# Vaccine Planning Work Group

In order to keep an accurate roll call, we ask that everyone joining this meeting rename themselves to include the following information:

- First Name
- Last Name
- Organization

Please type all questions into the chat box.

Presentations slides will be posted on the Maine Immunization Program website at: https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/communications.shtml

We appreciate the time and effort taken by everyone joining to help the Maine CDC with COVID-19 vaccine planning.

# Vaccine Planning Work Group

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Maine Immunization Program
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# Disclaimer

All information in this presentation is subject to change.

Information shared in these slides are assumptions as of 12/17/2020.

# Agenda

- Pfizer Updates
- Moderna
- V-safe
- Retail Pharmacy Program
- ImmPact Training
- Q&A
  - Ask logistics questions
  - Seek guidance
  - Ask for clarifying information

# Pfizer Vaccine

- Decrease in doses for week #2 Pfizer vaccine

- Additional doses per vial
  - FDA is aware of the issue and working with Pfizer to determine the best path forward, and will share additional updates as we have them. At this time, given the public health emergency, FDA is advising that it is acceptable to use every full dose obtainable (the sixth, or possibly even a seventh) from each vial, pending resolution of the issue. However, since these are preservative free vials, it is critical to note that any further remaining liquid that does not constitute a full dose should not be pooled from multiple vials to create one."

# Pfizer Vaccine

- Standing Orders Template
- Pre Vaccination Screening Tool

Pfizer-BioNTech COVID-19 Vaccine Information | CDC

# Pfizer-BioNTech COVID-19 Vaccine

## Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older

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

### Purpose

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

### Policy

- Where authorized under state law, standing orders enable eligible nurses and other healthcare professionals (e.g., pharmacists) to assess and vaccinate persons who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

### Procedure

- Assess persons 16 years of age and older for vaccination with Pfizer-BioNTech COVID-19 Vaccine based on the following criteria: No complete 2-dose COVID-19 vaccination history, regardless of brand. If 2 doses of a same-brand or mixed-brand series have been administered, no additional doses are recommended.
  - If the recipient has received 1 previous dose of Pfizer-BioNTech COVID-19 Vaccine, the second dose of the same brand should be administered.
  - This vaccine is administered in a **2-dose** series. Separate doses by at least 21 days.*
  - Pfizer-BioNTech COVID-19 Vaccine should not be administered at the same time with other vaccines. Separate Pfizer-BioNTech COVID-19 Vaccine from other vaccines by 14 days before or after the administration of COVID-19 vaccine.
- Screen for contraindications and precautions.
  - Contraindications
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose of Pfizer-BioNTech COVID-19 Vaccine or to a component of the vaccine.
  - Precautions
    - Severe allergic reaction (e.g., anaphylaxis) to a previous dose of any vaccine (not including Pfizer-BioNTech COVID-19 Vaccine).
    - Severe allergic reaction (e.g., anaphylaxis) to a medication that is injectable
    - Moderate to severe acute illness
- Provide Emergency Use Authorization (EUA) patient information.
  - Provide all recipients with a copy of the current federal EUA Fact Sheet for Recipients and Caregivers.
- Prepare to administer the vaccine.
  - Choose the correct needle gauge, needle length, and injection site for persons:
    - 16 through 18 years of age: 1-inch needle is recommended, administered in the deltoid muscle of the arm.
    - 19 years of age and older: See table below.

| Sex and Weight of Patient | Needle Gauge | Needle Length | Injection Site** |
|---|---|---|---|
| Female or male fewer than 130 lbs | 22–25 | ⅝***–1" | Deltoid muscle of arm |
| Female or male 130–152 lbs | 22–25 | 1" | Deltoid muscle of arm |
| Female 152–200 lbs | 22–25 | 1-1½" | Deltoid muscle of arm |
| Male 153–260 lbs | 22–25 | 1-1½" | Deltoid muscle of arm |
| Female 200+ lbs | 22–25 | 1½" | Deltoid muscle of arm |
| Male 260+ lbs | 22–25 | 1½" | Deltoid muscle of arm |

* If the 2nd dose Pfizer vaccine was given as early as 17 days after the 1st dose, then do not repeat a 2nd dose.
** Alternatively, the anterolateral thigh also can be used.
*** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (do not bunch subcutaneous tissue).

# Pfizer-BioNTech COVID-19 Vaccine

## Standing Orders for Administering Vaccine to Persons 16 Years of Age and Older

- Mix Pfizer-BioNTech COVID-19 Vaccine with 0.9% sodium chloride (normal saline, preservative-free) diluent according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling mixed vaccine.

- Administer 0.3 mL Pfizer-BioNTech COVID-19 Vaccine by intramuscular (IM) injection.Document vaccination.
- Document vaccination.
  - COVID-19 vaccination providers must document vaccine administration in their medical record systems within 24 hours of administration and use their best efforts to report administration data to the relevant system (e.g., Immunization Information System) for the jurisdiction as soon as practicable and no later than 72 hours after administration.
  - Document each recipient's vaccine administration information:
    - Medical record: The vaccine and the date it was administered, manufacturer, lot number, vaccination site and route, name and title of the person administering the vaccine
    - Vaccination record card: Date of vaccination, product name/manufacturer, lot number, and name/location of the administering clinic or healthcare professional. Give to the vaccine recipient.
    - Immunization information system: Report the vaccination to the appropriate state/local IIS.
- Additional preparation and administration information is available on the manufacturer's website at www.cvdvaccine.com.
- Be prepared to manage medical emergencies.
  - Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions:
    - Persons with a history of a any anaphylaxis: 30 min
    - All other persons: 15 minutes
  - Be prepared to manage a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For more information, please see:
    - CDC's *General Best Practice Guidelines for Immunization*, "Preventing and Managing Adverse Reactions," at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html.
    - Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting" at https://www.immunize.org/catg.d/p3082.pdf
- Report adverse events to the Vaccine Adverse Event Reporting System (VAERS).
  - While this vaccine is under Emergency Use Authorization (EUA), healthcare professionals are required to report to VAERS:
    - Vaccine administration errors (whether associated with an adverse event [AE] or not)
    - Serious AEs (irrespective of attribution to vaccination)
    - Multisystem inflammatory syndrome (MIS) in adults or children
    - Cases of COVID-19 that result in hospitalization or death
    - Any additional AEs and revised safety requirements per the Food and Drug Administration's conditions for use of an authorized vaccine throughout the duration of the EUA
  - Healthcare professionals are encouraged to report to VAERS:
    - Clinically important adverse events that occur after vaccination, even if you are not sure whether the vaccine caused the adverse event

### Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____ effective _____ until rescinded or until _____.

Medical director (or other authorized practitioner)
_____/_____/_____.

Adapted from Immunization Action Coalition Standing Orders templates. These templates for routinely recommended vaccines can be found at https://www.immunize.org/standing-orders/. We thank the Immunization Action Coalition for the use of their resources.

# 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?<br>If yes, which vaccine product?<br>☐ Pfizer<br>☐ 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

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

### Are you feeling sick today?

There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. **Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination.** Do not withhold vaccination if a person is taking antibiotics. **Vaccination of persons with current SARS-CoV-2 infection should be deferred until the person has recovered from acute illness and they can discontinue isolation.** While there is no minimum interval between infection and vaccination, current evidence suggests reinfection is uncommon in the 90 days after initial infection. Persons with documented acute SARS-CoV-2 infection in the preceding 90 days may delay vaccination until near the end of this period, if desired.

### Have you ever received a dose of COVID-19 vaccine?

**Two doses of the same COVID-19 vaccine product are recommended.** Check medical records, immunization information systems, and vaccination record cards to help determine the initial product received. Those who received a trial vaccine should consult with the trial sponsors to determine if it is feasible to receive additional doses.

### 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?

Allergic reactions, including severe allergic reactions, NOT related to vaccines or injectable therapies (e.g., food, pet, venom, environmental, or latex allergies; oral medications) are NOT a contraindication or precaution to vaccination with currently authorized COVID-19 vaccine. HOWEVER, individuals who have had severe allergic reactions to something, regardless of cause, **should be observed for 30 minutes after vaccination.** All other persons should be observed for 15 minutes.

### Was the severe allergic reaction after receiving a COVID-19 vaccine?

**History of severe allergic reaction (e.g., anaphylaxis) to a previous dose or component of the COVID-19 vaccine product being offered is a contraindication** to that 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 medication 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.

# Moderna

- FDA to meet on December 17-Moderna

- Once an EUA is issued, an EUA Letter of Authorization and EUA fact sheets will become available.

  The Letter of Authorization describes the scope and criteria for EUA issuance. EUA fact sheets will include one meant for healthcare providers and another meant for vaccine recipients and caregivers. Unlike a typical vaccine information statement (VIS), an EUA fact sheet is specific to one particular product (i.e. instead of referring to a class of vaccines).

# Ancillary Kits

| Contents: Each kit contains a label on the outside of the box with a complete inventory list. | Adult Kit* | Pediatric Kit* | Mixed Kit* |
|---|---|---|---|
| | • 829 needles (22-25G X 1″)<br>• 200 needles (22-25G X 1.5″)<br>• 205 mixing needles (21-25G X1.5″)<br>• 1024 syringes (1mL)<br>• 205 syringes (3mL or 5mL)<br>• 2458 alcohol pads<br>• 1000 vaccination record cards<br>• 10 needle gauge and length charts<br>• 20 face shields<br>• 40 surgical masks<br>• 200 Diluent vials | • 1024 needles (25G X 1″)<br>• 205 mixing needles (21-25G X1.5″)<br>• 1024 syringes (1mL)<br>• 205 syringes (3mL or 5mL)<br>• 2458 alcohol pads<br>• 1000 vaccination record cards<br>• 10 needle gauge and length charts<br>• 20 face shields<br>• 40 surgical masks<br>• 200 Diluent vials | • 926 needles (25G X 1″)<br>• 100 needles (22-25G X1.5″)<br>• 205 mixing needles (21-25G X1.5″)<br>• 1024 syringes (1mL)<br>• 205 syringes (3mL or 5mL)<br>• 2458 alcohol pads<br>• 1000 vaccination record cards<br>• 10 needle gauge and length charts<br>• 20 face shields<br>• 40 surgical masks<br>• 200 Diluent vials |

# v-safe

***V-safe*** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination.

Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine.

And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

V-Safe Poster and Patient Hand Out will be emailed out to the attendees of this meeting.


Get vaccinated.
Get your smartphone.
Get started with v-safe.
v-safe
after vaccination health checker
Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.
When you get your COVID-19 vaccination, ask your healthcare provider about getting started with v-safe
Learn more about v-safe
www.cdc.gov/vsafe
12/01/20

# Get vaccinated. Get your smartphone. Get started with v-safe.

## What is v-safe?

***V-safe*** is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after you receive a COVID-19 vaccination. Through ***v-safe***, you can quickly tell CDC if you have any side effects after getting the COVID-19 vaccine. Depending on your answers, someone from CDC may call to check on you. And ***v-safe*** will remind you to get your second COVID-19 vaccine dose if you need one.

Your participation in CDC's ***v-safe*** makes a difference—it helps keep COVID-19 vaccines safe.

## How can I participate?

Once you get a COVID-19 vaccine, you can enroll in ***v-safe*** using your smartphone. Participation is voluntary and you can opt out at any time. You will receive text messages from ***v-safe*** around 2 p.m. local time. To opt out, simply text "STOP" when ***v-safe*** sends you a text message. You can also start ***v-safe*** again by texting "START."

## How long do v-safe check-ins last?

During the first week after you get your vaccine, ***v-safe*** will send you a text message each day to ask how you are doing. Then you will get check-in messages once a week for up to 5 weeks. The questions ***v-safe*** asks should take less than 5 minutes to answer. If you need a second dose of vaccine, ***v-safe*** will provide a new 6-week check-in process so you can share your second-dose vaccine experience as well. You'll also receive check-ins 3, 6, and 12 months after your final dose of vaccine.

## Is my health information safe?

Yes. Your personal information in ***v-safe*** is protected so that it stays confidential and private.*

*To the extent ***v-safe*** uses existing information systems managed by CDC, FDA, and other federal agencies, the systems employ strict security measures appropriate for the data's level of sensitivity.

12/11/20

**v-safe**℠
after vaccination health checker

**Use your smartphone to tell CDC about any side effects after getting the COVID-19 vaccine. You'll also get reminders if you need a second vaccine dose.**

**Sign up with your smartphone's browser at vsafe.cdc.gov**

**OR**

**Aim your smartphone's camera at this code**

# How to register and use v-safe

You will need your smartphone and information about the COVID-19 vaccine you received. This information can be found on your vaccination record card; if you cannot find your card, please contact your healthcare provider.

## Register

1. Go to the ***v-safe*** website using one of the two options below:

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

**OR**

**Aim your smartphone's camera at this code**

2. Read the instructions. Click **Get Started**.
3. Enter your name, mobile number, and other requested information. Click **Register**.
4. You will receive a text message with a verification code on your smartphone. Enter the code in ***v-safe*** and click **Verify**.
5. At the top of the screen, click **Enter vaccine information**.
6. Select which COVID-19 vaccine you received (found on your vaccination record card; if you cannot find your card, please contact your healthcare provider). Then enter the date you were vaccinated. Click **Next**.
7. Review your vaccine information. If correct, click **Submit**. If not, click **Go Back**.
8. **Congrats! You're all set!** If you complete your registration before 2 p.m. local time, ***v-safe*** will start your initial health check-in around 2 p.m. that day. If you register after 2 p.m., ***v-safe*** will start your initial health check-in immediately after you register—just follow the instructions.
   You will receive a reminder text message from v-safe when it's time for the next check-in — around 2 p.m. local time. Just click the link in the text message to start the check-in.

## Complete a v-safe health check-in

1. When you receive a ***v-safe*** check-in text message on your smartphone, click the link when ready.
2. Follow the instructions to complete the check-in.

## Troubleshooting

***How can I come back and finish a check-in later if I'm interrupted?***

- Click the link in the text message reminder to restart and complete your check-in.

***How do I update my vaccine information after my second COVID-19 vaccine dose?***

- ***V-safe*** will automatically ask you to update your second dose information. Just follow the instructions.

**Need help with *v-safe*?**
Call 800-CDC-INFO (800-232-4636)
TTY 888-232-6348
Open 24 hours, 7 days a week
Visit www.cdc.gov/vsafe

# Retail Pharmacy Program Updates

Skilled Nursing Facility Clinics have started to be scheduled for the week of 12/21

- CVS, round 1 will take 1-2 weeks to complete
- Walgreens, round 1 will take 2-3 weeks to compete

# Trainings for ImmPact

AGENDA:

- New user log in
- Portal page – user manual and user resources link
- Ordering covid vaccine
- Accepting order on arrival
- Patient search
- Entering immunization for patient
- Reconciling inventory

# Trainings for ImmPact

Join Zoom Meeting

https://us02web.zoom.us/j/85955176464?pwd=Nk5Vd2ZybVduYlZSRHpYWFRQTjBsZz09

- Meeting ID: 859 5517 6464
- Passcode: wi3gYq

immpact.support@maine.gov

# Contact Information

C19Vaccine.MECDC@maine.gov

For questions regarding vaccine planning for COVID-19:

- Provider Enrollment Requirements
- CDC COVID-19 Vaccination Program Provider Agreement
- Any follow-up questions to these weekly Vaccine Planning Work Group Meetings

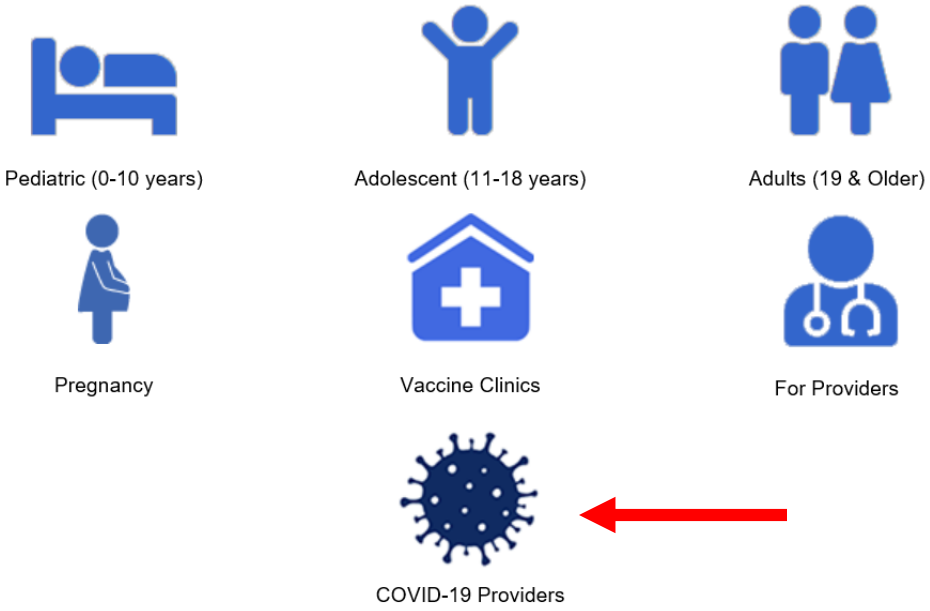
C19PA.MECDC@maine.gov

To submit documents for COVID-19 vaccine enrollment:

- CDC COVID-19 Vaccination Program Provider Agreement
- Storage & handling documentation if required

# Website Information

ImmunizeME.org



# Questions?

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