

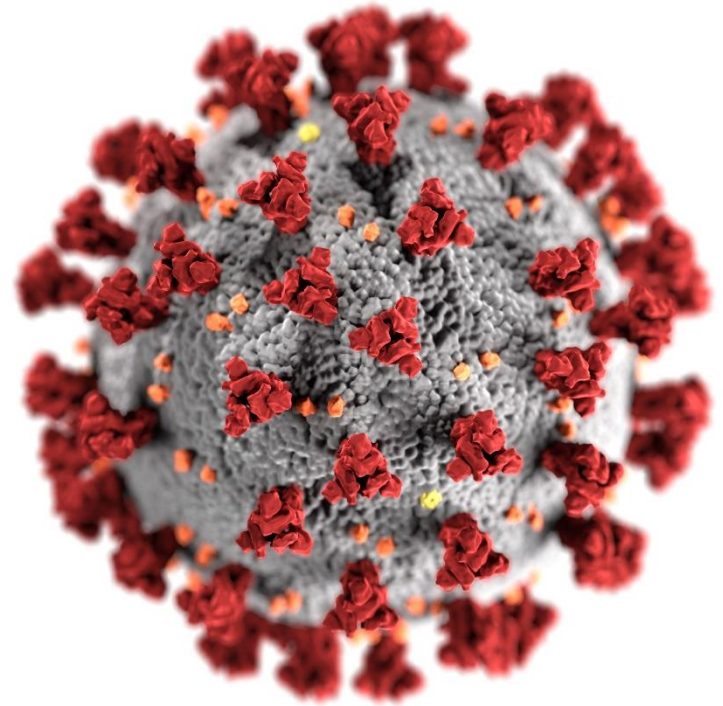
COVID-19 Vaccine Distribution Update

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CDC Vaccine Task Force

COVID-19 Vaccine Distribution Update

Date: Sept. 25, 2020



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

safety is a priority during vaccine development + approval

safety continues with CDC + FDA safety monitoring

PHASE 1
safety

PHASE 2
effectiveness

PHASE 3
safety + effectiveness

PHASE 4

safety monitoring for serious, unexpected adverse events

BASIC RESEARCH

DISCOVERY

PRE-CLINICAL STUDIES

IND SUBMITTED

CLINICAL STUDIES / TRIALS

BLA SUBMITTED

FDA REVIEW

FDA APPROVAL OF 1 NEW VACCINE

ACIP REVIEW

ACIP RECOMMENDATION

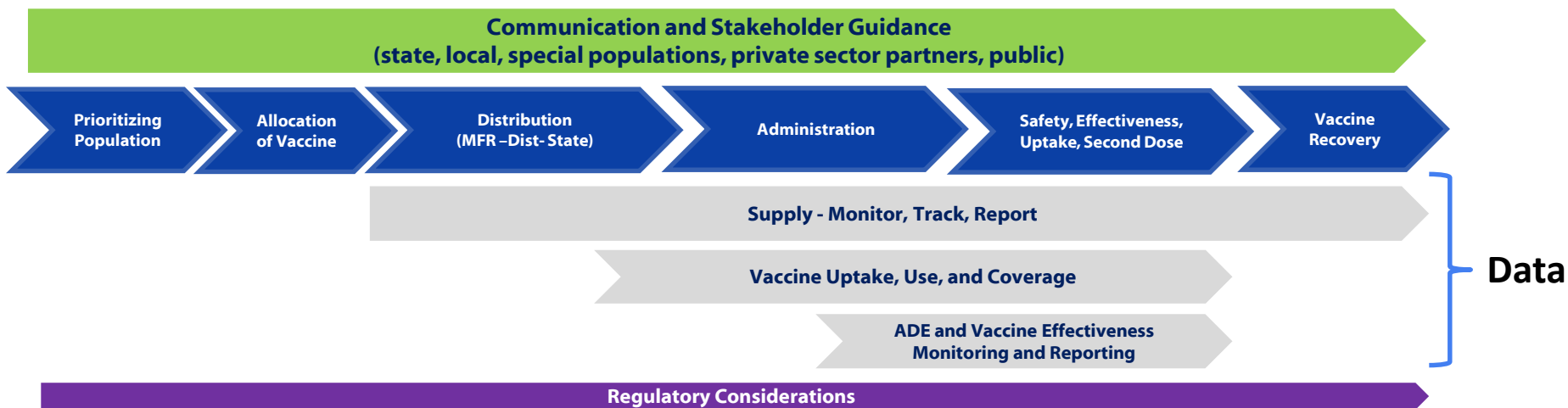
POST-APPROVAL MONITORING + RESEARCH



LEARN MORE

[FDA VACCINE DEVELOPMENT + APPROVAL PROCESS](http://go.usa.gov/xvvNd) <http://go.usa.gov/xvvNd>
[CDC VACCINE SAFETY MONITORING + RESEARCH](http://go.usa.gov/xvvNe) <http://go.usa.gov/xvvNe>

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.

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

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



Jurisdictional “Playbook” Released September 16, 2020



**Centers for Disease Control and
Prevention (CDC)**

September 16, 2020
Version 1.0

- 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

https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf



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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/manufacture codes, dose #
- Adverse events



Vaccinate with **Confidence**

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

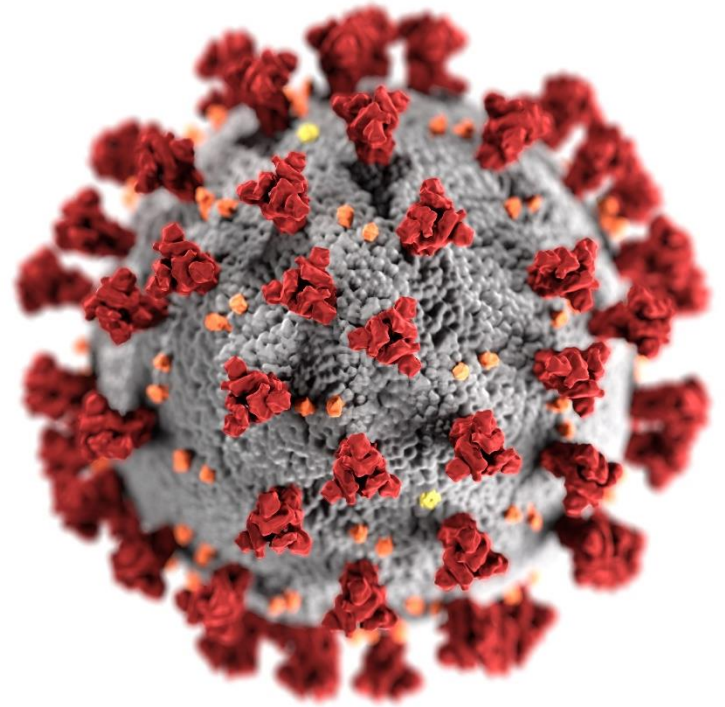
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Resources

- **COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:** https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf





For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

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

Required Data Element	Standard or Mass Vaccination
<i>Data elements required for IIS to report</i>	<i>Standard = IIS core data element Mass Vaccination = May require IIS enhancement</i>
Administrated 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	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

Optional Data Element	Standard or Mass Vax
<i>Data elements optional for IIS to report (e.g., state mass vaccination tool collects this information)</i>	<i>Standard = IIS core data element Mass Vax = May require IIS enhancement</i>
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