



OCT 14 2020

Dear Tribal Leader:

In September, the United States (U.S.) Department of Health and Human Services initiated Tribal Consultation to seek input from Tribal Leaders on COVID-19 Vaccine planning for Indian Country. In concert with this Tribal Consultation, I am writing to open a comment period through Wednesday, October 21, to request your input on the Indian Health Service (IHS) COVID-19 Pandemic Vaccine Draft Plan.

We developed and will continue to tailor the IHS COVID-19 Pandemic Vaccine Draft Plan based on available information and your input. Specifically, we will continue to assess, respond, and adapt federal guidance as new information becomes available regarding vaccine developments, vaccine storage requirements, risk groups, and recommendations prioritized by researchers and guidance bodies. Your comments and recommendations will be used to update the IHS COVID-19 Pandemic Vaccine Draft Plan accordingly.

The IHS COVID-19 Pandemic Vaccine Draft Plan is available on the IHS Web site at <https://www.ihs.gov/coronavirus/vaccine/>. Tribal programs may submit written comments on the Draft Plan to consultation@ihs.gov - SUBJECT LINE: IHS COVID-19 Pandemic Vaccine Draft Plan. **The deadline for written comments on this Tribal Consultation is Wednesday, October 21, 2020.**

Your valuable input on the IHS COVID-19 Pandemic Vaccine Draft Plan will help to ensure that a COVID-19 vaccine is effectively delivered to American Indian and Alaska Native communities that depend on the strong partnership between the federal government, tribes, and Urban Indian Organizations.

Sincerely,

/RADM Michael D. Weahkee, MBA, MHSA/
Assistant Surgeon General, U.S. Public Health Service
Director

Indian Health Service

COVID-19 Pandemic Vaccine Draft Plan

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Introduction

The COVID-19 pandemic has disproportionately affected American Indian/Alaska Native (AI/AN) populations across the country, with infection rates over 3.5 times higher than non-Hispanic whites¹. In addition, AI/AN individuals are over four times more likely to be hospitalized as a result of COVID-19². In addition to many public health measures in place, such as social distancing, mandatory curfews and closures, mask wearing and handwashing, COVID-19 vaccination remains the most promising intervention to further reduce disease, morbidity, and mortality in AI/AN people.

The Indian Health Service (IHS) supports the planning and monitoring of the IHS response to COVID-19 including COVID-19 vaccine distribution, allocation, and implementation. For the COVID-19 vaccine to be successful in allocation, distribution, administration, documentation, and monitoring, a system wide planning effort is needed immediately to be ready to implement vaccination activities as soon as an FDA-approved vaccine is available.

On September 16, 2020, the Centers for Disease Control and Prevention (CDC) issued a [COVID-19 Vaccination Interim Playbook for Jurisdiction Operations](#), Version 1.0, which covers many areas of vaccination program planning to ensure the development and implementation of a comprehensive plan. Jurisdictions, including IHS and CDC Immunization and Vaccines for Children Cooperative Agreement funding recipients, are required to address playbook requirements, describe their responsibility for ensuring activities are implemented, and submit plans to the CDC by October 16, 2020.

IHS is addressing playbook requirements and working with CDC to ensure IHS input is included and considered based on tribal and urban feedback. This IHS COVID-19 Pandemic Vaccine Draft Plan (“draft plan”) details how the IHS health care system will prepare for and operationalize a vaccine when it becomes available. This draft plan includes an overview of the IHS Vaccine Task Force and is divided into seven sections. Each section includes key IHS activities, assumptions, and specific actions for the Vaccine Task Force, Areas, and the IHS National Supply Service Center. These activities and actions are essential in coordinating the health care system response, and additional items may be added to fit local needs. This document provides important considerations for IHS Direct, Tribal and Urban Indian Health Programs as they prepare for, and determine, the most appropriate pathway to receive COVID-19 vaccine.

In order to develop a comprehensive plan, IHS requests written comments from IHS, Tribal and Urban Indian Organization (I/T/U) health programs on the draft plan by October 21, 2020. The United States (U.S.) Department of Health and Human Services (HHS) initiated tribal consultation on [COVID-19 Vaccination Planning for Indian Country](#) beginning September 28 through October 1, 2020. The request to provide written comments on the IHS COVID-19 Pandemic Vaccine Draft Plan is a separate input gathering activity under this consultation/confer umbrella. IHS will use the feedback provided from this request to update the draft plan accordingly. Tribal programs may submit written comments on the draft plan to consultation@ihs.gov. Urban programs may submit written comments to urbanconfer@ihs.gov. IHS federally operated programs may submit written comments to Area Directors.

¹ COVID-19 Among American Indian and Alaska Native Persons — 23 States, January 31–July 3, 2020 Weekly / August 28, 2020 / 69(34);1166–1169 <https://www.cdc.gov/mmwr/volumes/69/wr/mm6934e1.htm>

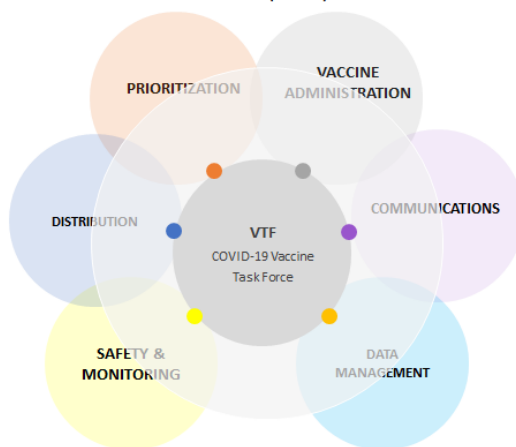
² Hospitalization rates per 100,000 population by age and race and ethnicity — COVID-NET, March 1, 2020–September 5, 2020. <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html>

This draft plan is based on currently available information. IHS will continue to assess, respond, and adapt federal guidance as new information becomes available regarding vaccine developments, vaccine storage requirements, risk groups, and prioritization recommendations by researchers and guidance bodies.

Operation – IHS Vaccine Task Force

The IHS Incident Command Structure (ICS) approved the COVID-19 Vaccine Task Force (VTF) to lead the Agency’s COVID-19 vaccine activities. The VTF shall guide development of action plans including prioritization strategies, distribution, vaccine administration, communications, data management, safety, and monitoring. The VTF Lead reports to IHS Incident Command Operations Officer to share/communicate progress as well as address barriers.

IHS COVID-19 Vaccine Task Force (VTF)



Vaccine Task Force: Prioritization Team

Team Composition: This team shall be led by Epidemiology and may include Office of Public Health Support and Office of Human Resources and others.

Role and Scope:

Identify critical and target population estimates for early phase COVID-19 vaccine distribution utilizing guidance from the CDC, CDC’s Advisory Committee on Immunization Practices (ACIP) and the National Academies of Sciences, Engineering, and Medicine. Develop algorithm for ensuring equitable allocation of COVID-19 vaccine across IHS. Collaborate across VTF teams and coordination to inform distribution, identify high-risk patients at local levels for vaccine administration, as well as ensure transparent communication.

Vaccine Task Force: Distribution and Allocation Team

Team Composition: This team shall be led by National Supply Service Center (NSSC) and may include National Pharmacy and Therapeutics Committee (NPTC), Office of Quality, Office of General Counsel (OGC), Prioritization Team, Area Point Of Contact and others.

Role and Scope:

Identify anticipated I/T/U healthcare facilities for vaccine distribution. Identify tribal and urban preference for IHS, state or local public health vaccine allocation. Promote transparency and open communication between IHS, tribes and states to ensure every facility with which NSSC is coordinating vaccine distribution has a source of distribution. Identify and procure resources, such as vaccine storage unit supplies and additional protective personal equipment (PPE) for vaccine administration. Work with CDC to ensure end to end inventory, tracking and ordering systems for COVID-19 vaccine. Advocate for delivery directly to end user. Plan for three phases of vaccine distribution (limited, large distribution, continued vaccination/shift to routine strategy).

Vaccine Task Force: Vaccine Administration Team

Team Composition: This team shall be led by Office of Clinical and Preventive Services and may include National Council of Chief Medical Officers (NCCMO), National Pharmacy Council (NPC), National Nurse Leadership Council (NNLC), Pharmacist Expanding Vaccine Access (PEVA) and others.

Role and Scope:

Develop resources and tools to assist local programs in vaccine administration and documentation. Develop template vaccination plans that can be tailored to each facility’s needs. Provide event planning strategies for various vaccination events (e.g., drive-up). Collaborate with Data Management team to develop electronic tools for identifying priority group lists, note templates, and coverage rate reports. Identify interdisciplinary workforce of nursing, public health nursing, pharmacy, and providers at National, Area and facilities NSSC is coordinating vaccine distribution to support local efforts. Collaborate with Communication team to develop clinical communication lines to channel information for support to clinicians and vaccinators.

Vaccine Task Force: Communications Team

Team Composition: This team shall be led by Public Affairs Staff and may include NCCMO, NPC, NNLC and others.

Role and Scope:

Work with internal departments, tribes and external partners, to develop key messages that are culturally appropriate. Coordinate internal and external communication. Develop a strategic communication plan for IHS vaccine allocation and distribution for internal and external audiences. Announce major milestones. Identify audiences/coordinating with stakeholders. Develop talking points. Create vehicles to use for messaging.

Vaccine Task Force: Data Management Team

Purpose: This team shall be led by Office of Information Technology (OIT) and may include Area Clinical Application Coordinators (CAC), Resource and Patient Management System (RPMS) advisory group and others.

Role and Scope:

Identify solutions to track COVID-19 vaccine, including vaccine administration data, reporting of inventory and ordering processes. Dedicate resources for facilities with which NSSC is coordinating vaccine distribution to ensure export of data to IHS and the CDC according to the required data reporting elements for COVID-19 vaccine. Determine feasibility of CDC supported platforms for use as a parallel pathway for these facilities for documentation processes. Advise Areas and facilities on data management strategies, based on the unique needs of the IHS, to document, track, and monitor vaccine.

Vaccine Task Force: Safety and Monitoring Team

Purpose: This team shall be led by NSSC and may include NPTC, Office of Quality and others.

Role and Scope:

Ensure ongoing pharmacovigilance - review Vaccine Adverse Event Reporting System (VAERS) and sentinel surveillance and provide visualization and analysis to identify significant findings. Provide systematic approach and communication for evidence-based monitoring of vaccine efficacy and safety. Develop educational training and informational resources for healthcare providers on adverse event reporting.

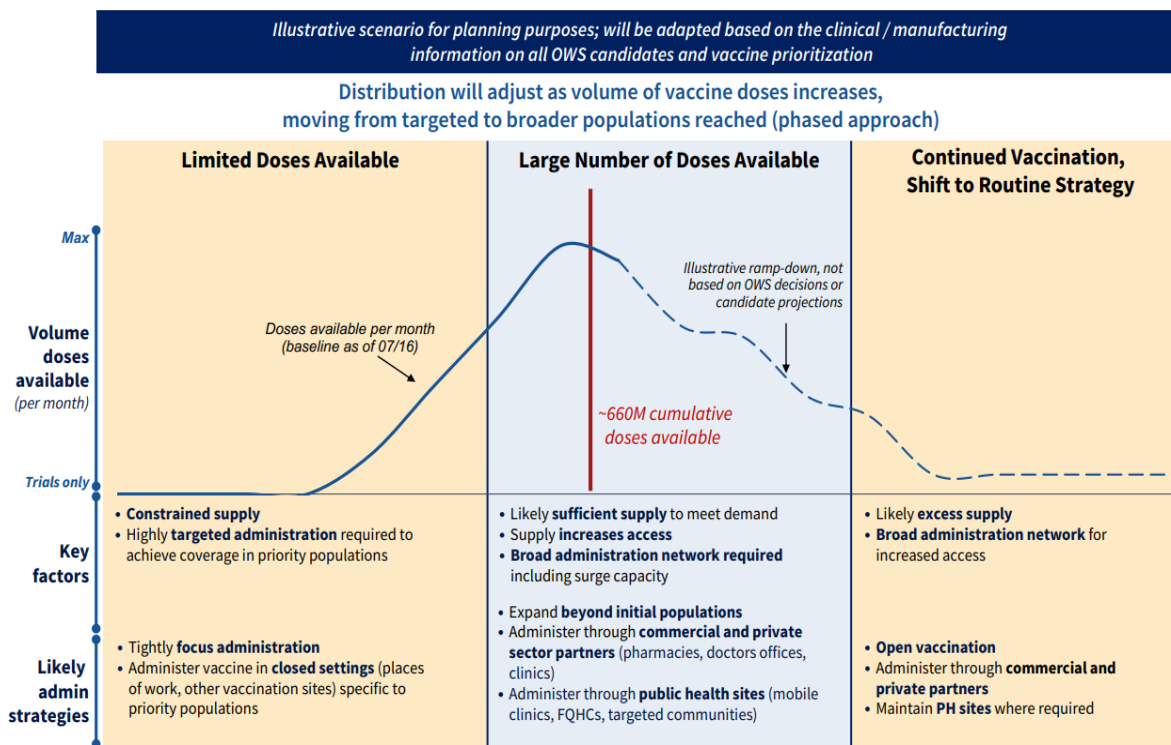
Section 1: Vaccine Availability

The COVID-19 vaccine is anticipated to be released in three phases based on vaccine approval by the U.S. Food and Drug Administration and availability, moving from targeted to broader populations. The IHS vaccine distribution and allocation will align with CDC recommendations with advice from and the Advisory Committee on Immunization Practices (ACIP) for priority populations.

IHS planning assumptions for the three phases of COVID-19 vaccine distribution, as suggested by the CDC:

- Phase 1: Limited Doses Available
 - Doses available per month constrained.
 - Highly targeted administration required to achieve coverage in priority populations.
 - Vaccine administered in closed settings specific to priority group.
- Phase 2: Large Number of Doses Available
 - Likely sufficient supply to meet demand.
 - Supply increases access.
 - Broad administration network required including surge capacity.
- Phase 3: Continued Vaccination, Shift to Routine Strategy
 - Likely excess supply.
 - Broad administration network for increased access.

Figure 1: CDC Recommended Vaccine Phase Planning



COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations:

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

Table 1: Key Activities

Indian Health Service COVID-19 Key Activities	
Pre-Planning	<p>Prioritization</p> <ul style="list-style-type: none"> • Identify AI/AN priority groups based on available information from CDC and ACIP. • Build data set to enable equitable distribution process – consider population calculator. • Engage tribal and federal partners and be transparent in distribution process once defined. <p>Distribution and Allocation</p> <ul style="list-style-type: none"> • Collaborate with CDC to identify strategy for de-centralized vaccine distribution strategy. • IHS NSSC will enroll in Vaccine Tracking System (VTrckS) through CDC for coordinated vaccine ordering. • Discuss with CDC vaccine allocation process. • Identify COVID-19 vaccine ordering platform and process for facilities with which NSSC will be coordinating vaccine distribution. • Plan for managing vaccine waste, loss and returns. • Coordinate process for breaking down vaccine orders less than 100 doses and redistribution (for refrigerated vaccine only). • Assign roles and responsibility at NSSC for managing COVID-19 vaccination orders, allocation, returns/losses, storage/handling, and questions. • Distribute educational information as available about vaccine distribution and ordering. <p>Data Management</p> <ul style="list-style-type: none"> • Complete a gap analysis of capacity and capability of facilities NSSC is coordinating vaccine with to accept and report required data. • Connect with CDC partners to review CDC platforms (ex. Vaccine Administration Management System [VAMS] and Immunization [IZ] Gateway) and determine IHS feasibility. • Establish framework for standard vaccine coverage and doses administered summary statistics. <p>Vaccine Administration</p> <ul style="list-style-type: none"> • Establish framework for reporting vaccine administration data both internal and external facing. • Evaluate templates and resources for vaccine administration for facilities NSSC is coordinating vaccine distribution response. • Develop templates and resources for vaccine administration. <p>Communication</p> <ul style="list-style-type: none"> • Establish a COVID-19 communications plan including identifying external and internal audiences, identifying communication tools and platforms. • Update website content to include COVID-19 vaccine information and resources. • Plan public education campaign that is culturally appropriate. <p>Safety and Monitoring</p> <ul style="list-style-type: none"> • Establish workflow and process for adverse event reporting. • Create process to prepare and report ongoing pharmacovigilance.

Indian Health Service COVID-19 Key Activities	
	<ul style="list-style-type: none"> • Create and disseminate education to the field surrounding safety and monitoring of COVID-19 vaccine.
Limited Doses	<p>Distribution and Allocation Team</p> <ul style="list-style-type: none"> • Apply allocation strategy to distribution process. • Process vaccine orders based on CDC allocations. • Focus distribution to closed settings serving critical/target populations as defined under Phase 1. • Generate and share standard summaries of doses distributed data. • Respond to issues regarding vaccine in the field (ex. recalls, expiration dates, disposal). <p>Data Management Team</p> <ul style="list-style-type: none"> • Maintain connection with IZ Gateway. • Maintain accurate data on vaccine distribution and administration. Comply with CDC guidance for submission of de-identified data. • Generate and share standard immunization coverage and doses administered reports according to plan. <p>Safety and Monitoring Team</p> <ul style="list-style-type: none"> • Collect adverse events reports and coordinate data reporting and follow-up with CDC. • Monitor COVID vaccine data quality and reach out to field clinicians as needed.
Large Number of Doses	<ul style="list-style-type: none"> • Continue all steps listed above in 'Limited Doses Available' phase. • Distribute vaccine broadly to facilities with which NSSC is coordinating vaccine distribution to increase access to the vaccine. • Partner with Area Offices to breakdown orders to fewer than 100 doses for smaller facilities.
Continued Vaccination	<ul style="list-style-type: none"> • Continue vaccination response as appropriate. • Incorporate distribution and use of COVID-19 vaccine into existing immunization program under OPHS/DEDP.

Section 2: Prioritization

Ensuring equitable and transparent allocation strategy when vaccine is available is a priority for IHS. Identifying critical and target population estimates for COVID-19 vaccine distribution based on early information provided from CDC, ACIP and the National Academies of Sciences, Engineering, and Medicine will assist in planning allocation and distribution strategies. Health Care Personnel (HCP) have been identified as the likely Tier I population that will receive the first 20 million vaccine doses in the U.S. as shown in Figure 1. Facilities with which NSSC will be coordinating vaccine distribution should consider estimating the amount of vaccine needed for each Tier based on the final CDC recommendations based on advice from the CDC/ACIP for COVID-19 vaccines and as determined by their local priorities. Initial IHS estimates will likely be based on existing data in the Clinical Reporting System (facility level), the National Data Warehouse (NDW), as well as pre-planning information provided by I/T/U programs considering NSSC distribution to inform high level planning for vaccine distribution.

Table 2: Prioritization Actions

Responsibility	Prioritization Actions
VTF Prioritization Team	<ul style="list-style-type: none"> • Leverage existing systems in place to extract and report data to inform decisions about those at the highest risk for exposure, those who are essential workers, and those vulnerable to experiencing severe outcomes. • Standardize data collection and provide guidance on data sources, tools and existing reports to extract data and estimate numbers of high-risk individuals to guide use of early and limited vaccine allocation. • Assist in developing an allocation strategy that ensures equity, especially when vaccine is limited.
Area	<ul style="list-style-type: none"> • Designate an Area COVID-19 Vaccine Emergency Management Point of Contact (EMPOC) and CAC to assist in data collection from facilities with which NSSC is coordinating vaccine on priority population estimates. • Offer assistance with prioritization if requested by facilities with which NSSC is coordinating vaccine.
Facilities with which NSSC will be coordinating vaccine distribution	<ul style="list-style-type: none"> • Identify local process to assess needs and review equity, considering CDC/ACIP recommendations and National Academies of Sciences, Engineering, and Medicine priority groups, especially when vaccine is limited. • Utilize local data analyst and/or local CACs to local reports to quantify individuals in the tiered risk groups. • Collect and report data to Area Vaccine EMPOC, who will then forward to NSSC POC.

Section 3: Vaccine Distribution and Ordering

Vaccine allocation and distribution information is evolving, and federal guidance will continue to inform planning for IHS. During the COVID-19 pandemic, IHS and NSSC developed communication and data collecting models for ordering and distributing personal protective equipment (PPE) and testing supplies that will help inform planning for the COVID-19 vaccine. Facilities that wish to receive the COVID-19 vaccine allocation through IHS will complete COVID-19 Vaccination Program Agreements, which will include CDC requirements.

Once the number of facilities to receive vaccine by IHS has been finalized, resources can be estimated by comparing projected allocations with facility estimates for each target population to determine the proportion of each that can be vaccinated and identify any potential deficits. It is anticipated initial FDA approved COVID-19 vaccines will be two-dose series, separated by 21 to 28 days. Facilities coordinating vaccine distribution with NSSC should plan should account for each vaccinated person to receive two doses of the same brand of COVID-19 vaccine, as brands are not interchangeable. Current recommendations are to fully vaccinate initial populations before expanding to additional target populations.

The following categories apply to facilities with which NSSC is coordinating vaccine distribution.

Coordination for Facilities

- Facilities requesting COVID-19 vaccine from NSSC will complete COVID-19 Vaccination Program Agreements.

Allocation of Limited Vaccine

- Assist in strategy for allocation process in the event there is limited vaccine.
- Develop a calculator to determine facility allocation and order sizes. The inputs into the calculator include but are not limited to, data received through the pre-planning phase.
- Vaccine availability will be communicated to ordering facilities.

Vaccine Ordering

- Facilities will order vaccines (brand specific).
- Area Vaccine EMPOC is being considered to collect vaccine orders and submit to NSSC.
- NSSC will review the orders, adjust as needed based on allocation, approve, and submit through VTrckS to CDC.
- Facilities will be notified of order tracking information.

Distribution of Vaccine to Facilities

- IHS will utilize de-centralized distribution model as defined by CDC, same as states and jurisdictions.
- NSSC will consider using a redistribution method for refrigerated vaccines, if orders less than 100 are requested.

Vaccine Inventory

- Inventory will be the responsibility of the facility as part of their vaccine ordering requirements. As federal guidance is provided, this section will be updated.

Table 3: Distribution and Allocation Actions

Responsibility	Distribution and Allocation Actions
VTF Distribution and Allocation Team	<p>Distribution and Allocation</p> <ul style="list-style-type: none"> Utilize projected vaccine allocations to IHS in conjunction with NSSC to evaluate ideal distribution strategy in early and later phases of vaccine availability. Advise all facilities with which NSSC is coordinating vaccine distribution that allocations may be intermittent and are not guaranteed due to severely limited supply, and specific storage requirements. Devise distribution strategies based on CDC allocation. Devise a standardized ordering process. <p>Storage</p> <ul style="list-style-type: none"> Evaluate capacity and capability for Areas and facilities with which NSSC is coordinating vaccine distribution to accept various vaccine preparations, including ultra-cold (-70 to -80°C), standard frozen (-20°C), and refrigerated vaccines. Identify additional storage units as needed. Identify and procure additional vaccine supplies not included in the kits, including gloves, bandages, and sharps containers.
Area	<p>Distribution and Allocation</p> <ul style="list-style-type: none"> Reach out to I/T/U to collect pre-planning information. Return pre-planning to Area Vaccine EMPOC who will send to NSSC POC. Assist as requested in vaccine ordering.
Facilities with which NSSC will be coordinating vaccine distribution	<p>Distribution and Allocation</p> <ul style="list-style-type: none"> Review agreements to assess storage, handling, and reporting requirements. Complete IHS COVID-19 Vaccination Program Agreement Track vaccine use as required by CDC, inventory and ordering based on acceptable processes as determined by OIT and Headquarters, when available. Follow CDC standards for return of unused/wasted/expired vaccine or re-distribution plans for excesses. <p>Storage</p> <ul style="list-style-type: none"> Enlist pharmacies, when possible, for receiving, storing, and monitoring vaccine. <ul style="list-style-type: none"> Medication storage is a standard practice for pharmacy departments. Many pharmacies within IHS are Vaccines for Children (VFC) providers and must adhere to the highest standard of storage and monitoring. Locations without pharmacies will need to meet the same minimum requirements for storage and handling. Temperature monitoring <ul style="list-style-type: none"> Use of continuous data loggers for continuous temperature monitoring, will be ideally recommended. If data logging is not possible, temperatures must be reviewed and recorded twice daily. Ideally monitor minimum and maximum temperatures twice daily. Stand-alone refrigerators and freezers are ideal. If using a dual fridge/freezer, the unit must have dual controls and ONLY the refrigerator may be used to store vaccines. No “dorm style” refrigerators (with small freezer in upper section) may be used. Must be able to accommodate initial allocation and may need to hold all second doses for each patient in reserve for up to 28 days for vaccine that require a two-dose series, depending on the brand and storage requirements.

Section 4: Vaccine Administration

Provider Training

- Disseminate training for vaccine administration (CDC training is being developed) including safe storage and handling.
- Consideration for Expanding Vaccinating Providers.
 - Leverage every appropriate level of provider for COVID-19 vaccine administration, including traditional and non-traditional vaccinators. Expand scope where possible (i.e., Community Health Workers, Pharmacy Technicians, Dentists, Optometrists, EMS, Fire/Rescue, Paramedics).

Communication

- Collaborate with the VTF Communications team to disseminate to the field:
 - Training resources
 - Administration resources
- When vaccine is widely available encourage vaccination through routine channels, when possible.
 - “Vaccines at EVERY visit” consistent with CDC Standards of Care.

Vaccination Events

- Assist in disseminating resources for closed points of distribution (POD) vaccination events when vaccine is in limited supply.
- Assist in disseminating resources for mass vaccination events.

Considerations for Vaccination Events

- Plan for first and second dose events, based on the brand specific dosing intervals.
- Ensure brand consistency in multi-dose vaccine series, including ordering appropriate brands for series completion, or keeping second dose in reserve for individuals that already received the first dose of a series.
- Pre-identify event locations:
 - Be mindful of social distancing; inclement weather; traffic patterns needed.
 - Begin planning events as soon as possible, with ability to roll out with short notice.
 - Potential locations: Outdoor parking lots; sporting venues; school gymnasiums; sports fields; bus garages; National Guard tents; churches; stores; community centers.
 - Potential events: Walk-up; Drive-up/drive-through; Hybrid; Mobile.
 - Coordinate In home visits:
 - Home health, Public Health Nurses (PHNs); home delivered meal programs.
- Adhere to social distancing and mask wearing measures:
 - One-way foot or vehicle traffic.
 - Signage and security to assist with flow.
 - Plan appointment-based events:
 - Pre-identify high risk individuals via prioritization strategy previously developed (described above).
 - Upon arrival, individuals added to a queue and contacted in order:
 - Patients may be offered a physical number ticket, a pager/contact device, and/or texted or called when it is their turn.
 - When contacted, screening is completed in person or remotely by phone for COVID-19 symptoms and vaccine contraindications/precautions, Emergency Use

Authorization (EUA) fact sheet or Vaccine Information Sheet (VIS) review, as applicable, and consent.

- Call individuals to vaccination area (via AM radio, numbers, pagers, text, or phone call).
- Allow for space, time and/or parking space for post-vaccination monitoring (15-30 minutes)
- Provide instructions for reporting adverse events.
- Provide second dose instructions (schedule appointment, provide follow-up).
- Billing component:
 - Identify resources and coding/billing groups to understand the potential for administration fees.
 - This will require coordination between medical coding, OIT, and billing/patient business departments.
 - Likely fee will be low, but appreciable.

Adverse Event Reporting

- Adverse Event tracking – through redundant active and passive surveillance systems, such as the Vaccine Administration Management System (VAMS), RPMS/Electronic Health Records (EHR), Vaccine Adverse Event Reporting System (VAERS), sentinel facility surveillance, FDA MedWatch and others as coordinated by the IHS Vaccine Task Force Safety & Monitoring Workgroup.

Table 4: Vaccine Administration Actions

Responsibility	Vaccine Administration Actions
VTF Vaccine Administration Team	<ul style="list-style-type: none"> • Consider creating an agency-wide standing order. • Develop a sample COVID-19 Vaccination Plan for local implementation. • Identify billing for potential vaccine administration fee. • Identify disposal plan – sharps/biohazard and regular waste. • Provide safe needle use materials following CDC safe injection practices.
Area	<ul style="list-style-type: none"> • Utilize the Area COVID-19 vaccine POC to mobilize to assist in developing facility vaccination plans and consider planning for mass vaccination and Points of Distribution (POD).
Facilities with which NSSC will be coordinating vaccine distribution	<ul style="list-style-type: none"> • Utilize concepts of Microplanning to develop a plan for mass vaccination and POD events. • Hold mass vaccination or POD and provide vaccinations. • Document vaccine administration appropriately as required by CDC.

Section 5: Communications

Starting before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 Vaccination Program. Building vaccine confidence broadly and among groups anticipated to receive early vaccination, as well as dispelling vaccine misinformation, are critical to ensure vaccine uptake.

- Develop or utilize a wide variety of culturally appropriate and regionally specific materials to educate on COVID-19 vaccines. Utilize current influenza campaign as model and incorporate COVID-19 vaccines as more information becomes available.
 - Develop or share materials for distribution:
 - Written information posted on various websites, both government and tribal.
 - FAQs and Fact Sheets
 - PSAs
 - Articles and short series/stories to incorporate into local tribal newspapers.
 - Disseminate materials in a wide variety of settings:
 - Tribal areas, ceremonies, rodeos, clinics and health care facilities, goods and services locations in and around reservations.
 - Incorporate vaccine information on IHS wide calls and email communications.
 - Utilize social media platforms (Instagram, Facebook, and Twitter) to provide concise, validated and culturally appropriate information about the vaccines, availability, high risk categories and those at “utmost risk” inside of that group.
- Identify existing and potential partners for AI/AN culturally appropriate messaging.
 - This is key for dispelling misinformation and reducing speculation and hesitancy surrounding these vaccines and should be instituted as soon as possible.
 - CDC - work through CDC Immunization Liaison.
 - Collaborate external partners where extensive COVID-19 materials are already available.

Table 5: Communication Actions

Responsibility	Communication Actions
VTF Communication Team	<ul style="list-style-type: none"> • Develop and implement a COVID-19 Vaccine Communications Plan.
Area	<ul style="list-style-type: none"> • Ensure bi-directional communication is shared.
Facilities with which NSSC will be coordinating vaccine distribution	<ul style="list-style-type: none"> • Incorporate local tribal leadership, community health workers, public health nurses, and others that are routinely in the communities in each area to collaborate and identify the most effective modes of information transmission.

Section 6: Data Management

COVID-19 vaccination documentation will need to be reported within 24 hours to the CDC. These documentation and reporting requirements will require immediate action and needs assessment for potential use of information systems by OIT and IHS Headquarters. Much of the planning and coordination must occur once the final determination is made by the CDC on use of Vaccine Administration Management System (VAMS) and the IZ Gateway integration, and if it will be required for vaccine allocation.

Gap Analysis

1. Catalogue Current Electronic Platforms:
 - a. The RPMS system provides an existing Immunization Tracking System to support administration and reporting of vaccines.
 - b. Tribal and Urban programs not using RPMS must have the capability to submit an HL7 2.5.1 version as part of certified EHR technology.
2. Assess facility specific access to the Immunization Information System (IIS) and the data exchange processes already in place.
 - a. Facilities with which NSSC is coordinating vaccine distribution are de-centralized; however, IHS will configure a central reporting approach to send information to the IZ Gateway for all facilities with which NSSC is coordinating vaccine distribution.
3. Identify feasibility for IZ Gateway implementation.
 - a. Because the IZ Gateway is configured to accept HL7 2.5.1 version messages, RPMS is already able to send messages in this format.
4. Assess IT needs for VAMS.
 - a. The VAMS is a potential solution for employee health vaccine administration. Employee health records are not entered into the RPMS EHR.
5. Contingency planning if information technology changes are not implemented.
 - a. IHS is already well positioned to implement the necessary data management strategies to support the COVID-19 vaccine response. If any interruptions occur in the use of the RPMS EHR, all facilities have paper-based continuity of operations plans. Once RPMS EHRs are online again, the paper-based information is entered into the RPMS EHR.

Table 6: Data Management Actions

Responsibility	Data Management Actions
VTF Data Management Team	<ul style="list-style-type: none"> ● Establish focused Data Management Team Workgroups. <ul style="list-style-type: none"> ○ Vaccine Distribution Inventory – Product distribution to facilities with which NSSC is coordinating vaccine distribution. <ul style="list-style-type: none"> ▪ Identification of data and reporting processes needed to track inventory, distribution, and administration of vaccines. ▪ Data collection and management to inform decisions about distribution. Utilize existing reporting options within the electronic platforms to quantify IHS COVID-19 vaccine needs. ○ Vaccine Administration at Point of Care - Patient vaccination data extraction. <ul style="list-style-type: none"> ▪ Identification of data entry and reporting processes needed, document vaccines administered to patients and reminders for subsequent doses in series. ▪ Build reminder notification in EHR for high risk populations as well as second dose reminder.

Responsibility	Data Management Actions
	<ul style="list-style-type: none"> ○ Population Analytics and Enterprise Reporting – reporting on population (e.g., by age, tribe, gender at a national level). <ul style="list-style-type: none"> ▪ Identification of reporting requirements to provide local and enterprise population reports. ● All workgroups will collaborate on the following: <ul style="list-style-type: none"> ○ Exploring requirements and approvals required for implementation of VAMS and IZ Gateway (if required) for facilities with which NSSC is coordinating vaccine distribution. ○ Consulting with OIT Division of Information Security to ensure all data collection and reporting processes comply with federal health IT security and privacy requirements. ○ Developing communication and training plans to advise Areas and facilities with which NSSC is coordinating vaccine distribution of a best practice for data management, based on the unique needs of the IHS, to document, track and monitor vaccine. ○ Work with any facility that may not be able to report immunization information due to technical challenges. ○ Identify and document tribes that choose not to participate in immunization reporting to the central OIT data repository – these facilities may choose to report directly to their state immunization repository or the CDC.
Area	<ul style="list-style-type: none"> ● RPMS facilities have the Immunization Tracking System installed as part of the certified EHR. ● Tribal and Urban facilities that do not use RPMS may or may not have an immunization tracking system; however, if they have a certified EHR, it is likely they have the capability.
Facilities with which NSSC will be coordinating vaccine distribution	<ul style="list-style-type: none"> ● Ensure installation of required immunization software and patch updates as updated by OIT. ● Report standard data practices for immunization data, including exports and IIS reporting status. ● Report barriers to immunization information system (IIS) reporting for individual facilities.

Section 7: Safety and Monitoring

The IHS National Pharmacy & Therapeutics Committee (NPTC) will analyze available clinical trial data and coordinate distributing clinical guidance regarding emerging vaccines, including vaccine safety and efficacy.

- Collaborate in the development of educational content targeting internal stakeholders (including vaccine-delivery teams, in conjunction with administration training), regarding:
 - Common side effects.
 - Adverse vaccine event reporting, regardless of perceived causation, including.
 - Completion of VAERS reports, with special emphasis on categorizing “IHS” for VAERS item #26 (in addition to race/ethnicity for item #24).
 - NPTC will coordinate educational efforts targeting enhanced VAERS report processes.
 - Existing local reporting processes, including appropriate EHR documentation.
- Promote appropriate informed consent for vaccine recipients regarding risks and benefits, including the potential for both common side effects and adverse events, utilizing verbal counseling as well as written materials, such as those required for vaccination (VIS or fact sheets, as appropriate per product requirements).
- NPTC, in collaboration with the IHS Divisions of Epidemiology and Patient Safety and Clinical Risk Management, will monitor vaccine safety including collection, analysis, and reporting of adverse vaccine events through various active and passive systems. This may include data from VAERS, Sentinel Facilities, the U.S. Food and Drug Administration (FDA) MedWatch, or other monitoring.

Resources:

- CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, Version 1.0: https://www.cdc.gov/vaccines/imz-managers/downloads/COVID-19-Vaccination-Program-Interim_Playbook.pdf
- CDC Roadmap to implementing pandemic influenza vaccination of critical workforce: https://www.cdc.gov/flu/pandemic-resources/pdf/roadmap_panflu.pdf
- CDC Vaccination guidance during a pandemic: <https://www.cdc.gov/vaccines/pandemic-guidance/index.html>
- CDC Vaccine storage and handling: <https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html>
- CDC VTrckS: <https://www.cdc.gov/vaccines/programs/vtrcks/index.html>

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

Background and Purpose

In the ever-changing COVID-19 landscape, the ongoing, rapid monitoring of COVID-19 vaccine uptake will be a critical part of the nation’s 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. CDC aims to provide guidance on the overall vaccination response, the role jurisdictions will play in this effort, and steps jurisdictions can take to prepare for a COVID-19 vaccine as soon as Fall 2020. CDC will need the assistance of all IIS and immunization program awardees to make this mission a reality.

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 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). This will enable CDC to reliably track COVID-19 vaccinations and analyze vaccination coverage by demographic factors once vaccine supplies are available.

DISCRETE DATA ELEMENTS

Table 1 below includes each data element that IIS will be required to report to CDC. Table 2 below 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 ‘Standard’ or ‘Mass Vaccination’. 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. The Vaccine Assessment Monitoring System (VAMS), CDC’s mass vaccination tool, can be used to collect both ‘Standard’ and ‘Mass Vaccination’ data elements. 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, de-duplicate, and reconcile vaccine administration information from multiple sources (e.g., jurisdictional immunization programs, pharmacies, Department of Defense, Veterans Affairs, Bureau of Prisons, and Indian Health Service).

Table 1. Required Data Elements

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>
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

Required Data Element*	Standard or Mass Vaccination
IIS Recipient ID	Standard
IIS vaccination event ID	Standard
Lot Number: Unit of Use	Standard
Lot Number: Unit of Sale	Standard
MX (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 facility (on the body)	Standard
Vaccine expiration date	Standard
Vaccine route of administration	Standard
Vaccination complete	Mass Vaccination

*Identifiable Information

Table 2. Optional Data Elements

Optional Data Element*	Standard or Mass Vaccination*
<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 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

Appendix B: Facility Planning Checklist

IHS COVID-19 VACCINE TASK FORCE (VTF)

VACCINE READINESS FACILITY PLANNING CHECKLIST - DRAFT

WHAT	WHEN	ACTION/NOTES
1. Pre-Planning		
<input type="checkbox"/> Create a Facility COVID-19 Vaccine Readiness Team. <ul style="list-style-type: none"> Consider membership that reflects the ICS or mirrors components of the IHS VTF teams: Distribution & Allocation, Prioritization, Data Management, Communications, Vaccine Administration, and Safety & Monitoring 		
<input type="checkbox"/> Create or update pandemic vaccination plan to include plans for COVID-19 vaccination.		
<input type="checkbox"/> Practice processes for socially distanced immunization clinics and assess lessons learned. <ul style="list-style-type: none"> Flu clinic – mass vaccination events, visits by appointment, drive up clinics. Child & Adult immunization clinics (routine and catch-up). Consider infection control measures. 		
<input type="checkbox"/> Determine priority populations. <ul style="list-style-type: none"> Collect HCP Personnel numbers (work with Employee Health, Infection Control, Human Resources and Medical Credentialing to obtain estimates): <ul style="list-style-type: none"> Direct Care HCP Non-Direct Care HCP 65+ HCP Residents in Tribally managed LTC facilities. Tribal Essential Workers (Law enforcement, tribal council, fire/rescue, EMS, transportation, food workers, teachers, others per Tribal leadership, and as recommended by CDC and ACIP). Estimate Population you intend to vaccinate. Estimate Population by age stratifications (0-18yrs, 19-64yrs, 65+ or alternate age groups per Tribal Leadership). Families of HCP and essential workers. 		Total HCP: Direct Care: Non-Direct Care: 65+ HCP: LTC: Essential: Est Pop: Age 0-18yrs: Age 19-64yrs: Age 65+ or Tribally defined elder: Families of HCP and essential workers:
<input type="checkbox"/> Discuss priority groups, how to identify them and how to reach them. <ul style="list-style-type: none"> Identify individuals in priority groups (iCare, RPMS/EHR, other reporting), review NASEM and CDC/ACIP guidance. Determine priority algorithm for your community/service unit (example: if your facility has 100 HCP but your first allotment of COVID-19 vaccine is only 20 – who will receive the vaccine first, and what criteria will be used to decide). 		

<input type="checkbox"/>	Designate COVID-19 Vaccine Point of Contact (EMPOC) at the Area Level to work with the individual facility workgroups, SMEs and POC.		Area POC:
<input type="checkbox"/>	Identify a COVID-19 Vaccine Point of Contact (POC) at each facility - typically pharmacy or nursing (Duties: request, receive, assess storage, monitor inventory, wastage and temperature monitoring, assure information management system, and documentation requirements are being completed). Consider VFC immunization coordinator.		Facility Names & POCs:
<input type="checkbox"/>	Become engaged at federal, state, and tribal level for COVID-19 planning: <ul style="list-style-type: none"> • State and local Department of Health • Tribal calls • White House Council on Native American Affairs Indian Country COVID-19 Update Calls • NIHB or other tribal organizations 		
<input type="checkbox"/>	Review lessons learned from H1N1 Response – what went well, what didn't?		
2. Communications			
<input type="checkbox"/>	Designate COVID-19 Vaccine Communications Coordinator role (draft materials, monitor social media, distribute information, build trust), ensure communication with Area office COVID-19 Vaccine teams and the IHS Vaccine Task Force. Consider communications through: <ul style="list-style-type: none"> • Social Media • Tribal newspapers • Flyers, posters, handouts 		
3. Requesting Vaccine			
<input type="checkbox"/>	Provide pre-planning information to Area Vaccine EMPOC (who will be providing to IHS COVID-19 VTF Team).		
<input type="checkbox"/>	Request COVID-19 Vaccine, Area Vaccine EMPOC will assist in coordination from NSSC.		
4. Receiving Vaccine			
<input type="checkbox"/>	Determine logistics: staff, supplies, locations for closed and open Points of Distribution (POD).		
<input type="checkbox"/>	Assign receiving roles (days, hours, location, who will receive), product will be shipped directly from McKesson or manufacturer. Refrigerated quantities <100 vials may be redistributed from NSSC if needed.		
5. Storing and Handling Vaccine			
<input type="checkbox"/>	Assess cold storage capacity estimates (available space to store COVID-19 vaccine), including: <ul style="list-style-type: none"> • Refrigerator • Freezer • Ultra-cold (unlikely need – consider inquiring with Federal or private partners), NOT RECOMMENDED TO PURCHASE, ultra-cold will come in storage containers. 		

<input type="checkbox"/>	Prepare for temperature monitoring requirements from the CDC - inventory and wastage (likely daily), consider purchasing data loggers if not already in use.		
6. Administering			
<input type="checkbox"/>	Train staff (required – CDC and IHS will provide training materials) on: <ul style="list-style-type: none"> • Safe storage and handling. • COVID-19 vaccine administration (brand dependent training). • Required documentation and inventory elements. • Mass Vaccination Points of Distribution (POD). 		
<input type="checkbox"/>	Phase 1 Priority Groups: Limited Doses Available <ul style="list-style-type: none"> • Outreach • Location(s) of closed PODs • Social distancing measures • Infection control • PPE and Supplies (outside of kits supplied with the vaccines) • Staffing • Documentation • Dose 2 recall 		
<input type="checkbox"/>	Phase 2 Priority Groups: Large Number of Doses Available <ul style="list-style-type: none"> • Outreach • Location(s) of closed PODs • Social distancing measures • Infection control • PPE and Supplies (outside of kits supplied with the vaccines) • Staffing • Documentation • Dose 2 recall 		
<input type="checkbox"/>	Phase 3 Priority Groups: Continued Vaccination, Shift to Routine Strategy <ul style="list-style-type: none"> • Outreach • Location(s) of closed PODs • Social distancing measures • Infection control • PPE and Supplies (outside of kits supplied with the vaccines) • Staffing • Documentation • Dose 2 recall 		
7. Documenting and Reporting Vaccine			
<input type="checkbox"/>	Designate COVID-19 Vaccine Documentation Coordinator role (assure compliance with vaccine tracking and reporting requirements, assure access to required information management systems), recommend CAC involvement.		
<input type="checkbox"/>	Reporting immunizations to CDC daily via State or IHS pathways (IHS will utilize HL7). <ul style="list-style-type: none"> • Process for documenting patient vaccines will remain unchanged. 		

	<ul style="list-style-type: none"> IT/CAC will need to ensure patches are installed and up to date. Data extraction daily to ensure CDC documentation requirements are met. 		
<input type="checkbox"/>	Assure accounts are active for immunization management systems as needed (will need access to state Immunization Information System (IIS) to check status of immunizations).		
<input type="checkbox"/>	Ensure appropriate reporting of vaccine adverse events through local process, electronic health record tracking and VAERS (specifically indicating "IHS" in item 26 of VAERS report).		
<input type="checkbox"/>	Ensure reporting of employee vaccinations, which may occur outside of the electronic health record and may require alternate documentation pathways.		
8. Recovery			
<input type="checkbox"/>	Update pandemic plan to reflect lessons learned and anticipate needs for future pandemic events.		

Resources

CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, Version 1.0

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