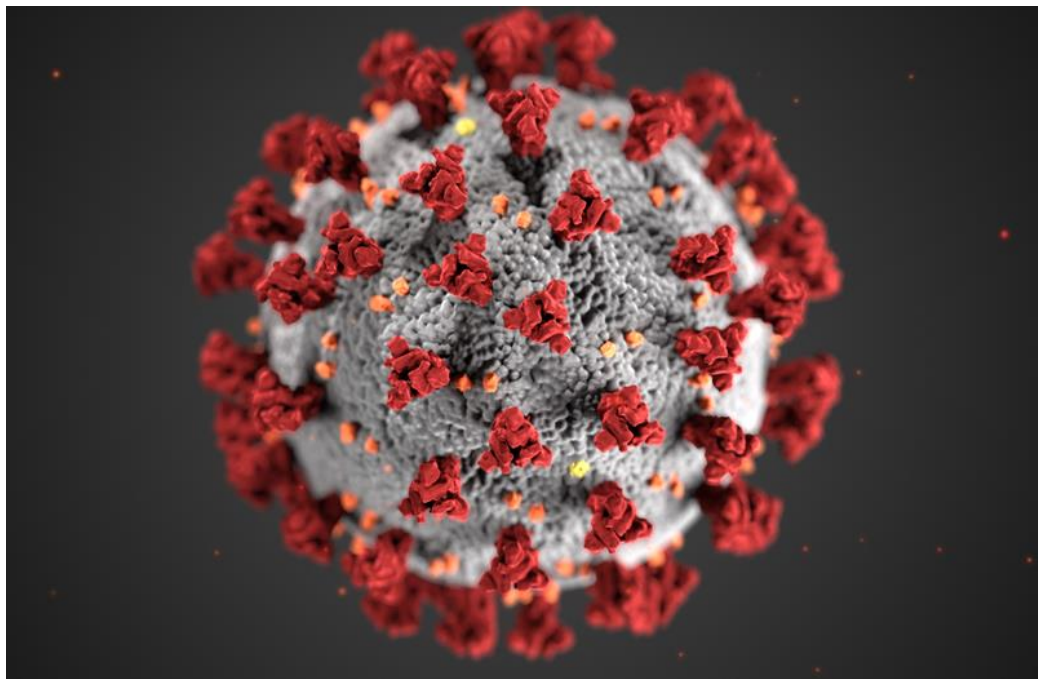


PENOBSCOT NATION HEALTH DEPARTMENT



2020-2021

COVID-19 Vaccine Distribution Plan

Penobscot Nation Health Department

COVID-19 VACCINE DISTRIBUTION PLAN

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INTRODUCTION |

A vaccine to prevent coronavirus disease 2019 (COVID-19) is perhaps the best hope for ending the pandemic. For the COVID-19 vaccine to be successful in allocation, distribution, administration, documentation, and monitoring, a comprehensive planning effort for the Penobscot Nation Health Department (PNHD) is necessary. Given the number of questions that remain about the vaccines themselves, their efficacy in different populations, the schedule of doses, cold-chain storage requirements, as well as data, reporting and monitoring, PNHD's COVID-19 vaccine distribution plan should be designed with flexibility in mind. Staff should be ready to implement vaccination activities as soon as an FDA-approved vaccine is available.

In a recent Centers for Disease Control and Prevention (CDC) *Morbidity and Mortality Weekly Report*, AI/AN populations in 23 states have been disproportionately affected by the COVID-19 pandemic, compared with the white population (Hatcher SM, 2020). Further, among federally recognized tribes such as the Penobscot, tribal membership confers a political status that confers access to health care services under treaty obligations of the U.S. government. The CDC findings highlight the important contribution of adequate health care and public health infrastructure resources to culturally responsive public health efforts. Covid-19 vaccination programs will succeed only if there is widespread belief that available vaccines are safe and effective and that policies for prioritizing their distribution are equitable and evidence-based. Unfortunately, trust in science and expertise are threatened, as the pandemic has shown with catastrophic results.

VACCINE AVAILABILITY

Guidance from the U.S. Department of Health & Human Services (HHS) indicates that any COVID-19 vaccine approved by the Food & Drug Administration (FDA) will be released in three (3) phases, moving from targeted to broader populations. Indian Health Services has stated that their vaccination allocation and distribution "...will align with the CDC recommendations with advice from the Advisory Committee on Immunization Practices (ACIP) for priority populations." (IHS COVID-19 Vaccine Draft Plan, Version 1, 2020). Because the Penobscot Nation Health Department (PNHD) has elected to receive any COVID-19 Vaccine distribution via Indian Health Services, these guidelines will also form the backbone of the PNHD plan.

State and Federal agencies are planning vaccine distribution based on the following model:

Phase I | Limited Doses Available

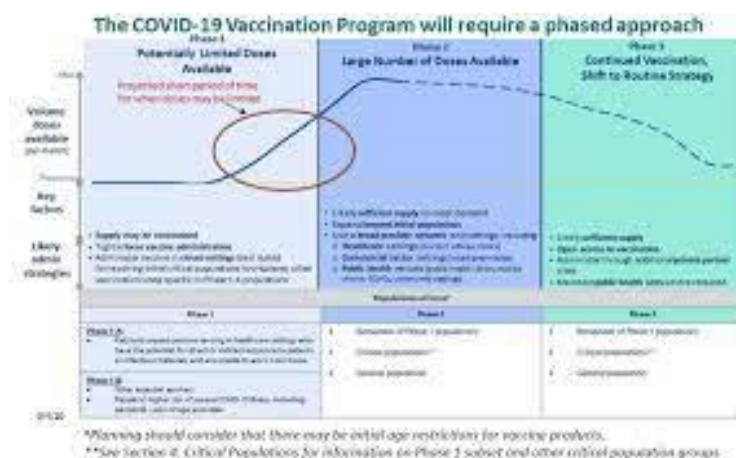
- Doses available per month are constrained
- Highly targeted administration required to achieve coverage in priority populations
- Administer in closed settings, including places of work for tribal departments or sites specific to priority populations

Phase II | Large Number of Doses Available

- Supply access increases
- Likely sufficient supply to meet demand
- Broad administration required, including surge capacity
- Administer through public health sites and large-volume models

Phase III | Continue Vaccination

- Shift to Routine Strategy
- Likely excess supply
- Broad administration via regular immunization channels



PRIORITIZATION

The Penobscot Nation Health Department intends to use as a baseline for vaccine prioritization the current CDC guidelines for those who are and who may be at increased risk for complications with COVID-19 infection. In a few areas, PNHD recommends re-prioritization of the vaccine using the principles of self-governance to better meet the specific need of the Penobscot community. These deviations from the CDC recommendations are noted below in red.

The Penobscot Nation Health Department recommends eligibility for COVID-19 vaccination be extended to non-native Penobscot Nation employees and non-native individuals with close social and economic ties to the Penobscot Nation, including but not limited to: residency in a native household, non-native dependents of eligible AI/AN, residency on Tribal land, etc. in accordance with the following guidance from Indian Health Services:

“The IHS’s authority to serve non-beneficiaries to prevent the spread of a communicable disease is specified at 25 U.S.C. § 1680c(d)(2). This authority also may be utilized by Tribes and Tribal Organizations, should they wish to exercise the authority for their programs, assuming it is consistent with the terms of their Indian Self-Determination and Education Assistance Act agreement with the IHS.”

The current recommendations for vaccine prioritization by phase are as follows:

Phase I | Limited Doses Available (5-10% Vaccine Availability)

- Frontline Healthcare Workers (Health Department and NOLI Staff)
- Public Safety
- PIN Essential Workers (Social Services, Maintenance, Housing)
- Elders 65+ years old
- Tribal Elders (55+) in congregate living situations (NOLI Home and Penobscot Senior Housing)
- Individuals in transient living situations (Homeless, residing in a shelter, etc.)
- Individuals who are at high risk for complications with Covid-19 infection
 - Cancer
 - Severe Chronic kidney disease/Dialysis
 - COPD (chronic obstructive pulmonary disease)
 - Heart conditions, such as heart failure, coronary artery disease, or cardiomyopathies
 - Immunocompromised state (weakened immune system) from: solid organ transplant, blood or bone marrow transplant, immune deficiencies, HIV, use of corticosteroids, or use of other immune weakening medicines
 - Obesity (body mass index [BMI] of 30 kg/m² or higher but < 40 kg/m²)
 - Severe Obesity (BMI ≥ 40 kg/m²)
 - Pregnancy
 - Sickle cell disease
 - Smoking
 - Type 2 diabetes mellitus

Phase II | Large Number of Doses Available (30-35% Vaccine Availability)

- Child Services (Teachers, Daycare workers, School Staff)
- Students in congregate living situations (College dorms, etc.)
- Penobscot Nation Employees
- Individuals who may be at increased risk for complications with Covid-19 infection
 - Asthma (moderate-to-severe)
 - Cerebrovascular disease (affects blood vessels and blood supply to the brain)
 - Cystic fibrosis
 - Hypertension or high blood pressure
 - Neurologic conditions, such as dementia
 - Liver disease
 - Overweight (BMI > 25 kg/m², but < 30 kg/m²)
 - Pulmonary fibrosis (having damaged or scarred lung tissues)
 - Thalassemia (a type of blood disorder)
 - Type 1 diabetes mellitus

Phase III | Continue Vaccination

- Young Adults
- Children
- Adults without underlying health conditions that qualify for a higher priority level

In the event an individual qualifies for vaccination under more than one priority level indicated above, the higher ranked priority will take precedence. These priority levels are not meant to be an exhaustive list of vaccination qualifiers.

Eligibility for vaccination at a higher priority level may be granted by a unanimous decision of both the Health Director and Medical Director. Any deviation from PNHD's vaccine eligibility guidelines using this model must be documented in the patient's Electronic Health Record (EHR) and signed by both Directors. These records must be maintained for six years per the IHS and CDC COVID-19 vaccination requirements.

VACCINE STORAGE AND ORDERING

Under the COVID-19 Vaccination Agreement with Indian Health Services, the Penobscot Nation Health Department will be required to order its vaccine allocation via the National Supply Service Center (NSSC).

Order requests will be based on projected demand. Potential usage will be calculated using several data sources, including medical diagnoses reports returned by the PNHD electronic health record, community surveys, reporting from Tribal Departments, etc. PNHD will be required to order brand-specific vaccines, and any individual receiving a multi-dose vaccine must be given the same medication for both doses.

Tribal Health Program's COVID-19 vaccination services must be conducted in compliance with "CDC's Guidance for Immunization Services During the COVID-19 Pandemic" for safe delivery of vaccines:

Tribal Health Program must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following:

1. Tribal Health Program must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the CDC COVID-19 Vaccination Program Provider Agreement, manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit, which will be updated to include specific information related to COVID-19 Vaccine;
2. Tribal Health Program must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit.
3. Tribal Health Program must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions.
4. Tribal Health Program must monitor and comply with COVID-19 Vaccine expiration dates; and
5. Tribal Health Program must report to IHS the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by CDC.
6. Tribal Health Program must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.

Vaccine distribution from Indian Health Services will also include shipments of Personal Protective Equipment (PPE) and ancillary supplies necessary for vaccine administration.

COVID-19 vaccines may require ultra-cold (-70 to -80°C), standard frozen (-20°C) or refrigeration storage. To meet these requirements, the Penobscot Nation Health Department has purchased supplement vaccine storage units the meet each of these category requirements.

When possible, PNHD will use continuous data loggers with backup for temperature monitoring.

VACCINE ADMINISTRATION

COVID-19 vaccinations will be administered with a standing order issued by the Penobscot Nation Medical Director. All clinical staff will complete the recommended CDC training for vaccine administration. Current PNHD staff members with clinical certifications sufficient to administer a vaccine via standing order include:

1. Medical Director
2. Nurse Practitioners
3. Registered Nurses
4. Pharmacist
5. Medical Assistants
6. Medical Program Coordinator
7. Health Director

Per the Indian Health Services' COVID-19 Vaccination Agreement:

Tribal Health Program 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, or tribal public health department to the extent authorized by law.

Before administering COVID-19 Vaccine, Tribal Health Program must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable). If the EUA fact sheet or VIS is available electronically, Tribal Health Program may provide it in electronic form to the recipient, adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable), if such person agrees to accept it electronically in the file format offered by Tribal Health Program.

Tribal Health Program's COVID-19 vaccination services must be conducted in compliance with "CDC's Guidance for Immunization Services During the COVID-19 Pandemic" for safe delivery of vaccines.

Likely scenarios for vaccination events per phase are as follows:

Phase I | Limited Doses Available (5-10% Vaccine Availability)

- Closed setting (Place of employment or residence)
 - Frontline Healthcare Workers
 - Public Safety
 - PIN Essential Workers
 - NOLI Home
 - Penobscot Senior Housing
- As needed during normal PNHD operations
 - Individuals in transient living situations (Homeless, residing in a shelter, etc.)
- Open Vaccination events (Drive-thru model and/or large-scale immunization clinics)
 - Individuals who are at high risk for complications with Covid-19 infection

- Elders 65+ years old

Phase II | Large Number of Doses Available (30-35% Vaccine Availability)

- Closed setting (Place of employment or residence)
 - Child Services (Teachers, Daycare workers, School Staff)
 - Penobscot Nation Employees
- As needed during normal PNHD operations
 - Students in congregate living situations (College dorms, etc.)
- Open Vaccination events (Drive-thru model and/or large-scale immunization clinics)
 - Individuals who may be at increased risk for complications with Covid-19 infection

Phase III | Continue Vaccination

- As needed during normal PNHD operations
 - Young Adults
 - Children
 - Adults without underlying health conditions that qualify for a higher priority level

Homebound elders and other individuals with special needs in the immediate service area (~30 mi radius) may request home vaccine administration from the Community Health Nurse. These requests will be filled whenever possible.

COMMUNICATIONS

To facilitate a frank and meaningful conversation with the Penobscot Community, the Penobscot Nation Health Department will hold a series of town hall events regarding vaccination concerns via Zoom, starting at the end of November. The events will focus on providing education and in-depth discussion about leading COVID-19 vaccine formularies, adverse reactions, efficacy, and any other community member questions or concerns.

Whenever possible, fact sheets and FAQs concerning the COVID-19 vaccines will be distributed to the community via the Health Department, email, Tribal websites, and social media to promote vaccine confidence.

Community members will be notified of large-scale vaccination events using these same platforms. Those individuals with medical conditions that qualify them for priority vaccination will be notified by phone and with a written follow-up letter of their eligibility and opportunities for vaccination.

Community interest and engagement regarding COVID-19 vaccination will be gauged using online survey tools.

SAFETY AND MONITORING

Tribal Health Program must report the following adverse events (AEs) after vaccination, and other AEs if later revised by CDC, to the Vaccine Adverse Event Reporting System (VAERS):

1. Vaccination administration errors, whether or not associated with an AE.
2. Severe COVID-19 illness (e.g., resulting in hospitalization).
3. Serious AEs regardless of causality. Serious AEs are defined as:
 - a. Death.
 - b. A life-threatening AE.
 - c. Inpatient hospitalization or prolongation of existing hospitalization.
 - d. Persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
 - e. A congenital anomaly/birth defect; and
 - f. 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.

Tribal Health Program will also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under EUA.

Tribal Health Programs are also encouraged to report to VAERS any AEs considered to be clinically significant. When completing the VAERS report, Tribal Health Program will enter "IHS" into item #26 (Immunization Project Report Number). This identifies the reporting Tribal Health Program as part of the Indian Health System comprising Federal, Tribal, and Urban programs for purposes of analyzing, monitoring, and reporting on patient safety. Any Adverse Event qualifying as a 'sentinel event' according to the definitions set forth by the State of Maine will be reported to the Maine Department of Health & Human Services.

Tribal Health Program must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient (if applicable), or other legal representative (if applicable). Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.

DATA MANAGEMENT

Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Tribal Health Program must record in the vaccine recipient's record and report required information to IHS. Details of required information (collectively, Vaccine Administration Data) for reporting can be found on CDC's website. Tribal Health Program must submit Vaccine Administration Data to IHS according to CDC documentation and data requirements. In addition to submitting the data to IHS, Tribal Health Program also may report this data to state or local jurisdiction Immunization Information Systems (IIS). PNHD will submit vaccination information to the State of Maine using IMMTRACT, the existing web-based IIS for vaccine reporting.

Tribal Health Program 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, or tribal public health department to the extent authorized by law.

The Penobscot Nation Health Department will utilize its electronic health record: RPMS, for documentation and required data collection activities. As a certified EHR, RPMS has an Immunization Tracking System installed that can provide immunization data in an HL7 2.5.1 format to Indian Health Services. However, non-natives and Tribal Employees receiving vaccinations via the Penobscot program will need to be reported via an alternate method. Currently, IHS is considering a Vaccine Administration Management System (VAM) for potentially reporting data in these scenarios.

SOURCES

Hatcher SM, A.-B. C. (2020, August 28). *Morbidity and Mortality Weekly Report (MMWR)*. Retrieved from Centers for Disease Control and Prevention: <https://www.cdc.gov/mmwr/volumes/69/wr/mm6934e1.htm>

(2020). *IHS COVID-19 Vaccine Draft Plan, Version 1*.

APPENDICES