

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

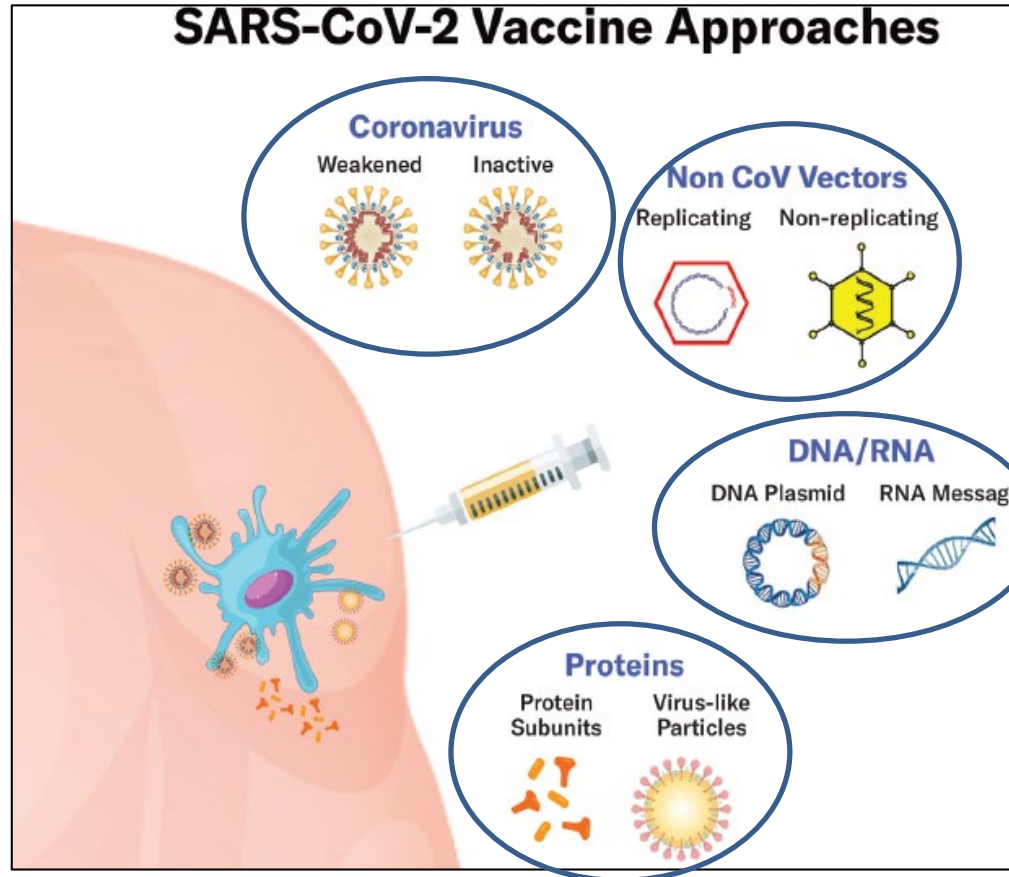
The planners and faculty for this activity do not have any relevant financial relationships to disclose with any Commercial Interests and do not have any conflicts of interest to resolve

COVID-19 Vaccines – Info for Clinicians

- Context
- Science of vaccines
- Clinical trials
- **New vaccines – J&J**
- **US CDC updates**
- Promoting vaccine equity
- Building vaccine confidence
- Reporting & tracking adverse events
- **State vaccination priorities & distribution**
- **ME DHHS vaccination resource updates**

Major Types of COVID Vaccines

- Weakened or inactive virus vaccines



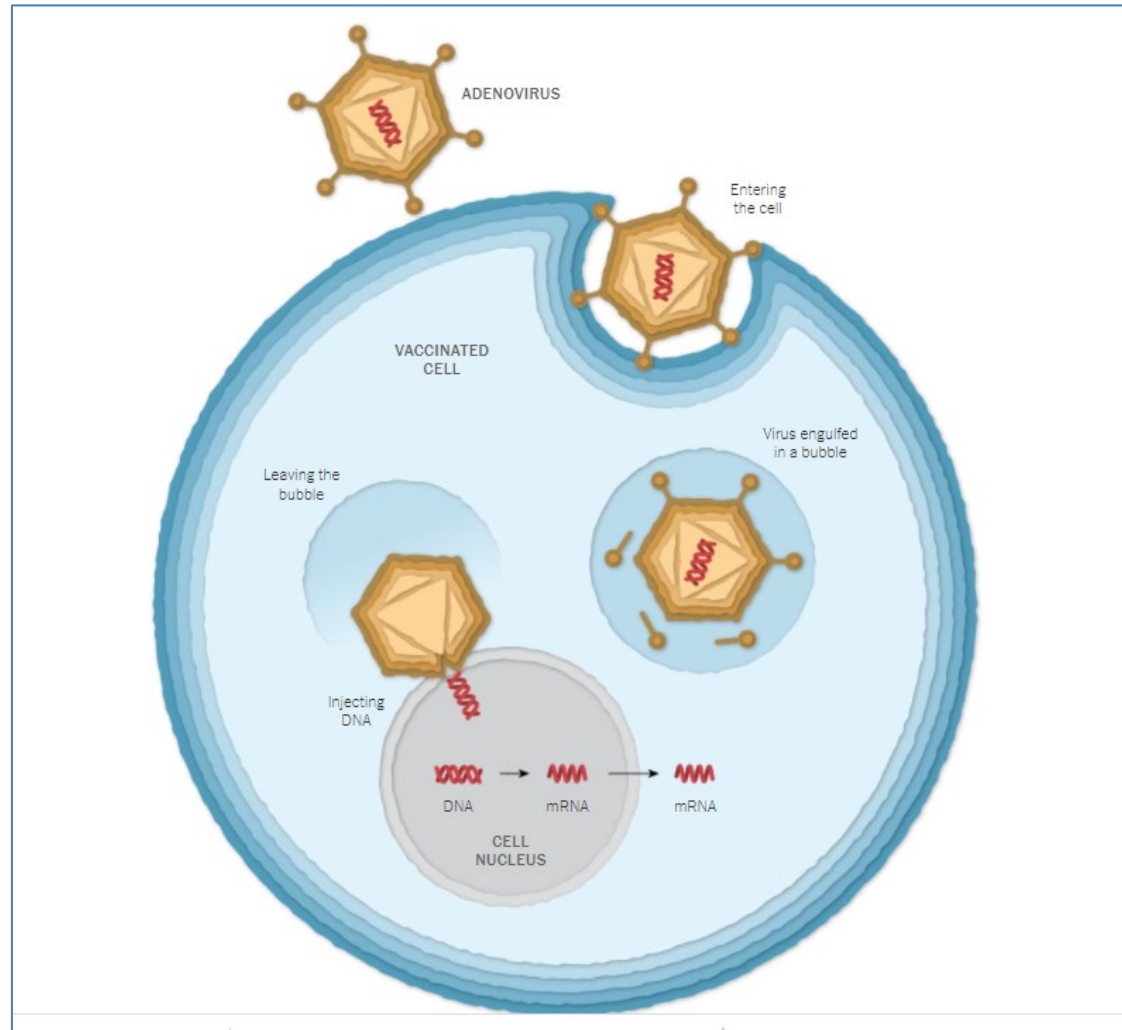
- Viral vector vaccines

- Nucleic acid (mRNA) vaccines

- Protein-based vaccines

How Viral Vector Vaccines Work

- Coronavirus gene segment embedded in attenuated viral vector (Ad26)
- Ad26 vector enters cell, releases DNA segment
- Triggers production of mRNA that codes for production of coronavirus spike protein
- Spike protein triggers anti-COVID immune response



J&J Vaccine Phase 3 Clinical Trials

- Included 43,783 adults (>18yo, 45% female)
 - 21,895 rec'vd vaccine vs. saline placebo
- Multiple countries: US, Brazil, So Africa, Colombia, Argentina, Peru, Chile, Mexico)
- Diverse populations:
 - 59% White; 19% Black; 3% Asian; 10% AI/AN
 - 45% Hispanic
- Median age: 52yo
 - 19.5% were 65yo & older; 3.7% were 75yo & older
- Participants 9.6% seropositive for COVID
- Known pregnancy excluded

J&J Vaccine

- FDA Emergency Use Auth (EUA) February 27, 2021
- Efficacy preventing moderate to severe/critical illness at 28D post-vaccination:
 - All clinical trial sites/countries: 66.3%
 - US participants: 72%
- 85% effective across sites preventing severe disease
- 100% effective preventing hospitalizations at 28D
- 100% effective preventing death
- Minimal adverse reactions
- One reported anaphylactic reaction
- Single dose & no special cold storage requirements

J&J Vaccine Safety Profile

- Most common adverse reactions:
 - Local injection site pain: 49%
 - Headache: 39%
 - Fatigue: 38%
 - Myalgias: 33%
 - Nausea: 14%
- Severe allergic reactions rare: only 1 reported to date
- NOTE: Same recommendations for post-vaccine observation as mRNA vaccines – i.e.
 - 30' for persons with hx of immediate allergic rxn to vaccines or h/o anaphylaxis of any cause
 - 15' for all others

COVID Vaccines & Efficacy

Company	Platform	Doses	Number of vaccine recipients	Protection from COVID-19 hospitalization at 28D post-dose 2	Protection from severe COVID-19 (+/- hospitalized)	Efficacy vs milder COVID-19 disease
Moderna	mRNA	2	~15,000	100%	100% (30 cases in placebo; 0 in vaccine reported, though 1 per FDA)	94.1%
Pfizer	mRNA	2	~18,600	100%	100% (9 cases in placebo arm; 0 in vaccine)	95%
Johnson & Johnson	Non-replicating human adenovirus vector	1	~22,000 in US, Latin America, South Africa	100%	85% across 3 sites (89% in S Africa where nearly all were variant)	72% US, 66% Latin America; 57% S Africa
AstraZeneca	Non-replicating chimp adenovirus vector	2	~8500	100%	100% (15 hospitalized in placebo arm; 0 in vaccine arm)	70% overall
Novavax	Spike protein/adjuvant	2	~9700 (Phase 3 UK; 2b SA)	100%	100% (but only 1 severe in placebo)	89.3% UK; 60% SA
Sputnik V	Ad26/AdS adenovirus vector	2	~15,000	100%	100% (20 in placebo arm; 0 vaccine arm)	91.6%

Adapted from table courtesy of Monica Gandhi, MD, MPH, UCSF , Feb 18, 2021¹⁰

J&J Vaccine: What's Included & What's Not

- J&J vaccine contains...
 - Recombinant, replication-incompetent adenovirus type 26 expressing SARS-CoV-2 spike protein
 - Polysorbate-80
 - Salts & sugars
- Vaccine does NOT contain...
 - Coronavirus
 - Thimerosal
 - Mercury
 - Eggs
 - Pork products
 - Polyethylene glycol (PEG)
 - Gelatin
 - Latex
 - Preservatives
 - GPS devices/microchips

J&J Vaccine & Fetal Cell Lines

- J&J vaccine developed using PER.C6 human fetal cell line
- Human cells from this cell line were used to grow vector adenovirus (Ad26) component of J&J vaccine
- Fetal cells are used in vaccine development because of their excellent ability to grow viruses
- Vaccines developed using these cell lines do NOT contain fetal cells
- J&J info: “Each dose may also contain residual amounts of host cell proteins (≤ 0.15 mcg) and/or host cell DNA (≤ 3 ng)”

J&J Vaccine – Patient Talking Points

- J&J is excellent vaccine
- Efficacy numbers in US are better than global efficacy
 - Likely related to larger impact of viral variants in other countries
- Efficacy of vaccines measured at different times & in different areas can't be directly compared
 - Pfizer & Moderna studied ~4 mos ago, before variants emerged
 - Moderna studied in US only
- Prevents severe disease & death: 100% effective in preventing death from COVID
- With single dose makes it easier to take
- No special refrigeration requirements; easier to distribute
- Getting more people vaccinated quickly is fastest way to get ahead of COVID variants & to end pandemic

COVID Vaccines: Key Similarities & Differences

Pfizer BioNTech

- mRNA vaccine
- Trial with >44,000 in multiple countries
- Efficacy 94.5%
- Minimal adverse rxn's
- 2nd dose at 21D
- Auth'd for ≥16yo
- Storage at -70C
- Can be refrigerated for 5D

Moderna

- mRNA vaccine
- Trial with >30,000 in US
- Efficacy >94.1%
- Minimal adverse rxn's
- 2nd dose at 28D
- Auth'd for ≥18yo
- Storage at -20C
- Can be refrigerated for 30D

J&J/Janssen

- Viral vector vaccine
- Trial with >43,800 in multiple countries
- Efficacy >66.1% overall, 72% in US
- Minimal adverse rxn's
- Single dose only
- Auth'd for ≥18yo
- Storage at 2°C to 8°C (36°F to 46°F)

Note: COVID vaccines *not* interchangeable; however, if first dose of mRNA vaccine was received but patient unable to complete with same or different mRNA vaccine, single dose of J&J COVID-19 vaccine may be administered at minimum interval of 28 days from mRNA dose

US CDC Updates for Fully-Vaccinated

Fully vaccinated people *in non-healthcare settings* can:

- Visit with other fully vaccinated people indoors without wearing masks or physical distancing
- Visit with unvaccinated people from single household who are at low risk for severe COVID-19 disease indoors without wearing masks or physical distancing
- Refrain from quarantine and testing following known COVID exposure if asymptomatic

US CDC Updates for Fully-Vaccinated

For now, fully vaccinated people should continue to:

- Take precautions in public (e.g. wearing well-fitted mask, physical distancing)
- Wear masks, practice physical distancing, and adhere to other prevention measures when visiting with...
 - Unvaccinated people at increased risk for severe COVID-19 disease, OR
 - People who have unvaccinated household member who is at increased risk for severe COVID-19 disease, OR
 - Unvaccinated people from multiple households
- Avoid medium- and large-sized in-person gatherings
- Get tested if experiencing COVID-19 symptoms
- Follow guidance issued by individual employers
- Follow CDC and health department travel requirements and recommendations

www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

US CDC Clinical Considerations - Updates

- Co-administration with other vaccines:
 - Vaccine series should routinely be administered alone, with min interval of 14D before or after administration of other vaccines
 - However, COVID-19 and other vaccines may be administered within shorter period when benefits of vaccination deemed to outweigh potential unknown risks of vaccine coadministration
- For pts who test COVID+ following full vaccination (ie. ≥ 2 weeks after 2-dose mRNA series or after single J&J):
 - Clinicians encouraged to request specimen be held
 - Report case to ME CDC Epi staff (Tel 800.821.5821)
 - Report case to VAERS

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

US CDC Clinical Considerations - Updates

- Approach to immunocompromised pts:
 - People with HIV infection, other immunocompromising conditions, or those taking immunosuppressive medications [might be at increased risk for severe COVID-19](#)
 - No data available to establish COVID-19 vaccine safety and efficacy in these groups; people with stable HIV infection were included in clinical trials, though data remain limited
 - However, currently authorized COVID-19 vaccines are not live vaccines and therefore can be [safely administered to immunocompromised people](#) – i.e. immunocompromised people can receive COVID-19 vaccination
 - Data currently insufficient to inform optimal timing of COVID-19 vaccination; however, based on [general best practices for vaccination of immunocompromised people](#), ideally vaccination should be completed at least 2 weeks before initiation of immunosuppressive therapies
 - When not possible to administer complete COVID-19 vaccine series in advance, people on immunosuppressive therapy can still receive COVID-19 vaccination
 - Decisions to delay immunosuppressive therapy to complete COVID-19 vaccination should consider the person's risks related to their underlying condition
- Antibody testing not currently recommended following COVID-19 vaccination; clinical utility of post-vaccination testing has not been established

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

Updated Approach to Allergy Considerations

- People with contraindication to one of mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna)
- However, people with contraindication to mRNA COVID-19 vaccines may be able to receive Janssen COVID-19 vaccine, and vice versa, provided certain measures are taken (see “precautions”)
- Known polysorbate allergy no longer contraindication to mRNA vaccination, but is a precaution to mRNA vaccines
- However, known polysorbate allergy is contraindication to J&J COVID-19 vaccine and thus, precaution to mRNA COVID-19 vaccination
- People with contraindication to J&J COVID-19 vaccine (e.g. known polysorbate allergy) may be considered for mRNA vaccines

Updated US CDC Triage for Allergy Issues

Appendix B: Triage of people presenting for COVID-19 vaccination

CONTRAINDICATION TO VACCINATION	PRECAUTION TO VACCINATION	MAY PROCEED WITH VACCINATION
<p>History of the following:</p> <ul style="list-style-type: none"> Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the vaccine† Immediate allergic reaction* of any severity after a previous dose or known (diagnosed) allergy to a component of the vaccine† 	<p>Among people without a contraindication, a history of:</p> <ul style="list-style-type: none"> Any immediate allergic reaction* to other vaccines or injectable therapies‡ <p>Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 vaccine, and vice versa. See footnote for additional information on additional measures to take in these people.#</p>	<p>Among people 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
<p>Actions:</p> <ul style="list-style-type: none"> Do not vaccinate. Consider referral to allergist-immunologist. Consider other vaccine alternative.† 	<p>Actions:</p> <ul style="list-style-type: none"> Risk assessment Consider referral to allergist-immunologist 30-minute observation period if vaccinated 	<p>Actions:</p> <ul style="list-style-type: none"> 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people

† See [Appendix C](#) for a list of ingredients. People with a contraindication to one of the mRNA COVID-19 vaccines should not receive doses of either of the mRNA vaccines (Pfizer-BioNTech or Moderna).

* 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.

State COVID Vaccine Updates

- Continue with Gov Mills age-based strategy, ideally:
 - March: 60+yo
 - April: 50+yo
 - May: 40+yo
 - June: 30+yo
 - July: 29yo and under, including children pending auth's
- Per fedl mandate, added school teachers & staff, child care
- Walmart, Walgreens, & Hannaford pharmacies now offering ~100 vaccination sites across state BUT these slots are limited to school teachers & staff & child care providers only
- HRSA distributing doses directly to some FQHCs (currently 2 FQHCs)

Maine Plan for Vaccine Distribution*

Phase 1a

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



All Other

- Older adults
 - ≥ 60 yo¹
- Then in successive 10yr age-bands²
 - April: 50yo & older
 - May: 40yo & older
 - June: 30yo & older
 - July and beyond: 29yo and under, including children pending authorization of vaccine for younger ages
- **NEW!** Per federal guidance, schools & child care (details TBD)

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

¹ 60+ yo: Currently being vaccinated

² 50-59yo: Anticipate starting vaccination early April

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

State COVID Updates: Transportation

- Maine DHHS offering free transportation to anyone needing ride to vaccination appt
- Managed by ModivCare (formerly LogistiCare), with contracts to CAPs & other agencies
- Individ's must first make vaccine appt
- Individ's with vaccine appt can schedule rides by calling tel. 1-855-608-5172 (Mon-Sat, 7A – 4P)
- Need to call at least 48hrs before vaccine appt
- Drivers will leave pts for appt, return at 60' or 90'

State COVID Updates: Call Line

- Community Vaccination Line: tel. 1-888-445-4111
- Available M-F: 7A -7P, & Sat-Sun: 8A - 2P
- Can help those who...
 - Do not have internet access
 - Need assistance connecting to or navigating online resources
 - Require interpretation assistance
 - Are home bound and need transportation
 - Have other questions about resources in their area
- *Will not provide faster access to clinic appts*

State COVID Updates

- ME DHHS updated COVID-19 Vaccine “[Full Use Policy](#)” encourages vaccine sites to never waste vaccine doses:
 - Sites can create waiting lists
 - Can offer “left-over” vaccine doses from opened vials to others outside of current age range
- Gov’s COVID Vaccine webpage includes [updated FAQs](#)
 - Vaccine eligibility limited to Maine residents, defined as “individual living in State of Maine with intent to remain indefinitely, or has entered State with job commitment and intends to live in Maine while working in Maine”
 - New section on vaccine eligibility for teachers, school staff, & child care workers

Ensuring Racial/Ethnic Equity

ME DHHS Equity webinar Wed, March 17, 7:30A

- **Register in advance** for this and additional webinars in 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
 - One tap mobile:
+13126266799,,93198786932#,,,0#,,416363#

***NOTE:** NO Clin Info Sessn Tues, Mar 16 (7:30A);
WILL hold Q&A session Fri, Mar 19 (12N)

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 that the categories may not be the way you would normally describe yourself.




Gov Mills Info COVID Vaccine

Online Services | Help | Search Maine.gov

STATE OF MAINE
Covid-19 Response
Office of the Governor

Home → Vaccines



COVID-19 Vaccination in Maine

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

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. Ensure vaccine providers can efficiently and quickly vaccinate as many people as possible.

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

[Find a COVID-19 vaccination site in Maine](#)

422,935 Doses Administered	
270,423 First Dose	152,512 Final Dose
Data refreshed: Mar 08, 2021	

Microsoft Power BI

[View Maine's COVID-19 vaccination dashboard](#)

Gov Mills Info COVID Vaccine

When can I get vaccinated?

To maximize our limited vaccine supply and ensure every dose is used to protect the health of Maine people, Maine is moving to an age-based approach for vaccination eligibility **effective March 3, 2021**. While vaccination is planned to proceed consecutively through the age groups outlined below, flexibility is possible based on vaccination progress and vaccine supply.

This age-based approach reflects recent data indicating age [is among the strongest predictors of whether a person may become seriously ill and die from COVID-19](#), offers greater certainty and predictability for Maine people to know when they are eligible for vaccination, and is easier for vaccine providers to implement and verify.



Vaccination Eligibility by Age

Effective March 3, 2021

Only Maine residents are eligible to receive a vaccine in Maine at this time. Exact dates for age-eligibility will be announced.

March 3: Age 60 and older

April: Age 50 and older

May: Age 40 and older

June: Age 30 and older

July: All ages, including children pending authorization of a child vaccine

[Find a COVID-19 vaccination site in Maine](#)

Gov Mills Info COVID Vaccine



People Age 60 and Older Now Eligible

Only Maine residents are eligible to receive a vaccine in Maine at this time. Exact dates for age-eligibility will be announced.

March 3: Age 60 and older

April: Age 50 and older

May: Age 40 and older

June: Age 30 and older

July: All ages, including children pending authorization of a child vaccine

[Find a COVID-19 vaccination site in Maine](#)

How to get a vaccination

COVID-19 Response Workers

Health care, public safety, and critical COVID-19 infrastructure personnel should contact their employer or their professional associations to learn how to get a vaccine.

Teachers, School Staff and Child Care Workers

Vaccination sites will soon start offering appointments to Maine PreK-12 teachers and school staff, and workers at licensed child care facilities. Federal policy directs Hannaford, Walgreens, and Walmart pharmacies to prioritize these workers. It may take time for appointments to become available. Age-eligible individuals may still also make a vaccine appointment at one of

Vaccination Sites

Age-eligible Maine residents are encouraged to make an appointment at a local vaccination site as soon as possible. **Maine residents age 60 and over** are now eligible for vaccination. [Find a vaccination site now.](#)

www.maine.gov/covid19/vaccines

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.

[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??