Vaccine Planning Work Group

In order to keep an accurate roll call, we ask that everyone joining this meeting rename themselves to include the following information:

- First Name
- Last Name
- Organization

Please type all questions into the chat box.

Presentations slides will be posted on the Maine Immunization Program website at: https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/communications.shtml

We appreciate the time and effort taken by everyone joining to help the Maine CDC with COVID-19 vaccine planning.

Vaccine Planning Work Group

Tonya Philbrick
Maine Immunization Program
May 27, 2021

Disclaimer

All information in this presentation is subject to change.
Information shared in these slides is current as of
as of 5/26/2021.

Agenda

- General Updates
- Vaccine ordering Pfizer 450
- Clinical Considerations
- VAERS
- Clinic Transition, Northern Light Health

Clinic transition

Mathew Marston, Pharm.D, MBA, BCPS, BCOP
Vice President-Pharmacy
Northern Light Health

General Updates

Maine Doses administered 5/26/2021

- 1,397,925 total doses administered ~
- 709,636 first doses~
- 688,289 final doses~
- 59.93% of population that have received their first doses*~
- 58.12% of population that have received their final doses*~
- 73.6% as reported on the US CDC Covid Data Tracker
  - At least 1 dose for the Population ≥ 18 Years of Age
  - CDC COVID Data Tracker

~Does not include all doses administered through federal partners, *Age Eligible

General Updates

Maine's Allotment Week #25 distribution

- 21, 420 doses of Pfizer
- 15,400 doses of Moderna
- 0 doses of J+J

450 Dose Pack Pfizer

Pfizer 450 Dose Pack

- The Pfizer 450 configuration will be added to your weekly allocations and ordering caps beginning on May 25th (allocations) and 27th (ordering caps).
- The Pfizer 1170 configuration will continue to be available as well.
- First deliveries are anticipated on Tuesday, June 1
- Roughly 35% of Pfizer allocations will consist of the 450 pack

Pfizer 450 Ancillary Kit

- Orders of Pfizer 450 require a selection of an adult or pediatric ancillary kit
- Pediatric kits contain all 1" needles
- All other contents of the kit remain the same
- **No dry ice refresher will be sent in follow up for the Pfizer 450 orders**

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

"Why are needles for vaccine administration in the ancillary supply kit different lengths? Why aren't they all 1-inch needles?"

COVID-19 vaccines are administered by intramuscular injection. For all intramuscular injections, the needle should be long enough to reach the muscle mass and prevent vaccine from seeping into subcutaneous tissue.

Ensuring the vaccine is given in the muscle is important to optimize immunogenicity and minimize adverse reactions at the injection site.

If vaccine is given subcutaneously with the incorrect needle length, patients may experience more pain, irritation, and redness at the injection site.

The appropriate needle length depends on age and body mass. CDC's needle gauge and length chart, included in the ancillary kits, outlines the Advisory Committee on Immunization Practices' recommendations for needle length.

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

“Is there general guidance for what we should do when vaccine administration errors occur?”

Interim recommendations for COVID-19 vaccine administration errors differ from ACIP’s general best practice guidelines.

Interim Clinical Considerations for Use of COVID-19 Vaccines | CDC

Site/route	• Incorrect site (i.e., site other than the deltoid muscle [preferred site] or anterolateral thigh [alternate site])	• Do **not** repeat dose.* Inform the recipient of the potential for local and systemic adverse events.
	• Incorrect route (e.g., subcutaneous)	• Do **not** repeat dose.* Inform the recipient of the potential for local and systemic adverse events.

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Age	• Unauthorized age group	• If received dose at age less than 12 years, do **not** give any additional dose at this time.[∞]
		• If age 12 to 17 years and a vaccine other than Pfizer-BioNTech was inadvertently administered:
		  ◦ If Moderna vaccine administered as the first dose, may administer Moderna vaccine as the second dose (as off-label use, because Moderna vaccine is **not** authorized in this age group).
		  ◦ If Janssen vaccine administered, do **not** repeat dose with Pfizer-BioNTech vaccine.

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Dosage	• Higher-than-authorized dose volume administered	• Do **not** repeat dose.*†
	• Lower-than-authorized dose volume administered (e.g., leaked out, equipment failure, recipient pulled away)	• If more than half of the dose was administered, do **not** repeat dose.* • If less than half of the dose was administered or the proportion of the dose cannot be estimated, administer the authorized dose immediately (no minimum interval) in the opposite arm.#

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Storage and handling	• Dose administered after improper storage and handling (e.g., temperature excursion, more than allowed time after first vial puncture)	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
	• Dose administered past the expiration/beyond-use date	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
	• Dose administered within 14 days before or after another (i.e., non-COVID-19) vaccine	• Do **not** repeat COVID-19 vaccine* or other vaccine(s) doses. This deviation from CDC guidance does **not** require VAERS reporting.

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

mRNA vaccines only (Pfizer-BioNTech and Moderna)	Intervals	• Second dose administered fewer than 17 days (Pfizer-BioNTech) or fewer than 24 days (Moderna) after the first dose (i.e., administered earlier than the 4-day grace period)	• Do **not** repeat dose.
		• Second dose administered more than 42 days after the first dose	• Do **not** repeat dose. This deviation from CDC guidance does **not** require VAERS reporting.
	Mixed series	• Incorrect mRNA COVID-19 vaccine product administered for second dose in 2-dose series	• Do **not** repeat dose. [§]

Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States

Pfizer-BioNTech only	Diluent	• ONLY diluent administered (i.e., sterile 0.9% sodium chloride)	• Inform the recipient that no vaccine was administered. Administer the authorized dose immediately (no minimum interval) in the opposite arm.[#]
		• No diluent, resulting in higher than authorized dose (i.e., 0.3 ml of undiluted vaccine administered)	• Do **not** repeat dose[*†] Inform the recipient of the potential for local and systemic adverse events.
		• Incorrect diluent type (e.g., sterile water, bacteriostatic 0.9% NS)	• Contact the manufacturer for guidance. If the manufacturer provides information supporting that the dose should be repeated, the repeated dose may be given immediately (no minimum interval) in the opposite arm.
		• Incorrect diluent volume (i.e., the vial contents were diluted with a diluent volume other than 1.8 ml, but a 0.3 ml dose was still administered)	• For doses administered with diluent volume less than 1.8 ml, inform the recipient of the potential for local and systemic adverse events.[*†] • For doses administered with diluent volume greater than 1.8 ml, do **not** repeat dose.[*] (Note: Dilution with a volume up to 4.0 ml [which exceeds vial capacity] results in more-than-half of the authorized dose administered.)

VAERS

For all vaccine administration errors:

- Inform the recipient of the vaccine administration error.
- Report the error to the Vaccine Adverse Event Reporting System (VAERS), unless otherwise indicated in the tables on the previous slides. Providers are required to report all COVID-19 vaccine administration errors—even those not associated with an adverse event—to VAERS.
- Determine how the error occurred and implement strategies to prevent it from happening again. A discussion on strategies to prevent errors can be found in the "Vaccine Administration" chapter of *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book). Additional resources can be found on CDC's vaccine administration web page, including a job aid for preventing errors.

VAERS

- The federal government takes all reports of vaccine adverse events seriously, and CDC and the U.S. Food and Drug Administration (FDA) are actively engaged in safety monitoring of COVID-19 vaccines. CDC uses numerous vaccine safety monitoring systems, including VAERS, to watch for adverse events (possible side effects) after vaccination.

- Who can report post-vaccination adverse events to VAERS?
  - Anyone can submit a report to VAERS. Healthcare professionals, health departments, vaccine manufacturers, vaccine recipients, and parents or family members of people who have received a vaccine are encouraged to submit a VAERS form if they experience any adverse events after getting any vaccine.

- What do CDC and FDA do when a VAERS report is submitted?
  - Experts from CDC and FDA monitor VAERS reports to identify adverse events that need to be studied further. All serious reports are reviewed daily by vaccine safety experts. Scientists at CDC and FDA use statistical models to help understand whether there are any safety signals for a vaccine product and compare them with safety signals for other vaccines to determine if further investigation is needed.

VAERS

- When does CDC follow up on reports submitted to VAERS?
  - VAERS staff obtains follow-up medical records for reports classified as serious. A serious report describes an event that resulted in permanent disability, hospitalization, life-threatening illness, or death. VAERS staff may also obtain follow-up medical records for adverse events of interest, like anaphylaxis. Reviewing these records can help CDC and FDA medical staff better understand cases.

- Will CDC follow up with people who submit VAERS reports?
  - The person who submits a VAERS report will receive a confirmation that VAERS has received the report or a reminder if important information was left out of the initial report. If additional information is needed, CDC may reach to healthcare providers relevant to the case.

- What happens when a death is reported to VAERS?
  - When a death is reported to VAERS, CDC obtains medical records about the person's death, including an autopsy report, if available. If no autopsy was performed, CDC will obtain a death certificate and other relevant medical records. VAERS scientists will **not** reach out to the person who submitted the report, unless the name of the hospital or vaccination provider is **not** included.

COVID Vaccination Dashboard

- https://www.maine.gov/covid19/vaccines/dashboard

Contact Information

C19Vaccine.MECDC@maine.gov

For questions regarding vaccine planning for COVID-19:

- Vaccine planning logistics – enrolled providers only
- Any follow-up questions to these weekly Vaccine Planning Work Group Meetings

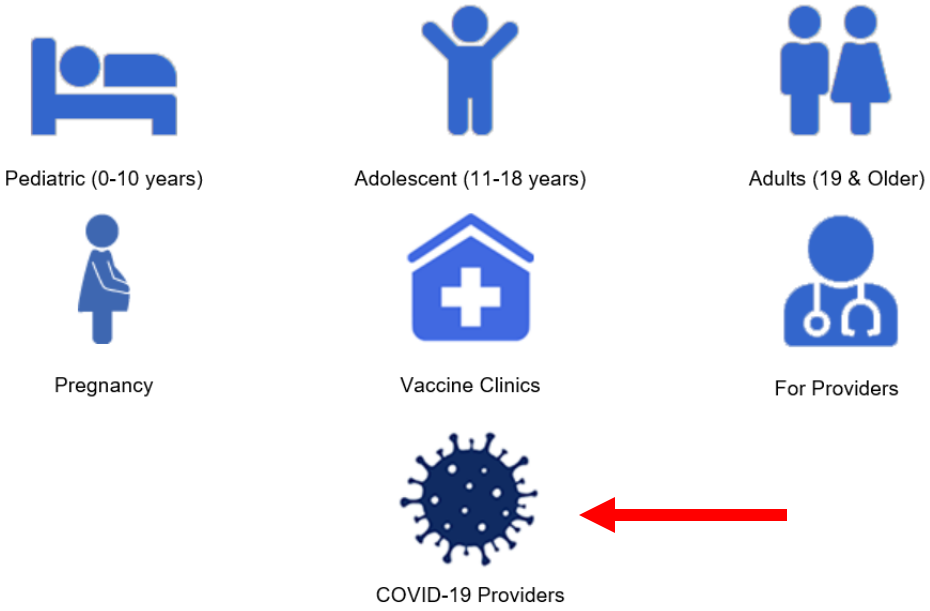
C19PA.MECDC@maine.gov

To submit documents for COVID-19 vaccine enrollment:

- CDC COVID-19 Vaccination Program Provider Agreement
- Storage & handling documentation if required

Website Information

ImmunizeME.org



Questions?

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