

Maine DHHS

COVID-19 Vaccines Information for Clinicians

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April 27, 2021



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

UPDATE!

- COVID-19 Vaccine Clinician Info Sessions moving in April to twice/monthly schedule
- Will host sessions on 2nd & 4th weeks/month
 - Tues 7:30AM (April 27, May 13 & onward)
 - Fri 12N (Apr 30, May 16 & onward)
- Will continue to record & post on CDC website
- Will also continue to host ME DHHS Health Equity webinar on 3rd Wed/mo (7:30AM)

COVID-19 Vaccines – Info for Clinicians

- Context
- Science of vaccines
- Clinical trials & emerging vaccines
- **Vaccine updates: J&J vaccine**
- **Addressing clinical questions**
- Reporting & tracking adverse events
- Impact of viral variants
- Promoting vaccine equity
- Building vaccine confidence
- **State vaccination priorities & distribution efforts**

J&J COVID-19 Vaccine: Last Week

- On Apr 13, US CDC & FDA recommended “pause” on use of J&J/Janssen COVID-19 vaccine to review data & potential actions
- Pause triggered by identification of 6 cases of cerebral venous sinus thrombosis (CVST) identified in combination with thrombocytopenia, w/ 1 death following administration of 6.85M doses of J&J vaccine
- All J&J vaccine use in Maine halted as of Apr 13 pending ACIP review of data & FDA/US CDC update

<https://www.cdc.gov/media/releases/2021/s0413-JJ-vaccine.html>

<https://emergency.cdc.gov/han/2021/han00442.asp>

J&J COVID-19 Vaccine: This Week

- Fri, Apr 23, US CDC & FDA lifted “pause” on use of J&J/Janssen vaccine following addnl review data & recommendation from ACIP
- Determined J&J vaccine benefits outweigh risks
- Addnl review identified total 15 cases of thrombosis-thrombocytopenia syndrome (TTS) following admin of 7.1M doses of J&J vaccine (includes original 6 cases)
- All of cases occurred in women between 18-59yo, with median age 37 yo; sx onset was 6-15D post-vaccination
- No cases of CVST have been reported in Maine
- Maine restarted use of J&J vaccine on Apr 24

www.fda.gov/news-events/press-announcements/fda-and-cdc-lift-recommended-pause-johnson-johnson-janssen-covid-19-vaccine-use-following-thorough

Thrombosis Thrombocytopenic Syndrome (TTS)

TTS is similar to Autoimmune Heparin Induced Thrombocytopenia

- Laboratory testing consistent with autoimmune heparin induced thrombocytopenia
 - Positive platelet factor 4 immunoassay and platelet activation assays
 - Platelet activation enhanced by addition of platelet factor 4
 - Platelet activation inhibited by high concentrations of heparin
 - Platelet activation blocked by intravenous immunoglobulin
- Clinical course consistent with heparin induced thrombocytopenia
 - Onset mirrors onset of autoimmune thrombocytopenia
 - Thrombosis and thrombocytopenia worsens with heparin treatment
 - Clinical manifestations improve with non-heparin anticoagulation and IVIG
- Etiology of Thrombotic Thrombocytopenia Syndrome is Unclear
 - Does not appear to molecular mimicry between platelet factor 4 and SARS-CoV2 spike protein
 - 0 of 222 patients with SARS-CoV-2 infection have platelet activating antibodies

Greinacher A, et al. N Engl J Med. 2021 Apr 9. PMID: 33835769. Greinacher A et al. Research Square April 16 2021

Management of TTS

Management of Thrombosis Thrombocytopenia Syndrome

- Maintain a high index of suspicion for any patient that presents with symptoms of a clot in association with thrombocytopenia after recent (within 3 weeks) administration of the J+J SARS CoV2 vaccine
- Confirm the thrombotic event
- Send testing for heparin-induced thrombocytopenia with platelet factor 4 immunoassay and platelet activation assay
- Consult a hematologist to confirm the diagnosis and rule out other diagnostic possibilities
- Treat clots with a non-heparin anticoagulant
- Treat the thrombocytopenia with intravenous immunoglobulin
 - Avoid platelet transfusions

American Society of Hematology COVID-19 Resources at <https://www.hematology.org/covid-19/vaccine-induced-immune-thrombotic-thrombocytopenia>

J&J COVID-19 Vaccine & TTS: US CDC COCA Call Tues, 4/27, 2PM

Johnson & Johnson/Janssen COVID-19 Vaccine and Thrombosis with Thrombocytopenia Syndrome (TTS): Update for Clinicians

Overview

This COCA Call will present the latest evidence on thrombosis with thrombocytopenia syndrome (TTS) after administration of the Johnson & Johnson/Janssen COVID-19 vaccine. Speakers will discuss information on TTS and updated vaccine recommendations.

Presenters

Sara Oliver, MD, MSPH

LCDR, U.S. Public Health Service

Co-lead, Advisory Committee for Immunization Practices COVID-19 Vaccines
Work Group

COVID-19 Response

Centers for Disease Control and Prevention

Tom Shimabukuro, MD, MPH, MBA

CAPT, U.S. Public Health Service

Vaccine Safety Team Lead

COVID-19 Response


Centers for Disease Control and Prevention

Call Details

When:

Tuesday, April 27, 2021,
2:00 PM – 3:00 PM ET


Webinar Link:

<https://www.zoomgov.com/j/1601111927?pwd=UTliM1BEWnJ0SkpKUzZnZUVDTVBxUT09> 

Passcode: 358595

Dial In:

US: +1 669 254 5252
or +1 646 828 7666
or +1 551 285 1373
or +1 669 216 1590

[International numbers](#) 

www.zoomgov.com/j/1601111927?pwd=UTliM1BEWnJ0SkpKUzZnZUVDTVBxUT09#success

J&J Vaccine: Benefits Outweigh Risks

Benefits of an Effective, Single-Dose, Easy-to-Use Janssen COVID-19 Vaccine Continue to Outweigh Risks

- Continue to face deadly pandemic, variants making containment more challenging globally
 - Janssen COVID-19 vaccine critically important to help halt spread of infection
- Janssen vaccine offers early and durable efficacy, protection against variants, and simplicity
 - Provides access to certain populations that typically face barriers to healthcare services
- Concerns that a restriction would leave significant proportion of the US unvaccinated
 - Puts reaching herd immunity at risk
- Janssen committed to understanding and communicating all risks, including very rare events of thrombosis with thrombocytopenia
 - Supports awareness, education and labeling; making this event more identifiable, diagnosable and treatable with improved chances for successful outcomes
- Janssen COVID-19 vaccine central in effort to end pandemic

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](tel: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



Re-Starting J&J & Vaccine Confidence

- US saw 20% decrease in COVID vaccinations during period of J&J pause
- Getting J&J back into use is critical
- Key messages following J&J “pause” & re-release
 - All authorized COVID vaccines are extremely safe
 - J&J vaccine remains extremely safe
 - TTS is rare event, >2 cases/1M vaccinated
 - Safety monitoring system (VAERS) works
 - Risks of not getting vaccinated far outweigh risks of getting COVID

(Re)Building Vaccine Confidence

Suggested key messages for clinicians from Dr Tom Frieden:

- COVID vaccines up to 95% effective, even more than annual flu vaccine, which is typically 40%-60% effective
- If people are vaccinated, we can prevent 100,000 or more deaths from COVID
- Nearly all doctors who have been offered vaccine have taken it
- If you get infected with COVID, it's much more likely to cause you long term problems than getting vaccinated.
- The more we vaccinate, the safer it will be to see family and friends

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

- Current:
 - **All individuals 16yo & older**

*Updates posted to Gov Mills COVID Vaccine website: www.maine.gov/covid19/vaccines
NOTE: Facilities booking appts listed at: www.maine.gov/covid19/vaccines/vaccination-sites

Health Equity “Pop-Up” Clinics

- Community partners invited to apply to host Pop-Up clinics to improve vaccine confidence & access for underserved communities
- Selected organizations linked with MIP-approved vaccine provider
- Community sponsors select physical location, plan logistics, provide staff or volunteers on site to serve as greeters, cultural brokers, interpreters
- Vaccine providers work with community sponsors to coordinate scheduling & ensure clinical and support staff

Ensuring Racial/Ethnic Equity

ME DHHS Equity webinar Wed, May 19, 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:** Clinician Info Sessn's now being held on 2nd & 4th Tues (7:30A) & Fri (12N) each month

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.



Updates for Vaccine Point-of-Distribution (POD) Sites

- Encouraging POD sites to accept walk-in's
- Note MidCoast “Golden Ticket” concept to provide for rapid vaccine access following primary care-patient conversations
- State will now support special POD clinics for workers, esp. those at increased COVID risk, & for students in higher education settings
- However, such clinics will need to be planned with regular vaccine supply

New State Vaccination Efforts: FEMA MVU

- FEMA Mobile Van Units (MVU) hosting mobile clinics around Maine over next ~2 months
- Currently: Biddeford
- Next wk: Fryeburg (Apr 30 – May 3), Turner
- Now again offering J&J vaccine
- (Apr 13 – 23 used Moderna – 2nd doses TBD)
- Vaccination by appointment + walk-up
- Doing ~300-500+ vaccinations/day
- Appts can be sched'd via ME Community Vaccination Line: tel. 1-888-445-4111 or [VaccinateME.maine.gov](https://www.vaccinateME.maine.gov)

Community Vaccination 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*

Transportation Assistance

- Maine DHHS offering free transportation to anyone needing ride to vaccination appt
- Individ's must first schedule vaccine appt
- Those 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
- Managed by ModivCare (formerly LogistiCare), with contracts to CAPs & other agencies
- Drivers will leave pts for appt, return at 60' or 90'

Gov Mills Info COVID Vaccine

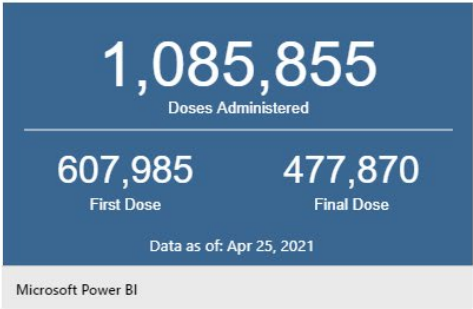


Maine is committed to an accessible, flexible, and equitable vaccination effort.

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.

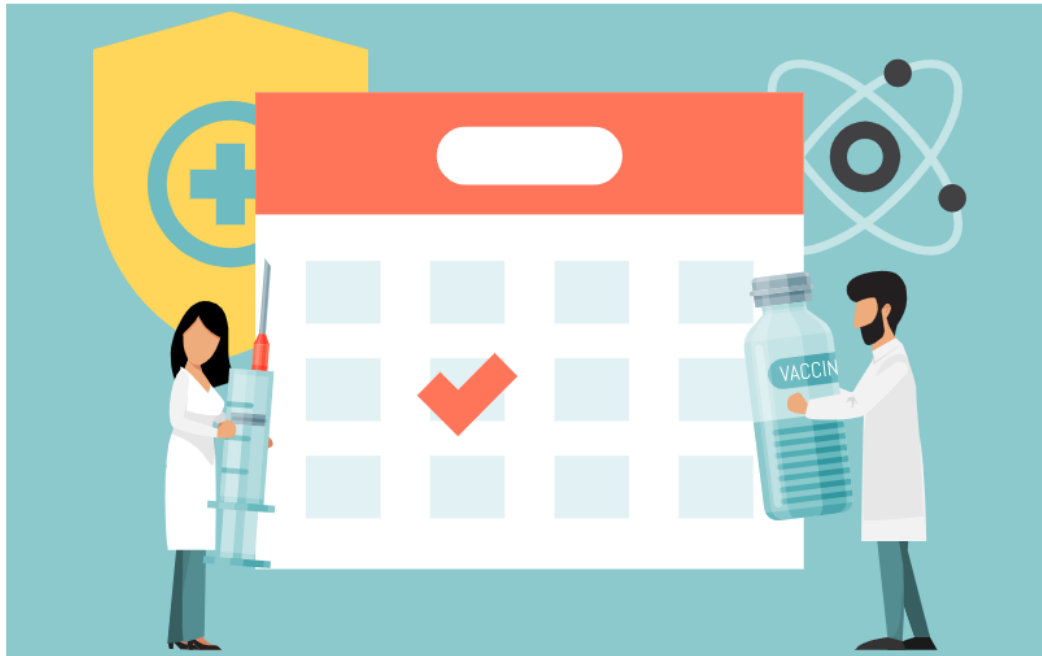
To learn more about vaccines and the vaccination process, please consult our [FAQs](#).



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

Gov Mills Info COVID Vaccine

When can I get vaccinated?



All Maine residents age 16+ are now eligible for vaccination

Some vaccine sites are now accepting appointments for newly eligible residents, while others are preparing to offer appointments in the coming days.

To make an appointment:

Find a COVID-19 vaccination site in Maine

Call the Community Vaccination Line at 1-888-445-4111.

Only Maine residents are eligible to receive a vaccine in Maine. For details, [please visit our FAQs.](#)

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How to make a vaccine appointment in Maine

Vaccine Locations

All Maine residents age 16 and over are now eligible for vaccination. [Find a site](#) to schedule your appointment.

Community Vaccination Line

[1-888-445-4111](#)

Monday-Friday, 7 a.m. to 7 p.m., or Saturday-Sunday: 8 a.m.- 2 p.m.

The Community Vaccination Line **helps Maine people schedule appointments at vaccine clinics.**

For translation services, call the number and state your desired language (for example: "Spanish"). Deaf and hard of hearing individuals may dial 711 and asked to be connected to the number above. The vaccination line does not provide faster access to appointments.

Need a Ride To Your Vaccine Appointment?

[1-855-608-5172](#)

The Department of Health and Human Services is offering a [free option for Maine people](#) who need a ride to and from a COVID-19 vaccination appointment. Call 1-855-608-5172 to reserve a ride at least 48 hours in advance of your appointment.

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ME CDC COVID Vaccine Resources

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

Maine.gov Agencies | Online Services | Help | Search Maine.gov

Select Language

Contact Us | News | Online services | Publications | Subject index

Search Disease Surveillance Search

Coronavirus Disease 2019 (COVID-19) - Updates and Information

DHHS → MeCDC → Disease Surveillance → MIP Home → COVID-19 Vaccine Providers Portal

Thurs 17 Dec 2020

General Information

- MIP Home
- COVID-19 Vaccine Providers Portal
- COVID-19 Vaccine Provider Enrollment
- COVID-19 Vaccine Storage and Handling Resources
- COVID-19 Vaccine Emergency Use Authorization (EUA) Fact Sheets/VIS Forms
- COVID-19 Vaccine Safety
- COVID-19 Vaccine Communications

Report a Disease

2-1-1 Social Services Help

COVID-19 Vaccine Providers Portal

- 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)
- COVID-19 Vaccine Info for Clinicians

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

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

Presenters

- **Lisa Letourneau MD, MPH**

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COVID-19 Vaccines

Questions??