

Maine DHHS

COVID-19 Vaccines Clinical Updates

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August 2021



COVID-19 Vaccines Discussion

- Overview of current COVID-19 vaccines & recent updates
- COVID vaccine adverse events
 - Pericarditis/myocarditis
 - How to report adverse reactions (VAERS)
- Current status of COVID-19 variants
- Breakthrough COVID infections in vaccinated individuals
- Recent US CDC changes to masking recommendations
- Q&A

Current COVID-19 Vaccines: Key Similarities & Differences

Pfizer BioNTech

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

Moderna

- mRNA vaccine
- Trial with >30,000 in US
- Efficacy >94.1%
- Minimal adverse reactions
- 2nd dose at 28D
- Auth'd for ≥18yo
- 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 reactions
- Single dose only
- Auth'd for ≥18yo
- Can be stored at room temp

COVID-19 Vaccines: What's New?

- FDA continues to track vaccine stability over time, has updated “shelf-life” times for all vaccines
- Pfizer & Moderna have filed for full FDA approval for vaccines ages 12yo & above; FDA review process underway
 - Anticipate decision on Pfizer by early Sept 2021
 - Moderna decision likely ~6wks later
- ACIP meeting later this wk to consider potential benefits of 3rd vaccine for immunosuppressed patients
- Pfizer & Moderna are expanding clinical trials for 5-11yos, expect they will file for FDA Emergency Use Authorization (EUA) for children 5-11yo by year end

Myocarditis & Pericarditis

- ~1000 cases of myocarditis and pericarditis have been reported after mRNA COVID vaccines (Pfizer & Moderna) in adolescents and young adults; symptoms generally mild
- Remains rare event compared to number of vaccines given
- US CDC continues to recommend COVID-19 vaccination for all people 12yo+
- Clinicians should consult US CDC [Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults](#)
- Healthcare providers should report all cases of suspected myocarditis & pericarditis [VAERS](#)

Reporting Adverse Events to VAERS

How to report an adverse event to VAERS

- Go to vaers.hhs.gov
- Submit a report online
- For help:
 - Call 1-800-822-7967
 - Email info@VAERS.org
 - video instructions <https://youtu.be/sbCWhcQADFE>
- Please send records to VAERS ASAP if contacted and asked
 - HIPAA permits reporting of protected health information to public health authorities including CDC and FDA



What About Viral Variants?

- Variants expected as natural process of genetic mutations that occur with viral replication
- Best way to prevent emergence of more variants is through vaccination → less transmission → less viral replication → fewer opportunities for mutation
- Viral variants can cause virus to be more easily spread, potentially cause more serious disease
- Studies to date have shown all approved vaccines remain generally effective against variants

COVID-19 – Delta Variant: Why Worry?

- Much more transmissible
- Has caused rapid spread Delta variant:
 - Early May 2021: <1% of COVID cases
 - Currently: 83% of all COVID cases in US
 - Likely ~70-80% 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 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

US CDC Updated Recommendations for Vaccinated Individuals: Masking (7/27/21)

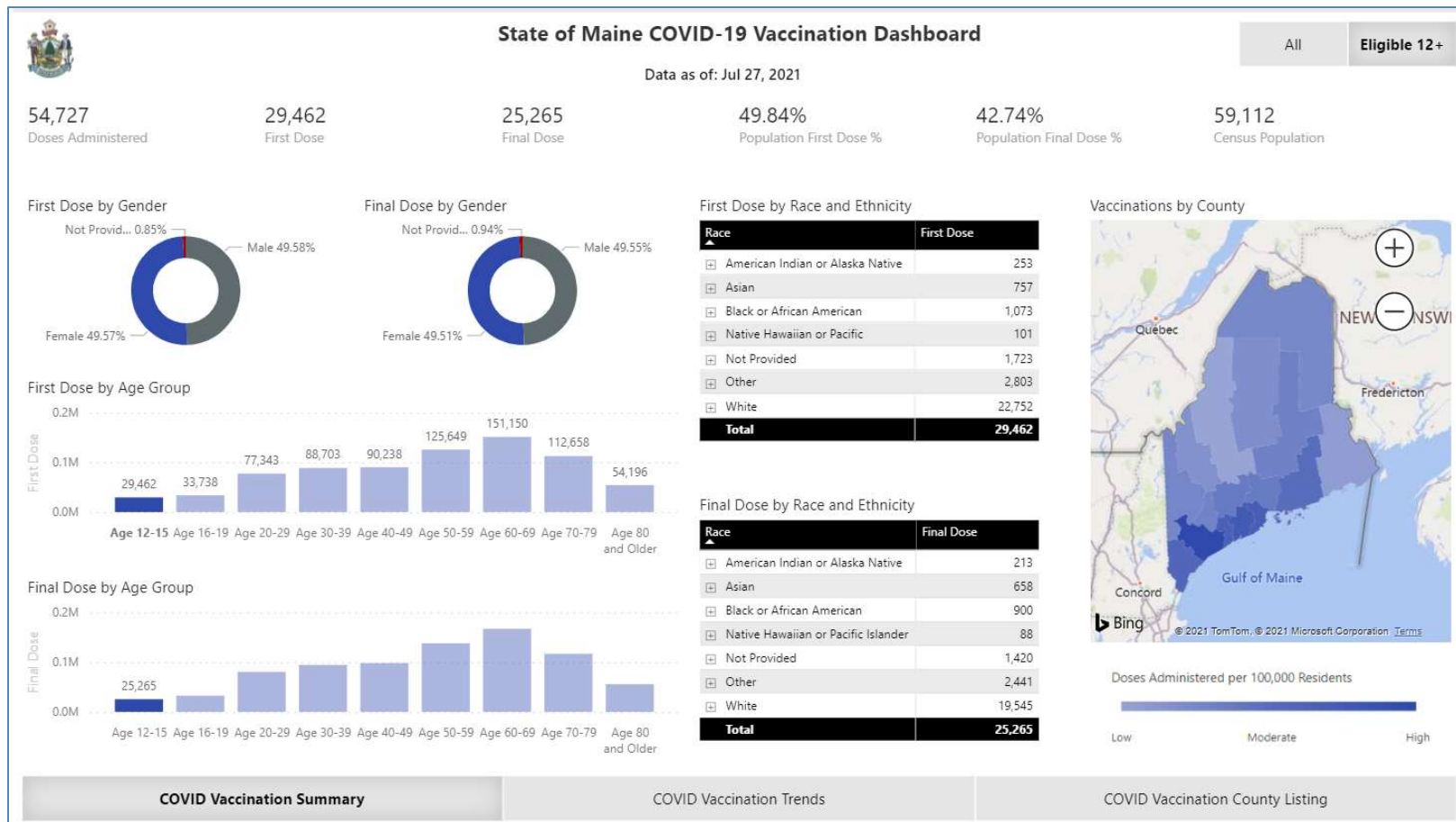
- US CDC recommends that fully vaccinated people wear masks indoors when in areas with "substantial" and "high" COVID-19 transmission (nearly 2/3'rds all US counties)
- To check Maine counties currently with "substantial" spread: www.maine.gov/covid19/
- Also rec's masking for all schools (teachers + students)
- Update driven by fact that vaccinated people infected with Delta variant can carry high levels of virus
- Masking helps protect self and others

US CDC Updated Recommendations for Vaccinated Individuals: Testing (7/27/21)

- US CDC new recommendations for vaccinated individuals with known “close contact” COVID exposure (i.e., contact within 6’ for 15mins or more):
 - Get COVID (PCR) test at 3-5D post-exposure
 - Wear mask until negative test results
 - (Vaccinated still don’t need to quarantine)
- Higher risk viral levels with Delta variant mean that even vaccinated people can get COVID, and/or transmit it to others

Maine Youth Covid-19 Vaccination Rates

- Currently, vaccine data is available by age group and county for youth. Zip code level data is available for all ages on the [COVID-19 Vaccination Dashboard | Covid-19 \(maine.gov\)](https://maine.gov/covid-19-vaccination-dashboard)



Maine Youth Covid-19 Vaccination Rates

- In mid-August, youth (age 10-19) vaccination rates (% and at least one dose) will be available at the SAU level via map
- Population estimates for each SAU come from the 2019 5-year American Community Survey ZIP code level population estimates.
 - Data suppressed if <5 students in this age group in the SAU
 - Youth vaccination rates reported to the Maine CDC through ImmPact

School Staff Vaccination Rates & Reporting

- High vaccination rates help ensure school safety
- Facilitates in-person learning and protects vulnerable students and staff
- DHHS is requiring school staff to report COVID – 19 vaccine rates effective September 1
- Vaccination rates (%) will be publicly posted to guide local decision-making safety policies
- Public reporting will resemble the [Maine Health Care Worker COVID-19 Vaccination Dashboard](#)

How to Assist Schools/SAUs to Raise Rates

1. Partner with SAUs: SAUs can complete a survey/application with COVID vaccination plans for 2021-2022. They can request help connecting to a vaccine provider through this link: [2021-22 School COVID Vaccine Clinic Survey and Application](#)
2. Share community/family resources for vaccination: [COVID-19 Vaccine Information & Resources](#)
3. Participate in community forums with schools, local medical and public health experts
4. Learn about additional resources about hosting a vaccination clinic in the [School Location Vaccine Clinic \(SLVC\) Toolkit](#)

Maine Immunization Program Communications Regarding Schools

- Sent letter to Providers on [Preparing Students for 2021-22 School Year 8 4 21.pdf](#) with focus on required school vaccines
- Hosting Webinar: Thursday, August 12th at noon, “Connecting Providers and Schools for COVID-19 Administration”
- As 2021-22 school year quickly approaches, we will be focusing efforts on promoting COVID-19 vaccination for adolescents within schools and community settings
- COVID-19 vaccination available for all children 12 years of age and older and will be the key to keeping Maine’s COVID-19 cases down throughout the school year
- If you are school nurse and interested in supplying COVID-19 vaccine to your students or are a provider interested in partnering with a local school to provide the COVID-19 vaccination, please join the Maine Immunization Program for virtual meeting to discuss plans for the fall. [Zoom Meeting](#) link.

Q&A

- Questions?
- Other issues?

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](#)

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