

Maine DHHS

COVID-19 Vaccines Information for Clinicians

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Welcome

- Introductions
- Session goals & format
- CME available (0.5 AMA PRA Cat 1 Credit/session)
 - **If CME desired, pls email your name & session attended to COVIDCME.DHHS@maine.gov**
- Future sessions
- Current context

Disclosures


The planners and faculty for this activity do not have any relevant financial relationships to disclose with any Commercial Interests and do not have any conflicts of interest to resolve

COVID-19 Vaccines – Info for Clinicians

- Context
- Science of vaccines
- **Assessing & managing allergy issues**
- **Safety monitoring**
- **New vaccines**
- Promoting vaccine equity
- Vaccine hesitancy
- Reporting & tracking adverse events

Prevaccination Checklist – US CDC

Prevaccination Checklist for COVID-19 Vaccines



For vaccine recipients: Patient Name _____

The following questions will help us determine if there is any reason you should not get the COVID-19 vaccine today. Age _____

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.

	Yes	No	Don't know
1. Are you feeling sick today?			
2. Have you ever received a dose of COVID-19 vaccine?			
<ul style="list-style-type: none"> • If yes, which vaccine product did you receive? <input type="checkbox"/> Pfizer <input type="checkbox"/> Moderna <input type="checkbox"/> Another product _____ 			
3. Have you ever had an allergic reaction to:			
<small>(This would include a severe allergic reaction (e.g., anaphylaxis) that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</small>			
• A component of the COVID-19 vaccine, including polyethylene glycol (PEG), which is found in some medications, such as laxatives and preparations for colonoscopy procedures			
• Polysorbate			
• A previous dose of COVID-19 vaccine			
4. Have you ever had an allergic reaction to another vaccine (other than COVID-19 vaccine) or an injectable medication? <small>(This would include a severe allergic reaction (e.g., anaphylaxis) that required treatment with epinephrine or EpiPen® or that caused you to go to the hospital. It would also include an allergic reaction that occurred within 4 hours that caused hives, swelling, or respiratory distress, including wheezing.)</small>			
5. Have you ever had a severe allergic reaction (e.g., anaphylaxis) to something other than a component of COVID-19 vaccine, polysorbate, or any vaccine or injectable medication? This would include food, pet, environmental, or oral medication allergies.			
6. Have you received any vaccine in the last 14 days?			
7. Have you ever had a positive test for COVID-19 or has a doctor ever told you that you had COVID-19?			
8. Have you received passive antibody therapy (monoclonal antibodies or convalescent serum) as treatment for COVID-19?			
9. Do you have a weakened immune system caused by something such as HIV infection or cancer or do you take immunosuppressive drugs or therapies?			
10. Do you have a bleeding disorder or are you taking a blood thinner?			
11. Are you pregnant or breastfeeding?			

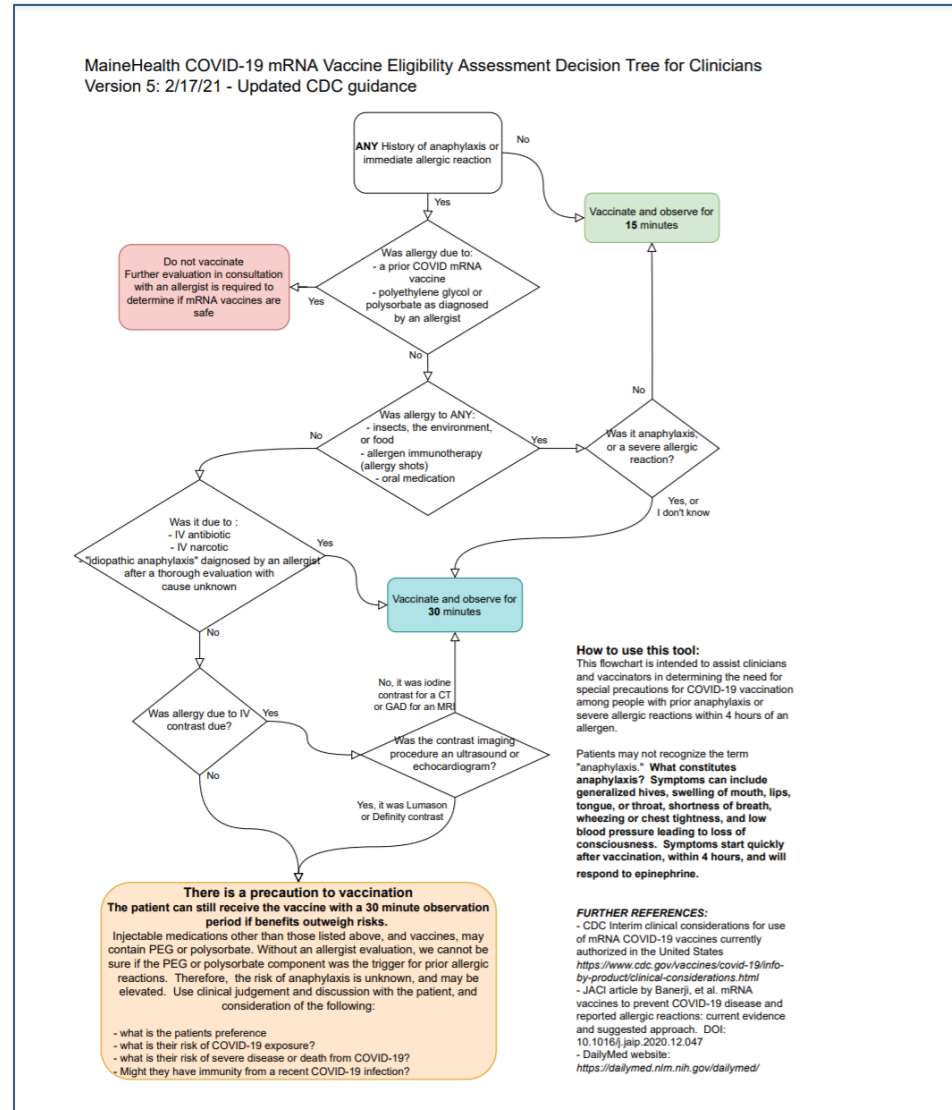
Form reviewed by _____ Date _____

01/05/2021 CS321629-E Adapted with appreciation from the Immunization Action Coalition (IAC) screening checklists 1

<https://www.cdc.gov/vaccines/covid-19/downloads/prevaccination-screening-form.pdf>

MaineHealth Vaccine Eligibility Algorithm

MaineHealth COVID-19 mRNA Vaccine Eligibility Assessment Decision Tree for Clinicians
Version 5: 2/17/21 - Updated CDC guidance



How to use this tool:
This flowchart is intended to assist clinicians and vaccinators in determining the need for special precautions for COVID-19 vaccination among people with prior anaphylaxis or severe allergic reactions within 4 hours of an allergen.

Patients may not recognize the term "anaphylaxis." What constitutes anaphylaxis? Symptoms can include generalized hives, swelling of mouth, lips, tongue, or throat, shortness of breath, wheezing or chest tightness, and low blood pressure leading to loss of consciousness. Symptoms start quickly after vaccination, within 4 hours, and will respond to epinephrine.

FURTHER REFERENCES:
- CDC Interim clinical considerations for use of mRNA COVID-19 vaccines currently authorized in the United States
<https://www.cdc.gov/vaccines/COVID-19/info-by-product/clinical-considerations.html>
- JACI article by Banerji, et al. mRNA vaccines to prevent COVID-19 disease and reported allergic reactions: current evidence and suggested approach. DOI: 10.1016/j.jaip.2020.12.047
- DailyMed website: <https://dailymed.nlm.nih.gov/dailymed/>

There is a precaution to vaccination
The patient can still receive the vaccine with a 30 minute observation period if benefits outweigh risks.
Injectable medications other than those listed above, and vaccines, may contain PEG or polysorbate. Without an allergist evaluation, we cannot be sure if the PEG or polysorbate component was the trigger for prior allergic reactions. Therefore, the risk of anaphylaxis is unknown, and may be elevated. Use clinical judgement and discussion with the patient, and consideration of the following:

- what is the patient's preference
- what is their risk of COVID-19 exposure?
- what is their risk of severe disease or death from COVID-19?
- Might they have immunity from a recent COVID-19 infection?

Triage – Allergy Considerations

Appendix B: Triage of persons presenting for mRNA COVID-19 vaccination

	CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
ALLERGIES	<p>History of the following are contraindications to receiving either of the mRNA COVID-19 vaccines[‡]:</p> <ul style="list-style-type: none"> 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[‡]* 	<p>Among persons without a contraindication, a history of:</p> <ul style="list-style-type: none"> Any immediate allergic reaction[‡] to other vaccines or injectable therapies[*] 	<p>Among persons without a contraindication or precaution, a history of:</p> <ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Do not vaccinate[*] Consider referral to allergist-immunologist 	<ul style="list-style-type: none"> Risk assessment 30-minute observation period if vaccinated Consider deferral of vaccination for further risk assessment and possible referral to allergist-immunologist 	<ul style="list-style-type: none"> 30-minute observation period: Persons with a history of anaphylaxis (due to any cause) 15-minute observation period: All other persons

* PEG and polysorbate are common excipients in many vaccines, injectable therapies, and other products. Persons with a known (diagnosed) allergy to PEG, another mRNA vaccine component, or polysorbate, have a contraindication to vaccination. Persons with a reaction to a vaccine or injectable therapy that contains multiple components, one of which is PEG, another mRNA vaccine component or polysorbate, but in whom it is unknown which component elicited the immediate allergic reaction have a precaution to vaccination.

[‡] 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 B 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

Allergy References

ARTICLE IN PRESS

Special Article

mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Suggested Approach

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The U.S. Food and Drug Administration (FDA) has recently issued an Emergency Use Authorization (EUA) for 2 highly effective coronavirus disease 2019 (COVID-19) vaccines from Pfizer-BioNTech and Moderna. This has brought hope to millions of American in the midst of an ongoing global pandemic. The FDA EUA guidance for both vaccines is to not administer the vaccine to individuals with a known history of a severe allergic reaction (eg, anaphylaxis) to any component of the COVID-19 vaccine. The Centers for Disease Control and Prevention (CDC) additionally advises individuals with a history of an immediate allergic reaction to a vaccine or injectable or any history of anaphylaxis be observed for 30 minutes after COVID-19 vaccination. All other individuals should be observed for 15 minutes after COVID-19 vaccination. Staff at vaccine clinics must be able to identify and manage anaphylaxis. Post-FDA EUA, despite very strong safety signals in both phase 3 trials, reports of possible allergic reactions have raised public concern. To provide reassurance and support during widespread global vaccination, allergists must offer clear guidance to individuals based on the best information available, but also in accordance with the broader recommendations of regulatory agencies. This review summarizes vaccine allergy epidemiology and proposes drug and vaccine allergy expert opinion informed risk stratification for Allergy specialist use in conjunction with

guidance of public health and regulatory authorities. The risk stratification schema guide care for (1) individuals with different allergy histories to safely receive their first mRNA COVID-19 vaccine and (2) individuals who develop a reaction to their first dose of mRNA COVID-19 vaccine. © 2020 American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2021;■:■-■)

Key words: mRNA; COVID-19; Vaccine; Allergy; Allergic reactions; Anaphylaxis; Guidelines; Risk stratification; Polyethylene glycol; Polysorbate

INTRODUCTION

Vaccination, one of the most effective public health interventions modern medicine can offer, has become increasingly relevant as the global pandemic from coronavirus disease 2019 (COVID-19) continues to worsen throughout the world. In the United States, the pandemic has risen to crisis levels in every state, setting records with tens of thousands of new cases reported daily and deaths mounting. As of January 9, 2021, more than 89 million people globally have had confirmed infections and almost 2 million have died of COVID-19.¹ Medical necessities are often in short supply, hospitals are overwhelmed, and health care

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Vertex, Regeneron, and Biocryst; is codirector of IID Pty Ltd, which holds a patent for HLA-B*57:01 testing for abacavir hypersensitivity, and has a patent pending for Detection of Human Leukocyte Antigen-A*32:01 in connection with Diagnosing Drug Reaction with Eosinophilia and Systemic Symptoms without any financial remuneration and not directly related to the submitted work. Funders

Allergy References

- www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html
- www.cdc.gov/vaccines/covid-19/downloads/pre-vaccination-screening-form.pdf
- Medication look up for Polysorbate and PEG:
dailymed.nlm.nih.gov/dailymed/index.cfm
- Vaccine look up for Polysorbate:
www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/b/excipient-table-2.pdf
- www.jaci-inpractice.org/action/showPdf?pii=S2213-2198%2820%2931411-2

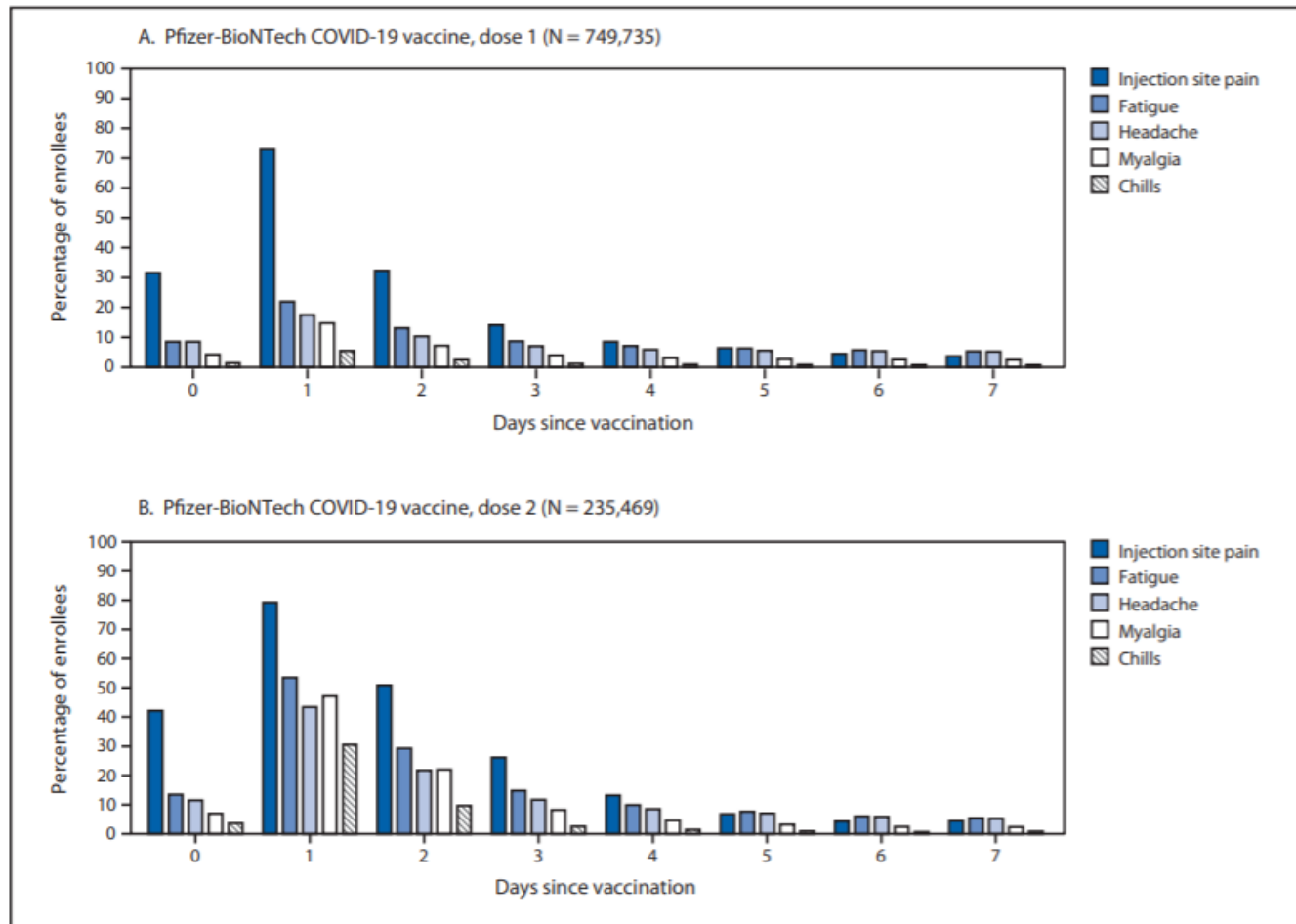
J&J Adenovirus Vector Vaccine

- Single dose vaccine, no special cold-storage requirements
- Single dose 72% effective in US, 66% effective across all sites at preventing moderate to severe COVID-19 at 28D post-vaccination
- 85% effective across sites in preventing severe disease
- 100% efficacy preventing hospitalization & death
- Single dose & no cold storage requirements allow for wider distribution across settings
- More rapid vaccination of large groups offers communities important protection
- Anticipate FDA review Feb 26

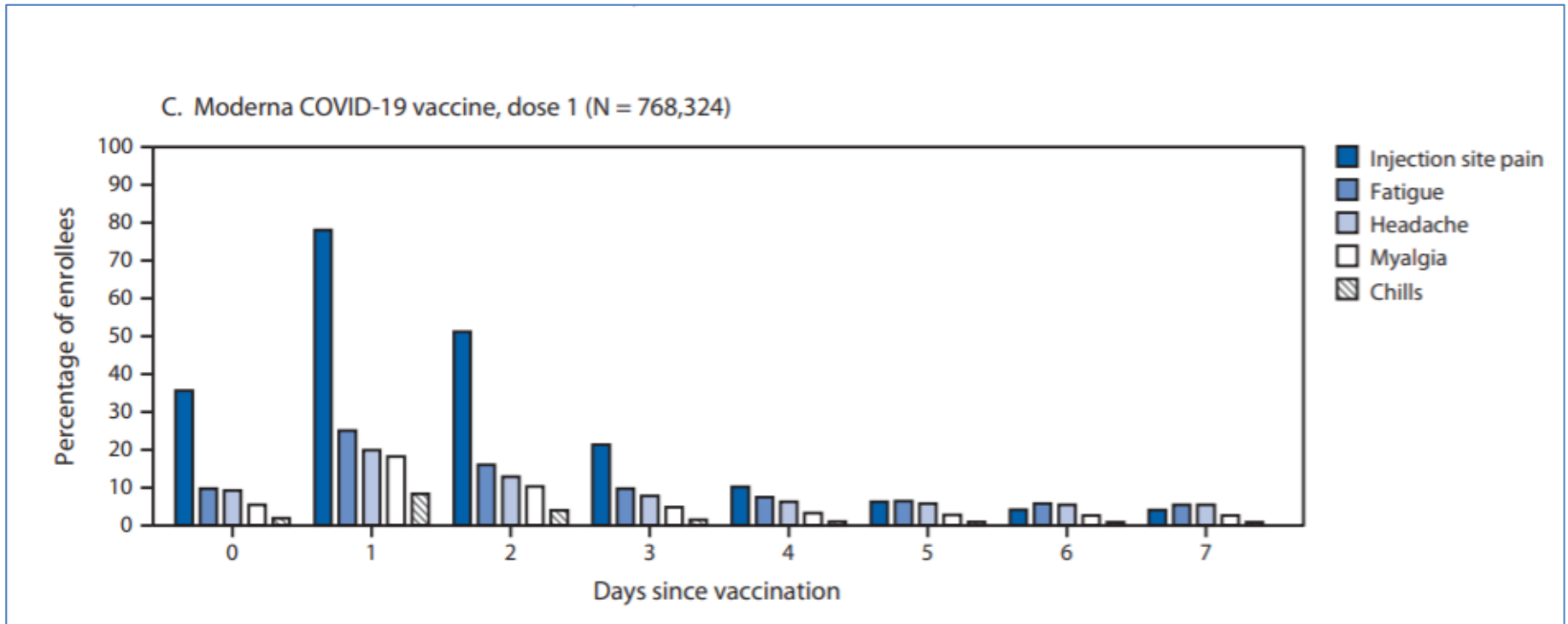
www.jnj.com/johnson-johnson-announces-single-shot-janssen-covid-19-vaccine-candidate-met-primary-endpoints

Pfizer Vaccine: First Month Safety Monitoring

FIGURE. Percentage of enrollees who reported common local and systemic reactions by day after receipt of the first dose of Pfizer BioNTech COVID-19 vaccine (A), second dose of Pfizer BioNTech COVID-19 vaccine (B), and first dose of Moderna COVID-19 vaccine (C) — v-safe, United States, December 14, 2020–January 13, 2021



Moderna: First Month Safety Monitoring



<https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/>

Promoting Vaccine Equity

ME DHHS Health Equity monthly webinars

- 3rd Wed/mo, 7:30 – 8:30AM
- **Register in advance** for monthly series:
<https://zoom.us/meeting/register/tJcsfuGvpj0jGdaRiW5Y15qnYa2AMVriHgal> , *OR*
- **Log on at the time of the webinar** with following link: <https://zoom.us/j/93198786932>
– Meeting ID: 931 9878 6932, Passcode: 4FrT7H

Promoting Racial/Ethnic Equity

WHY ARE YOU ASKING MY RACE AND ETHNICITY?

We care about equity.

Maine is committed to ensuring that COVID-19 vaccines are distributed equitably to all Mainers. We understand that the pandemic has disproportionately affected Black, Latinx, Asian and Tribal populations and want to ensure that vaccines reach those communities.

We want to serve your needs.

Like other demographic data, this information helps state and local entities understand how programs and policies are working for various groups. We use the data to make changes to those programs and policies so they are culturally and linguistically tailored to communities. In short, it holds us accountable and helps us to better serve your needs.

To help ensure equal opportunity.

We have an obligation to detect and deal with apparent inequity. Government, policy makers, and advocates use this data to identify potential gaps and advocate for change that improves the lives of communities.

What about privacy? Race v. ethnicity?

We compile this information to create statistics for groups of people that share particular answers. We do not disclose personally identifying information. We are legally bound to strict confidentiality requirements. Individual records are not shared with anyone, including state agencies and enforcement entities.

Race is a socially determined category used to describe real or perceived differences between groups of people. **Ethnicity** is a socially determined category used to describe nationality, or shared custom or culture. We use standard categories that allow us to compare across other systems and states. We understand the categories may not be the way you would normally describe yourself.



Getting Vaccinated for COVID-19

January 2021



Fighting the pandemic has been hard, but now we have vaccines to protect us from COVID-19.



The vaccine is provided at no cost to you.
The federal government will cover the cost of your vaccine. You should not be charged or billed. Your provider should also not charge you for an office visit if you only go in to get the vaccine.

You will need to get two doses of the Moderna or Pfizer-BioNTech vaccines.



You will get two doses of the Moderna or Pfizer-BioNTech vaccine, three to four weeks apart. You must get the second dose from the same manufacturer as the first dose. You should also plan to get both doses at the same vaccination site.



Both available vaccines are safe and effective.
The vaccines are very effective. The U.S. Food and Drug Administration (FDA) authorized the vaccines for emergency use and found no serious safety concerns. Independent experts agree the vaccines are safe and effective.



People at highest risk will get the vaccine first.
Maine's supply of vaccine is very limited, so Maine has focused on saving the lives of those at greatest risk of illness or death from COVID-19 and protecting those directly engaged in the fight against the virus. As Maine gets more vaccine doses, more people will be able to be vaccinated. It will take some time, but over time everyone will be able to get vaccinated when we have enough doses. Visit www.maine.gov/covid19/vaccines/vaccination-sites or call 211. (For interpreter services, say your language when the call is answered.)



You may feel side effects.
Like other routine vaccines, you may get a sore arm, fever, headaches, or fatigue after getting vaccinated. These are signs the vaccine is working.



Stay safe.
After you get the vaccine, wear your mask, stay six feet (two meters) apart, and avoid gatherings to protect those who have not yet been vaccinated.

Available in 10 languages

Are you a
Maine
Resident Age
70 or Older?



You are now eligible for
vaccination against COVID-19

Find a vaccine site near you

Click here: <https://www.maine.gov/covid19/vaccines/vaccination-sites>

During Your Vaccination Visit

Maintain physical distancing at least 2 meters/6 feet



You will receive a vaccination card

- Take a picture, save it, and bring it to your appointment for your second dose



Wear your mask



You will receive a fact sheet about which vaccine you received (Pfizer or Moderna)



Tell your vaccine provider if you have a history of previous severe allergic reactions



The COVID-19 vaccine is free if you are uninsured

- If you have insurance (private or Medicare); Bring your insurance card



Share with other community members that you received the vaccine



You will be asked to self report race and ethnicity

- By doing so, you are ensuring vaccine equity distribution
- Data won't be used against you

Important resources

Find FAQs about the vaccine here:
<https://www.maine.gov/covid19/vaccines/public-faq>
Select target language

What to expect after getting a COVID-19 Vaccine:
<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html>
Select target language

Information for MaineCare Members:
<https://www.maine.gov/dhhs/sites/maine.gov.dhhs/files/inline-files/Vaccine-Info-Sheet-January-2021.pdf>

City of Portland Public Health Division's Minority Health Program

State COVID Vaccine Updates

- [Maine residency requirement](#)
- ME CDC HAN – [Notifiable Conditions update](#) – ongoing monitoring for variants
- ME DHHS “[Full Use Policy](#)”
- Opportunities for [Community Collaborative proposals](#)
- Adherence to State of Maine priority [Phases](#)
- Walgreens & Walmart vaccination sites

Maine Phases for Vaccine Distribution*

Phase 1a

- Health Care Personnel
- Residents & staff of long-term care facilities
- Public safety
- State COVID response critical personnel



Phase 1b

- Older adults
 - ≥ 70 yo¹
 - 65-69 yo²
- Persons with high-risk medical conditions
- Front line essential workers



Phase 1c

- Other essential workers

Phase 2

- Persons aged 16-64 & not already eligible


*Updates posted to Gov Mills COVID Vaccine website: www.maine.gov/covid19/vaccines

¹ 70+yo: Currently being vaccinated

² 65-69yo: Anticipate starting vaccination early March

NOTE: Facilities booking appts listed at: www.maine.gov/covid19/vaccines/vaccination-sites


Gov Mills Info COVID Vaccine



STATE OF MAINE
Covid-19 Response
Office of the Governor

Home

Home → Vaccines



COVID-19 Vaccination in Maine

Maine is committed to an accessible, flexible, and equitable vaccination effort.

Due to limited vaccine supply, our vaccination strategy has two immediate goals:

1. Save the lives of Maine people at greatest risk of serious illness or death from COVID-19.
2. Protect those directly engaged in the fight against COVID-19.

Once vaccine supply increases, Maine will offer vaccination to everyone as soon as possible.

To learn more about this process and when you can expect your COVID-19 vaccination, please consult our [FAQs](#) and [Latest Updates](#).

[See the list of COVID-19 vaccination sites in Maine](#)

View Maine's COVID-19 vaccination dashboard

296,253	
Doses Administered	
200,322	95,931
First Dose	Final Dose
Data refreshed: Feb 22, 2021	
Microsoft Power BI	

Gov Mills Info COVID Vaccine



Maine is currently in Phase 1b.

Please review the groups and phases below to learn when you are eligible for vaccination. While vaccination is planned to proceed in this order -- starting with the first group in each phase and then advancing to the next -- some overlap and flexibility is expected. As of early February, only older Mainers -- those 70 and older -- qualify for vaccination in Phase 1b.

- Phase 1a: December through January
- Phase 1b: February through April

Now eligible for vaccination:

- Maine Residents Age 70+

Eligibility pending due to insufficient supply:

- Maine Residents Age 65-69
- Adults of all Ages With High-Risk Medical Conditions
- Certain Critical Front Line Workers

- Phase 1c: May and June
- Phase 2: June and Beyond

[Read detailed descriptions of each phase to determine when you are eligible for vaccination.](#)

Gov Mills Info COVID Vaccine

The screenshot shows a web browser window with the URL [maine.gov/covid19/vaccines](https://www.maine.gov/covid19/vaccines). The page title is "When can I get vaccinated?". Below the title, a paragraph explains that due to limited vaccine supply, Maine uses a phased approach. The main content area is divided into two sections: "Maine is currently in Phase 1a." and "How to get a vaccination".

When can I get vaccinated?

Due to the limits on vaccine supply, Maine is using a phased approach to providing vaccines. While vaccination is planned to proceed consecutively through the groups and phases below, flexibility in order is expected to ensure Maine maximizes every dose it receives.

Maine is currently in Phase 1a.

Given the limited supply, only Maine residents may receive a vaccine in Maine at this time.

- Phase 1a: December through January
- Phase 1b: February through April
- Phase 1c: May and June
- Phase 2: June and Beyond

[Read detailed descriptions of each phase and when you are eligible for a vaccine.](#)

How to get a vaccination

Phase 1a	Phase 1b	Phases 1c and 2
Health care, public safety, and critical COVID-19 infrastructure personnel eligible for vaccination in Phase 1a should contact their employer or their professional associations to learn how to get a vaccine.	People age 70 and over may begin getting vaccinated now, subject to vaccine availability and health system readiness. A list of COVID-19 vaccination sites for people 70 and over is now available here. Additional sites will be added as vaccinations are scheduled. Vaccination information for other Phase 1b groups, including Maine people aged 65-69 , will be posted here once available.	Vaccination information for all other people eligible in future phases will be posted here as soon as it is available.

ME CDC COVID Vaccine Resources

The screenshot shows the website <https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/index.shtml>. The page is titled "Division of Disease Surveillance" and "Maine Center for Disease Control & Prevention". A red banner at the top reads "Coronavirus Disease 2019 (COVID-19) - Updates and Information". The main content area is titled "COVID-19 Vaccine Providers Portal" and contains eight circular icons representing different resources: "COVID-19 Vaccine Provider Enrollment", "COVID-19 Vaccine Storage & Handling", "COVID-19 EUA Fact Sheets/VIS Forms/Standing Orders", "COVID-19 Vaccine Safety", "COVID-19 Communications", "U.S. CDC COVID-19 Website", "State of Maine COVID-19 Vaccine Orders (PDF)", and "COVID-19 Vaccine Info for Clinicians". A blue arrow points to the "COVID-19 Vaccine Info for Clinicians" icon. The left sidebar includes a "Report a Disease" button and a "2-1-1 Social Services Help" logo.

[ME CDC COVID-19 Vaccine Resources](https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/index.shtml)

www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/index.shtml

Vaccine questions? Email:
C19vaccine.MECDC@maine.gov

Presenters

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COVID-19 Vaccines

Questions??