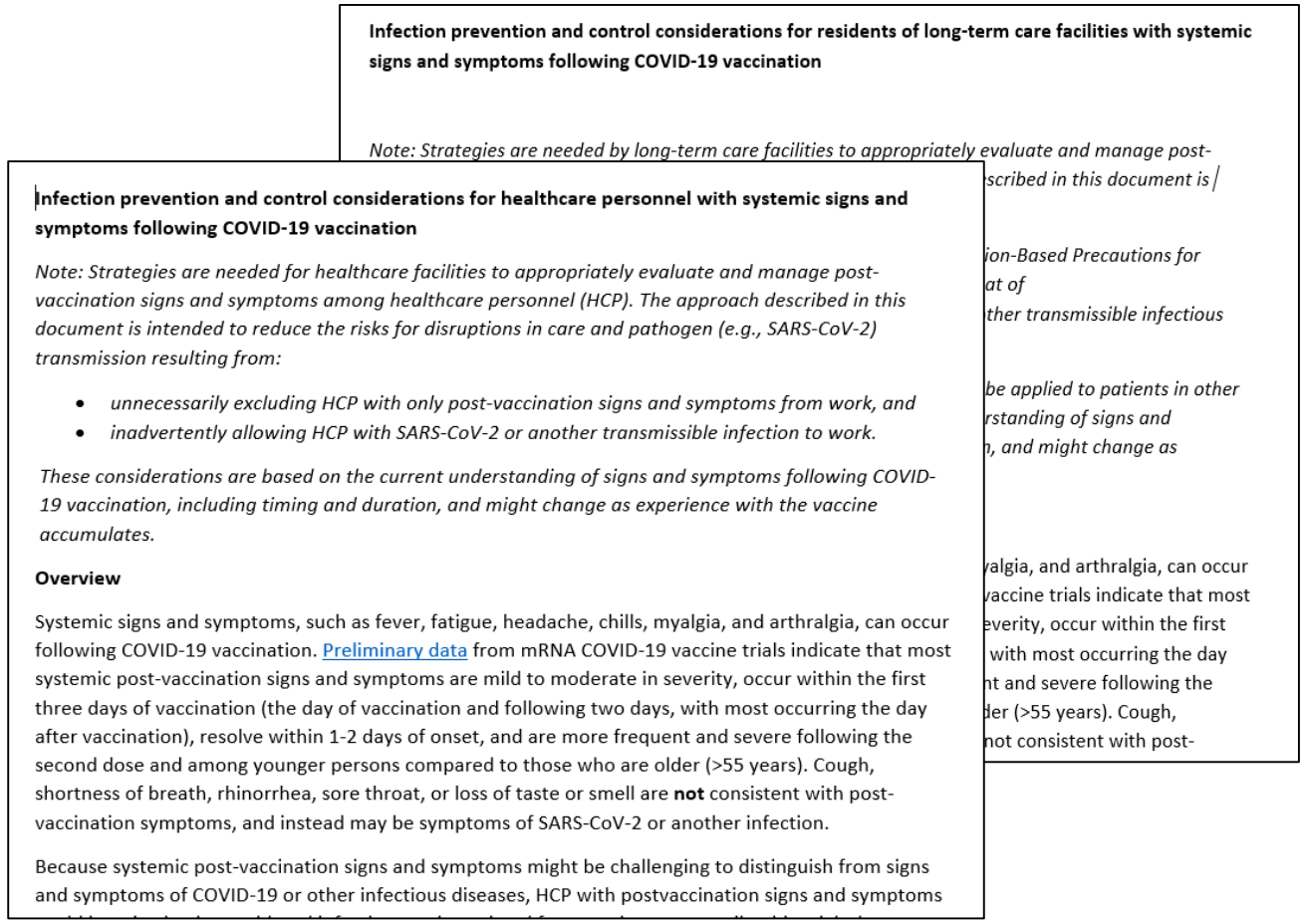
Post-Vaccination Symptoms- Reactogenicity

- Before vaccination, providers should counsel vaccine recipients about expected local and systemic post-vaccination symptoms
- Depending on vaccine product, age group, and dose:
  - **80-89%** of clinical trial participants reported ≥1 **local** reaction (e.g., pain or swelling at injection site; swollen lymph nodes on same side as vaccinated arm)
  - **55-83%** of clinical trial participants reported ≥1 **systemic** reaction (e.g., fever, fatigue, muscle aches, headache, chills)
  - Most are mild-moderate in severity, occur within first 3 days of vaccination, and resolve within 1-2 days of onset
  - More frequent and severe following the second dose and among younger age groups

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

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-
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algia, and arthralgia, can occur
accine trials indicate that most
everity, occur within the first
with most occurring the day
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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

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: mRNA 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)

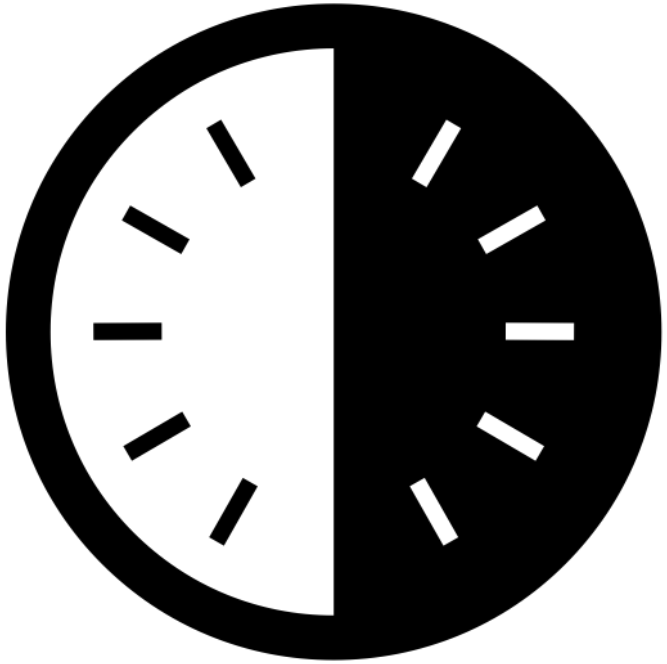
- These persons may still receive vaccination, but should be counseled about the unknown risks of developing a severe allergic reaction and balance these risks against the benefits of vaccination

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

Observation period following vaccination

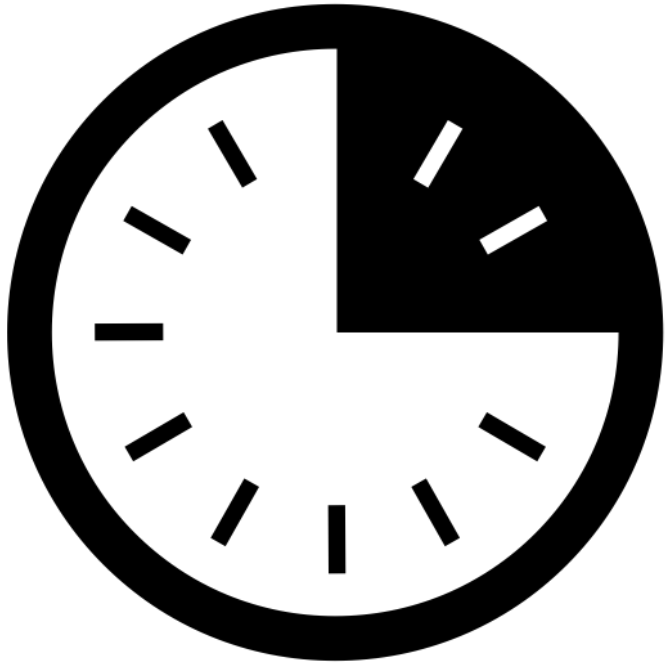
- Vaccine providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:

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



30 minutes

All other persons



15 minutes

Ingredients* included in mRNA COVID-19 vaccines

Description	Pfizer-BioNTech COVID-19 vaccine	Moderna COVID-19 vaccine
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	1 monomethoxypolyethyleneglycol-2,3-dimyristylglycerol with polyethylene glycol of average molecular weight 2000 (PEG2000-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)	heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate
Salts and Sugars	potassium chloride	Tris buffer containing sucrose and sodium acetate
	monobasic potassium phosphate	
	sodium chloride	
	dibasic sodium phosphate dihydrate	
	sucrose	

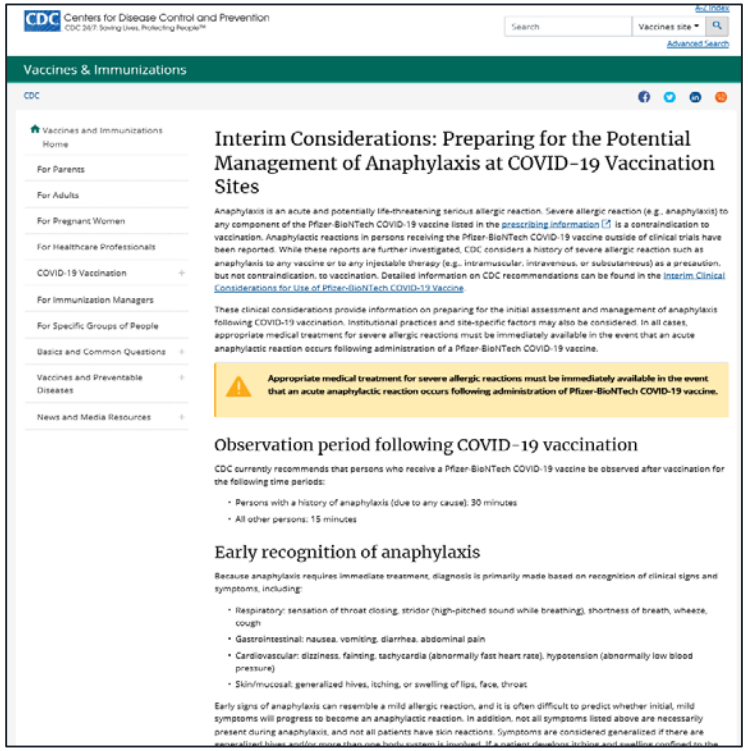
*As reported in the prescribing information

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

Additional tools to identify persons with contraindications and precautions to vaccination

Interim considerations:

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



CDC Centers for Disease Control and Prevention

Vaccines & Immunizations

- Vaccines and Immunizations Home
- For Parents
- For Adults
- For Pregnant Women
- For Healthcare Professionals
- COVID-19 Vaccination
- For Immunization Managers
- For Specific Groups of People
- Basics and Common Questions
- Vaccines and Preventable Diseases
- 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:

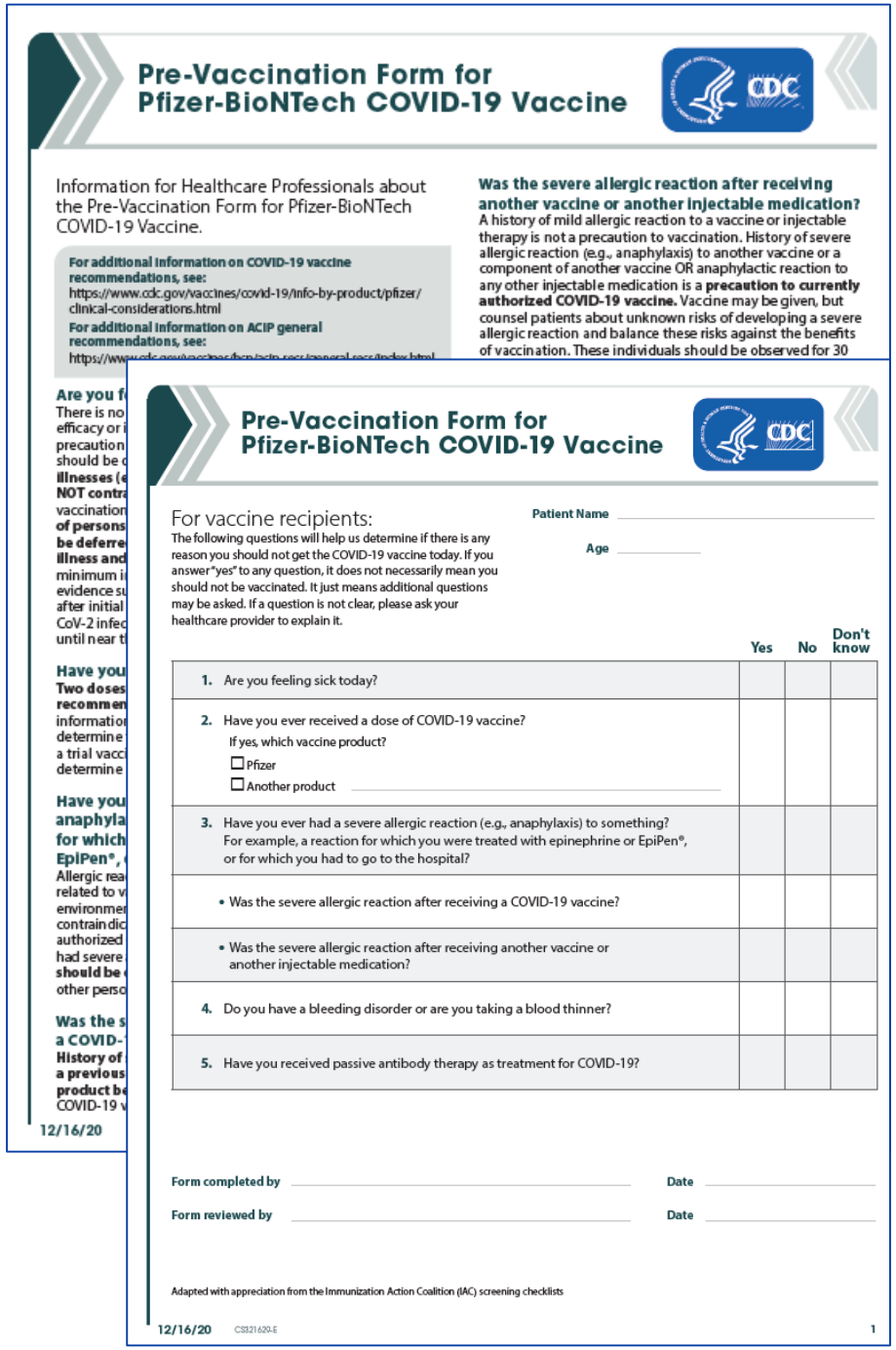
- Persons with a history of anaphylaxis (due to any cause): 30 minutes
- All other persons: 15 minutes

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



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

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

For additional information on COVID-19 vaccine recommendations, see:
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/clinical-considerations.html

For additional information on ACIP general recommendations, see:

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

12/16/20

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 checklists

12/16/20 CS321629-E 1

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

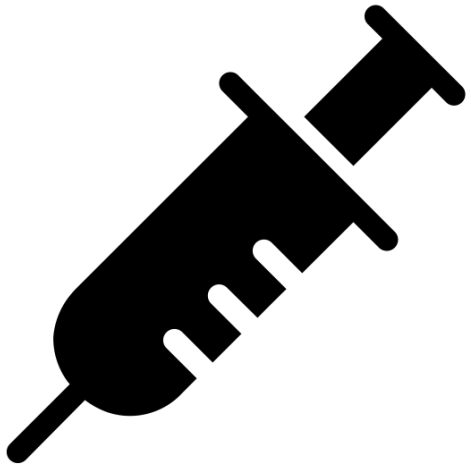
https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/anaphylaxis-management.html

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

Anaphylaxis in persons following mRNA COVID-19 vaccines

- Cases of anaphylaxis have been reported (as of Dec 19/2020, following Pfizer-BioNTech COVID-19 vaccination)
  - 2 cases in United Kingdom
  - 6 cases* in United States (~272K doses administered)

- US cases:
  - Rapid onset following vaccination
  - One person had prior history of anaphylaxis (to rabies vaccine)

* 6 confirmed cases meeting Brighton Collaboration criteria 1 or 2, through December 18, 2020 at 2300 hrs EST

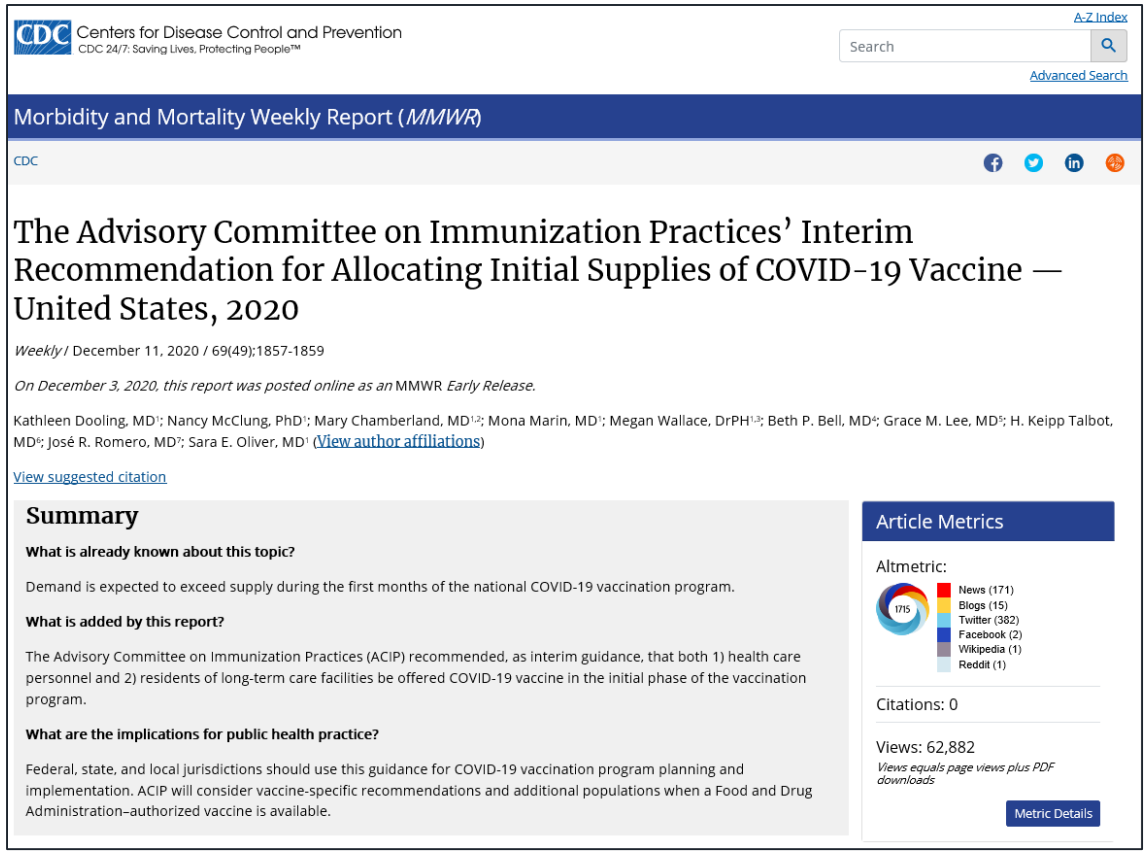
Your role

- Recognize, respond, and report anaphylaxis following COVID-19 vaccination to **VAERS** ✓
- Report adverse events to **VAERS** in accordance with FDA EUA reporting requirements and CDC guidance ✓
- Participate in CDC's **v-saf**e program yourself when you get vaccinated and encourage patients to participate in **v-safe** ✓
- **Communicate** with patients on vaccine safety ✓

ACIP recommendations for Vaccine allocation/prioritization

ACIP recommendations for use of COVID-19 vaccines

- Phased allocation of COVID-19 vaccines



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Morbidity and Mortality Weekly Report (*MMWR*)

CDC

The Advisory Committee on Immunization Practices' Interim Recommendation for Allocating Initial Supplies of COVID-19 Vaccine — United States, 2020

Weekly / December 11, 2020 / 69(49);1857-1859

On December 3, 2020, this report was posted online as an MMWR *Early Release.*

Kathleen Dooling, MD[1]; Nancy McClung, PhD[1]; Mary Chamberland, MD[1,2]; Mona Marin, MD[1]; Megan Wallace, DrPH[1,3]; Beth P. Bell, MD[4]; Grace M. Lee, MD[5]; H. Keipp Talbot, MD[6]; José R. Romero, MD[7]; Sara E. Oliver, MD[1] (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

Demand is expected to exceed supply during the first months of the national COVID-19 vaccination program.

What is added by this report?

The Advisory Committee on Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel and 2) residents of long-term care facilities be offered COVID-19 vaccine in the initial phase of the vaccination program.

What are the implications for public health practice?

Federal, state, and local jurisdictions should use this guidance for COVID-19 vaccination program planning and implementation. ACIP will consider vaccine-specific recommendations and additional populations when a Food and Drug Administration–authorized vaccine is available.

Article Metrics

Altmetric:

1715

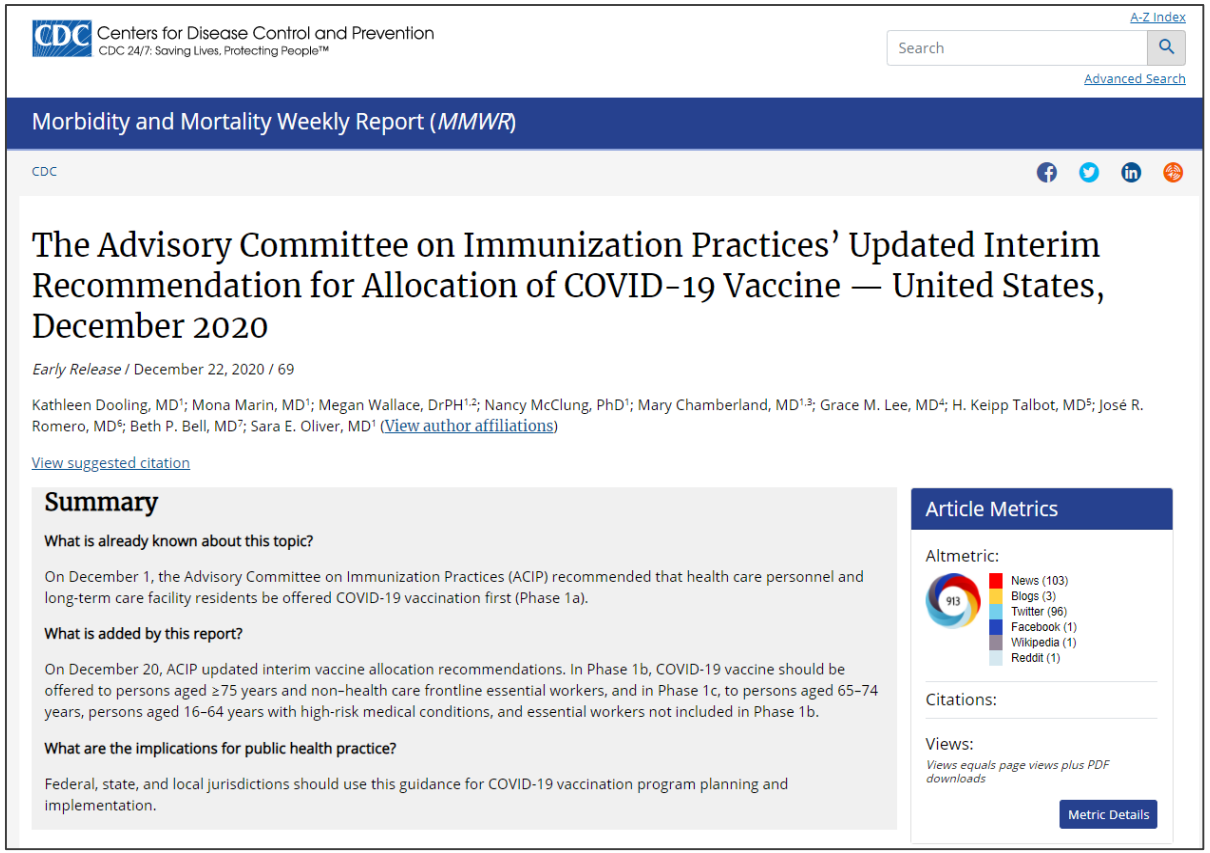
News (171)
Blogs (15)
Twitter (382)
Facebook (2)
Wikipedia (1)
Reddit (1)

Citations: 0

Views: 62,882

Views equals page views plus PDF downloads

Metric Details



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Morbidity and Mortality Weekly Report (*MMWR*)

CDC

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

Early Release / December 22, 2020 / 69

Kathleen Dooling, MD[1]; Mona Marin, MD[1]; Megan Wallace, DrPH[1,2]; Nancy McClung, PhD[1]; Mary Chamberland, MD[1,3]; Grace M. Lee, MD[4]; H. Keipp Talbot, MD[5]; José R. Romero, MD[6]; Beth P. Bell, MD[7]; Sara E. Oliver, MD[1] (View author affiliations)

View suggested citation

Summary

What is already known about this topic?

On December 1, the Advisory Committee on Immunization Practices (ACIP) recommended that health care personnel and long-term care facility residents be offered COVID-19 vaccination first (Phase 1a).

What is added by this report?

On December 20, ACIP updated interim vaccine allocation recommendations. In Phase 1b, COVID-19 vaccine should be offered to persons aged ≥75 years and non–health care frontline essential workers, and in Phase 1c, to persons aged 65–74 years, persons aged 16–64 years with high-risk medical conditions, and essential workers not included in Phase 1b.

What are the implications for public health practice?

Federal, state, and local jurisdictions should use this guidance for COVID-19 vaccination program planning and implementation.

Article Metrics

Altmetric:

913

News (103)
Blogs (3)
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Metric Details

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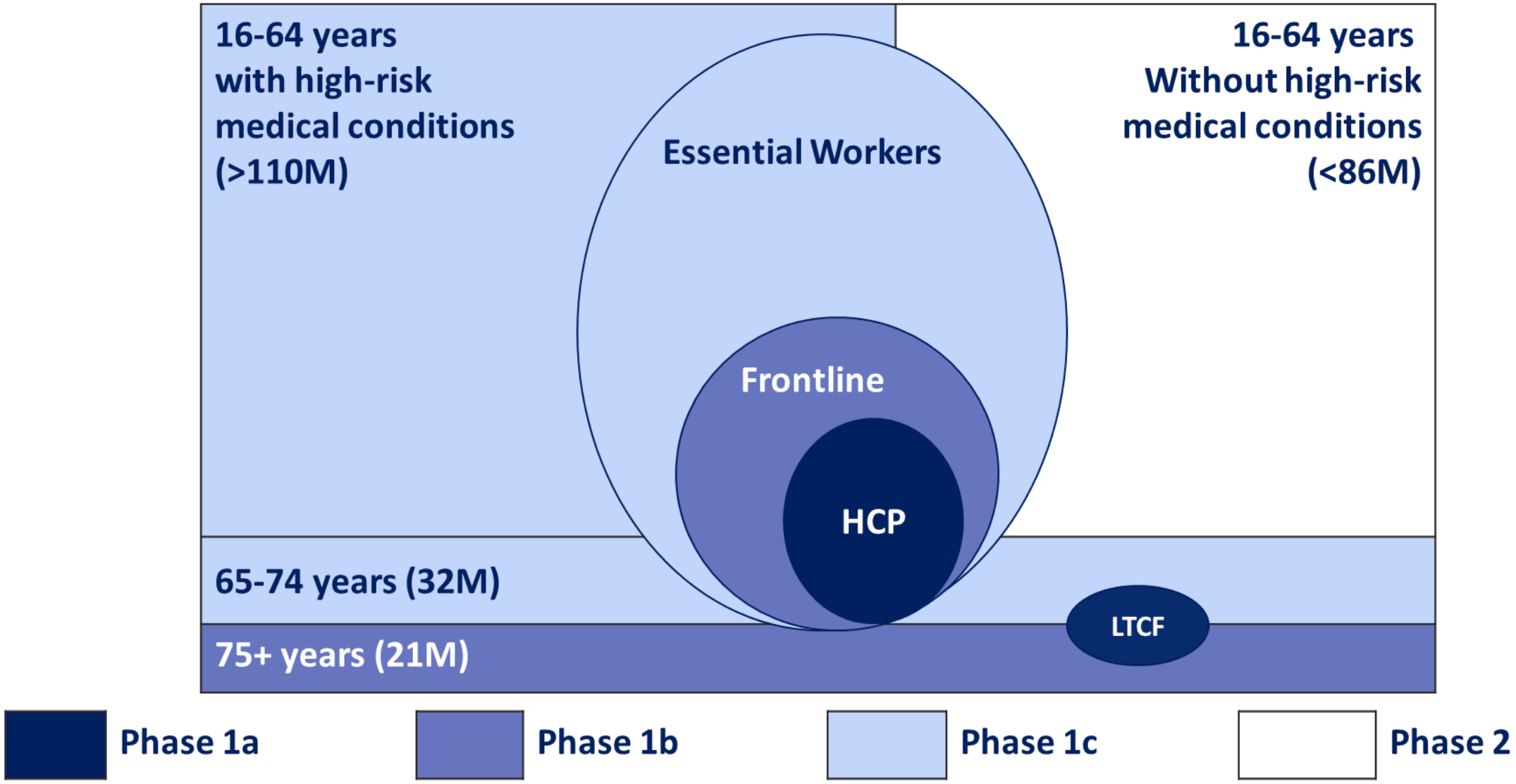
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_w

COVID-19 vaccination phases



Phased allocation: Balancing Goals

	Prevention of Morbidity & Mortality	Preservation of Societal Functioning
1a	LTCF residents	Health care personnel
1b	Persons 75 years and older	Frontline Essential Workers
1c	Persons 65-74 years Persons 16-64 with high-risk medical conditions	Other Essential Workers

- Ensure safety and effectiveness of COVID-19 vaccines
- Ensure equity in vaccine allocation and distribution

Essential Workers

Frontline Essential Workers (~30M)

- First Responders (Firefighters, Police)
- Education (teachers, support staff, daycare)
- Food & Agriculture
- Manufacturing
- Corrections workers
- U.S. Postal service workers
- Public transit workers
- Grocery store workers

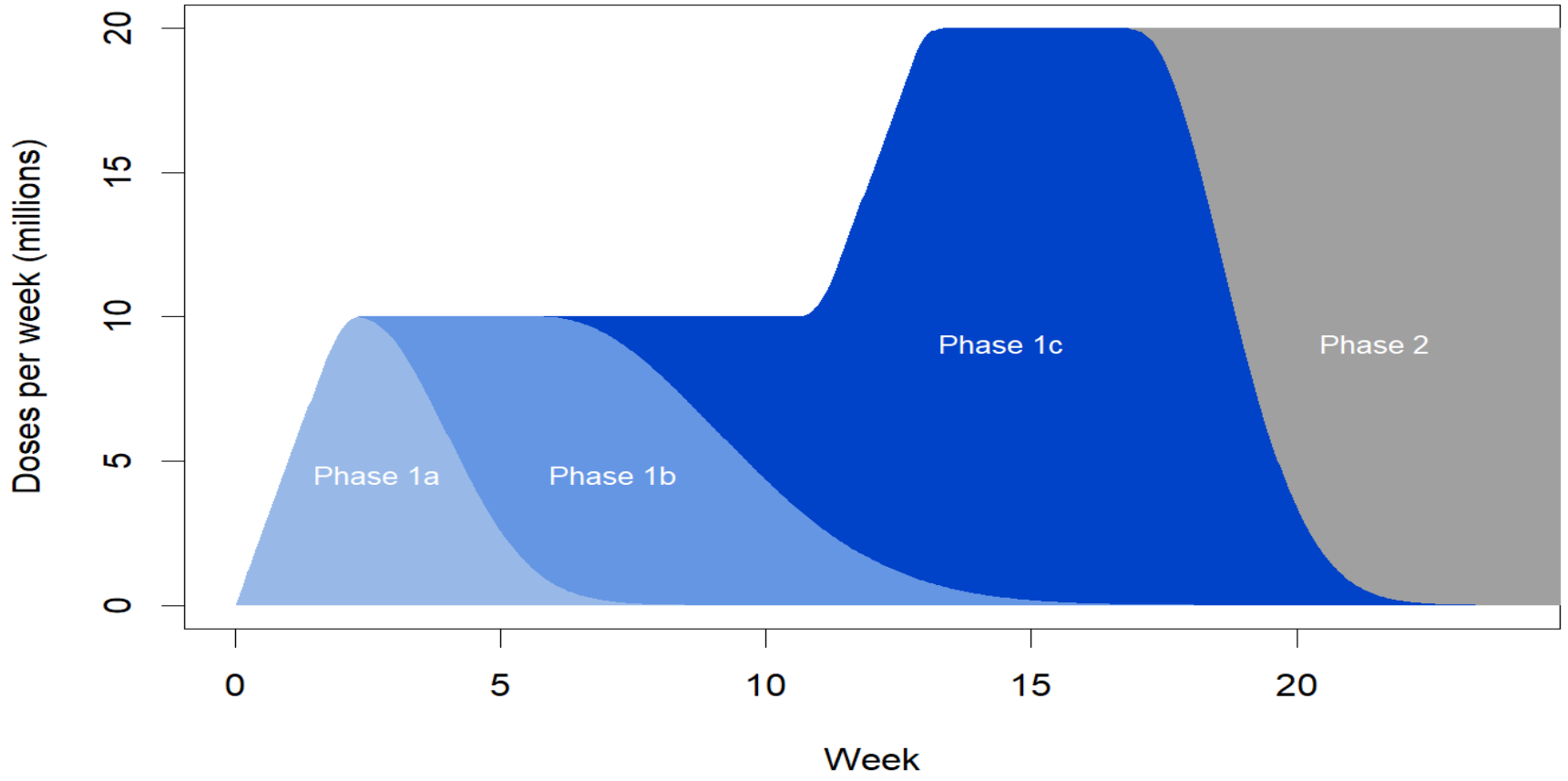
Other Essential Workers (~57M)

- Transportation and logistics
- Food Service
- Shelter & Housing (construction)
- Finance
- IT & Communication
- Energy
- Media
- Legal
- Public Safety (Engineers)
- Water & Wastewater

Frontline Essential Workers: workers who are in sectors essential to the functioning of society and are at substantially higher risk of exposure to SARS-CoV-2

*CISA: Essential Critical Infrastructure Workers: https://www.cisa.gov/news/2020/08/18/cisa-releases-updated-guidance-essential-critical-infrastructure-workers

Example of Phase 1 & Phase 2 COVID-19 vaccine roll-out



Transitioning Between Phases

- Strategy for transitioning between phases will be necessary to move to the next phase as **supply increases** and **exceeds demand** for the current phase
- Phases may **overlap**; not necessary to fully complete vaccination in one phase before moving to the next phase
- Decisions on moving to the next phase made at a **state/local** level

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

Considerations for transitioning between phases

- When demand in the current phase appears to have been met (e.g., appointments for vaccination are < 80% filled for several days)
- When supply of authorized vaccine increases substantially (e.g., more vaccine doses are available than are necessary to complete vaccination of persons in the current phase)
- When most people in the current phase are vaccinated (e.g., when approximately 60-70% of the target population in a phase has been vaccinated)
- When vaccine supply within a certain location is in danger of going unused unless vaccination is expanded to persons in the next phase

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

Considerations- sub prioritization

- Groups of workers that are the most critical to maintaining core societal functions
- Groups of workers with unavoidable higher risk of exposure
- Groups of workers in sites where high rates of transmission and outbreaks can occur regularly (e.g., correctional and detention facility workers)

- Considerations for sub-prioritization may be informed by CDC's Social Vulnerability Index or other similar indices

Summary & what's on the horizon

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

Summary

- 2 mRNA vaccines currently authorized for use in U.S.
  - >90% VE
  - Moderate self-limited reactogenicity
  - Higher than expected anaphylaxis– vaccination sites must be ready to manage
- Phased allocation of vaccine is necessary while demand > supply
  - Equitable and fair
  - Use all doses in a timely way
- Next few months
  - Increased production of mRNA vaccines
  - Viral vector vaccines (Janssen and AstraZeneca)

Resources

MMWRs
Pfizer-BioNTech: https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm?s_cid=mm6950e2_w
Moderna: https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e1.htm?s_cid=mm695152e1_w
Vaccine Allocation: https://www.cdc.gov/mmwr/volumes/69/wr/mm6949e1.htm
https://www.cdc.gov/mmwr/volumes/69/wr/mm695152e2.htm?s_cid=mm695152e2_w

CDC considerations
Pregnancy: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/pregnancy-breastfeeding.html
Underlying medical conditions: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html

Vaccine Safety
VAERS: http://vaers.hhs.gov
VSAFE: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html

Other CDC resources
Vaccine tracker: https://covid.cdc.gov/covid-data-tracker
For Healthcare Professionals: https://www.cdc.gov/vaccines/covid-19/hcp/index.html

Engaging in Effective COVID-19 Vaccine Conversations https://www.cdc.gov/vaccines/covid-19/hcp/engaging-patients.htm

Questions?


DEPARTMENT OF HEALTH & HUMAN SERVICES USA
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Back-up slides

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

Moderna: Efficacy post ONLY 1 dose

Table 15. Vaccine Efficacy[a] of mRNA-1273 to Prevent COVID-19 From Dose 1 by Time Period in Participants Who Only Received One Dose, mITT Set

First COVID-19 Occurrence After Dose 1	Vaccine Group N=996 Case n (%)	Placebo Group N=1079 Case n (%)	VE (%) (95% CI)*
After dose 1	7/996 (87.5)	39/1079 (96.7)	80.2% (55.2%, 92.5%)
After dose 1 to 14 days after dose 1	5/996 (38.0)	11/1079 (41.1)	50.8% (-53.6%, 86.6%)
>14 days after dose 1**	2/983 (87.2)	28/1059 (96.2)	92.1% (68.8%, 99.1%)

Surveillance time in person years for given endpoint across all participants within each group at risk for the endpoint
* VE is calculated as 1-ratio of incidence rates (mRNA-1273/Placebo). The 95% CI of VE is calculated using the exact method conditional upon the total number of cases, adjusting for person-years
**Participants who were not at risk (cases or censored at prior time period) are excluded from this analysis
[a] Based on interim analysis: Novemer 7, 2020 efficacy data cutoff.

Moderna FDA VRBPAC Briefing Document: https://www.fda.gov/media/144434/download

Pfizer: efficacy post dose 1

Table 13. Primary Efficacy Endpoint –All-Available Efficacy Population

Efficacy Endpoint	BNT162b2 N[a]=21669 Cases n1[b] Surveillance Time[c] (n2[d])	Placebo N[a]=21686 Cases n1[b] Surveillance Time[c] (n2[d])	Vaccine Efficacy % (95% CI)
First COVID-19 occurrence after Dose 1 – Dose 1	50 4.015 (21314)	275 3.982 (21258)	82.0 (75.6, 86.9)[f]
After Dose 1 to before Dose 2	39	82	52.4 (29.5, 68.4)
Dose 2 to 7 days after Dose 2	2	21	90.5 (61, 98.9)
≥7 Days after Dose 2	9	172	94.8 (89.8, 97.6)

[a] N = number of participants in the specified group.
[b] n1 = Number of participants meeting the endpoint definition.
[c] Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 or 14 days after Dose 2 to the end of the surveillance period depending on specified endpoint.
[d] n2 = Number of participants at risk for the endpoint.
[e] Credible interval for VE was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time.
[f] Confidence interval (CI) for VE is derived based on the Clopper and Pearson method adjusted to the surveillance time.

Pfizer FDA VRBPAC Briefing: https://www.fda.gov/media/144245/download