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.
COVID-19 Vaccines – Info for Clinicians

- Context
- 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
### ACIP Recommendations for Phased Distribution

<table>
<thead>
<tr>
<th>Phase 1a</th>
<th>Phase 1b</th>
<th>Phase 1c</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Health Care Personnel*</td>
<td>• Persons aged ≥ 75 years</td>
<td>• Persons aged 65-74 years</td>
</tr>
<tr>
<td>• Residents of long-term care facilities</td>
<td>• Persons aged 65-74 years</td>
<td>• Persons aged 16-64 years with high-risk medical conditions</td>
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<tr>
<td>(= ~131,500 individuals)</td>
<td>• Front line essential workers</td>
<td>• Non-front line essential workers</td>
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**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/Infct 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](#)
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.

US CDC: What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccine
Key Similarities & Differences

**Pfizer BioNTech**
- mRNA vaccine
- Trial with >44,000
- Efficacy 94.5%
- Minimal adverse rxn’s
- 2\(^{nd}\) dose at 21D
- Auth’d for ≥16yo
- Storage at -70C
- Can be refridg’d for 5D

**Moderna**
- mRNA vaccine
- Trial with >30,000
- Efficacy >94.1%
- Minimal adverse rxn’s
- 2\(^{nd}\) dose at 28D
- Auth’d for ≥18yo
- Storage at -20C
- Can be refridg’d for 30D
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
From ACIP Dec 19-20, 2020 meeting safety presentation:

• As of December 19, 2020: 272,001 doses of Pfizer-BioNTech COVID-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
• Recommendations apply to both Pfizer-BioNTech and Moderna COVID-19 vaccines
• Guidance may change as further information becomes available
• Definition of immediate allergic reaction to vaccine or medication:
  – 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
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\textsuperscript{nd} dose reminder systems
- Post-vaccine safety monitoring
Preparing for Practice-Based Vaccination

Observation period following vaccination

Persons with a precaution to vaccination or a history of anaphylaxis (due to any cause)

All other persons

30 minutes

15 minutes
COVID-19 Vaccine- 2nd Dose Issues

• Second dose reminder systems
• COVID vaccine cards
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

Co-managed by CDC and FDA
http://vaers.hhs.gov

https://vaers.hhs.gov/index.html
Federal V-SAFE Program

**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
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
ME CDC COVID-19 Vaccine Resources

ME CDC COVID-19 Vaccine Resources

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Questions??