

# Maine DHHS

## **COVID-19 Vaccines Information for Clinicians**

Medicaid Advisory Committee

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# COVID-19 Vaccines – How We Save Lives

Vaccines don't save lives.

Vaccinations save lives.

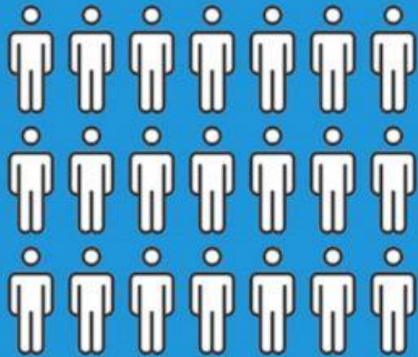


# Vaccine Development Process

## Covid-19 Vaccine Watch

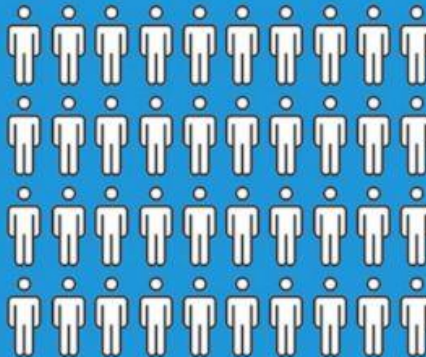
VACCINE HUMAN TRIAL PHASES

### Phase I



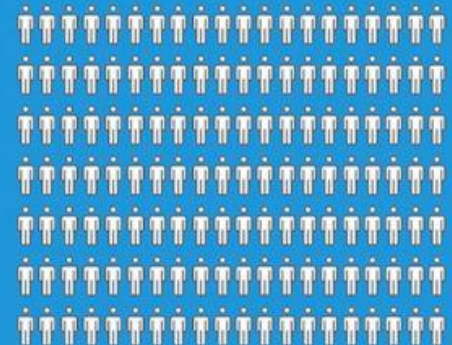
Usually less than 100 people, and monitors for safety at multiple doses.

### Phase II



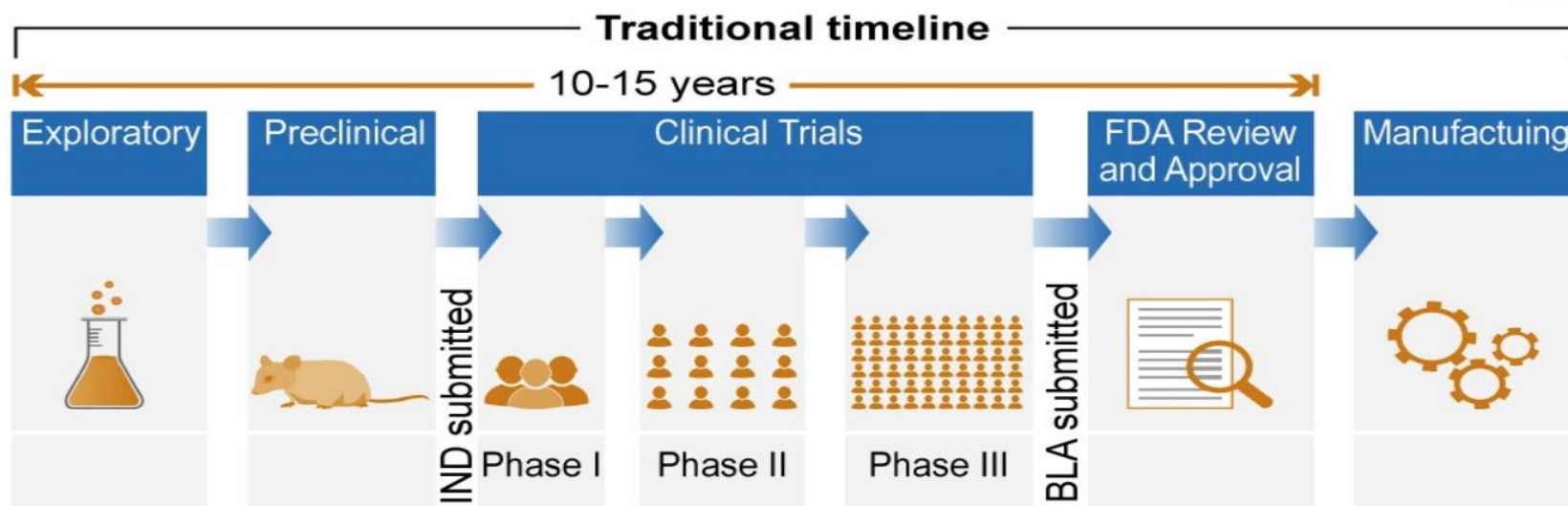
Slightly larger and looks for safety and early effectiveness.

### Phase III



Large scale, normally 30,000 patients, and is the test of effectiveness and long term safety in multiple populations.

# FDA Approval Process



BLA = Biologics License Application

EUA = Emergency Use Authorization

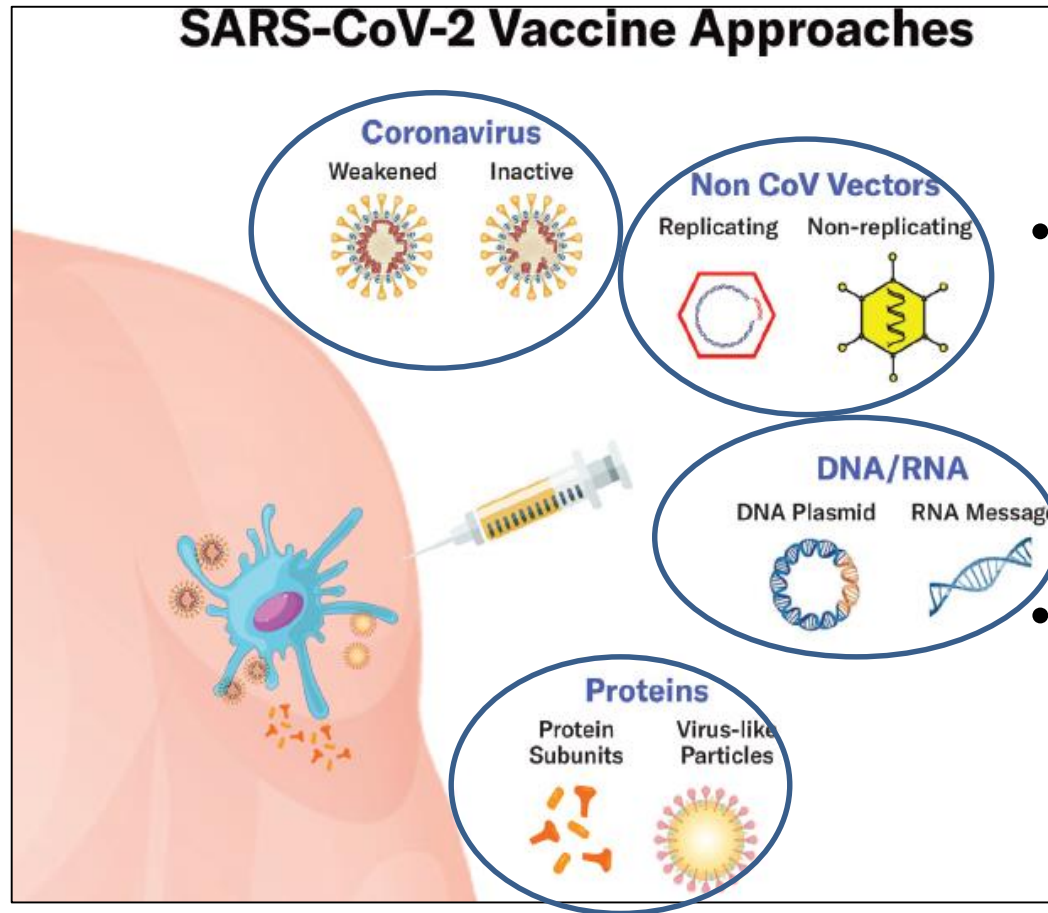
IND = Investigational New Drug

Source: GAO analysis of GAO-20-215SP, FDA, HHS, and Pharmaceutical Research and Manufacturers of America (PhRMA) documentation. | GAO-20-583SP



# Major Types of COVID Vaccines

- Weakened or inactive virus vaccines
- (Non-COVID) viral vector vaccines



• Nucleic acid (mRNA, DNA) vaccines

• Protein-based vaccines

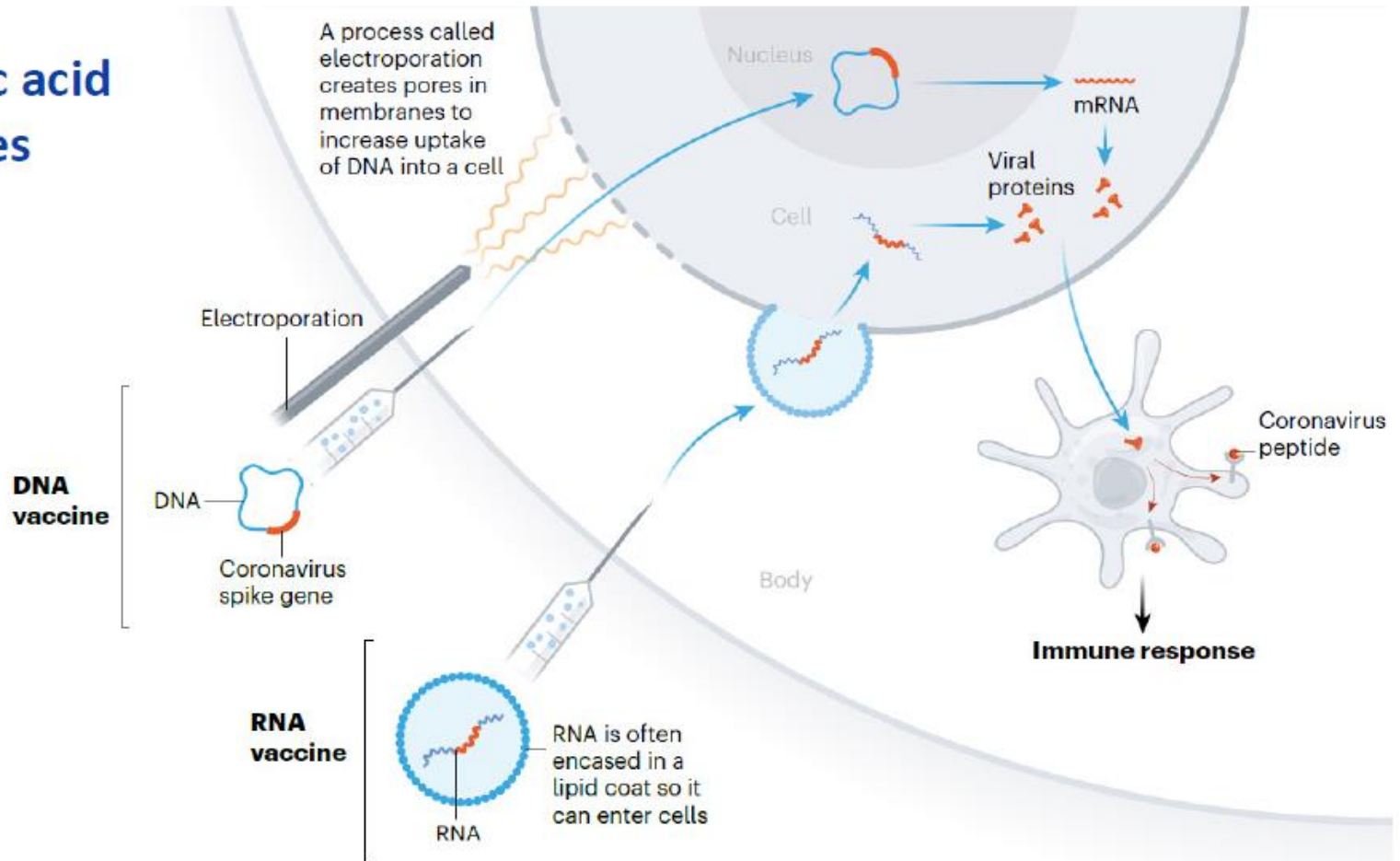
# mRNA Vaccines: Pfizer & Moderna

## Explaining mRNA COVID-19 vaccines

- mRNA vaccines take advantage of the process that cells use to make proteins in order to trigger an immune response
  - Like all vaccines, COVID-19 mRNA vaccines have been **rigorously tested** for safety before being authorized for use in the United States
  - mRNA technology is **new, but not unknown**. They have been studied for more than a decade
  - mRNA vaccines **do not contain a live virus** and do not carry a risk of causing disease in the vaccinated person
  - mRNA from the vaccine never enters the nucleus of the cell and **does not affect or interact with a person's DNA**

# Nucleic Acid Vaccines

## Nucleic acid vaccines



*Nature*. Vol 580. April 30, 2020. <https://media.nature.com/original/magazine-assets/d41586-020-01221-y/d41586-020-01221-y.pdf>

# Key Similarities & Differences

## **Pfizer BioNTech**

- mRNA vaccine
- Trial with >44,000
- Efficacy 94.5%
- Minimal adverse rxn's
- 2<sup>nd</sup> dose at 21D
- Auth'd for  $\geq 16$ yo
- Storage at -70C
- Can be re Fridg'd for 5D

## **Moderna**

- mRNA vaccine
- Trial with >30,000
- Efficacy >94.1%
- Minimal adverse rxn's
- 2<sup>nd</sup> dose at 28D
- Auth'd for  $\geq 18$ yo
- Storage at -20C
- Can be re Fridg'd for 30D



# Pfizer & Moderna Vaccines: What's Included & What's Not

- mRNA vaccines contain:
  - Nucleoside-modified mRNA that encodes for SARS-CoV-2 spike protein
  - Polyethylene glycol (PEG)
  - Lipids (phosphocholine, cholesterol, others)
  - Salts & sugars
- mRNA vaccines don't contain:
  - Live virus
  - Thimerosal
  - Mercury
  - Fetal cells
  - Pork products

# Anaphylaxis in US Following COVID Vaccination

From ACIP Dec 19-20, 2020 meeting safety presentation:

- As of December 19, 2020: 272,001 doses of Pfizer-BioNTechCOVID-19 vaccine had been administered
- US CDC identified 6 case reports of anaphylaxis following Pfizer-BioNTech vaccine meeting Brighton Collaboration criteria for anaphylaxis
- Cases occurred within recommended observation window and were promptly treated
- All suspect cases were notified through VAERS or CDC notification processes

# US CDC: Anticipate & Manage Anaphylaxis

- Nat’ly, 6 anaphylactic rxs (12/19/20)
- Allergy cautions for both Pfizer-BioNTech and Moderna COVID-19 vaccines
- Anyone with anaphylactic rxn to COVID vaccine should not get 2<sup>nd</sup> dose
- Anyone with immediate allergic rx should get allergist consult –i.e.  
Any hypersensitivity-related signs or symptoms such as urticaria, angioedema, respiratory distress (e.g., wheezing, stridor), or anaphylaxis that occur within four hours following administration

The screenshot shows the CDC website's 'Vaccines & Immunizations' section. The main heading is 'Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States'. Below this, there is a yellow warning box with a triangle icon and the text 'Interim Considerations: Preparing for the Potential Management of Anaphylaxis at COVID-19 Vaccination Sites'. The main text discusses the Advisory Committee on Immunization Practices (ACIP) interim recommendations for the use of Pfizer-BioNTech and Moderna COVID-19 vaccines. It mentions that these vaccines are lipid nanoparticle-formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2. The text also states that these interim CDC clinical considerations are informed by data submitted to the Food and Drug Administration for Emergency Use Authorization (EUA) of the vaccines, other data sources, general best practice guidelines for immunization, and expert opinion. It notes that these considerations for mRNA vaccines only apply to the currently authorized vaccine products in the United States (i.e., Pfizer-BioNTech and Moderna COVID-19 vaccines). Considerations will be updated as additional information becomes available or if additional vaccine products are authorized. In addition to the following considerations, the EUA conditions of use and storage, handling, and administration procedures described in the prescribing information should be referenced when using the Pfizer-BioNTech and Moderna COVID-19 vaccines. The page also includes sections for 'Authorized age groups' and 'Administration'. The 'Authorized age groups' section states that under the EUAs, the following age groups are authorized to receive vaccination: Pfizer-BioNTech: ages ≥16 years; Moderna: ages ≥18 years. It also notes that children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time. The 'Administration' section states that the mRNA COVID-19 vaccine series consist of two doses administered intramuscularly: Pfizer-BioNTech (30 µg, 0.3 ml each); three weeks (21 days) apart; Moderna (100 µg, 0.5 ml); one month (28 days) apart.

**Authorized age groups**

Under the EUAs, the following age groups are authorized to receive vaccination:

- Pfizer-BioNTech: ages ≥16 years
- Moderna: ages ≥18 years

Children and adolescents outside of these authorized age groups should not receive COVID-19 vaccination at this time.

**Administration**

The mRNA COVID-19 vaccine series consist of two doses administered intramuscularly:

- Pfizer-BioNTech (30 µg, 0.3 ml each); three weeks (21 days) apart
- Moderna (100 µg, 0.5 ml); one month (28 days) apart

# Preparing for Practice-Based Vaccination

- Temperature requirements, handling implications
- Equipment, PPE required for vaccination
- Anaphylaxis response meds & equipment
- Required reporting to ME CDC
- Timing system for 15-30' post-vaccine observation
- 2<sup>nd</sup> dose reminder systems
- Post-vaccine safety monitoring

# Vaccine Adverse Reporting

- US CDC + FDA: Vaccine Event & Adverse Reporting System ([VAERS](#))
- US CDC: Vaccine Safety Assessment for Essential Workers (V-SAFE)- smart phone app
- National Health Care Safety Network (NHSN) – LTC residents



# Federal VAERS Program



## VAERS

Vaccine Adverse Event  
Reporting System

Co-managed by  
CDC and FDA

<http://vaers.hhs.gov>

**VAERS** Vaccine Adverse Event Reporting System  
www.vaers.hhs.gov

About VAERS

Report an Adverse Event

VAERS Data

Resources

Submit Follow-Up Information

Have you had a reaction following a vaccination?

1. Contact your healthcare provider.
2. Report an Adverse Event using the VAERS online form or the new downloadable PDF. *New!*

**Important:** If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

¿Ha tenido una reacción después de recibir una vacuna?

1. Contacte a su proveedor de salud.
2. Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. *Nuevo!*



What is VAERS?



REPORT AN ADVERSE EVENT

Report significant adverse events after vaccination.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.



SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

<https://vaers.hhs.gov/index.html>

# Federal V-SAFE Program



## Active Safety Monitoring for COVID-19 Vaccines

- **V-safe** is a new CDC smart-phone based monitoring program for COVID-19 vaccine safety
  - Uses text messaging and web surveys to check-in with vaccine recipients after vaccination
  - Participants can report any side effects or health problems after COVID-19 vaccination
  - Includes active telephone follow-up by CDC for reports of significant health impact



12/2/20

# Vaccine Hesitancy & Trust

- Historical context, BIPOC concerns
  - Tuskegee Syphilis Experiment (1952-1972!)
  - Henrietta Lacks – HeLa cells
  - Other...
- Factors impacting individual decision-making
  - Trust in government
  - Community vs. individual benefit
- Impact of FDA EUA vs. full approval

# ACIP Recommendations for Phased Distribution

## Phase 1a

- Health Care Personnel\*
- Residents of long-term care facilities  
(= ~131,500 individuals)



## Phase 1b

- Persons aged  $\geq 75$  years
- Front line essential workers

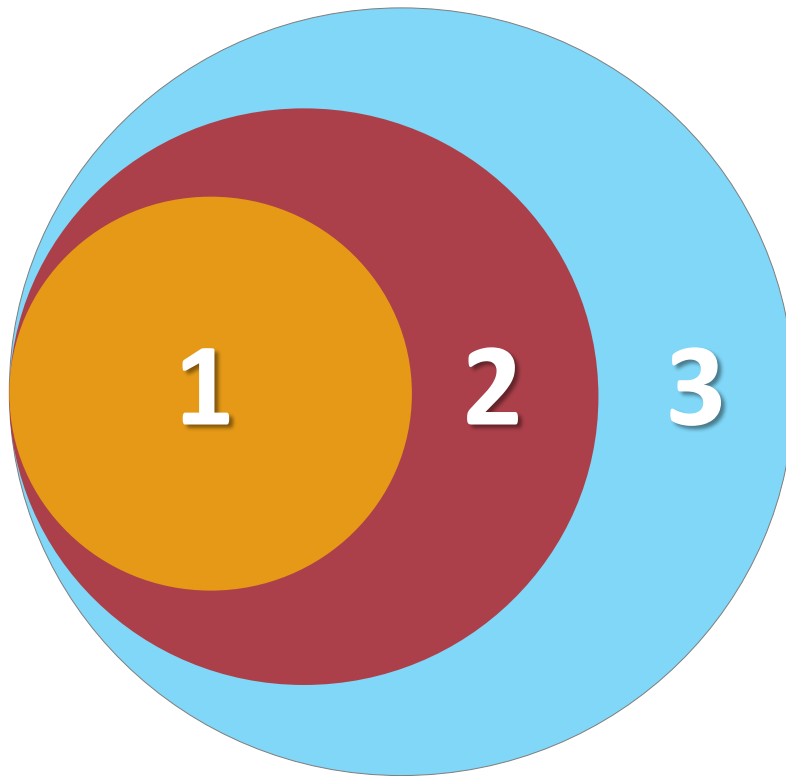


## Phase 1c

- Persons aged 65-74 years
- Persons aged 16-64 years with high-risk medical conditions
- Non-front line essential workers

[ACIP defines HCP](#) as ““paid and unpaid personnel serving in health care settings *who have potential for direct or indirect exposure to patients or infectious materials...* HCP comprise clinical staff members, including nursing or medical assistants and support staff members (e.g. those who work in food, environmental, and administrative services)”

# Phase 1a – Health Care Personnel Distrib'n\*



## **Grp 1: Acute care (Wks 1-4)**

- Personnel who provide direct inpatient care (ED, ICU, COVID units)
- Non-hospital (EMS)
- Home health
- Medical practices

## **Grp 2: Patient-facing/Infctst Matl (Wks 4-6)**

- Care for highest-risk patients (cancer, dialysis).
- Work with aerosols (dental)
- BH, CHW, optometry, school nurses, massage, etc.
- Environmental services at each practice

## **Grp 3: Non-patient facing (Wks 6+)**

- IT, finance, management, medical records, etc.

\* In addition to Long Term Care program

More info on Gov Mills COVID-19 Vaccine webpage: [Health Care Personnel FAQs](#)



# Phase 1a – Health Care Personnel - Grps

## **Group 1: Health Care Personnel Needed to Preserve Critical Health Care Services:**

Paid and unpaid personnel, including both clinicians and support staff, who physically work in hospitals, acute care settings, Emergency Medical Services, or home health on a regular basis and have direct contact with patients, or have the potential for direct or indirect exposure to patients or infectious materials. This includes outpatient clinicians and their staff who provide care to patients at risk of hospitalization such as providers in urgent care centers, medical practices providing acute care, dialysis centers, and oncology practices.

**Group 2: Other Patient-Facing Health Care Personnel:** Paid and unpaid personnel, including both clinicians and support staff, who physically work in other health care settings on a regular basis and have direct contact with patients, or have the potential for direct or indirect exposure to patients or infectious materials. Examples include personnel who work with aerosols, such as in dental fields; health care providers with prolonged contact with patients; practitioners in behavioral health, optometry, school nurses, and environmental services workers at health care practices.

**Group 3: Non-Patient Facing Health Care Personnel:** Paid and unpaid personnel, such as health care administrators, who do not have direct contact with patients or the potential for direct or indirect exposure to infectious materials, but work in health care settings on a regular basis alongside personnel who have direct contact with patients or exposure to infectious materials.

[www.maine.gov/covid19/vaccines/mainehhealthcarepersonnel](http://www.maine.gov/covid19/vaccines/mainehhealthcarepersonnel)

# COVID-19 – Maine Vaccinators

Must be ME CDC-approved COVID Vaccine Provider:

- Hospitals
- Enrolled/registered physician & dental practices
- EMS (for EMS, Public Safety)
- Pharmacies
  - Pharmacy Partnership for LTC (Walgreens, CVS)
  - Commercial pharmacies
- Others - TBD

# COVID-19 Vaccines – Info Sessions for Clinicians

- Clinician info sessions each Tues (7:30A) & Fri (12N)
- Session recordings & slides [posted to ME CDC website](#)
- Evolving curriculum:
  - Science of vaccines
  - Vaccine development & approval process
  - Vaccine distribution prioritization
  - Vaccines & safety considerations
  - Preparing for practice-based vaccination
  - Vaccine hesitancy & patient conversations
  - Vaccine storage, handling & administration
  - Reporting & tracking adverse events

# ME CDC COVID Vaccine Resources

The screenshot shows the 'COVID-19 Vaccine Providers Portal' on the Maine Department of Health and Human Services website. The page features a navigation menu on the left with links to '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', and 'COVID-19 Vaccine Communications'. A 'Report a Disease' button is also present. 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. The page also includes a 'Select Language' dropdown, a search bar, and a 'Contact Us' link.

## [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](https://www.maine.gov/dhhs/mecdc/infectious-disease/immunization/covid-19-providers/index.shtml)

Vaccine questions? Email:  
[C19vaccine.MECDC@maine.gov](mailto:C19vaccine.MECDC@maine.gov)

# Additional COVID Vaccine Resources

- [HHS Fact Sheet Operation Warp Speed](#)
- [NY Times Vaccine Tracker](#)
- [ME COVID Vaccine Plan](#)
- [ME CDC COVID-19 Vaccine Provider Portal](#)
- [ME CDC COVID-19 Vaccine Info for Clinicians](#)
- [ME CDC COVID-19 Vaccine Provider Enrollment](#)
- [US CDC COVID-19 Vaccine Resources for Providers](#)
- [US CDC COVID-19 Vaccine Training for Providers](#)
- [US CDC Engaging Patients in COVID Vaccines](#)
- [US CDC Answering Likely Questions on COVID Vaccine](#)
- [FDA Issues EUA for Pfizer-BioNTech COVID-19 Vaccine](#)



# Presenters

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