Appendix B: COVID-19 Vaccination Scenarios for Jurisdictional Planning—Phase 1, Q4 2020 (updated 9/15/2020)

The planning scenarios described below should be used by state and local jurisdictions to develop operation plans for early COVID-19 vaccination when vaccine supply may be constrained. The scenarios describe potential COVID-19 vaccine requirements, early supply estimates in the event that a vaccine is authorized under EUA, and populations that may be recommended for vaccination during this early period. These scenarios are designed to support jurisdictional, federal, and partner planning, but they are still considered hypothetical. The COVID-19 vaccine landscape is evolving and uncertain, and these scenarios may change as more information is available.

Planners should assume that by January 2021, significantly more COVID-19 vaccine may be available for distribution and plans will need to evolve to address additional vaccine availability. Please refer to COVID-19 vaccine planning assumptions and additional guidance from the Centers for Disease Control and Prevention.

Scenario 1: FDA has authorized vaccine A for Emergency Use Authorization (EUA) in 2020

Availability Assumptions

	Vaccine availability under EUA by			
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine A	~2 million (M) doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C) storage requirements, for large sites only

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 the US Government (USG) at room temperature) 3. Ancillary supply kits (for administration and mixing) • 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 dry ice within 24 hours of receiving shipment and again 5 days later) ***Thawed but NOT reconstituted (2–8 °C)*** • Must use within 5 days (discard unused doses after 5 days) ***Reconstituted (room temperature)*** • Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)
ORDERS ***Large quantities, to large administration sites only*** • Minimum order: ~1,000 doses • Maximum order: ~5,000 doses	**ADMINISTRATION** ***2-dose series (21 days between doses)*** • On-site mixing required; reconstitute with diluent just prior to administration • Administer by intramuscular (IM) injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES ***Healthcare personnel*** — public health, closed point of dispensing (POD), temporary/off-site vaccination clinics + potential for mobile clinics ***Other essential workers*** — public health, closed POD, temporary/off-site vaccination clinics + potential for mobile clinics ***People at higher risk of severe COVID-19 illness*** — potential for mobile clinics to long-term care facilities (LTCFs)	

Additional Considerations for Early Vaccination Planning

- "Healthcare personnel" includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the critical populations as possible, given limitations with the product. For example: Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput.

Scenario 2: FDA has authorized vaccine B for EUA in 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine B	~1M doses	~10M doses	~15M doses	Central distributor 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 ***Refrigerated (2–8 °C)*** • Must use within 14 days ***Room temperature*** • Must use within 6 hours (discard any unused vaccine after 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 IM injection
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES ***Healthcare personnel*** — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics ***Other essential workers (specifics TBA)*** —occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics ***People at higher risk of severe COVID-19 illness (e.g., LTCF residents)*** — commercial pharmacy partners + mobile clinics	

Additional Considerations for Early Vaccination Planning

- "Healthcare personnel" includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine B can be stored at 2–8 °C.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach critical populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given limitations with the product.

Scenario 3: FDA has authorized vaccines A and B for EUA in 2020

Availability Assumptions

Vaccine availability under EUA by				
Candidate	**End of Oct 2020**	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine A	~2M doses	10M–20M doses	20M–30M doses	Ultra-cold (-70 °C), for large sites only
Vaccine B	~1M doses	~10M doses	~15M doses	Central distribution capacity required (-20 °C)
Total	**~3M doses**	**20M–30M doses**	**35M–45M doses**	

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 dry ice within 24 hours of receiving shipment and again 5 days later)

Thawed but NOT reconstituted (2–8 °C)

- Must use within 5 days (discard unused doses after 5 days)

Reconstituted (room temperature)

- Must use within 6 hours (discard any unused, reconstituted vaccine after 6 hours)

ORDERS

Large quantities, to large administration sites only

Minimum order: ~1,000 doses

Maximum order: ~5,000 doses

ADMINISTRATION

2-dose series (21 days between doses)

- On-site mixing required; reconstitute with diluent just prior to administration
- Administer IM injection

PRIORITIZED POPULATIONS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Healthcare personnel — public health, closed POD temporary/off-site vaccination clinics + potential for mobile clinics

Other essential workers (specifics TBA) — public health, closed POD temporary/off-site vaccination clinics + potential for mobile clinics

LTCF residents & staff — potential for mobile clinics to facilities

Vaccine B

SHIPMENT

2 separately shipped components

Vaccine

- To central distributor (at -20 °C)
- Multidose vials (10 doses/vial)

Ancillary supply kits

- Direct to site from USG (at room temperature)

ON-SITE VACCINE STORAGE

Frozen (-20 °C)

- Storage in shipping container OK

Refrigerated (2–8 °C)

- Must use within 14 days

Room temperature

- Must use within 6 hours (discard any unused vaccine after 6 hours)

ORDERS	ADMINISTRATION
Central distribution capacity required	***2-dose series (28 days between doses)***
• Required by Dec 2020 • Maintained at -20 °C	• No on-site mixing required • Administer by intramuscular (IM) injection

INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINE ADMINISTRATION SITES

Healthcare personnel — healthcare clinics + healthcare occupational health clinics + public health, closed POD, temporary/off-site vaccination clinics + mobile clinics

Other essential workers (specifics TBA) —occupational health + hospital clinics + public health, closed POD, temporary/off-site vaccination clinics

People at higher risk of severe COVID-19 illness — commercial pharmacy partners + mobile clinics

Additional Considerations for Early Vaccination Planning

- "Healthcare personnel" includes paid or unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to people with COVID-19 or infectious materials.
- Jurisdictions should plan for real-time shipment of doses.
- Administration sites (during Phase 1) will not be required to store vaccine products beyond the period of time Vaccine A can be stored in the ultra-cold shipment box or Vaccine B can be stored at 2–8 °C.
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on administration sites that can reach prioritized populations with as much throughput as possible.
- Stability testing is ongoing for Vaccine A and Vaccine B; the storage and handling requirements presented here may shift. The requirements in these scenarios are likely the strictest set of requirements for which planning is needed.
- Jurisdictions should consider partnering with the private sector and with local hospital systems to provide vaccine in closest proximity to the prioritized populations as possible, given the limitations with the product. For example: Vaccine A may be administered through mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput.

Appendix C: Phase 1 Population Group Worksheet Example

PHASE 1-A POPULATION GROUP: HEALTHCARE PERSONNEL

Sub-Group	Agency/Organization	Point of Contact (POC)	POC Number	Contact e-mail	Key Group	Estimate # in Key Group
Long Term Care	*Town Nursing Home*	*Jane Smith*	*123-456-7899*	townnh@gmail.com	*Direct Care Staff*	*50*
	County Nursing Home	*John White*	*123-789-1234*	conursinghome@co.gov	*Direct Care Staff*	*50*
Hospitals	*ABC Hospital*	*Joe Admin*	*123-555-6666*	jadmin@abchosp.com	*ICU Staff*	*50*
					Direct Care Staff	*200*
	City X Hospital	*Sue Jones*	*123-666-5555*	cityx@hospital.com	*Direct Care Staff*	*300*
Public Health	*Anywhere Health Dept.*	*Ann Stewart*	*123-222-1234*	astewart@cohd.gov	*Clinic Staff*	*50*
					Staff Providing Direct Care	*40*
Other Healthcare Essential Workers	*County Emergency Services*	*Sam Stone*	*123-555-9876*	sstone@coems.gov	*Ambulance Staff*	*25*
	Medical Reserve Corp	*Mike Reserve*	*123-777-8888*	mrcmike@mrc.com	*Clinic Volunteers*	*30*

Appendix D: CDC IIS Data Requirements for COVID-19 Vaccine Monitoring

CDC IIS Data Requirements for COVID-19 Vaccine Administration

Background and Purpose

The ongoing, rapid monitoring of COVID-19 vaccine uptake will be a critical part of the nation's COVID-19 response efforts. Immunization programs and immunization information systems (IIS) will play a critical role in vaccine delivery, the monitoring of vaccine doses administered, and generation of vaccination coverage estimates among several different population groups.

A strong, nationally coordinated approach is critical to collecting, tracking, and analyzing vaccination data, especially in early phases of vaccine administration, which is expected to occur in non-traditional settings. This document outlines the anticipated vaccine administration data elements IIS will report to CDC. The required data elements in this document represent demographic and vaccination information routinely captured by an IIS during a vaccination event. In addition to the ability to collect and report these data elements, IIS will also be required to report information from these data elements 1) in a timely fashion (within 24 hours of administration) and 2) through a connection to the Immunization Gateway (IZ Gateway) or data lake. This will enable CDC to reliably track COVID-19 vaccinations and analyze vaccination coverage by demographic factors once vaccine supplies are available. The vaccine administration data elements in this document will continue to evolve to include inventory and distribution elements as those parameters are finalized.

Discrete Data Elements

Table 1 includes each data element that IIS will be required to report to CDC. Table 2 includes each data element that will be optional for IIS to report to CDC. Optional data requirements will support additional national coverage analysis and vaccination monitoring efforts. Data elements are also categorized as "Mass Vaccination" or "Standard". Standard data elements are likely already collected by IIS, whereas Mass Vaccination data elements are likely to require enhancements or a Mass Vaccination module for data collection and reporting. Any identifiable data elements will be used to facilitate deduplication of data within the Immunization Data Lake, an analytic environment that will be used to consolidate, deduplicate, and reconcile vaccine administration information from multiple sources (e.g. jurisdictional immunization programs, pharmacies, Department of Defense, Veterans Affairs, Bureau of Prisons, Indian Health Service). Identifiable elements will not be stored in the Data Lake environment.

Table 1. Required Data Elements

Required Data Element	Mass Vaccination or Standard
Data elements required for IIS to report	***Mass Vaccination = may require mass vaccination module or enhancement*** ***Standard = IIS Core Data Element commonly collected during routine vaccination***
Administered at location: facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard
Administration date	Standard
CVX (Product)	Standard
Dose number	Standard
IIS Recipient ID*	Standard
IIS vaccination event ID	Standard

Lot Number: Unit of Use and/or Unit of Sale	Standard
MVX (Manufacturer)	Standard
Recipient address*	Standard
Recipient date of birth*	Standard
Recipient name*	Standard
Recipient sex	Standard
Sending organization	Standard
Vaccine administering provider suffix	Standard
Vaccine administering site (on the body)	Standard
Vaccine expiration date	Standard
Vaccine route of administration	Standard
Vaccination series complete	Mass Vaccination

**Identifiable Information*

Table 2. Optional Data Elements

Optional Data Element	Mass Vaccination or Standard
Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)	***Mass Vaccination = may require mass vaccination module or enhancement*** ***Standard = IIS Core Data Element commonly collected during routine vaccination***
Comorbidity status (Y/N)	Mass Vaccination
Recipient ethnicity	Standard
Recipient race	Standard
Recipient missed vaccination appointment (Y/N)	Mass Vaccination
Serology results (Presence of Positive Result, Y/N)	Mass Vaccination
Vaccination Refusal (Y/N)	Standard

**Identifiable Information*