

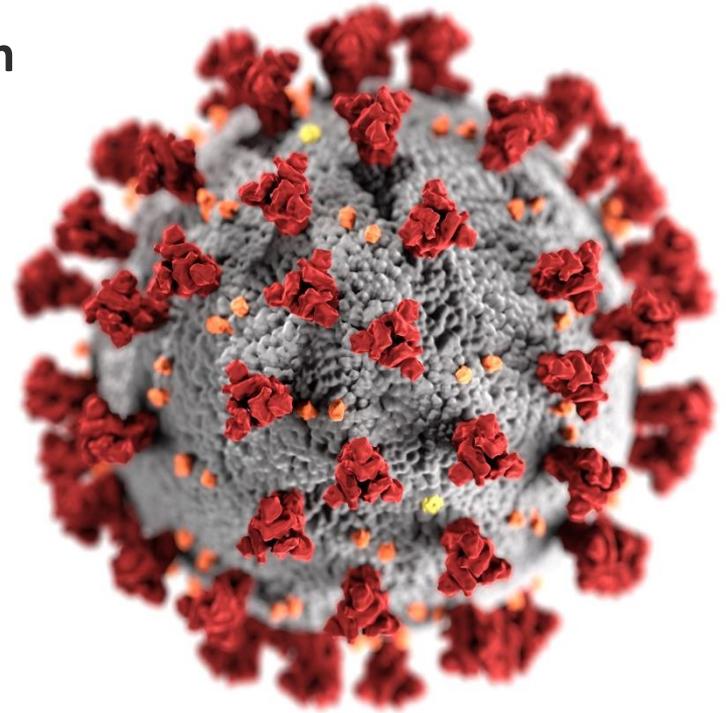
COVID-19 Vaccine Planning Update

COVID-19 Vaccine Implementation Discussion

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CDC Vaccine Task Force

CDC/ATSDR Tribal Advisory Committee Meeting

October 16, 2020



cdc.gov/coronavirus

Overview

- Overview of current COVID-19 vaccine planning assumptions
- Overview of the *COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations* (the playbook)
- Potential COVID-19 vaccine distribution scenarios for tribal nations and American Indian/Alaska Native communities
- Review of tribal regional consultation

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

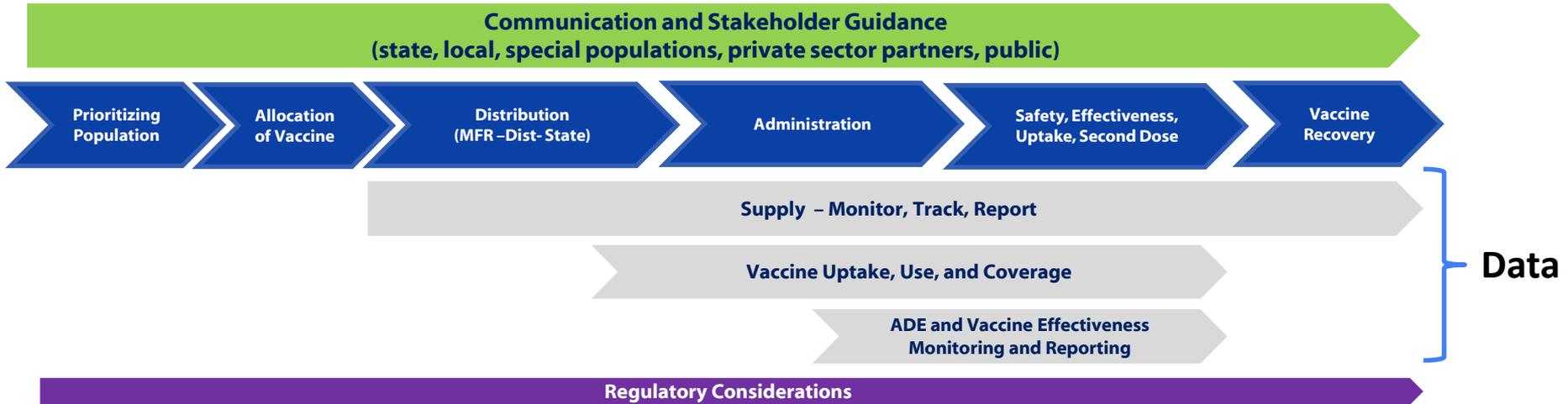


LEARN MORE

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

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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.

Planning Assumptions



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 protection** for most COVID-19 vaccines

Other Considerations for Planning

- 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 public 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.**
- Vaccination provider sites are not advised to purchase ultra-cold storage equipment at this time as there will likely be other options for storing the vaccine for an extended period.

Initial Vaccination with Limited Vaccine Supply

- Advisory Committee on Immunization Practices (ACIP) will provide recommendations with guidance on who should receive COVID-19 vaccines if supply is limited.
 - CDC recommends that tribal nations follow ACIP recommendations.
 - Tribal governments will determine the population they choose for initial vaccination.

Populations to Ensure Access to COVID-19 Vaccination in Earlier Phases

Critical infrastructure



People at increased risk for severe illness



People at increased risk of acquiring or transmitting COVID-19



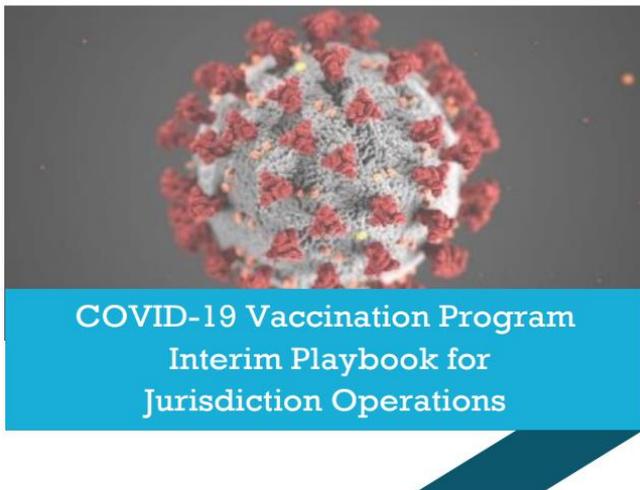
People with limited access to vaccinations



COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations



Jurisdiction* 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

***Jurisdiction refers to the 64 states, territories, and large cities that are current recipients of CDC immunization cooperative agreements.**

9/22/20





DRAFT

Vaccinate with **Confidence**

CDC's Strategy to Reinforce Confidence in COVID-19 Vaccines

**Reinforce
Trust**

Strategy: Regularly share clear and accurate COVID-19 vaccine information and take visible actions to build trust

**Empower
Healthcare
Providers**

Strategy: Promote confidence among healthcare personnel in their decision to get vaccinated and to recommend vaccination to their patients

**Engage
Communities
& Individuals**

Strategy: Practice equitable and inclusive community engagement



Potential COVID-19 Vaccine Distribution Scenarios for Tribal Nations and American Indian/Alaska Native (AI/AN) Communities



Proposed Vaccine Distribution to Tribes and Urban AI/AN Communities

- Proposed distribution model
 - **Tribal nations to decide their preference for vaccine allocation and distribution** – whether to receive vaccine at the facility level through a state/local immunization program or through IHS
- Advantages
 - Leverages existing vaccine distribution processes
 - Leverages existing vaccine and clinical infrastructure
 - IHS, Tribal and Urban Indian (I/T/U) Clinics

Vaccine Distribution Planning

- Role of tribal nations:
 - Meet with tribal health authorities and I/T/U clinics to discuss COVID-19 vaccine distribution preference.
 - Participate in COVID-19 vaccine planning discussions with state/local and IHS partners.
- Role of state/local public health jurisdictions:
 - Engage tribal nations in vaccine distribution planning.
 - Document vaccine allocation preference for each facility.
 - For tribal nations that prefer to receive vaccine through a state/local jurisdiction, ensure they are included in the state/local distribution plan.

Vaccine Distribution Planning

- Role of CDC:
 - Provide ongoing technical assistance to support decision-making.
 - Assist in establishing how tribal nations will access vaccine.
 - Ensure tribal choice for vaccine allocation is consistent with existing federal policy for dispensing medical countermeasures.
- Role of IHS:
 - Engage tribal nations in vaccine distribution planning.
 - For tribal nations that prefer to receive vaccine through IHS, ensure they are included in the IHS distribution plan.

Tribal Regional Consultation



Tribal Regional Consultation

- **To seek input from tribal leaders on COVID-19 vaccination planning for tribal nations**
- Announced by Deputy HHS Secretary Hargan on September 24
- Six regional consultation calls during the week of September 28
- Written feedback is currently under review

Consultation Themes

- **Choice for vaccine distribution**
- **Populations to receive vaccine**
- **Determining tribal population estimates**
- **Type of vaccine to receive**
- **Communication on vaccine safety and efficacy**

Choice for Vaccine Distribution

- **Tribal nations have varying preferences for vaccine distribution.**
 - *We recognize that for some tribal nations, this is particularly complex.*
 - *We anticipate that for some tribal nations served by multiple facilities, a combined state/local public health and IHS approach may be needed to ensure all the health facilities serving the nation have access to vaccine, though each facility will need to determine one source for vaccine.*
 - *Vaccine can be shipped only to locations with the capacity to store, handle, transport, and administer vaccine as required.*

Populations to Receive Vaccine

- **Tribal nations have authority to determine what populations should receive COVID-19 vaccine when vaccine allocations are not sufficient to cover the entire population.**
 - *CDC recommends that tribal nations follow ACIP recommendations.*
 - *However, the federal government respects tribal sovereignty and their right to provide vaccine in a manner determined by the tribe to be most beneficial.*
 - *American Indians and Alaska Natives are considered at increased risk for complications from COVID-19 due to several factors, including limited access to health care, increased likelihood of living in rural areas or in multigenerational housing, and higher rates of underlying medical conditions.*

Populations to Receive Vaccine

- **Tribal nations request that the entire community, not just tribal members, have access to vaccine.**
 - *CDC recommends that tribal nations work closely with their state/local public health jurisdiction to ensure this happens.*
 - *Even if a tribe decides that they prefer to access the vaccine through IHS, coordination with the state/local public health jurisdiction will be necessary to ensure community-wide coverage.*

Determining Tribal Population Estimates

- Tribal nations should determine their service area population numbers for each service unit.
 - *As tribes engage with either a state/local public health jurisdiction or IHS, they will need to provide population information to assist with planning.*
 - *Tribes should review “**Section 3: Phased Approach to COVID-19 Vaccination**” and “**Section 4: Critical Populations**” of the CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations for information about estimating the size of their population.*
 - *In planning, it is acceptable to request vaccine for non-beneficiaries living or accessing care within their service unit.*

Type of Vaccine to Receive

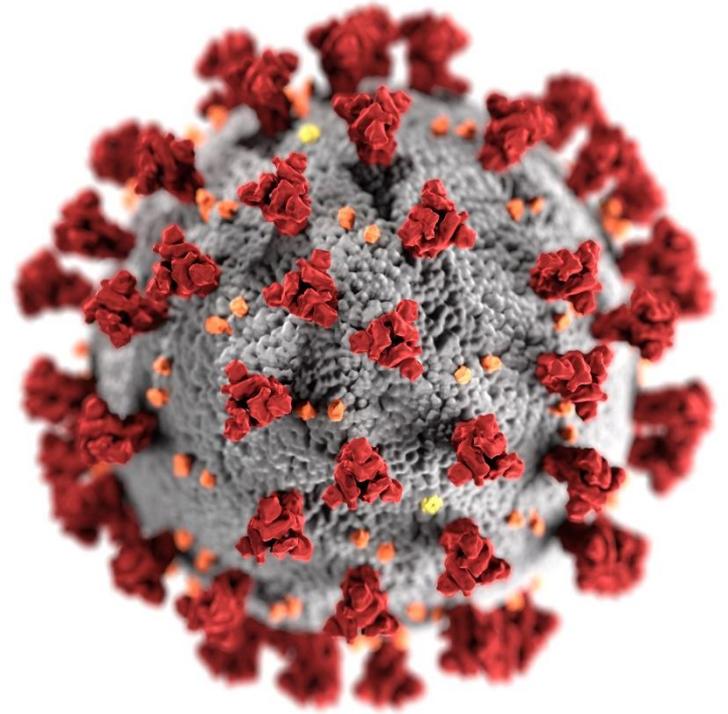
- **Tribal nations request that they may choose which vaccine product they receive.**
 - *Tribes should work with a state/local public health jurisdiction or IHS (depending on preference) to understand the process for ordering vaccine and specifying the vaccine product of interest.*
 - *All products will be authorized or approved by FDA only when sufficient trials have been completed and the trial results have been carefully studied.*
 - *Tribes should work with IHS or their state/local public health jurisdiction, depending on the option they have chosen for vaccine distribution, regarding which vaccine product they will receive.*

Communication on Vaccine Safety and Efficacy

- **Tribal nations are asking for culturally appropriate communication materials and strategies.**
 - *CDC recognizes that accurate and culturally appropriate information on COVID-19 vaccination is critical and is working on this with partners.*
 - *HHS and CDC are committed to providing technical assistance to tribes on communication strategies, and we will work closely with IHS on this.*

Considerations and Next Steps

- Reach out to state/local immunization public health programs to understand COVID-19 vaccination process and requirements.
- Reach out to tribal health authorities and the I/T/U facilities to discuss COVID-19 vaccine distribution options and determine what the best approach is for your community.
 - Review vaccine ordering and reporting processes at the I/T/U clinic(s).
- Consider electronic health record used and current capacity for reporting required COVID-19 data elements.
 - Connectivity with the state immunization information system (IIS)
 - Current data reporting to IHS
- Determine best model for COVID-19 vaccine distribution—IHS or state/local jurisdiction—and communicate decision to IHS and jurisdiction.



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.

