COVID-19 Vaccine

December 15, 2020

RHODE ISLAND

Agenda

- COVID-19 Vaccine Development and Approval
- Vaccine Safety
- Vaccine Distribution in Rhode Island
- Questions

EUA and ACIP Approval Timeline

- November 20, 2020: Pfizer/BioNTech applied for Emergency Use Authorization (EUA) from FDA
- November 30, 2020: Moderna applied for EUA from FDA
- December 3, 2020: The CDC's Advisory Committee on Immunization Practices (ACIP) convened and released initial recommendations, which included nursing homes and other long-term care facility staff residents in Phase 1 of vaccine distribution.
- December 11, 2020: Pfizer received approval through an EUA.
- December 12, 2020: ACIP voted to recommend to CDC the Pfizer BioNTech COVID-19 Vaccine for persons 16 years of age and older under the FDA's EUA.
- December 13, 2020: CDC approved the Pfizer vaccine and released an MMWR – full clinical considerations not released with initial information.
- December 14, 2020: Rhode Island hospitals begin vaccinating high-risk hospital workers
- TBD: CDC set to release full guidance, including clinical considerations.

Pfizer vs. Moderna: Key Information

	Efficacy	Storage	Shelf Life / Requirements	2nd Dose Timing
Pfizer BIONTECH	• 95% effective beginning 28 days after first dose • Participant Population: 43,000	• Storage Temp: -70°C • Shipper Requirements: Must be closed within 1 min of opening, cannot be opened more than 2x per day	• Shelf Life (-70°C): 6 months • Shelf Life: (2-8°C): 24 hours • Shelf Life (RT): <2 hours • Post-Dilution Use: 6 hours	• 3 weeks
moderna	• 94.1% effective beginning 14 days after first dose • Participant Population: 30,000	• Storage Temp: -20°C	• Shelf Life (-20°C): 6 months • Shelf Life: (2-8°C): 30 days • Shelf Life (RT): 12 hours • No dilution required	• 4 weeks

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The Safety Review Process

Vaccine Development

The Food and Drug Administration (FDA) oversees the development of vaccines as the vaccine goes through three phases:

- Phase 1: 20-100 healthy volunteers participate in vaccine trial
- Phase 2: Several hundred volunteers participate in vaccine trial
- Phase 3: Hundreds/thousands volunteers participate in vaccine trial

The FDA will only license a vaccine if it is proven to be effective and safe.

More than 70,000 people have participated in the trials for the Pfizer and Moderna COVID-19 vaccines.

Vaccine Production

- Vaccine is produced in lots. The manufacturer is required to test all lots for safety, purity, and potency.
- Lots will only be released for purchase and sale if FDA reviews the safety and quality data.
- FDA regularly inspects manufacturing facilities to ensure safety and quality of vaccine and of manufacturing processes.

Diversity of Clinical Trial Participants – Pfizer Vaccine

Trial Progress

The clinical trial has enrolled **44,863 participants** and **43,004 have received their second vaccination** at approximately **150 clinical trial sites** in **6 countries.**

Participant Diversity

Approximately **42%** of overall and **30%** of U.S. participants have diverse backgrounds.

Race/Ethnicity	Overall Study	U.S. Only
Asian	5%	6%
Black	10%	10%
Hispanic/Latinx	26%	13%
Native American	1.1%	1.3%

Participant Age

Ages 12-15	697
Ages 16-17	733
Ages 18-55	25,527
Ages 56+	17,893

Updated as of Monday, December 14. Updates are made on a weekly basis.

The Safety Review Process

Safety monitoring does not stop after vaccines are licensed. There are several overlapping programs that CDC's Office for Immunization Safety uses to monitor safety in an on going way. For example:

- *Vaccine Adverse Event Reporting System (VAERS)* helps CDC and FDA monitor any problems. Health concerns can be reported by anyone to the system for careful review (patients, healthcare providers, etc.).
- *Vaccine Safety Datalink (VSD)* is a partnership between CDC and nine healthcare organizations and monitors the safety of vaccines. Data is collected at each of the nine sites, and the VSD conducts studies about any rare and serious effects.
- *Clinical Immunization Safety Assessment* (CISA) is a collaboration of CDC and several medical centers that focuses on conducting research about vaccine-associated health risks in certain groups of people.
- *Post Licensure Rapid Immunization Safety Monitor* (PRISM) is a program that analyzes health information collected from more than 190 million people.

The Safety Review Process

Expanded Safety Monitoring Systems for COVID-19 Vaccine

Emergency Preparedness for Vaccine Safety

- During a disease outbreak that necessitates a large vaccination campaign, CDC initiates emergency preparedness activities to ensure the vaccines stay safe.
- There is a designated Vaccine Safety Officer for each state and territory.
- Rhode Island's Vaccine Safety Officer is Tricia Washburn.

V-SAFE

- Run by CDC.
- Anyone who gets COVID vaccine will receive texts or can take web-based surveys about how they are doing after getting the vaccine. V-SAFE will immediately call anyone who reports a medically significant adverse event.

National Healthcare Safety Network (NHSN)

- A monitoring system in place at acute care and long-term care facilities that will report to VAERS.

Rhode Island COVID-19 Vaccine Subcommittee

- Dr. Tom Bledsoe, Rhode Island Hospital
- Dr. Sapna Chowdhry, Thundermist Health Center
- Dr. Kerry LaPlante, URI School of Pharmacy
- Dr. Pablo Rodriguez, Care New England
- Dr. Justin Berk, Medical Programs Director, Rhode Island Department of Corrections
- John Fulton, Epidemiologist and Sociologist, Brown University School of Public Health
- Dr. Beth Lange, Coastal Medical
- Jonathan Brice, Superintendent, Bristol/Warren Regional School District
- Dr. Wilfredo Perez, Tri-county Community Action Agency
- Reverend Chris Abhulime, King's Tabernacle
- Larry Warner, United Way
- Dr. Karen Tashima, Director of Clinical Trials, Lifespan Immunology Center
- Dr. Sabina Holland, Hasbro Children's Hospital
- Kathy Heren, Rhode Island Long-term Care Ombudsman
- Dr. Eugenio Fernandez, Asthenis Pharmacy
- Joan Kwiatkowski, CEO, PACE
- Dr. Wendy Chicoine, Providence Community Health Centers
- Dr. Christopher Ottiano, Medical Director, Neighborhood Health Plan
- Teresa Paiva-Weed, Hospital Association of Rhode Island

How You Know the Vaccine is Working

- Vaccines contain antigens, which are substances that cause our immune systems to respond.
- Sometimes we notice the response, like when you feel aches or soreness after a flu shot.
- People may feel some soreness at the site of injection, some aches, and fatigue after receiving the COVID-19 vaccine. This may be more noticeable than what people experience after a flu shot. It will clear up after a few days.
- This is a normal, healthy response. It means that you are developing protection against COVID-19. These are signs that the vaccine and your immune system are working.

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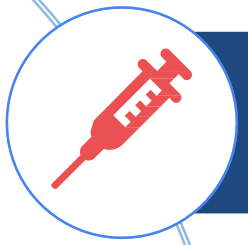
Vaccine Coming to Rhode Island

- Anticipated initial shipment of Pfizer vaccine – 10,000 first doses
- Anticipated initial shipment of Moderna vaccine – 19,000 first doses
- Anticipated subsequent shipments – approximately 8,000 doses per week of both vaccines
- Second doses will start arriving in Rhode Island roughly 3 weeks after first doses

  Two doses are needed for someone to be fully immunized
- Additional COVID-19 vaccines could get approved, increasing the vaccine coming to Rhode Island

Guiding Principles for Vaccine Distribution

EQUITY



Safety is paramount. Vaccine safety standards will not be compromised at all.

Minimize Morbidity. Prioritization of vaccine distribution should minimize deaths and hospitalizations as much as possible.

Efficient Distribution. During a pandemic, efficient, expeditious and equitable distribution and administration of approved vaccine is critical.

Access. Ensure access to vaccines for all Rhode Islanders, particularly those who may have limited transportation options.

Potential Phases of COVID-19 Distribution in Rhode Island

Phase 1:

- High-risk healthcare workers (e.g. hospital staff, EMS, home care and hospice workers);
- Long-term care facility staff and residents, individuals in congregate settings who are > 65 or immunocompromised and congregate setting staff;
- COVID responders, non-hospital healthcare workers and healthcare provider staff (e.g. at community health centers, urgent care clinics, pharmacies, etc.), other first responders, targeted high-density communities, individuals being treated through specialty healthcare providers for multiple comorbid conditions.

Phase 2:

- K-12 teachers, school staff, child-care workers
- Critical workers in high-risk settings
- Other individuals and staff in high-risk settings
- Other individuals with comorbidities
- Other adults 65+ not in Phase 1

Phases are not yet finalized for Rhode Island and will be discussed by the COVID-19 Vaccine Subcommittee meeting this week.

Potential Phases of COVID-19 Distribution in Rhode Island

Phase 3:

- Young adults
- Others not included in Phase 1-2 in essential industries

Phases are not yet finalized for Rhode Island and will be discussed by the COVID-19 Vaccine Subcommittee meeting this week.

Phase 4:

- Everyone who did not have access to vaccine in previous phases

Likely Phase 1 Distribution Channels

- **Hospitals**
  Hospitals will receive vaccine and redistribute within their systems.

- **Immunizers for long-term care and assisted living facilities**
  Through a pharmacy partnership, vaccine will go to CVS and Walgreens to vaccinate staff and residents of long-term care facilities and assisted living facilities.

- **Mass vaccinators**
  RIDOH has established partnerships for mass vaccination through organizations such as The Wellness Company and Rhode Island's Medical Reserve Corps. They will host vaccine clinics for priority populations. Rhode Island will also have a vendor to redistribute vaccine across the state.

- **Regional clinics for certain Phase 1 populations**
  First responders, home health agency workers, and other priority populations will be able to get vaccinated at clinics.

Initial Clinical Guidance, COCA Call 12/13/2020

- Pregnant and breastfeeding women in high-risk groups should be offered the vaccine, with the opportunity to discuss with their healthcare provider.
- Those who previously had COVID-19 infection should still be vaccinated, but individuals who received monoclonal antibodies or convalescent plasma should not be vaccinated until 90 days after they received them.
- Those who have received any other vaccine within 14 days should not be vaccinated until the 14 days has passed.
- For those with active COVID illness, a risk assessment should be conducted and, if possible, wait for vaccination until symptoms have subsided, or at least 10 days after isolation has ended.
- Those with a history of severe allergic reaction (e.g., anaphylaxis) to another vaccine (not Pfizer-BioNTech vaccine) or to an injectable medication should undergo a risk assessment but can be vaccinated; their post-vaccination observation period should be 30 minutes.
- Those with a history of severe allergic reaction (e.g., anaphylaxis) to any component of the Pfizer-BioNTech vaccine (e.g., lipid nanoparticles, polyethylene glycol (PEG)) should not be vaccinated.
- Individuals with a history of other allergies (to food, pets, insects, environmental, latex, oral medications) or a family history of anaphylaxis should be vaccinated.

High-Density Communities and Equity Considerations

- Equitable access to the vaccine is a core priority and will continue to be on the forefront of all of our decisions
- We are incorporating feedback on equity considerations from the COVID-19 Vaccine Subcommittee, Equity Council, and other partners and stakeholders into our planning processes.
- The State is actively exploring options for supporting early vaccination in high-density communities. More information will be shared as those plans solidify.
- Given how hard COVID-19 has hit some Rhode Island communities, it is especially important for many people to get vaccinated. This will help reduce existing disparities and ensure Rhode Islanders in every ZIP code are protected from this disease.

Important Considerations

- Not all members of each phase will be vaccinated at the same time. Prioritization will need to happen within phases (based on vaccine availability).
- The amount of vaccine coming into Rhode Island and the timing of shipments of vaccine are subject to change. This affects planning.
- Plans for places where vaccine will be administered for Phases 2 through 4 are being developed. Eventually, venues will likely include doctors' offices, community clinics, pharmacies, and other sites.
- Rhode Island will be vaccinated over months, not weeks. Traditional measures to prevent spread will still be critical (masks, social distancing, etc.).

Questions?

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