COVID-19:
Preparing Vermont for a Vaccine

Phase 1-A: Hospitals
Vermont Department of Health

Thursday, December 10, 2020
Overview

• COVID-19 Vaccines and Vermont Phased Rollout
• Storage and Handling
• Ordering and Distribution
• IMR Access and Reporting
• Safety and Emergency Use Authorization (EUA)
• Administration and Clinics
• Staying informed
COVID-19 Vaccine and Vermont Phased Rollout

Christine Finley, APRN, MPH - Immunization Program Manager
The Vaccine Life Cycle
safety at every phase

GUIDE
ACIP
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES
BLA
BIOLGICS LICENSE APPLICATION
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION
FDA
FOOD AND DRUG ADMINISTRATION
IND
INVESTIGATIONAL NEW DRUG APPLICATION

safety is a priority during vaccine development + approval

VACCINE

DEVELOPMENT

PHASE 1
safety

PHASE 2
effectiveness

PHASE 3
safety + effectiveness

FDA REVIEW

BLA REVIEW

IND SUBMITTED

CLINICAL STUDIES/TRIALS

FDA APPROVAL OF NEW VACCINE

ACIP REVIEW

POST-APPROVAL MONITORING + RESEARCH

PHASE 4
safety monitoring for serious, unexpected adverse events

safety continues with CDC + FDA safety monitoring

BASIC RESEARCH

DISCOVERY

PRE-ClinICAL STUDIES

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvvNd

CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvNNe
Pfizer’s and Moderna’s vaccine candidates were developed using a new vaccine technology employing messenger RNA (mRNA). When authorized or approved, these will be the first vaccines approved using mRNA technology.

**Traditional Vaccines:** Introduce viral protein or antigen into the body to trigger an immune response

**mRNA Vaccines:** Deliver messenger RNA into the body that act as instructions to create protein

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**Facts about COVID-19 mRNA Vaccines**

They cannot give someone COVID-19

- mRNA vaccines do not use the live virus that causes COVID-19.

They do not affect or interact with our DNA in any way.

- mRNA never enters the nucleus of the cell, which is where our DNA (genetic material) is kept.
- The cell breaks down and gets rid of mRNA soon after it is finished using the instructions.
Vaccine Efficacy

- Pfizer / BioNTech vaccine
  - 95% effective in study participants
  - Over 43,000 participants no serious safety concerns

- Moderna vaccine
  - 94.5% effective in study participants
  - Over 30,000 participants no serious safety concerns
Phased Approach

The COVID-19 Vaccination Program will require a phased approach

- **Phase 1**
  - Potentially Limited Doses Available
  - Projected short period of time for when doses may be limited
  - Likely sufficient supply to meet demand
  - Expand beyond initial populations
  - Use a broad provider network and settings: including healthcare settings (doctors’ offices, clinics), commercial sector settings (retail pharmacies), public health venues (public health clinics, mobile clinics, FQHCs, community settings)

- **Phase 2**
  - Large Number of Doses Available

- **Phase 3**
  - Continued Vaccination, Shift to Routine Strategy
  - Likely sufficient supply
  - Open access to vaccination
  - Administer through additional private partner sites
  - Maintain public health sites where required
COVID-19 Vaccine Initial Allocation

Phase 1A: Health care workers (HCW) likely to be exposed/treat COVID-19 patients

- Long-term care facility residents and staff who have patient contact
- Clinical and support staff who have patient contact in settings at high risk for COVID-19 patient contact:
  - HCW (all classes including support personnel) primarily located in the ED, Med-Surg and ICU providing care to COVID patients
  - HCW (all classes including support personnel) caring for COVID patients in other settings
  - EMS with patient contact
- Home health care clinical staff and caregivers who have contact with multiple patients/vulnerable people
- Other health care providers/staff who have patient contact
COVID-19 Vaccine Storage and Handling
Ines Burazerovic, MPH, CHES - VFC Coordinator
COVID-19 Vaccine Management

1. Cold Chain Management
2. Vaccine Delivery
3. Temperature Monitoring Devices and Requirements
4. Vaccine Specific Handling Guidelines
5. Temperature Excursions
Cold Chain Flowchart

- Vaccine manufacturing
- Vaccine distribution
- Vaccine arrival at provider facility
- Vaccine storage and handling at provider facility
- Vaccine administration

Responsibilities:
- Manufacturer responsibility
- Manufacturer/distributor responsibility
- Provider responsibility
Vaccine Distribution – Pfizer (-60 to -80°C/-76 to -112°F)

Facilities without ultracold capacity
• Delivered by a depot driver at monitored refrigerated temperatures.

• Monitored during transit with a state supplied LogTag device and a transportation paper log.

• Placed in a monitored refrigerator immediately upon receipt.

• Once removed from ultra-cold storage at the depot, sites will have 120 hours to use the vaccine.

• The 120 hour start time and expiration time will be documented with the delivery.

Facilities with ultracold capacity (if not direct ship)
• Delivered by a depot driver at monitored refrigerated temperatures.

• Monitored during transit with a state supplied LogTag device and a transportation paper log.

• Once removed from ultra-cold storage at the depot, sites will have 120 hours to use the vaccine.

• When vaccine allocation improves there could be direct shipments.
Vaccine Distribution – Moderna (-25 to -15°C/-13 to 5°F)

- May be delivered by a depot driver at monitored freezer temperatures.
- May be direct shipped at monitored freezer temperatures from McKesson in multiples of 100 doses.
- Monitored during transit with a state supplied LogTag device and an hourly paper log.
- Should be moved out of the vaccine carrier and placed under proper storage conditions (-25 to -15°C)* immediately.
- Facilities without a freezer may store Moderna vaccine in the refrigerator at 2 – 8°C for 30 days.

* Note: Please ensure your freezer stays within this range before accepting Moderna vaccine.
Digital Data Loggers (DDL)

- LogTag Analyzer
- SensoScientific Cloud-Based Wi-Fi
- Third Party Systems
Temperature Documentation Requirements

Facilities need to check and record storage unit minimum and maximum temperatures at the start of each day. Documentation can be done on a paper temperature log or digitally.

Each recording needs to have:

- Minimum/maximum temperature
- Date
- Time
- Name of person who checked and recorded the temperature
- Any actions taken if a temperature excursion occurred
- If a reading is missed, leave a blank entry in the log
Vaccine Specific Handling Guidelines – Pfizer Vaccine

**Ultra Cold Freezer:** -60 to -80°C/-76 to -112°F for 6 months

**Refrigerator:** 2-8°C/~36 - 46°F for up to 120 hours. Do not refreeze.

- 5 doses per vial
- Discard any puncture vial after 6 hours
- Room temperature storage is no more than 2 hours. Diluted vaccine should be stored at refrigerated temperatures.
- Minimum order of 195 vials (975 doses)
- Unless site can store and utilize this quantity, Pfizer vaccine will be transferred to you from the Depot
**Vaccine Specific Handling Guidelines – Moderna Vaccine**

**Freezer:** -25 to -15°C/-13 to 5°F for 6 months

**Refrigerator:** 2-8°C/~36 - 46°F for up to 30 days. Do not refreeze.

**Room Temperature:** Up to 12 hours

- 10 preservative free 0.5mL doses per vial
- No dilution required
- Discard any puncture vial after 6 hours
- Minimum order of 10 vials (100 doses)
- Can ship directly from McKesson
Temperature Excursions

Temperature Excursion: Whenever a vaccine experiences a period of time outside of recommended temperatures

**Notify**
Appropriate staff at your facility

**Document**
Label outside of unit “DO NOT USE”

**Contact**
The Health Department Immunization Program

**Correct**
If applicable: Close the door
Plug the unit in

**DO NOT:**
- Adjust the temperature
- Move the vaccine
- Add ice packs to refrigerators
If Temperature Excursion Occurs, Contact Immunization Program

1. Refrain from making assumptions about the vaccine viability
2. Gather temperature excursion information
3. Do not move the vaccine
4. Vaccine viability will be assessed and communicated

If you experienced a temperature excursion, contact the Immunization Program during standard business hours promptly by phone 1-800-640-4374 or email ahs.vdhimmunizationprogram@vermont.gov
COVID-19 Vaccine Ordering and Distribution

Karen Halverson, Immunization Program Vaccine Manager
Elan Curran, Immunization Program Specialist
COVID-19 Distribution Plan

1. Allocation
2. Ordering
3. Ancillary Supplies
4. Vaccine Accountability
5. VaccineFinder
Allocation: The Health Department Immunization Program will manage allocations and ordering

- From our first allocation, shipments of Pfizer’s COVID-19 vaccine will come to the Immunization Program Depot, and to the UVM Medical Center.

- Due to the limited allocation, large minimum order (975 doses) per delivery location, and ultracold temperature requirements (-70°C), Pfizer vaccine will initially be transferred from the Depot to all other hospitals.

- Transfer of the Pfizer vaccine from the Depot will be tailored to the receiving facilities storage capacity and planned timing for administration. Vaccine must be transferred at refrigerator temperature, limiting the length of time it remains viable to 120 hours.

- Moderna’s COVID-19 vaccine is expected soon after the Pfizer vaccine and allows for smaller minimum orders (100 doses). This vaccine may be delivered directly from McKesson Specialty or transferred from the Depot.
Vaccine Orders: The Health Department Immunization Program will keep you informed

• The Immunization Program will order vaccines from our allocation on your behalf based on priority groups served, throughput, and the capacity to store vaccine.

• States expect weekly vaccine allocation from the CDC which will include second doses for ordering at the appropriate time. More information on 2\textsuperscript{nd} dose planning will be provided at a later date.

• The hospital COVID vaccine coordinator should expect a phone call today or tomorrow to discuss specifics for the vaccine coming in each of the next two weeks.

• Communication will be ongoing, between the Health Department and the hospital Emergency Preparedness contact, the COVID vaccine coordinator, and back-up, to ensure awareness of the vaccine supplied, delivery timing, and number of doses to expect.

• Vaccine doses you receive will appear in the Health Department’s vaccine inventory management system after a transfer or an order has been made by the Immunization Program on your behalf.
Ancillary Supplies

- Vaccine deliveries may be made Monday through Friday. For direct shipments, ancillary supplies will arrive separately, before or the same day as vaccine. When delivered from the Health Department Depot they’ll arrive with the vaccine.

- Ancillary supply kits will be automatically added to vaccine orders and do not require additional action or separate ordering.

- Kits will include diluent, needles, syringes, alcohol prep pads, a COVID-19 vaccination record card for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields.

- Kits will not include sharps containers, gloves, bandages, or other supplies.
Vaccine Accountability: The Vaccine Inventory Management System (VIMS)

VIMS is accessed through the Vermont Immunization Registry (IMR).

1. Click on the Immunization Registry Log On graphic.
2. Username is “first name.last name” and the password is established with your user access set up.
3. On the main menu screen, Select Vaccine Inventory Management System (VIMS) from the left navigation menu.

If you have forgotten your username, password or do not know if you have IMR access, contact Immunization Registry User Support at 888-688-4667 or IMR@vermont.gov.

For more information on VIMS documentation of Returns/Waste, and reconciling inventory, visit the Vaccine Ordering Page.

Weekly reconciliation of COVID-19 vaccine is required. Adjustments for wastage or expiration should be logged the day they occur.
All vaccines have expiration dates, and some routinely recommended vaccines have a beyond use date (BUD), which is calculated based on the date the vial is first punctured and the storage information in the package insert.

For COVID-19 vaccines:

- The expiration date may change for some vaccines as more stability data become available.

- The Emergency Use Authorization (EUA) Fact Sheets for Vaccine Providers or manufacturer websites will provide more information about expiration dates and BUDs.

- The CDC is developing tools to assist with the complicated administration timing of the COVID-19 vaccines.
VaccineFinder & VTrckS:

CDC materials may contain references to required daily COVID-19 vaccine inventory reporting through VaccineFinder as well as mention of the ordering system VTrckS.

Vermont will report on your behalf using data from VIMS vaccine distribution and reconciliation and doses administered data reported to the Immunization Program.

All requirements are fulfilled through your usage of VIMS and the IMR.
IMR Access and COVID-19 Reporting

Bridget Ahrens, MPH - Immunization Registry Manager
Vermont Immunization Registry (IMR)
COVID-19 Vaccine: Give A Dose, Report A Dose

HOSPITALS

EHR
Direct entry

HL7
IMR

BE PREPARED
Ask your EHR vendor to add the CVX codes for Covid-19 vaccine!

<table>
<thead>
<tr>
<th>Trade Name</th>
<th>CVX Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderna COVID-19 Vaccine®</td>
<td>207</td>
</tr>
<tr>
<td>Pfizer-BioNTech COVID-19 Vaccine®</td>
<td>208</td>
</tr>
</tbody>
</table>

All doses must be reported within 72 hours.
All Data Reporting Comes from the IMR

- Need to check patient history?
- Need to know if it’s too soon for the next dose?
- Need to enter data?

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Need Access to the Vermont Immunization Registry (IMR)?

**IMR is your go-to resource**

Form for Hospital User Access:

Form for District Office or Medical Provider Site access:
Need to Know How to Use the IMR and Forecaster?

**FEATURED IMR TUTORIAL**
How to Use Vaccine Forecaster
https://youtu.be/lM45xc1WDW8

**IMR BASIC TUTORIALS**
How and why to add vaccine to library
https://youtu.be/8SBauz0lxoc

How to manually enter an immunization quickly
https://youtu.be/PqkGfWRktB4

How to manually add a patient
https://youtu.be/NxKQj288y80

OWL use the IMR!
IMR User Support is Just an Email or a Phone Call Away.

(888) 688-4667
Password resets – call here first

IMR@vermont.gov
COVID-19 Vaccine Safety

Molly Nicholson - CDC Public Health Advisor
COVID-19 Vaccine Safety

1. Vaccine Adverse Events Reporting System (VAERS)
2. V-Safe
VAERS accepts all reports from everyone regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event.

**Key Strengths**
- Rapidly detects potential safety problems
- Can detect rare adverse events

**Key Limitations**
- Inconsistent quality and completeness of information
- Generally cannot determine cause and effect
How to Report an Adverse Event to VAERS

- Go to [www.vaers.hhs.gov](http://www.vaers.hhs.gov)
- Submit a report online
- For help:
  - Call 1-800-822-7967
  - Email info@VAERS.org
  - Video instructions [https://youtu.be/sbCWhcQADFE](https://youtu.be/sbCWhcQADFE)
V-Safe: After Vaccination Health Checker

- V-safe is a new CDC smartphone-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 side effects and health impact events after COVID-19 vaccination
  - Includes active telephone follow-up by CDC for reports of significant health impact
  - Captures information on pregnancy status and enables follow-up on pregnant women
Recommending v-safe

• Healthcare providers give a one-page enrollment sheet to patients at the time of vaccination
• Healthcare providers counsel patients on the importance of enrolling in v-safe
• CDC will create an electronic version of the v-safe information sheet for printing
COVID-19 Emergency Use Authorization (EUA), Administration and Clinics

Merideth Plumpton, RN - Nurse Program Manager – Immunization Program
COVID-19 Emergency Use Authorization, Vaccine Administration and Clinics

- Emergency Use Authorization
- Pfizer Vaccine
- Moderna Vaccine
- Patient Observation
- Resources for IM injection
Emergency Use Authorization (EUA)

What is an EUA?

• Authority of FDA Commissioner to permit emergency use of certain medical products under Project BioShield Act 2004

• Statutory criteria must be met:
  • Serious of life threatening disease/condition
  • Reasonable belief product may be effective
  • Known/potential benefits outweigh known/potential risks
  • No adequate, approved alternative

• Allows for rapid and widespread deployment for millions of individuals during a public health emergency

• Case-by-case waivers may be permitted
FDA Issuance on an EUA

- When FDA issues and EUA for a product, the following will become available:
  - EUA Letter of Authorization
  - EUA Fact Sheets

- Issued EUA documents and any subsequent amendments will be posted on FDA’s website

- Additional CDC educational and communication materials consistent with EUA

- Healthcare workers have liability protection under the Public Readiness and Emergency Preparedness (PREP) Act
Emergency Use Authorization (EUA) Fact Sheets

EUA Fact Sheet for Vaccination Providers

• Replaces the package insert found with vaccine

EUA Fact Sheet for Recipients

• Replaces VIS for licensed vaccines
• Required by law to give to patient or guardian before vaccine administration
• Written informed consent is not required under EUA
EUA Fact Sheet Delivery Methods

EUA Fact Sheet for Vaccination Providers and EUA Fact Sheet for Recipients
- Can be offered in an accessible form (e.g., printable as a hard copy)
- Through mass media (e.g. print, broadcast, radio, or internet)
- Through videos
Pfizer / BioNTech vaccine:

- Ultra-cold storage (-60 to -80°C)
- Can store at refrigerated temperatures (2 to 8°C) for 120 hrs.
- Vaccine to be given as intramuscular (IM) injection
- Two dose vaccine series given 21 days apart
- Vial contains 5 doses of vaccine
- Needs to be reconstituted
Modernova vaccine:

• Freezer storage (-25 to -15°C) up to 6 months
• Refrigerated storage (2 to 8°C) up to 30 days
• Vaccine to be given as intramuscular (IM) injection
• Two dose vaccine series given 28 days apart
• Vial contains 10 doses of vaccine
• Vaccine is frozen liquid – no reconstitution necessary

• Once thawed, swirl vial gently before drawing up a dose, do NOT shake
Immune Response to COVID-19 Vaccines

- Please inform vaccine recipients ahead of time. If they have this response it is normal, body’s way of building immunity to COVID-19.
- Pfizer has listed the following as immune responses after vaccination:
  - Sore arm, fatigue, headache, muscle pain, chills, joint pain, fever
  - Reactions more frequent after second dose of vaccine
  - Symptoms could last several days
  - Employees could have to temporarily stay home
- Plan to stagger vaccination for staff, especially second dose
- Plan for employees who develop symptoms after vaccination

https://www.fda.gov/media/144245/download
Vaccine Considerations

• Important to get both doses of vaccine!

• Health Care Workers who have had COVID in the preceding 90 days should delay vaccination to allow those who remain susceptible to infection.

• Potential for longer patient observation period
Billing for COVID-19 Vaccines

• Providers can bill for an office visit when administering COVID-19 vaccine if the visit meets the criteria for office visit coding under a recipient’s plan.

• Vaccine providers will be able to charge an administration fee. However, participating vaccine providers must administer COVID-19 vaccine regardless of the vaccine recipient’s ability to pay or their coverage status.

• For uninsured patients, the vaccine provider can seek reimbursement for an administration fee from the HRSA Provider Relief Fund.
Stay informed!

• Sign up for CDC notification of new resources and changes.

• Refer to VDH website regularly for updated resources and information.

• VDH Immunization Program will hold “Office Hours” on specific topics. These will be an informal place to ask questions. Stay Tuned!
Questions?

Ordering, Vaccine Storage and Handling, Vaccine Specific Information
E-mail: AHS.VDHImmunizationProgram@vermont.gov
Phone: 1-800-640-4374

Immunization Registry and Reporting
E-mail: IMR@vermont.gov
Phone: 1-888-688-4667

Vaccine Logistics and Clinic Planning
E-mail: AHS.VDHHOCHospitalCommunicationBD@vermont.gov
Vermont Department of Health Links

1- IMR webpage
https://www.healthvermont.gov/health-statistics-vital-records/registries/immunization

2- VIMS Return or Waste

3- Vaccine Ordering Page

4- Immunization Registry Form for Hospital User Access

5- Immunization Registry Form for District Office or Medical Provider Site Access
CDC Links

Healthcare Professionals: Preparing for COVID-19 Vaccination
https://www.cdc.gov/vaccines/covid-19/hcp/index.html

Talking to Patients about COVID-19 Vaccines
https://www.cdc.gov/vaccines/covid-19/hcp/talking-to-patients.html

Understanding mRNA COVID-19 Vaccines
EUA Resources

What is an EUA
• https://www.youtube.com/watch?v=iGkwaESsGBQ&t=45s

EUA for Vaccines Explained
• https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained

FDA Guidance: EUA for COVID-19 Vaccines

FDA Guidance: Development & Licensure of COVID-19 Vaccines