U.S. Department of Health and Human Services

INDIAN HEALTH SERVICE

COVID-19 Pandemic Vaccine Plan
November 2020

IHS COVID-19 Pandemic Vaccine Plan November 2020

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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 whites[1]. In addition, AI/AN individuals are over four times more likely to be hospitalized as a result of COVID-19[2]. 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 a Food and Drug Administration (FDA) approved vaccine is available.

On September 16, 2020, the Centers for Disease Control and Prevention (CDC) issued guidance to ensure jurisdictions develop and implement a comprehensive vaccination plan. The CDC's *COVID-19 Vaccination Interim Playbook for Jurisdiction Operations*, covers many areas of vaccination program planning for jurisdictions, including IHS and CDC Immunization and Vaccines for Children Cooperative Agreement funding recipients. Under the CDC COVID-19 Vaccination Program, jurisdictions are required to address playbook requirements, describe their responsibility for ensuring activities are implemented, and submit plans to the CDC.

This IHS COVID-19 Pandemic Vaccine Plan November 2020 details how the IHS health care system will prepare for and operationalize a vaccine when it becomes available. This plan includes an overview of the IHS Vaccine Task Force and is divided into seven sections. Each section includes activities, assumptions, and specific actions IHS will take to coordinate vaccine distribution. The activities and actions identified in this document are essential in coordinating the health care system response, and additional items may be added to fit local needs. This plan provides important guidance for all IHS Direct Service facilities and Tribal health programs and Urban Indian Organizations (I/T/U) that choose to receive COVID-19 vaccine coordinated through IHS.

This 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.

Tribal Consultation and Urban Confer

On September 24, 2020, the United States (U.S.) Department of Health and Human Services (HHS) initiated tribal consultation on COVID-19 Vaccination Planning for Indian Country. HHS hosted six regional consultations during the period of September 28 through October 1, 2020. On September 25, 2020, IHS also initiated Urban Confer on COVID-19 Vaccination Planning for Indian Country. The deadline for written tribal consultation and urban confer comments was on October 9, 2020. On October 14, 2020,

[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

IHS initiated tribal consultation and urban confer to seek input on the IHS COVID-19 Pandemic Vaccine Draft Plan. The deadline for written comments closed on October 21, 2020. The IHS Vaccine Task Force teams reviewed all edits and comments received on the draft plan. The input received is incorporated into the IHS COVID-19 Pandemic Vaccine Plan November 2020; as appropriate.

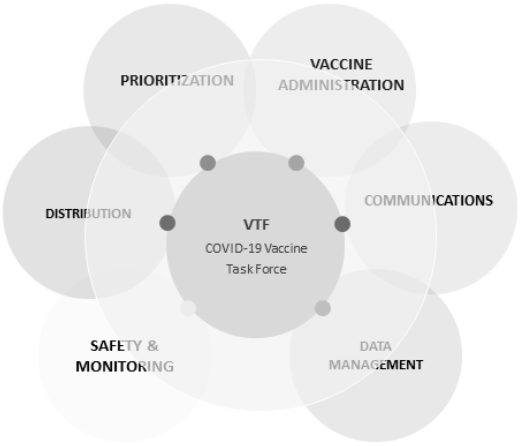
The IHS vaccine plan and distribution strategy align with CDC recommendations with advice from the CDC Advisory Committee on Immunizations Practice (ACIP) and National Academies of Sciences, Engineering, and Medicine (NASEM) for priority populations.

The IHS COVID-19 Vaccine Task Force

In early March 2020, IHS senior leadership activated the Headquarters Incident Command Structure (ICS) to respond to COVID-19. On September 4, 2020, the ICS approved the IHS COVID-19 Vaccine Task Force (VTF) to lead the Agency's COVID-19 vaccine activities. The VTF is under the direction of the IHS Incident Command Operations Officer/Chief Medical Officer, a VTF Lead and two co-leads, and includes representatives from headquarters, Areas, and Service Units. The VTF is comprised of broad clinical federal employee representation and is established in accordance with the Federal Advisory Committee Act.

The VTF guides the guide development of action plans and is comprised of six teams focused on vaccine administration, communications, data management, safety and monitoring, distribution, and prioritization. The VTF Lead reports to IHS Incident Command Operations Officer to share updates, communicate priorities, and address barriers. A few IHS Areas have also established their own respective vaccine task forces, resulting in strengthened distribution preparedness activity at the Area level.

IHS COVID-19 Vaccine Task Force (VTF)



Prioritization Team

This team is led by an Epidemiologist and includes the Office of Public Health Support, Office of Human Resources, and others. Role and scope: Engage I/T/Us to collect critical and target population estimates for early phase COVID-19 vaccine distribution utilizing guidance from the CDC, CDC's ACIP, and NASEM. The vaccine needs will be informed by the population estimates determined by I/T/U facilities. Provide guidance and technical assistance for I/T/Us to develop plans for ensuring equitable allocation of COVID-19 vaccine across IHS. Collaborate with other VTF teams to inform distribution, reporting and data management, and ensure transparent communication.

Distribution and Allocation Team

This team is led by NSSC and includes the National Pharmacy and Therapeutics Committee (NPTC), Office of Quality, Office of the General Counsel (OGC), Prioritization Team, Area Point of Contacts, and others. Role and scope: Identify anticipated I/T/U facilities desiring vaccine distribution from IHS. 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 I/T/U facility with which NSSC is coordinating vaccine distribution has a source of distribution. Identify and procure resources, such as vaccine storage and monitoring 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 are operational and accessible to I/T/U facilities prior to distribution of the vaccine. Assure I/T/U facilities receive ongoing and timely information regarding vaccine availability, distribution, access procedures, and reporting requirements for ongoing receipt of 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 Administration Team

This team is led by the Office of Clinical and Preventive Services (OCPS) and includes the 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 I/T/U facilities in vaccine administration and documentation. Develop resources and sample documents that can be tailored to each I/T/U facility's needs. Provide event planning strategies for various vaccination events (e.g., drive-up). Collaborate with Data Management and Prioritization Teams to develop electronic tools and resources 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 I/T/U facilities NSSC is coordinating vaccine distribution to support I/T/U facility efforts. Collaborate with Communication team to develop clinical communication lines to channel information for support to clinicians and vaccinators.

Communication Team

This team is led by Public Affairs Staff and includes the 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 COVID-19 vaccine allocation and distribution for internal and external audiences. Work with the Vaccine Administration Team and the Safety and Monitoring Team to provide I/T/U facilities clinical information to make informed decisions regarding specific vaccine products. Announce major milestones. Identify audiences and coordinate with stakeholders. Develop talking points for senior leadership regarding the VTF and IHS COVID-19 vaccine plan. Create vehicles to use for messaging.

Data Management Team

This team is led by the Office of Information Technology (OIT) and includes Area Clinical Application Coordinators (CAC), Resource and Patient Management System (RPMS) advisory group, and others. Role and scope: Identify solutions to track and document COVID-19 vaccine, including vaccine administration data, reporting of inventory and ordering processes. Dedicate resources for I/T/U 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. Utilize CDC supported platforms for use as a parallel pathway for I/T/U facilities needing alternate documentation processes. Advise Area Offices, and

I/T/U facilities on data management strategies to document, track, and monitor vaccine. Provide information technology support to I/T/U facilities to implement necessary upgrades and infrastructure for CDC reporting.

Safety and Monitoring Team

This team is led by the IHS NPTC in collaboration with the NSSC, the IHS Division of Patient Safety and Clinical Risks Management (Office of Quality), Division of Epidemiology and Disease Prevention (Office of Public Health Support), and the IHS ACIP Liaison. Role and scope: Provide field-level education to I/T/U facilities regarding adverse vaccine event (AVE) monitoring & reporting processes, clinical review & guidance for FDA-authorized/approved vaccines, AVE active surveillance of sentinel sites and passive surveillance via Vaccine Adverse Event Reporting System (VAERS). Conduct AVE analysis for the IHS service population, and report results to key stakeholders.

Section 1: Vaccine Availability

The COVID-19 vaccine is anticipated to be released in three phases based on vaccine approval by the FDA and availability, moving from targeted to broader populations. The IHS vaccine distribution and allocation will align with guidance provided from CDC, ACIP, and NASEM for priority populations. The earliest approved COVID-19 vaccine may be available in November 2020 with limited supplies. Vaccine supply is anticipated to increase substantially in 2021. Initial COVID-19 vaccines will either be approved as licensed vaccines or authorized for use under an Emergency Use Authorization (EUA) issued by the FDA. The CDC proposes early phase vaccine distribution to include 40 million vaccine doses by the end of December 2020.

IHS recognizes the sovereign authority of Tribal nations to provide for the welfare of its people.

- I/T/U facilities shall determine their population estimates with guidance from CDC, ACIP and NASEM. An I/T/U facility's population estimates can be different from their Indian Health Service user population and may include non-American Indian/Alaska Native individuals. Upon determination of its population estimates, the I/T/U facilities will coordinate with IHS to assure the appropriate type and quantity of vaccine are allocated. IHS developed a pre-planning tool (See Appendix B) to allow I/T/U facilities to provide their population estimates and priority group numbers to inform vaccine allocation efforts.
- I/T/U facilities shall determine their priority groups when there are limited vaccine resources. I/T/U facilities may deviate from CDC/ACIP prioritization groups to immunize under other priorities that meet the spirit of the CDC/ACIP designated priorities within allocations of COVID-19 vaccine received.
- In the event more than one vaccine is approved for use and available, I/T/U facilities shall be able to determine which vaccine or vaccines it chooses to receive and administer to its population. IHS shall distribute vaccine per I/T/U choices as vaccine is available.

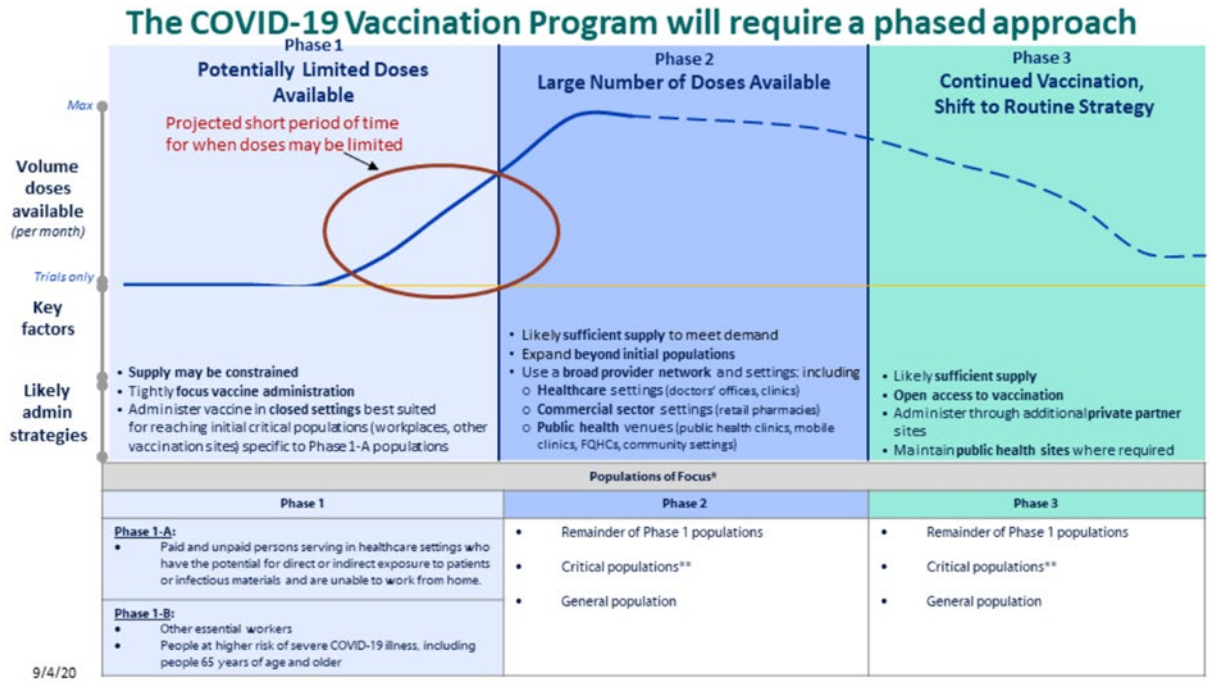
It is anticipated initial FDA approved COVID-19 vaccines will be two-dose series, separated by 21 to 28 days. I/T/U facilities receiving their vaccine distribution through IHS should account for each vaccinated person to receive two doses of the same brand of COVID-19 vaccine, as brands are not interchangeable. Current recommendations are to fully vaccinate initial populations before expanding to additional target populations. 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 determined by the I/T/U facilities; facilities may deviate from CDC/ACIP prioritization groups to immunize under other priorities that meet the spirit of the CDC/ACIP designated priorities within allocations of COVID-19 vaccine received.
    - 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.
    - Expand beyond initial populations.
    - Administration through commercial and private partners.

- Administer through public health sites.

- Phase 3: Continued Vaccination, Shift to Routine Strategy
  - Likely excess supply.
  - Broad administration network for increased access.
  - Administration through commercial and private partners.
  - Maintain public health site where required.

Figure 1: CDC Recommended Vaccine Phase Planning



Planning should consider that there may be initial age restrictions for vaccine products.

***See Section 4: Critical Populations for information on Phase 1 subset and other critical population groups.*

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

Key Activities - Pre-Planning before Vaccine Availability

1. Prioritization
   - With I/T/U facilities, identify AI/AN priority groups using available information from CDC, ACIP, and NASEM for guidance.
   - Develop tools to facilitate estimating the size of priority populations once identified. Standardization of the process for estimating population sizes may help to uphold the commitment to equitable distribution of vaccine across all IHS. Engage I/T/Us, and federal partners in all phases of development of a final distribution process ensuring transparency, equity, and respect for Tribal sovereignty.

2. Distribution and Allocation
   - Collaborate with CDC to identify strategy for de-centralized vaccine distribution.
   - IHS NSSC will utilize Vaccine Tracking System (VTrckS) through CDC for coordinated vaccine ordering.

- Discuss with CDC vaccine allocation process for jurisdictions, ensuring equitable allocation for I/T/U facilities who are coordinating vaccine distribution through NSSC.
- Identify COVID-19 vaccine ordering platform and process for I/T/U facilities with which NSSC will be coordinating vaccine distribution.
- Plan for managing vaccine waste, loss and returns.
- Coordinate process for breaking down vaccine orders for redistribution, if needed for smaller sites.
- 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.

3. Vaccine Administration
    - Establish framework for reporting vaccine administration data both internal and external facing.
    - Evaluate templates and resources for vaccine administration for I/T/U facilities with which NSSC is coordinating vaccine distribution response.
    - Develop templates and resources for vaccine administration.

4. Communication
    - Establish a COVID-19 vaccine 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.

5. Data Management
    - Complete a gap analysis of capacity and capability of I/T/U facilities with which NSSC is coordinating vaccine distribution to report CDC required data.
    - Connect with CDC partners to review CDC platforms (ex. Vaccine Administration Management System [VAMS] and Immunization [IZ] Gateway) and confirm IHS connectivity.
    - Establish framework for standard vaccine coverage and summary statistics/analytics for stakeholders as appropriate.
    - Assure that data management systems are operational, and that I/T/U facilities are on boarded to the critical data flows and electronic systems in advance of vaccine distribution.
    - Assist I/T/U facilities with information technology support when needed to ensure required reporting elements.

6. Safety and Monitoring
    - Develop and implement system-wide education regarding IHS-specific VAERS reporting processes and other pharmacovigilance strategies prior to vaccine distribution.
    - Establish pharmacovigilance workflow and processes for adverse event monitoring/surveillance, analysis, and reporting.

Phase 1: Limited Doses Available

Distribution and Allocation Team

- Apply allocation plan to distribution process.

- Process vaccine orders based on CDC allocations.
- Focus distribution to closed settings serving critical/target populations as defined by I/T/U facilities in Phase 1.
- Generate and share standard summaries of doses distributed data.
- Respond to issues regarding vaccine in the field (ex. recalls, expiration dates, disposal).
- Provide guidance to redistribute doses to smaller or more remote I/T/U facilities within reasonable geographic distances or areas.
- It is anticipated initial FDA approved COVID-19 vaccines will be two-dose series, separated by 21 to 28 days. I/T/U facilities receiving their vaccine distribution through IHS 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.

Communication Team

- Promote awareness of vaccine risks and benefits, dispel misinformation, and address public concerns about safety

Data Management Team

- Maintain connection with IZ Gateway.
- Maintain accurate data on vaccine distribution and administration. Comply with CDC guidance for submission of data.
- Generate and share immunization coverage and doses administered reports.
- Provide ongoing technical support for I/T/U facilities to ensure data reporting is meeting CDC requirements.

Safety and Monitoring Team

- Conduct active (sentinel sites) and passive (VAERS) adverse vaccine event surveillance with data analysis and reporting to key stakeholders.
- Report and distribute urgent safety-related messages in a timely manner to I/T/U facilities.

Phase 2: Large Number of Doses Available

- Continue all steps listed above in 'Limited Doses Available' phase.
- Distribute vaccine broadly to I/T/U facilities with which NSSC is coordinating vaccine distribution to increase access to the vaccine.

Phase 3: Continued Vaccination, Shift to Routine Strategy

- Continue vaccination response as appropriate.
- Incorporate distribution and use of COVID-19 vaccine into existing immunization program under Office of Public Health Support, Division of Epidemiology Disease Prevention.

Section 2: Prioritization

Ensuring an equitable and transparent distribution plan when vaccine is available is a priority for IHS. Collecting and documenting population estimates from I/T/U facilities will inform COVID-19 vaccine distribution plans. As of early November 2020, final ACIP recommendations have not been released for priority populations for vaccination when supplies are limited. Health Care Personnel (HCP) have been identified as the likely Phase 1-a population that will receive the first 20-40 million vaccine doses in the U.S., as shown above in Figure 1. Additional priority groups may include essential workers, high risk individuals who have underlying medical conditions, those aged ≥65 years or some combination (e.g., essential workers 65 and older or who have one or more high risk medical conditions). Residents in congregate living facilities such as long-term care facilities and jails may also be prioritized.

IHS has identified I/T/U facilities that will use the IHS NSSC for vaccine distribution and estimates for the amount of vaccine they will require. These estimates were reported by I/T/U facilities and will be used for determining the size of vaccine priority populations for IHS. IHS is working with I/T/U facilities to ensure that the most accurate information available is used for identifying vaccine requirements and to ensure that estimates provided by I/T/U facilities will be used.

It is important to recognize the many unknowns that exist, for example, the efficacy of any given vaccine in patients of different ages or with certain conditions and how that might influence the ACIP prioritization considerations for a specific vaccine, the availability of any given vaccine or the acceptability of any vaccine to a given priority group. The VTF intends to navigate these issues using the best available scientific data, guidance provided from CDC, ACIP, NASEM and in cooperation with leaders representing I/T/U facilities.

Key Activities - VTF Prioritization Team

- Collect pre-planning information from I/T/U facilities including their determinations for priority populations.
- If an I/T/U facility has not provided prioritization data, the VTF Prioritization Team will work with the I/T/U to 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 in those I/T/U that need assistance. These include but are not limited to information from IHS Office of Human Resources, RPMS/EHR tools (iCARE, VGEN, QMAN reports) and national data warehouse (NDW).
- Assist Distribution Team in developing an allocation plan that ensures equity, especially when vaccine is limited.
- I/T/U facilities receiving their vaccine distribution through IHS should account for each vaccinated person to receive two doses of the same brand of COVID-19 vaccine, as brands are not interchangeable.

Area Offices

- Designate an Area Vaccine Point of Contact (AVPOC) and Clinical Applications Coordinator (CAC) to assist in data collection and planning for I/T/U facilities with which NSSC is coordinating vaccine distribution.

- Offer assistance with prioritization if requested by I/T/U facilities with which NSSC is coordinating vaccine distribution.

I/T/U facilities with which NSSC will be coordinating vaccine distribution

- I/T/U facilities will develop their own, local process to determine needs, identify priority groups and ensure equity. The final ACIP prioritization recommendations, which will be based on the NASEM framework and vaccine performance data, will be made available as a guide.
- I/T/U facilities will provide population estimates to AVPOC, who will submit to NSSC point of contact (POC).

Population Estimates

The estimates below are aggregated from pre-planning population estimates provided by I/T/U facilities who will be coordinating vaccine distribution through NSSC. Population Estimates are current as of November 16, 2020.

Critical Population	Population Estimate
Healthcare Personnel (Direct, non-direct, and emergency medical services)	43,783
Essential workers (other emergency services, law enforcement, food and transportation, teachers, childcare providers)	120,671
Patients in tribal long-term care facilities	76,311
Elders	374,411
Patients at high-risk factors for COVID-19 illness	894,260
Total people estimated to be vaccinated*	2,056,347

*Total includes critical populations and young healthy adults (not reported in the table above).

Section 3: Vaccine Distribution and Ordering

Vaccine allocation and distribution information is evolving, and federal guidance will continue to inform planning for I/T/U facilities. 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. These models will help inform planning for the COVID-19 vaccine. Tribal Health Programs and UIOs that choose to receive the COVID-19 vaccine through IHS, must complete a signed *CDC COVID-19 Vaccination Program Agreement - Vaccines Coordinated through IHS*. These agreements include all CDC COVID-19 vaccination program requirements.

The VTF shall request and document I/T/U facilities' priority group estimates (See Appendix B: I/T/U Pre-Planning Tool) to establish a total number of vaccine doses for Phase 1. If there is not enough vaccine to distribute to each I/T/U facility's priority populations, VTF will determine an equitable distribution methodology to fulfill I/T/U facilities' requests. For example, if the total number of vaccine doses needed to serve priority populations as reported by all I/T/U facilities is 100,000 but IHS only has 60,000 to distribute, then IHS multiplies each I/T/U facility's requested amount by 60%.

Once the number of I/T/U facilities receiving vaccine through IHS has been finalized, resources can be estimated by comparing projected vaccine allocations with I/T/U facility estimates for each target population in order to determine the proportion of the population that can be vaccinated and to identify any potential deficits. It is anticipated initial FDA approved COVID-19 vaccines will be two-dose series, separated by 21 to 28 days. I/T/U facilities receiving their vaccine distribution through IHS 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. IHS VTF will provide I/T/U facilities with updated vaccine availability and CDC allocation information.

The following categories apply to I/T/U facilities with which NSSC is coordinating vaccine distribution.

Pre-Planning

- The IHS pre-planning tool was developed to collect key vaccine planning information (See Appendix B) from I/T/U facilities to estimate populations and plan for early phase limited vaccine allocation.
    - In early October 2020, IHS Area Directors distributed a facility pre-planning tool to I/T/Us.
    - Population estimates and anticipated priority groups were based on the information provided directly from the I/T/Us. AVPOCs collected, reviewed, and compiled their respective Area pre-planning tool and returned to NSSC.
- The COVID-19 vaccine and ancillary kits are being supplied by the United States Government (USG) at no cost to the American people. The delivery of the vaccine is being contracted through McKesson's Med Surge Division and although IHS currently contracts with McKesson's Pharmaceutical Division there will be no costs to I/T/U facilities for McKesson delivery of COVID-19 vaccine and ancillary kits.
- For ultra-cold vaccine, the vaccine and supplies will be provided at no cost, but the vaccine will ship directly from the manufacturer to the I/T/U facility.

- Once orders are processed by the NSSC, shipping information will be made available to the NSSC and ordering facility. Exact processes are not yet defined, but this information will be available for monitoring and tracking purposes.
- NSSC is identifying sources for additional supplies and personal protective equipment necessary for vaccine administration that will not be included in the ancillary kits, such as sharps containers, bandages and gloves.
- Ancillary supplies will be packaged in kits and will be automatically ordered and sent to the facility in amounts to match vaccine orders in VTrckS.
    - For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine, including:
        - Needles, 105 per kit (various sizes for the population served by the ordering vaccination provider);
          o 25-gauge, 1" (if vaccination indicated for pediatric population);
          o 22–25-gauge, 1-1.5" (adult);
        - Syringes, 105 per kit (ranging from 1–3 mL);
        - Alcohol prep pads, 210 per kit;
        - 4 surgical masks and 2 face shields for vaccinators per kit;
        - COVID-19 vaccination record cards for vaccine recipients, 100 per kit; and,
        - Vaccine needle guide detailing the appropriate length/gauge for injections based on route, age (for children), gender, and weight (for adults).
        - If a COVID-19 vaccine requires mixing with diluent is ordered and shipped from CDC's centralized distributor, a mixing kit that includes the necessary needles, syringes, and alcohol prep pads will also be automatically added to the order.
    - For vaccines that are shipped directly from the manufacturer, a combined kit will be included. This combined kit will include administration supplies (as noted above), mixing supplies, and vials of diluent to prepare the vaccine for use in quantities appropriate to match the number of doses.

Coordination of CDC COVID-19 Vaccination Program Agreements

- CDC COVID-19 Vaccination Program Agreement for Tribal Health Programs Coordinated through IHS
    - IHS VTF Leadership will coordinate distribution of CDC COVID-19 Vaccination Program Agreements with Area Offices to distribute to Tribal Health Programs for coordination of COVID-19 vaccine distribution through IHS.
    - AVPOC will be responsible for collecting and returning signed COVID-19 Vaccination Program Agreements to the IHS VTF Distribution Team Lead.
- CDC COVID-19 Vaccination Program Agreement for UIOs coordinated through IHS
    - IHS VTF Leadership will coordinate distribution of CDC COVID-19 Vaccination Program Agreements with Area Offices to distribute to UIOs for coordination of COVID-19 vaccine distribution through IHS.
    - AVPOC will be responsible for collecting and returning signed COVID-19 Vaccination Program Agreements to the IHS VTF Distribution Team Lead.
- CDC COVID-19 Vaccination Program Memorandum of Agreement between IHS and CDC regarding CDC Coronavirus Disease 2019 (COVID-19) Federal Agency Vaccination Program

- IHS Direct Service facilities will receive a copy of the COVID-19 Vaccination Program Agreement signed by the IHS Director.
- Direct service facilities who will be receiving COVID-19 vaccine must complete "Form B" and return to their AVPOC.

Allocation of Vaccine

- COVID-19 vaccine will be allocated to each jurisdiction, including IHS. Preliminary, collected data will assist in mapping anticipated distribution based on characteristics such as population estimates, storage and handling capabilities, and vaccine characteristics. It is anticipated that initial allocations of each approved COVID-19 vaccine will be coordinated based on these characteristics until manufacturing allows for vaccination of all persons that desire vaccination.
- Allocation will be based on pre-planning estimates provided by I/T/U facilities. IHS will allocate equitable vaccine based on guidance from CDC, ACIP and NASEM for recommended priority groups (as described above under Section 2: Prioritization) before moving to the next priority population.
- More details about the CDC distribution for ultra-cold and planning scenarios is included In Appendix A.
- During Phase 1, it is anticipated there will be limited vaccine available. If IHS is only allocated a limited supply of ultra-cold vaccine this will be coordinated in collaboration with AVPOC and I/T/Us. Once vaccine is in sufficient supply vaccine may be ordered by I/T/Us based on preferences for brand, storage and need, and will be distributed based on the total percent allocation from the CDC and Operation Warp Speed based on I/T/U facilities population estimates. I/T/U facilities during Phase 1 are encouraged to collaborate with their AVPOC for ultra-cold vaccines. If an I/T/U wishes to not receive a specific brand of vaccine during Phase 1 this should be coordinated through AVPOC.
- IHS will communicate vaccine availability and opportunities for ordering to I/T/U facilities in a timely manner.

Vaccine Ordering

- During early/limited Phase 1 vaccine distribution, I/T/U facilities can either receive direct allocation or I/T/U facilities can request vaccine brand specific and quantities from their AVPOC in a timely manner.
- I/T/U facilities will order vaccines (brand specific) after full phase 1-a allocation through an Operation Warp Speed (OWS) oracle platform.
- In the event more than one vaccine is approved for use and available, each I/T/U facility will order which vaccine or vaccines to receive and administer to its population.
- NSSC will review the orders, adjust as needed based on allocation, approve, and submit through the VTrckS to CDC.
- I/T/U facilities will be notified of order tracking information through an email or a shipping link provided in the ordering portal.

Distribution of Vaccine to I/T/U Facilities

- IHS will utilize a de-centralized distribution model as defined by CDC, same as states and jurisdictions, where vaccine will be shipped directly from the contracted wholesale distributor or the manufacturer to the I/T/U facility.

The CDC allows IHS to coordinate redistribution for smaller orders of vaccines, see *CDC Supplemental COVID-19 Vaccine Redistribution Agreement*. As required by CDC, there must be a signed *CDC Supplemental COVID-19 Vaccine Redistribution Agreement* and a signed *CDC COVID-19 Vaccination Program Agreement - Vaccines Coordinated through IHS,* as appropriate, for the I/T/U facility conducting redistribution. Because of sensitive cold chain requirements, the I/T/U facilities should closely coordinate transport and delivery with the receiving I/T/U facility to minimize vaccine loss due to temperature excursions. An I/T/U facility requesting to redistribute vaccine and appropriate ancillary kit must submit the *CDC COVID-19 Vaccination Program Agreement - Vaccines Coordinated through IHS* along with information including vaccine and adjuvant, brand, lot, expiration, quantity, redistribution location, and VTrcks ID to NSSC. NSSC approval must be received before redistributing vaccine. Vaccine may be redistributed between two separate ordering facilities, with a *CDC COVID-19 Vaccination Program Agreement - Vaccines Coordinated through IHS*.

- Vaccine will be only be redistributed according to manufacture guidance.
- Vaccine will be only be redistributed via local personnel trained in vaccine cold-chain management and transport.
- Vaccine will not be redistributed via commercial couriers.

Vaccine Inventory

- IHS VTF will share required inventory reporting requirements as they become available from CDC.
- Inventory will be the responsibility of the I/T/U facilities as part of their vaccine ordering requirements as per CDC.

Vaccine Storage

- Evaluate capacity and capability for Areas and I/T/U 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.
- I/T/U facilities to identify additional storage units as needed.
- NSSC to identify and procure additional vaccine supplies not included in the kits, including gloves, bandages, and sharps containers.

Vaccine Wastage and Disposal

- Doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted are required to be reported by I/T/U facilities as required by the CDC.
- I/T/U facilities must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.
- Significant wastage, more than 25% of distributed doses, will be reviewed by NSSC and considered when future orders are placed. The I/T/U should discuss the nature of the wastage (i.e. mechanical failure of a storage unit versus premixing too many doses for an event), underlying cause and potential future solutions to minimize waste with NSSC when planning for future orders.

Additional I/T/U Facility Considerations and Requirements (applicable to I/T/U facilities with which NSSC is coordinating vaccine distribution)

- Distribution and Allocation
    - I/T/U facilities to complete COVID-19 Vaccination Program Agreement as appropriate.
    - I/T/U facilities to complete onboarding for inventory and ordering platform.

- I/T/U facilities follow CDC standards for return of unused/wasted/expired vaccine or re-distribution plans for excesses.

- Storage
  - I/T/U facilities will be responsible for storing vaccines as per manufacturer recommendations and CDC vaccine storage and handling recommendations.
  - Enlist pharmacies, when possible, for receiving, storing, and monitoring vaccine.
    - Locations without pharmacies will need to meet the minimum manufacturer and CDC requirements for storage and handling.
    - It is the responsibility of the I/T/U facilities to ensure the cold-chain of the vaccine is maintained once the vaccine arrives at the facility, during transfer to another facility or off-site vaccination event.
    - Should 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 manufacturer and CDC requirements for storage and handling.
- Temperature Monitoring
  - I/T/U facilities shall use continuous data loggers for continuous temperature monitoring, as required by CDC.
  - Vaccines with temperature excursions should be quarantined and the manufacturer contacted to determine viability.
  - Stand-alone refrigerators and freezers are recommended. 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.

Section 4: Vaccine Administration

Provider Training

Training of providers for COVID-19 vaccination is critical to ensure safe and effective delivery of the vaccine.

- The Vaccine Administration Team will disseminate education and training resources for vaccine administration (CDC training is being developed) and brand specific manufacturer training. The VTF will provide educational resources in a central repository on ihs.gov/coronavirus/vaccine.
- Site Vaccine Point of Contact (SVPOC) will be responsible for ensuring COVID-19 vaccine providers have completed training on:
    - ACIP COVID-19 vaccine recommendations when available.
    - How to order and document receipt of COVID-19 vaccine.
    - COVID-19 vaccine storage and handling, including and redistribution and transport requirements.
    - How to administer vaccine, including mixing with diluent, appropriate needle size, anatomic sites for vaccine administration, avoiding shoulder injury with vaccine administration.
    - How to document and report vaccine administration use RPMS/EHR, commercial off the shelf (COTS) systems, and/or the Vaccine Management System (VAMS).
    - How to manage vaccine inventory, including accessing and managing product expiration dates.
    - How to report vaccine inventory.
    - How to manage and report temperature excursions.
    - How to document and report vaccine wastage/spoilage.
    - Procedures for reporting adverse events as well as vaccine administration errors to VAERS.
    - Vaccinators are aware of, know where to locate, and understand the information in EUA fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.
    - Prior to vaccination, the EUA fact sheets or VISs must be offered to vaccine recipients.
    - How to submit I/T/U facility information and daily vaccine inventory reports for COVID-19 vaccination clinics.
- 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

- The Vaccine Administration Team will collaborate with the VTF Communications team to disseminate materials to the field and host on: www.ihs.gov/coronavirus/vaccine.
    - Education and training resources.
    - Administration resources.
    - Sample vaccination protocols, standing orders, and vaccine event checklists for local adaptation and use.
- When vaccine is widely available encourage vaccination through routine channels.
    - “Vaccines at EVERY visit” consistent with CDC Standards of Care.

Vaccination Events

- Develop local COVID-19 action plan (See Appendix C).
- Action plans should consider plans for closed points of dispensing (PODs), open points of dispensing (PODs), routine scheduled vaccination appointments as well as consideration of events planned with local and state health jurisdictions.
- The Vaccine Administration Team will assist in disseminating resources for closed points of dispensing (POD) vaccination events when vaccine is in limited supply.
- The Vaccine Administration Team will assist in disseminating resources for vaccination events with recognition of social distancing and scheduled appointments to be incorporated.

Considerations for Vaccination Events

- IHS estimates that vaccinators would spend approximately 7 minutes to review consent, vaccinate and document the administration of a vaccine. This correlates to approximately 65 vaccinations given in an 8-hour day per vaccinator as a maximum capacity.
- I/T/U facilities should take into consideration this hypothetical rate of vaccination per provider to assess capacity and throughput. Vaccine quantity on hand, number of patients needing vaccination, and number of vaccinators will be critical in determining the event and support needs.
- 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; Tribal Chapter Houses; Tribal building/centers.
        - Potential events: Walk-up; Drive-up/drive-through; Hybrid; Mobile.
        - Potentially consider coordination of 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, 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.
    - Second dose planning:
        - I/T/U facilities should plan for first and second dose events, based on the brand specific dosing intervals.
        - A COVID-19 vaccination record card will be provided to every vaccine recipient/parent/legal representative upon the receipt of the first dose of vaccine.
        - Individuals should be encouraged to bring the COVID-19 vaccination record card with them for their second dose. This request should be communicated at the time of card creation and with any reminder system used in advance of a second dose appointment.
        - Upon receipt of the first dose of a COVID-19 vaccine at any I/T/U facility, a second dose appointment should be scheduled within the recommended follow-up time frame.
        - Second dose reminders are encouraged, in the form of phone calls, robocalls, texts, or other methods used and approved by the patient and I/T/U facilities.
        - In the case that VAMS is used, second dose reminders are an included component of the electronic platform.
        - For I/T/U facilities utilizing RPMS/EHR, RPMS and iCare reports may be used to generate lists of individuals due for second doses.
        - Individuals that missed a second dose should be contacted to determine the nature or reason why the second dose was not sought.
            - If the individual declined to be vaccinated with a second dose, a declination should be documented using the same data flow used for the initial vaccine (electronic health record vs VAMS).
            - If the patient received a second dose at another facility, a historical dose should be entered after confirmation of the record is requested and reviewed to confirm brand continuity and appropriate spacing.
            - If the individual reports a previous adverse event after the initial dose, ensure documentation in all appropriate reporting pathways, including VAERS.
- Vaccine Administration Fee:
    - COVID-19 vaccine and ancillary supplies will be procured and distributed by the federal government at no cost to I/T/U facilities. Only a charge for an administration fee is eligible to be billed to third party insurance.
    - Though the Vaccine Administration Team is working to identify third-party billing reimbursement potential for vaccine administration fees, vaccination must be offered to all individuals regardless of their insurance status or ability to pay for vaccination administration fees.
    - The Vaccine Administration Team is working to identify Centers for Medicare and Medicaid (CMS) guidance documents and resources to understand the potential billing of vaccine administration fees for Medicare and Medicaid beneficiaries.
    - Billing of vaccination administration fees will require coordination between medical coding, OIT, and billing/patient business departments.

Adverse Event Reporting

In collaboration with the Safety & Monitoring Team, see Section 7.

Section 5: Communications

The Indian Health Service is committed to providing accurate, timely, transparent, complete, and audience-appropriate information about the COVID-19 vaccine. Before COVID-19 vaccines are available, clear, effective communication will be essential to implementing a successful COVID-19 Vaccination Program. This information is designed for individuals making COVID-19 vaccination decisions for themselves and their family, providers, tribal and urban leaders, and others.

The focus of a communication plan will be to promote awareness of vaccine risks and benefits, dispel misinformation, and address public concerns about safety.

Communication should center on the careful planning and research that goes into developing a vaccine, recommendations for who should receive the vaccine, the availability and cost of the vaccine (no cost), and assuring the public that safety is a top priority. Communication strategy should also reflect the health literacy level and English proficiency of specific target population groups.

- Communication plan will utilize a wide variety of culturally appropriate messages and materials to inform the public on COVID-19 vaccines. Utilize current influenza campaign as a model and incorporate COVID-19 vaccines as more information becomes available.
    - Identify and develop or share materials for local distribution that may include:
        - Written information posted on various vetted websites, both government and tribal.
        - Frequently asked questions and fact sheets.
        - Public service announcements.
        - Articles and short series/stories to incorporate into local tribal newspapers and newsletters
    - Coordinate the development of key messages, tone, and imagery – adjusting to changing needs and community concerns and should identify internal and external influencers to deliver messages to identified audiences that will include vaccine hesitant individuals and their influencers. Influencers may include tribal leaders, policy makers, media, tribal elders, traditional healers, policymakers, public health practitioners, and health providers.
    - Determine communication tools and channels used to disseminate vaccine information such as evidence-based recommendations; use of media and digital communication; provider education and training; and support of stakeholder organizations
    - Dissemination plan should include materials to be distributed in a wide variety of settings such as ceremonies, rodeos, clinics and health care facilities, goods and services locations, community centers in and around reservations and urban facilities.
        - Other forms for the dissemination of information may include stakeholder calls, email communication, social media, and media engagement.
- Identify existing and potential partners such as epicenters and regional tribal organizations to identify channels for dissemination and existing culturally appropriate communication materials addressing vaccine hesitancy and communication.

Section 6: Data Management

IHS has a long-history of providing vaccinations to our employees and beneficiaries. COVID-19 vaccine administration will build upon the existing platforms already in place as well as incorporate new platforms to allow for timely documentation. CDC has identified required data elements that all I/T/U facilities receiving COVID-19 vaccine must comply with (see Appendix D). In addition to the ability to collect and report these data elements, IHS 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. IHS has identified the software requirements to meet the required data elements as well as data extracts necessary for data submission to CDC.

CDC and Operation Warp Speed (OWS) Data Platforms

CDC Immunization Gateway (IZ Gateway)

The immunization gateway facilitates electronic messaging of vaccination records in a secure infrastructure.

CDC Immunization Clearinghouse (IZ Clearinghouse)

The clearinghouse is a centralized immunization data collection repository where all immunization data is kept until it is de-duplicated and de-identified.

CDC Data Lake

The Data Lake will provide a catalogue of different COVID-19 vaccine-related data sources that can be used to aid in monitoring COVID-19 vaccine ordering, distribution, coverage, and uptake.

Vaccine Administration Management System (VAMS)

The CDC Vaccine Administration Management System (VAMS) is a cloud-hosted application that provides an option for a jurisdiction or provider to plan and execute mass vaccine administrations in either fixed base or mobile settings. It fills a gap if jurisdiction or provider needs vaccination clinic software or mobile solution and supports vaccination clinic workflow.

Vaccine Tracking System (VTrckS)

VTrckS is CDC's centralized vaccine ordering platform for jurisdictions.

OWS Tiberius

Tiberius (or Protect-OWS) is the Operation Warp Speed (OWS) platform. Provides a COVID-19 vaccine distribution planning, tracking, modeling, and analysis ecosystem to support the OWS mission. Integrates data sources from Federal agencies, State and Local partners, private sector partners, and open data providers. Provides flexible and near real-time data-backed applications that enable users of all types to make data driven decisions.

Vaccine Documentation - Beneficiaries

RPMS/EHR Users

- I/T/U facilities with HealthShare 2017, Certified Heath IT (CHIT) 2015 and current immunization patches installed:
    - Non-Federal Facilities:

        - Document vaccine administration in RPMS/EHR per usual process.
        - Vaccine administration data reported daily via Health Level Seven (HL7) version 2.5.1 message to National Data Warehouse (NDW), which will be collected by the IHS Aggregate Server, then transmitted to the CDC Immunization Clearinghouse.
    - Federal Facilities:
        - Document vaccine administration in RPMS/EHR per usual process.
        - Vaccine administration data reported daily via Health Level Seven (HL7) version 2.5.1 message to the IHS Aggregate Server, then transmitted to the CDC Immunization Clearinghouse.

- I/T/U facilities without HealthShare 2017, Certified Heath IT (CHIT) 2015 and current immunization patches installed:
    - Software upgrades necessary for data transmission to the IHS Aggregate Server:
        - Windows Systems
            - Upgrade to Windows 2016 Operating System software.
            - Upgrade Database Operating System from Ensemble to HealthShare 2017.
            - Load RPMS/EHR 2015 Certified Health IT (CHIT) Software Patches.
            - Load Immunization patches.
        - AIX Systems
            - Upgrade to AIX version 7.2 Operating System.
            - Upgrade Database Operating System from Ensemble to HealthShare 2017.
            - Load RPMS/EHR 2015 Certified Health IT (CHIT) Software Patches.
            - Load Immunization patches.
    - Unable to complete necessary software upgrades to install immunization patches.
        - Document vaccine administration in the VAMS information will be uploaded through network connections to the CDC IZ Gateway.
        - Record vaccination as a historical dose in RPMS/EHR for forecasting and internal reporting purposes.

Non-RPMS/EHR Users

- Non-Federal Facilities
    - Preferred
        - Document vaccine administration in health record per usual process.
        - Vaccine administration data reported daily via Health Level Seven (HL7) version 2.5.1 file to National Data Warehouse (NDW), which will be collected by the IHS Aggregate Server, then to CDC Clearinghouse.
    - Optional
        - Document vaccine administration in the VAMS, a CDC developed application for documentation.

Vaccine Documentation – Non-Beneficiaries

- I/T/U facilities can use either RPMS/EHR or CDC VAMS using processes described above for beneficiaries.

Vaccine Documentation – Employees

All I/T/U facilities are required to report vaccine administration to CDC.

- Non-Federal Facilities
    - Document vaccine administration in VAMS, information will be uploaded through network connections to the CDC IZ Gateway.
    - Document employee vaccine administration RPMS/EHR or COTS, as appropriate.
- Federal Facilities
    - Document vaccine administration in VAMS, information will be uploaded through network connections to the CDC IZ Gateway.
    - Place copy of vaccine administration certificate in employee's official employee health record after employee health accounts for the disclosure on the IHS-505 form and places the IHS-505 form in the employee health record.
    - If an employee is a beneficiary and also wants their vaccine in their patient health record, they will sign an IHS-810 for the disclosure from their employee health record to the patient health record.

Vaccine Documentation – Contingency Planning

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.

Vaccine Documentation – Internal Monitoring of Data Reporting

IHS VTF will monitor data reporting including vaccine administration, ordering and inventory through Tiberius. Identified data gaps or inconsistencies will be further evaluated and IHS VTF will work with I/T/Us to resolve data reporting concerns. Area Directors will be notified of I/T/U facilities who are not reporting, corrective action will be taken.

Vaccine Documentation – Internal Vaccination Rate & Coverage Reports

- VAMS and Tiberius data will be used to track and monitor vaccination rates, where appropriate.
- For I/T/U facilities using RPMS/EHR, the IHS VTF anticipates creation of internal reporting to quantify the number of individuals that have received doses of COVID-19 vaccine, as well as the number of individuals that have completed a series. The internal reports will be stratified by age groups. The vaccination rate repots will be created once vaccine CVX codes and national drug codes are available and can be incorporated into RPMS/EHR and when possible in other commercial off the shelf electronic health records. Report templates are in draft form but will await the critical elements necessary to proceed.

Vaccine Documentation – Maintaining Records

I/T/U facilities must preserve the vaccine recipients' records for at least six (6) years following vaccination, or longer if required by applicable law. Such records must be made available to any federal (including IHS), state, local, tribal or territorial public health department to the extent authorized by law.

Date Use Agreement

As required by CDC, IHS will include the data use language into the IHS and CDC Memorandum of Agreement to share vaccination data with the CDC IZ Gateway as required.

Program Onboarding and Training

- Data Management team will host introduction and tabletop training available November 2, 2020 through November 19, 2020, with the goal of having all onboarding and training complete the week of November 16, 2020.
- The audience is I/T/U facilities and Area and Site Clinical Informaticists, Health Informaticists, Health Information Management Professionals, Public Health Nurses, Pharmacists, Clinicians, Chief Executive Officers, Chief Medical Officers, Nurse Management, Immunization Coordinators, Clinical Staff, Quality Assessment/Performance Improvement, Risk Management, Procurement, OIT Directors, Human Resources, Dental Professionals, and Statistics.
- The goal is to provide training and information for critical software requirements (HealthShare 2017, Certified Health IT 2015, COVID-19 immunization patches, Health Level 7 (HL7) message), on boarding for VAMS, Oracle portal orientation, vaccine tracking system (VTrckS) discussion, vaccine adverse event reporting system (VAERS) review, and key documentation considerations for data and work flows.

Key Activities - VTF Data Management Team

- Identify and apply the requirements for implementation of VAMS and IZ Gateway (if required) for I/T/U facilities with which NSSC is coordinating vaccine distribution.
- Consult with OIT Division of Information Security to ensure all data collection and reporting processes comply with federal health IT security and privacy requirements.
- Develop communication and training plans to advise Areas, and I/T/U 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 I/T/U facilities that may not be able to report immunization information due to technical challenges and provided information technology support when needed.
- Identify and document I/T/U facilities that choose not to participate in immunization reporting to the central OIT data repository – these I/T/U facilities may choose to report directly through VAMS.
- A testing schedule to systematically test all I/T/U facilities' data flow is being planned prior to vaccine release. To date, three Federal sites with up-to-date patches for RPMS/EHR have successfully transmitted test files to confirm that the HL7 data flow pathway is operational.

Area Offices

- Identify I/T/U facilities' RPMS/EHR and non-EHR platforms used. Assess the capability to document COVID-19 vaccination administration information.
- Offer support to I/T/U facilities that do not use RPMS/EHR may or may not have an immunization tracking system; however, if they have a certified EHR, it is likely they have the capability.

I/T/U Facilities

- Ensure installation of required immunization software and patch updates as recommended by OIT.
- Report standard data practices for immunization data, including exports IHS reporting status.
- Report barriers to data IHS reporting for I/T/U facilities.

Section 7: Safety and Monitoring

The IHS NPTC will analyze available clinical trial data and coordinate distributing clinical guidance regarding emerging vaccines, including vaccine safety and efficacy.

Vaccine Adverse Events Reporting System (VAERS)

VAERS is a national early warning system to detect possible safety problems with vaccines. Anyone (a doctor, nurse, pharmacist, or any member of the general public) can submit a report to VAERS. VAERS is not designed to detect whether a vaccine caused an adverse event, but it can identify "signals" that might indicate possible safety problems requiring additional investigation. The main goals of VAERS is to:

- Detect new, unusual, or rare adverse events that happen after vaccination;
- Monitor for increases in known side effects;
- Identify potential patient risk factors for particular types of health problems related to vaccines;
- Assess the safety of newly licensed vaccines; and,
- Detect unexpected or unusual patterns in adverse event reports.

VAERS Reporting

Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report adverse events following COVID-19 vaccination and should report clinically important adverse events even if they are not sure if the vaccination caused the event.

- Vaccination administration errors, whether or not associated with an adverse event (AE);
- Severe COVID-19 illness (e.g., resulting in hospitalization);
- Serious AEs regardless of causality. Serious AEs are defined as:
    - Death;
    - A life-threatening adverse event;
    - Inpatient hospitalization or prolongation of existing hospitalization;
    - Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
    - A congenital anomaly/birth defect; and
    - Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above.

Key Activities

- VTF Safety and Monitoring Team will 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).

- Monitor vaccine safety, in collaboration with the IHS Divisions of Epidemiology and Patient Safety and Clinical Risk Management, including collection & analysis of adverse vaccine events through both active and passive surveillance systems, such as:
    - VAERS.
    - NPTC network of sentinel sites in IHS Areas (tribal/federal, inpatient/outpatient) via hub-and-spoke model of active surveillance.
    - Other resources, as indicated (i.e. VAMS, RPMS/EHR).
- Report adverse event findings (i.e. sentinel events, trends) to key stakeholders, as appropriate, including I/T/U facilities.
- Provide updates to I/T/Us regarding available vaccine safety data on AI/AN enrolled in COVID-19 vaccine clinical trials, if available.

Resources

- CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations, Version .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 Phase 1 Planning Scenarios

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

Availability Assumptions

Vaccine availability under EUA by			
Candidate	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine A	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 • 2 mL multidose vials (5 doses/vial) • Direct to site from manufacturer (on dry ice) in thermal shipping container • Thermal shipper estimated specs: 400 mm X 400 mm X 560 mm, (15.75" X 15.75" X 22.0") • Each shipper can hold up to 5 trays, and each tray will hold up to 195 vials. • Tray (i.e., "pizza box") estimated specs: 229 mm X 229 mm X 40 mm (9" X 9" X 1.6") 2. Diluent and ancillary supply kits (for administration and mixing) • Direct to site from the federal government (at room temperature) 3. Thermal shipper should be returned after use. Instructions for mail-back and labels will be forthcoming.	**ON-SITE VACCINE STORAGE** ***Ultra-Cold Temp Frozen (-60°C to -80°C)*** • Freezer units capable of ultra-cold temperatures (UCTs) • The shipping container (thermal shipper) may be used to store vaccines: o Once received (day 1), the thermal shipper should be replenished with pelleted dry ice within 24 hours. o Shippers should be replenished with dry ice every 5 days thereafter to maintain required temperature. o Total amount of dry ice needed per thermal shipper "recharge" is ~23 kg. o On day 15, transfer the vaccine to refrigerated temperatures (2–8°C). Use within 5 days (120 hours). o Shippers may only be opened two times a day. • Temperature monitoring must be in alignment with CDC guidance, irrespective of re-icing. o Thermal shipper may be monitored using a temperature probe on the container, in alignment with guidance provided by CDC and information provided by the manufacturer. o Direct handling of dry ice needed for recharging the containers will require the use of appropriate PPE. ***Thawed but NOT diluted (2°C to 8°C)***

	• Product may be removed from ultra-cold storage or thermal shipper, thawed, and stored at 2°C–8°C for up to 5 days (discard unused doses after 5 days). • Cannot return to ultra-cold storage or thermal shipper once thawed ***Diluted (room temperature)*** • If removed directly from ultra-cold temperatures, vaccine must be thawed ~30 minutes at room temperature before dilution. • Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C. • Must use diluted vaccine within 6 hours (discard any unused, diluted vaccine after 6 hours)
ORDERS ***Large quantities, to large provider sites only*** • Minimum order: ~1,000 doses • Maximum order: ~5,000 doses	**ADMINISTRATION** ***2-dose series (21 days between doses)*** • On-site mixing required; dilute with diluent just prior to administration; all 5 doses must be administered within 6 hours of dilution; remainder of diluted vaccine should be discarded. • Administer by intramuscular (IM) injection.
INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINATION PROVIDER SITES ***NOTE: Primary vaccination provider sites may consider providing vials to other sites. HOWEVER, all cold chain requirements should be maintained and logged in accordance with the information provided above.*** ***Healthcare personnel*** — public health clinics, closed points of dispensing (PODs), temporary/off-site vaccination clinics + potential for mobile clinics ***Other essential workers*** — public health clinics, closed PODs, temporary/off-site vaccination clinics + potential for mobile clinics ***Adults with underlying medical conditions and people 65 years of age and older*** — open PODs in strategic locations, potential for mobile clinics at long-term care facilities (LTCFs) or partnership with pharmacy on-site clinics for LTCFs, correctional/detention facilities, and other congregate settings	

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.
- Vaccination provider 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 thermal shipper or at refrigerated temp (2°C–8°C, see "Thawed but NOT diluted" section).
- Given the challenging storage, handling, and administration requirements, early vaccination should focus on vaccination provider 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 vaccine product storage and handling requirements. For example, Vaccine A may be administered by mobile clinics if multiple mobile clinics are planned over a short period of time to ensure sufficiently high throughput. Vaccine A may also be placed in healthcare systems and support multiple clinics in one system (where product can be shared and repositioned from one site to another at 2°C–8°C).
- Ensure equitable access for adults with underlying medical conditions and people 65 years of age and older who are part of other critical populations. Additional vaccination provider sites may be required to reach these populations.

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

Availability Assumptions

Vaccine availability under EUA by			
Candidate	**End of Nov 2020**	**End of Dec 2020**	**Notes**
Vaccine B	~10M doses	~15M doses	Central distributor capacity required (-20°C)

Distribution, Storage, Handling, and Administration Assumptions

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 (-25°C to -15°C until ready for use)

Note: This is a narrower range than for varicella-containing vaccines.

Refrigerated (2°C to 8°C)

- Must use within 7 days if the vial has not been entered
- Thaw before use:
  - Thaw in refrigerated conditions between 2°C to 8°C for 2 hours. Let vial stand at room temperature for 15 minutes before administering.
  - Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour.
  - After thawing, do not return vial to the freezer.

Room temperature

- The total time between removal from refrigeration and administration should be no more than 12 hours.
- Once the vial has been entered, it must be used within 6 hours (discard any unused vaccine after 6 hours).

ORDERS

Central distribution capacity

- Required by Dec 2020
- Maintained at -20°C

ADMINISTRATION

2-dose series (1 month between doses)

- No on-site mixing required
- Once thawed, swirl vaccine gently prior to withdrawing a dose. Do NOT shake.
- Administer by intramuscular (IM) injection.

INITIAL POPULATIONS OF FOCUS AND ANTICIPATED VACCINATION PROVIDER SITES

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

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

Adults with underlying medical conditions and people 65 years of age and older — 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.
- Ensure equitable access for adults with underlying medical conditions and people 65 years of age and older who are part of other critical populations. Additional vaccination provider sites may be required to reach these populations.

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

Availability Assumptions

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

Distribution, Storage, Handling, and Administration Assumptions

Vaccine A

SHIPMENT

3 separately acquired components (mixed on site)

1. Vaccine
   - 2 mL multidose vials (5 doses/vial)
   - Direct to site from manufacturer (on dry ice) in thermal shipping container
   - Thermal shipper estimated specs: 400 mm X 400 mm X 560 mm (15.75" X 15.75" X 22.0")
   - Each shipper can hold up to 5 trays, and each tray will hold up to 195 vials.
   - Tray (i.e., "pizza box") estimated specs: 229 mm X 229 mm X 40 mm (9" X 9" X 1.6")
2. Diluent and ancillary supply kits (for administration and mixing)
   - Direct to site from the federal government (at room temperature)
3. Thermal shipper should be returned after use. Instructions for mail-back and labels will be forthcoming.

ON-SITE VACCINE STORAGE

Ultra-Cold Temp Frozen (-60°C to -80°C)

- Freezer units capable of ultra-cold temperatures (UCTs)
- The shipping container (thermal shipper) may be used to store vaccines:
  - Once received (day 1), the thermal shipper should be replenished with pelleted dry ice within 24 hours.
  - Shippers should be replenished with dry ice every 5 days thereafter to maintain required temperature.
  - Total amount of dry ice needed per thermal shipper "recharge" is ~23 kg.
  - On day 15, transfer the vaccine to refrigerated temperatures (2°C to 8°C). Use within 5 days (120 hours).
  - Shippers may only be opened two times a day.
- Temperature monitoring must be in alignment with CDC guidance, irrespective of re-icing.
  - Thermal shipper may be monitored using a temperature probe on the container, in alignment with guidance provided by CDC and information provided by the manufacturer.
  - Direct handling of dry ice needed for re-icing the containers will require the use of appropriate PPE.

Thawed but NOT diluted (2°C to 8°C)

- Product may be removed from the ultra-cold storage or thermal shipper, thawed, and stored at 2°C to 8°C for up to 5 days (discard unused doses after 5 days).
- Cannot return to ultra-cold storage or thermal shipper once thawed

	Diluted (room temperature) • If removed directly from ultra-cold storage, vaccine must be thawed ~30 minutes at room temperature before dilution. • Once vaccine is thawed, it must be diluted within 2 hours. If unable to dilute within 2 hours, store at 2°C–8°C. • Must use diluted vaccine within 6 hours (discard any unused diluted vaccine after 6 hours)
ORDERS ***Large quantities, to large provider sites only*** Minimum order: ~1,000 doses Maximum order: ~5,000 doses	**ADMINISTRATION** ***2-dose series (21 days between doses)*** • On-site mixing required; dilute with diluent just prior to administration; all 5 doses must be administered within 6 hours of dilution; remainder of diluted vaccine should be discarded. • Administer by IM injection.
PRIORITIZED POPULATIONS AND ANTICIPATED VACCINATION PROVIDER SITES ***Healthcare personnel*** — public health clinics, closed PODs, temporary/off-site vaccination clinics + potential for mobile clinics ***Other essential workers (specifics TBA)*** — public health clinics, closed PODs, temporary/off-site vaccination clinics + potential for mobile clinics ***Adults with underlying medical conditions and people 65 years of age and older*** — commercial pharmacy partners, open PODs in strategic locations, potential for mobile clinics at LTCFs, correctional/detention facilities, and other congregate settings	
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 (-25°C to15°C until ready for use)
	Note: This is a narrower range than for varicella-containing vaccines.
	Refrigerated (2°C to 8°C)
	• Must use within 7 days if the vial has not been entered.
	• Thaw before use:
	  • Thaw in refrigerated conditions between 2°C to 8°C for 2 hours. Let vial stand at room temperature for 15 minutes before administering.
	  • Alternatively, thaw at room temperature between 20°C to 25°C for 1 hour.
	  • After thawing, do not return vial to the freezer.
	Room temperature
	• The total time before administration and after removal from the refrigerator should be no more than 12 hours.
	• Once the vial has been entered, it must be used within 6 hours (discard any unused vaccine after 6 hours).

Appendix B: I/T/U Facility Pre-Planning Tool

The IHS Vaccine Task Force (VTF) requested Areas to complete a pre-planning data collection tool. The tool is based on inputs provided by I/T/Us and is used to determine key reporting information and population estimates for COVID-19 vaccine planning. Information requested included the following:

- Area
- Receiving Facility (end user)
- Street
- City
- State
- Zip Code
- Federal/Tribal/Urban
- Healthcare facility (yes/no)
- Anticipated preference for vaccine distribution (IHS/State/Undecided)
- Intend to stock and administer COVID-19 vaccine (yes/no)
- Vaccine POC (name)
- Vaccine POC (email)
- CEO/Director (name)
- CEO/Director (email)
- Can receive shipments at a physical address not PO Box (yes/no)
- If "no" list parent facility for receiving shipment
- Receiving days and hours for deliveries
- What Electronic Health Record does the facility use
- On site pharmacy (yes/no)
- On-site ultra-cold storage capability (-70°C to -80°C) (Yes/No)
- Do you have access to ultra-cold storage through public/private partners (yes/no)
- On site freezer (yes/no)
- Freezer has ability to maintain vaccine at -20°C (yes/no)
- Is there sufficient freezer space for potential COVID-19 vaccine (yes/no)
- On site vaccine refrigerator (yes/no)
- Refrigerator temp range of +2°C to +8°C (yes/no)
- Is there sufficient refrigerator space for potential COVID-19 vaccine (yes/no)
- How do you monitor vaccine temperatures (data loggers, manual, other)
- Total number of healthcare personal (direct, non-direct and emergency medical staff)
- Estimated number of essential workers (ex. law enforcement, teachers, transportation, food industry, government, long-term care staff)
- Number of residents in tribal long-term care
- Number of elders
- Estimated number of patients at high-risk for COVID-19 illness
- Estimated number of people you anticipate providing COVID-19 vaccine

Appendix C: IHS COVID-19 Facility Planning Checklist - EXAMPLE

This Facility Planning Checklist Example may be used as a guide to assist I/T/U facilities in determining readiness for vaccine distribution and is optional for facility use. The checklist is divided into eight sections. Activities are listed for each section, a box is included to check completed activities, space is included for anticipated completion timeframe, and an actions/notes section is included.

1. Pre-Planning

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	Create a I/T/U Facility COVID-19 Vaccine Readiness Team. • 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		
☐	Create or update pandemic vaccination plan to include plans for COVID-19 vaccination.		
☐	Practice processes for socially distanced immunization clinics and assess lessons learned. • Flu clinic – mass vaccination events, visits by appointment, drive up clinics. • Child & Adult immunization clinics (routine and catch-up). • Consider infection control measures.		
☐	Determine priority populations. • Collect HCP Personnel numbers (work with Employee Health, Infection Control, Human Resources and Medical Credentialing to obtain estimates): 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.		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:

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
	• Estimate Population by age stratifications (0-18yrs, 19-64yrs, 65+ or alternate age groups per Tribal Leadership). • Families of HCP and essential workers.		
☐	Discuss priority groups, how to identify them and how to reach them. • 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 I/T/U 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).		
☐	Designate COVID-19 Area Vaccine Point of Contact (AVPOC) at the Area Level to work with the I/T/U facility workgroups, SMEs and POC.		Area POC:
☐	Identify a COVID-19 Vaccine Point of Contact (POC) at each I/T/U 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.		I/T/U Facility Names & POCs:
☐	Become engaged at federal, state, and tribal level for COVID-19 planning: • 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		
☐	Review lessons learned from H1N1 Response – what went well, what didn't?		

2. Communications Checklist

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	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: • Social Media • Tribal newspapers		

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
	• Flyers, posters, handouts		

3. Requesting Vaccine

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	Provide pre-planning information to AVPOC (who will be providing to IHS COVID-19 VTF Team).		
☐	Request COVID-19 Vaccine, Area Vaccine EMPOC will assist in coordination from NSSC.		

4. Receiving Vaccine

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	Determine logistics: staff, supplies, locations for closed and open Points of Dispensing (POD).		
☐	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

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	Assess cold storage capacity estimates (available space to store COVID-19 vaccine), including: • Refrigerator • Freezer • Ultra-cold (unlikely need – consider inquiring with Federal or private partners), NOT RECOMMENDED TO PURCHASE, ultra-cold will come in storage containers.		
☐	Prepare for temperature monitoring requirements from the CDC - inventory and wastage (likely daily), consider purchasing data loggers if not already in use.		

6. Administering

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	Train staff (required – CDC and IHS will provide training materials) on: • Safe storage and handling. • COVID-19 vaccine administration (brand dependent training).		

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
	• Required documentation and inventory elements. • Points of Dispensing (POD).		
☐	Phase 1 Priority Groups: Limited Doses Available • 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		
☐	Phase 2 Priority Groups: Large Number of Doses Available • 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		
☐	Phase 3 Priority Groups: Continued Vaccination, Shift to Routine Strategy • 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

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	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.		
☐	Reporting immunizations to CDC daily via State or IHS pathways (IHS will utilize HL7).		

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
	• Process for documenting patient vaccines will remain unchanged. • IT/CAC will need to ensure patches are installed and up to date. • Data extraction daily to ensure CDC documentation requirements are met.		
☐	Assure accounts are active for immunization management systems as needed IHS		
☐	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).		
☐	Ensure reporting of employee vaccinations, which may occur outside of the electronic health record and may require alternate documentation pathways.		

8. Recovery

Check when complete (√)	Activity	Completion Timeframe	Action/Notes
☐	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 2.0

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

Table 1 below includes each data element that IHSIHS will be required to report to CDC. Table 2 below includes each data element that will be optional for IHSIHS 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, whereas Mass Vaccination data elements are likely to require enhancements or a Mass Vaccination module for data collection and reporting. The 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
Data elements required for IHSIHS to report	*Standard = IHS core data element* *Mass Vaccination = May require IHS enhancement*
Administrated at location: I/T/U facility name/ID	Standard
Administered at location: type	Standard
Administration address (including county)	Standard
Administration date	Standard
CVX (Product)	Standard
Dose number	Standard
IHS Recipient ID	Standard
IHS 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
Recipient ethnicity	Standard
Recipient race	Standard
Sending organization	Standard
Vaccine administering provider suffix	Standard
Vaccine administering I/T/U 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*
Data elements optional for IHS to report (e.g., state mass vaccination tool collects this information)	*Standard = IHS core data element* *Mass Vax = May require IHS enhancement*
Comorbidity status (Y/N)	Mass Vaccination
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.*