Vaccine Planning Work Group

September 3, 2020

All information in this presentation is subject to change, information shared in these slide are assumptions as of 9/2/2020

Tonya Philbrick, Maine Immunization Program

Maine Immunization Program-Influenza

The following presentations may be used for both children and adults:

Trade Name/NDC#	**Age indications based on licensure of the product**	**Presentations**	**MIP ordering requirement for specific patient population**
Flucelvax / 70461-0320-03	4 years and older	.50ml prefilled syringe Quad	Children 4 years thru 18 years and all adults
Flulaval / 19515-0816-52	6 months and older	.50ml prefilled syringe Quad	Children 6 months thru 18 years and all adults
Flumist / 66019-0307-10	2 years thru 49 years	Single dose sprayer Quad	Children 2 years thru 18 years and adults thru 49 years
Fluzone / 49281-0420-50	6 months and older	.50ml prefilled syringe Quad	Children 6 months thru 18 years and all adults

Maine Immunization Program-Influenza

The following presentations are for adults only due to funding source restrictions:

Trade Name/NDC#	**Age indications based on licensure of the product**	**Presentations**	**MIP ordering requirement for specific patient population**
Afluria / 33332-0320-01	36 months and older	.50ml prefilled syringe Quad	All Adults
Fluarix / 58160-0885-52	6 months and older	.50ml prefilled syringe Quad	All Adults
Flucelvax / 70461-0420-10	4 years and older	Multi-dose vial Quad	All Adults
Fluzone / 49281-0633-15	6 months and older	Multi-dose vial Quad	All Adults

Scenario 1: Vaccine A demonstrates sufficient efficacy/safety for EUA in 2020

Availability Assumptions

Candidate	Vaccine availability by End of Oct 2020	End of Nov 2020	End of Dec 2020	Notes
Vaccine A	~2M doses	10–20M doses	20–30M doses	Ultra-cold (-70 °C), for larg

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A	
SHIPMENT *3 separately acquired components (mixed on site)* 1. Vaccine • Direct to site from manufacturer (on dry ice) • Multidose vials (5 doses/vial) 2. Diluent • Direct to site from USG (at room temperature) 3. Ancillary supply kits • Direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** *Frozen (-70 °C ± 10 °C)* • Must be used/recharged within 10 days • Storage in shipping container OK (replenish dr needed) *Thawed but NOT reconstituted (2–8 °C)* • Must use within 24-48 hours *Reconstituted (room temperature)* • Must use within 6 hours
ORDERS *Large quantities, to large administration sites only* • Minimum order: ~1000 doses • Maximum order: ~5,000 doses	**ADMINISTRATION** *2-dose series (21 days between doses)* • On-site mixing required; reconstitute with dilu to administration • Administer by intramuscular (IM) injection

Vaccine Assumption- Candidate A

Scenario 2: Vaccine B demonstrates sufficient efficacy/safety for EUA in 2020

Availability Assumptions

Candidate	Vaccine availability by End of Oct 2020	Vaccine availability by End of Nov 2020	Vaccine availability by End of Dec 2020	Notes
Vaccine B	~1M doses	~10M doses	~15M doses	Central distro capacity required (-20 °C)

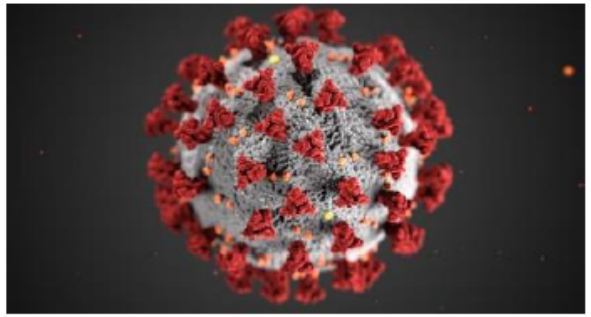
Distribution, Storage, Handling, and Administration Assumptions

Vaccine B	
SHIPMENT *2 separately shipped components* 1. Vaccine • To central distributor (at -20 °C) • Multidose vials (10 doses/vial) 2. Ancillary supply kits • Direct to site from USG (at room temperature)	**ON-SITE VACCINE STORAGE** *Frozen (-20 °C)* • Storage in shipping container OK (replenish dry ice as needed) *Refrigerated (2–8 °C)* • Must use within 7-14 days *Room temperature* • Must use within 6 hours
ORDERS *Central distribution capacity required* • Required by Dec 2020 • Maintained at -20 °C	**ADMINISTRATION** *2-dose series (28 days between doses)* • No on-site mixing required • Administer by intramuscular (IM) injection

Vaccine Assumption- Candidate B

COVID Vaccine Planning Assumptions

Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted simultaneously with large-scale manufacturing. It is not known which vaccines will be approved. COVID-19 vaccination program plans must be flexible and accommodate multiple scenarios. For the purpose of initial planning, consider the following assumptions.



COVID-19 VACCINE

- Limited COVID-19 vaccine doses may be available by early November 2020, but COVID-19 vaccine supply will increase substantially in 2021.
- Initially available COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an Emergency Use Authorization (EUA) issued by the U.S. Food and Drug Administration (FDA).
- Cold chain storage and handling requirements for each COVID-19 vaccine product will vary from refrigerated (2° to 8°C) to frozen (-20°C) to ultra-cold (-60° to -80°C) temperatures, and ongoing stability testing may impact these requirements. *Note: These temperatures are based on information available as of August 26, 2020. Updated information will be provided as it becomes available.*
- Jurisdictions should develop strategies to ensure the correct match of COVID-19 vaccine products and dosing intervals. For most vaccines, two doses of COVID-19 vaccine, separated by either ≥21 or ≥28 days, will be needed for immunity, and second-dose reminders for patients will be necessary. Both doses will need to match each other (i.e., be the same vaccine product).
- Some COVID-19 vaccine products will likely require reconstitution with diluent or adjuvant at the point of administration.

Vaccine Ordering and Distribution

- COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers. CDC will share more information about reimbursement claims for administration fees as it becomes available.
- Ancillary supply kits will include needles, syringes, alcohol prep pads, COVID-19 vaccination record cards for each vaccine recipient, and a minimal supply of personal protective equipment (PPE), including surgical masks and face shields, for vaccinators. o Each kit will include supplies needed to administer 100 doses of vaccine.
- CDC will use its current centralized distribution contract to fulfill orders for most COVID-19 vaccine products as approved by jurisdiction immunization programs. Some vaccine products, such as those with ultra-cold temperature requirements, will be shipped directly from the manufacturer.
- Jurisdiction-enrolled vaccination providers will follow the jurisdiction's vaccine ordering procedures.
- COVID-19 vaccination providers will be required to report ongoing COVID-19 vaccine inventory.
- Vaccine orders will be approved and transmitted in CDC's Vaccine Tracking System (VTrckS) by jurisdiction immunization programs for vaccination providers they enroll.
- Vaccine (and adjuvant, if required) will be shipped to provider sites within 24 hours of order approval by the immunization program, if supply is available. Ancillary supply kits and diluent (if required) will ship separately from the vaccine due to different cold chain requirements, but shipment will be timed to arrive with or before the vaccine.

Vaccine Ordering and Distribution, cont.

For COVID-19 vaccines that require reconstitution with diluent or mixing adjuvant at the point of administration, these ancillary supply kits will include additional necessary syringes, needles, and other supplies for this purpose.

- Sharps containers, gloves, bandages, and other supplies will not be included.
- Jurisdictions may need to plan for additional PPE, depending on vaccination site needs.

Minimum order size for CDC centrally distributed vaccines will be 100 doses per order for most vaccines. Minimum order size for direct-ship vaccines may be much larger. CDC will provide more detail as it becomes available.

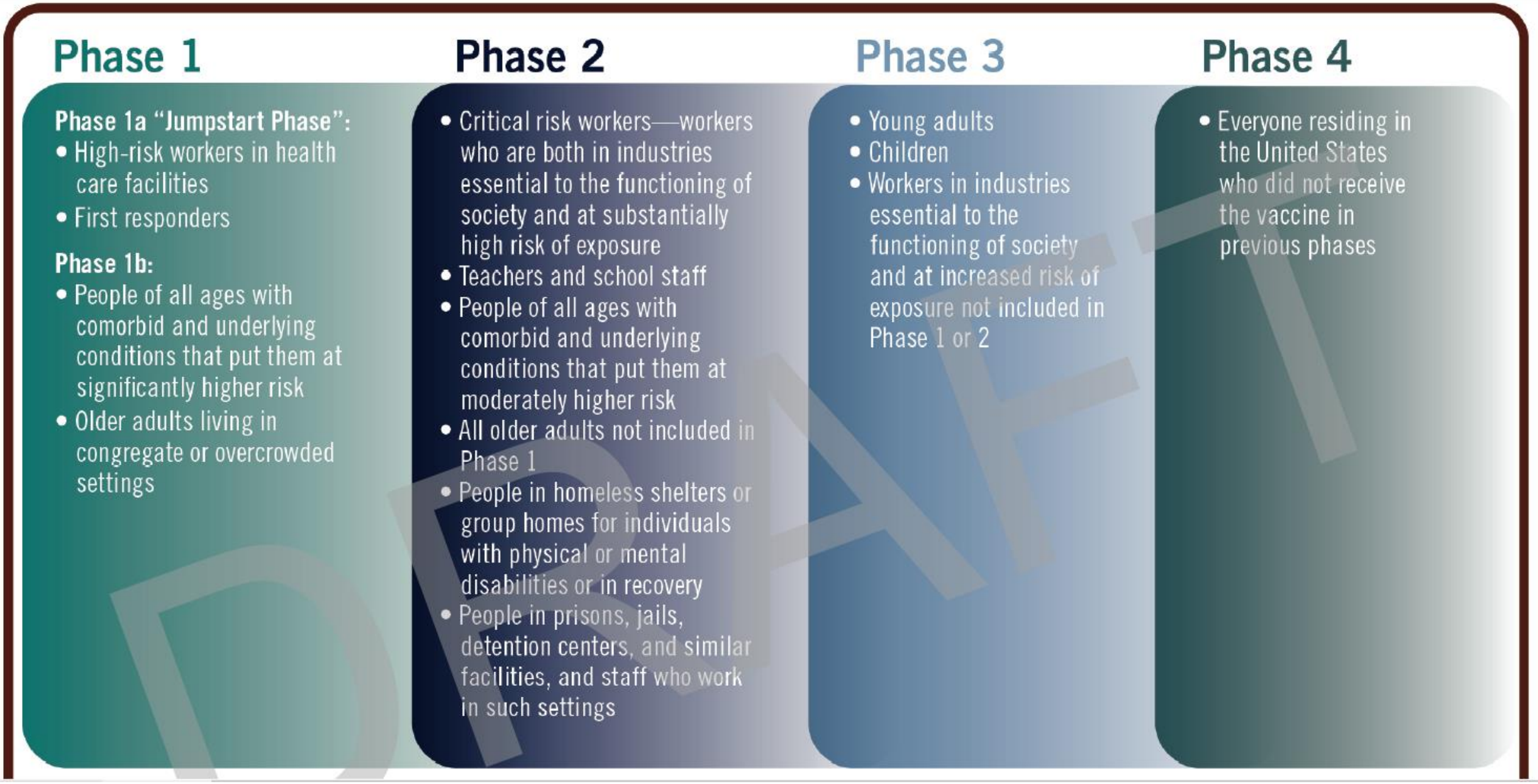
Vaccine will be sent directly to vaccination provider locations for administration or designated depots for secondary distribution to administration sites.

Jurisdictions are not advised to purchase ultra-cold storage equipment at this time; ultra-cold vaccine may be shipped from the manufacturer in coolers that are packed with dry ice, can store vaccine for an extended period of time, and can be repacked for longer use. CDC will provide additional detail as it becomes available.

Priority Groups-Assumptions

The Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine (NASEM) are considering who should be recommended to receive early, limited doses of COVID-19 vaccine.

With assistance and input from NASEM, ACIP will advise the CDC Director on which people are recommended to receive vaccine when supply is limited. As more vaccine quickly becomes available, the goal is for everyone who wants one to be able to easily get a COVID-19 vaccine.



http://nap.edu/25914, **Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine, 9/2/2020**

Survey to Hospitals

Next Week Updates

- Vaccine Administration Data Reporting
  - Roles of Electronic Medical Records, the Immunization Information System (ImmPact), and the CDC's Vaccine Administration Management System (VAMS)
- Communication Campaigns
  - Educational materials about COVID-19 vaccination provider enrollment, COVID-19 vaccine ordering, COVID-19 vaccine storage, handling, administration (i.e., reconstitution, adjuvant use, administration techniques), etc.
  - Messaging and resources specific to general public and special populations.
- Vaccine Safety
  - Use of the Vaccine Adverse Event Reporting System