

Maine DHHS

COVID-19 Vaccines Clinical Updates

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COVID-19 Vaccines Discussion

- Overview of current COVID-19 vaccines & recent updates
- FDA approval of Pfizer COVID-19 vaccine
- Recent updates re: mRNA vaccine dosing:
 - Recommended 3rd dose for immunocompromised individuals
 - Anticipated recommendation for 3rd dose at ≥ 8 mos
- COVID-19 variants & vaccine efficacy
- Breakthrough COVID infections in vaccinated individuals
- Emergency rule for COVID vaccination in Health Care Workers
- Q&A

Current COVID-19 Vaccines: Key Similarities & Differences

Pfizer BioNTech

- mRNA vaccine
- Trial with >44,000 in multiple countries
- Efficacy in initial trials 94.5%
- Minimal adverse reactions
- 2nd dose at 21D
- FDA approved for ≥16yo
- FDA auth'd for 12-15yo
- Can be refrigerated for 30D

Moderna

- mRNA vaccine
- Trial with >30,000 in US
- Efficacy in initial trials 94.1%
- Minimal adverse reactions
- 2nd dose at 28D
- FDA auth'd for ≥18yo
- Can be refrigerated for 30D

J&J/Janssen

- Viral vector vaccine
- Trial with >43,800 in multiple countries
- Efficacy in initial trials >66.1% overall, 72% in US
- Minimal adverse reactions
- Single dose only
- FDA auth'd for ≥18yo
- Can be stored at room temp

COVID-19 Vaccines: What's New

- FDA has granted full approval for Pfizer COVID-19 vaccine for ages 16yo & above (8/23/2021)
- Granted under FDA Biologics License Approval (BLA)
- Pfizer vaccine also continues to be available under EUA for...
 - Individuals 12 through 15 yo
 - Administration of 3rd dose in certain immunocompromised individuals
- (Will now be marketed by Pfizer as Comirnaty)

www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine

3rd Dose COVID-19 Vaccine for Immunocompromised

- FDA authorized & US CDC now recommending 3rd dose of mRNA vaccine for moderately to severely immunocompromised people, specifically those who...
 - Have been receiving active cancer treatment for tumors or cancers of the blood
 - Received an organ transplant and are taking medicine to suppress the immune system
 - Received a stem cell transplant within the last 2 years or are taking medicine to suppress the immune system
 - Have moderate or severe primary immunodeficiency (such as DiGeorge syndrome, Wiskott-Aldrich syndrome)
 - Have advanced or untreated HIV infection
 - Are in active treatment with high-dose corticosteroids or other drugs that may suppress your immune response

3rd Dose COVID-19 Vaccine for Immunocompromised

- 3rd dose should be at least 28D after 2nd dose
- Interchangeability:
 - 3rd dose should be with same mRNA vaccine initially given
 - If mRNA vaccine product given for first two doses is not available or is unknown, either mRNA COVID-19 vaccine product may be administered
- Individuals should not receive more than three mRNA vaccine doses
- 3rd dose recommendation for moderately to severely immunocompromised people does *NOT* apply to those who received J&J vaccine
- US CDC does **not** recommend additional doses or booster shots for any other population at this time

Coming Soon?

3rd Dose mRNA COVID-19 Vaccines

- President Biden announced on 8/18/2021 that his administration plans to make Covid-19 vaccine booster shots available to all Americans starting on 20 September
- Cited rising infections from Delta variant
- Anticipate recommendation will be offering 3rd shot for those who completed mRNA vaccine series ≥ 8 mos prior
- Note: still awaiting...
 - FDA authorization for 3rd dose (outside of immunocompromised)
 - US CDC recommendation for 3rd dose

www.hhs.gov/about/news/2021/08/18/joint-statement-hhs-public-health-and-medical-experts-covid-19-booster-shots.html

COVID-19 Vaccines: What's Anticipated

- Moderna has filed for full FDA approval for vaccines in ages 12yo & above; FDA review process underway
 - Anticipate decision in ~4-6wks
- Pfizer & Moderna have filed for FDA Emergency Use Authorization (EUA) for vaccines in children 5-11yo
 - Anticipate decision by year end

Ordering COVID-19 Vaccine

- Providers participating in Maine Immunization Program & approved as COVID-19 Vaccine Providers can order COVID-19 vaccine through Pandemic Vaccine Ordering tool in ImmPact
- Minimum & maximum quantities available via ImmPact:

	Pfizer	Moderna	J&J
Minimum	1170	140	100
Maximum	7020	700	500

- Providers can also order less than minimum dose size by submitting email request to MIP:

C19Allocations.MECDC@Maine.gov

COVID-19 – Delta Variant: Current Status

- Has caused rapid spread Delta variant:
 - Early May 2021: <1% of COVID cases
 - Currently: >93% of all COVID cases in US
 - Last report: ~100% of all cases in Maine
- Presents significant risks to all, particularly unvaccinated individuals
- Reproduces faster = shorter incubation
- Produces more viruses = higher viral load

COVID-19 Vaccines & Efficacy Against Variants

- Studies have shown modest decrease in efficacy of COVID-19 vaccines in preventing infection with rise in viral variants
- BUT continue to show sustained high protection from severe COVID-19 infections requiring hospitalization

[Sustained Effectiveness of Pfizer & Moderna Vaccines Against COVID-19 Assoc'd Hospitalizations Among Adults - MMWR Aug 18, 2021](#)

COVID-19 Breakthrough Infection After Vaccination

- Since vaccine efficacy is ~90%, normal to have some level of “breakthrough” infection after vaccination
- Most vaccinated individuals with breakthrough infection have mild to no symptoms
- Many cases identified through routine surveillance in workplaces, etc.
- Vaccines remain highly effective in preventing COVID-related severe disease, hospitalization, & death
- 99% of all COVID deaths were in unvaccinated individuals

ME DHHS Emergency Rule for COVID-19 Vaccination in Health Care Workers

- On August 12, 2021, Mills Administration announced that health care workers in Maine must be fully vaccinated against COVID-19 by October 1, 2021
- Emergency rule amends long-standing [ME rule](#) that requires employees of designated health care facilities to have several immunizations to reduce risk of exposure to, and possible transmission of, vaccine-preventable diseases
- Maine CDC amended existing rule to include COVID-19 vaccine to protect health and lives of Maine people, safeguard Maine's health care capacity, limit COVID spread
- Emergency rule [available online](#) (see "Emergency" section)
- Rule in place for 90D; will be followed by proposed rule that will offer notice & comment period (in person or writing)

ME DHHS Emergency Rule for COVID-19 Vaccination in Health Care Workers

Designated Healthcare Facilities in rule:

Healthcare Facility	Designated in Amended Vaccination Rule?
Hospital	Yes
Nursing Facility	Yes
Residential Care Facility- Adult	Yes
Residential Care Facility- Children	No
Transitional Youth Shelters	No
Private Non-Medical Institution (PNMI)	Depends on Licensure: <ul style="list-style-type: none"> •If PNMI Adult Residential Care facility: Yes •If PNMI Child Residential Care facility: No •If Assisted Living: No
Waiver Group Home	Depends on Licensure: <ul style="list-style-type: none"> •If Residential Care facility: Yes •If Assisted Living: No
Multi-level Facility	Yes, if any part of the facility is subject to the rule.
Assisted Living Facility	No, unless part of a multi-level facility.
Shared Living Home	No
Community/Work Support Center	No
Adult Day Health Center	No, unless part of a multi-level facility.
Senior Center	No
School Based Health Clinic	No
Home Health Agencies	Yes
Personal Care Agencies	No
Hospice Facility	No, unless part of a multi-level facility.
Ambulatory Surgical Center	No, unless operated under hospital license.
Dental Practices	Yes
Emergency Medical Service (EMS) organizations	Yes

ME DHHS Emergency Rule for COVID-19 Vaccination in Health Care Workers

- [FAQs](#) available on Gov's COVID website:



The screenshot shows the State of Maine's COVID-19 Response website. At the top, it says "STATE OF MAINE Covid-19 Response Office of the Governor". Below that is a breadcrumb trail: "Home → Vaccines → Public FAQ → Health Care Worker Vaccination FAQs". The main content area features a large image of healthcare workers in a clinical setting, with a white text box overlaid that reads "COVID-19 Vaccination in Maine". Below the image, it says "Page last updated 08-19-2021." followed by the heading "Health Care Worker Vaccination FAQs". The text below the heading states: "On August 12, 2021, the Mills Administration [announced that health care workers in Maine must be fully vaccinated](#) against COVID-19 by October 1." It then explains that the State of Maine has long required immunization of employees at designated health care facilities to reduce the risk of exposure and transmission of vaccine-preventable diseases. Finally, it notes that these FAQs address mandatory COVID-19 vaccination of health care workers in Maine, with a link to the emergency rule issued on August 12, 2021.

Organizations Subject to the Immunization Rule

- 1. Which health care facilities are subject to the requirements for employee immunization?
- 2. What is a "multi-level facility"?

ME DHHS Emergency Rule for COVID-19 Vaccination in Health Care Workers

- Healthcare Worker Vaccination Rule Stakeholder Webinar: Fri, Aug 27, 2021, 11:00 AM
- Please register in advance for this webinar:
https://mainestate.zoom.us/webinar/register/WN_hh7M3FsERiGz2qp1RvOcuA
- After registering, you will receive confirmation email containing information about joining webinar
- ME DHHS representatives will briefly introduce rule and will take questions
- Participants encouraged to review [FAQ](#) before webinar

COVID-19 Vaccination for Nsg Home Staff

- President Biden announced on Aug 18 that federal government will be introducing requirement that all nursing home staff be COVID-19 vaccinated as condition for facility participation in Medicare & Medicaid payment
- CMS, in collaboration with US CDC, is currently developing new rule
- Cited data showing higher levels of staff vaccination linked to fewer outbreaks among residents, many of whom are at an increased risk of infection, hospitalization, or death
- Federal HHS indicating interim rule regarding this requirement should be out in September 2021

www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-action-protect-americas-nursing-home-residents-covid-19

Q&A

- Questions?
- Other issues?
- **NOTE: ME DHHS/CDC COVID-19 Clinician Info Sessions are regularly held on 2nd Tues/mo at 7:30AM (next on Sept 14) via Zoom or phone:**
<https://zoom.us/j/6218434986?pwd=dEJoNEVRSkVSN2dwZlJ5WEI3WjJsZz09>
Meeting ID: 621 843 4986
Passcode: 338847
One tap mobile: +13017158592,,6218434986#,,,,,0#,,338847#

Additional COVID Vaccine Resources

- [Coronavirus Disease 2019 \(COVID-19\) | US CDC](#)
- [COVID-19 Vaccine Communication Toolkit for Community-Based Organizations: Getting Started | CDC](#)
- [Maine COVID-19 Vaccines \(maine.gov\)](#)
- [Maine COVID-19 Vaccines FAQ](#)
- [Maine COVID-19 Vaccination Sites](#)
- [Maine COVID-19 Vaccination Dashboard](#)

Presenters

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