COVID-19 Vaccine Distribution Update

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COVID-19 Vaccine Distribution Update

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cdc.gov/coronavirus
Overview

- Overview of current COVID-19 vaccine distribution planning assumptions
- Overview of the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations ("The Playbook")
- Potential COVID-19 vaccine distribution scenarios for Tribal and Urban American Indian/Alaska Native communities
The Vaccine Life Cycle

safety at every phase

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

VACCINE DEVELOPMENT

PHASE 1
safety
PHASE 2
effectiveness
PHASE 3
safety + effectiveness

FDA APPROVAL OF NEW VACCINE
ACIP REVIEW
SAFE SURVIORS
POST-APPROVAL MONITORING + RESEARCH

safety continues with CDC + FDA safety monitoring

safety is a priority during vaccine development + approval

BASIC RESEARCH
DISCOVERY
PRE-CLINICAL STUDIES
IND SUBMITTED
CLINICAL STUDIES/TRIALS
BLA SUBMITTED

FDA VACCINE DEVELOPMENT + APPROVAL PROCESS http://go.usa.gov/xvNld
CDC VACCINE SAFETY MONITORING + RESEARCH http://go.usa.gov/xvNNe
Multiple Critical Components to Vaccine Implementation

Public health impact relies on rapid, efficient, and high uptake of complete vaccine series, with focus on high-risk groups.

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Key Planning Assumptions
Limited doses may be available by the end of 2020, but supply will likely increase substantially in 2021.

Initial supply will either be approved as a licensed vaccine or authorized for use under an EUA issued by the FDA.

Cold chain storage and handling requirements are likely to vary from refrigerated to ultra-cold frozen.

Two doses, separated by 21 or 28 days, will be needed for immunity for most COVID-19 vaccines.
Planning Assumptions

- COVID-19 vaccine and supplies will be procured and distributed by the federal government at no cost to enrolled COVID-19 vaccination providers.
- Due to vaccine storage and handling and reporting requirements, COVID-19 vaccines will be distributed through existing clinical and health infrastructure.
  - **Three different vaccine cold chain parameters:**
    - Refrigerated (2-8 C): 1-4 vaccines
    - Frozen (-20 C): 1-2 vaccines
    - Ultra-cold (-70 C): 1 vaccine
  - Vaccine orders will have a **minimum order size of 100 doses**
- Administration sites 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.
Initial Vaccination with Limited Vaccine Supply

- Due to initial limited supply, administration sites will need to identify priority groups for vaccination.
- Advisory Committee on Immunization Practices (ACIP) will provide guidance on priority groups
  - Tribal governments determine the population they choose to serve*
    and groups for initial vaccination

*Text provided by the American Indian Health Commission of Washington State
Critical Populations to Ensure Access

- Critical infrastructure
- People at increased risk for severe illness
- People at increased risk of acquiring or transmitting COVID-19
- People with limited access to vaccinations

Draft – for planning purposes only and subject to change

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Jurisdictional “Playbook” Released September 16, 2020

- Partner Engagement
- Locating Critical Populations
- Vaccination Provider Recruitment, Enrollment and Training
- Vaccination Program Communication
- Vaccine Ordering and Distribution
- Vaccine Storage and Handling (preliminary)
- Vaccine Safety Monitoring (preliminary)
- CDC Dashboards


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Required Reporting for COVID-19 Vaccine

- Administration sites will need to provide daily reporting on required data elements (see Appendix D in the Playbook for a comprehensive list)
- Inventory – Doses received, Doses wasted/expired
- Doses Administered
  - Facility information
  - Patient information
    - Name, DOB, Sex, date of administration, location of injection
  - Vaccine information
    - Lot number, expiration date, vaccine/manufacturer codes, dose #
- Adverse events
CDC’s strategic framework for strengthening vaccine confidence and preventing outbreaks of vaccine preventable diseases.

**Protect communities**

- **Strategy: Protect communities at risk from under-vaccination**
  - Leverage immunization data to find and respond to communities at risk
  - Work with trusted local partners to reach communities at higher risk of disease
  - Ensure vaccines are available, affordable, and easy-to-get in every community

**Empower families**

- **Strategy: Get providers and parents effective information resources**
  - Expand resources for health care professionals to help them have effective vaccine conversations with parents
  - Work with partners to start conversations before the first vaccine appointment
  - Help providers foster a culture of immunization in their practices

**Stop myths**

- **Strategy: Stop misinformation from eroding public trust in vaccines**
  - Work with local partners and trusted messengers to improve confidence in vaccines among key groups at higher risk of disease and communities of color
  - Establish partnerships to contain the spread of misinformation
  - Educate key new stakeholders (e.g., state policy makers) about vaccines
Resources

For more information, contact CDC
1-800-CDC-INFO (232-4636)

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.
Backup

Use for section headers
### Data Requirements: Required

<table>
<thead>
<tr>
<th>Required Data Element</th>
<th>Standard or Mass Vaccination</th>
</tr>
</thead>
</table>
| Data elements required for IIS to report | Standard = IIS core data element  
Mass Vaccination = May require IIS enhancement |
| Administrated at location: facility name/ID | Standard |
| Administrated 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 | Standard |
| Lot Number: 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 complete | Mass Vax |

*Identifiable data
Data Requirements: Optional

<table>
<thead>
<tr>
<th>Optional Data Element</th>
<th>Standard or Mass Vax</th>
</tr>
</thead>
</table>
| *Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)* | *Standard = IIS core data element*
| Comorbidity status (Y/N)                                                            | Mass Vax                                     |
| Recipient ethnicity                                                                  | Standard                                     |
| Recipient race                                                                       | Standard                                     |
| Recipient missed vaccination appointment (Y/N)                                       | Mass Vax                                     |
| Serology results (Presence of Positive Result, Y/N)                                  | Mass Vax                                     |
| Vaccination Refusal (Y/N)                                                            | Standard                                     |

*Identifiable data

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