

INTERIM DRAFT

NORTH DAKOTA COVID-19
VACCINATION PLAN

Updated October 16, 2020

Version 1.2

DRAFT



Contents

Acronyms	6
Introduction	7
Lessons Learned from H1N1	8
Response Goals for Pandemic Vaccination.....	10
COVID-19 Mass Vaccination Planning Assumptions.....	11
Logistical Assumptions	12
Organizational Structure and Partner Involvement	13
Unified Command Planning Team.....	14
Internal COVID-19 Vaccination Planning Team.....	14
Internal/External COVID-19 Vaccination Planning Committee	14
CDC/HHS Microplanning	14
Tabletop Exercises	15
Current Unknowns and Contingency Planning	15
How persons who have tested positive for COVID-19 will be prioritized.....	15
Type of vaccine that will be available and cold chain requirements of vaccines.....	15
Potential adverse effects of a vaccine.	16
Vaccine amounts.....	16
Vaccine Timing.....	16
Use of adjuvant.....	16
Multiple FDA approved products with different specifications.	17
Packaging.....	17
Current Significant Gaps	17
Provider Recruitment and Enrollment	19
Potential Providers	22
Vaccine Administration Capacity	23
Vaccination of Out-of-State Residents.....	24

Vaccine Prioritization and Critical Populations.....	24
Critical infrastructure workforce.....	25
People at increased risk for severe COVID-19 illness.....	25
People at increased risk of acquiring or transmitting COVID-19.....	25
People with limited access to routine vaccination services	25
Estimates of Priority Groups.....	25
Vaccination of Special and Dependent Populations.....	28
Homebound.....	28
Long Term Cares	29
Custodial institutions and special populations	30
American Indians.....	31
New Americans/Foreign Born/Immigrant Populations.....	32
Priority Vaccination of Infrastructure	32
Advisory Committee on COVID-19 Vaccination Ethics.....	33
Vaccine Allocation.....	34
Vaccine Ordering and Processing.....	35
Physical Vaccine Management and Cold Chain.....	36
Management of Priority Vaccine Unstable at Zero Degrees or Higher	36
Vaccine A:.....	36
Vaccine B:.....	36
Models for Distribution of Ultra-Cold Vaccine (Vaccine A)	36
Three Phase Distribution	37
Scenarios for Vaccine Distribution.....	40
Scenario 1 Background.....	40
Vaccine A: Ultra-cold with minimum quantity of 1,000 doses only.....	40
Phase 2: General Public Added to Phase 1 Target Populations.....	43
Scenario 2.....	46
Vaccine B: Frozen vaccine only with minimum quantity of 100 doses.....	46

Scenario 3	48
Assumptions:	48
Distribution:.....	48
Scenario 4	49
Scenario 5	49
State Vaccine Storage.....	49
Local Vaccine Storage	51
State Warehouse Vaccine Processing	52
Vaccine Administration Fees	54
Vaccine Program Communication	55
Public.....	55
Healthcare Providers	57
Vaccine Hesitancy.....	58
Vaccine Administration Documentation and Reporting.....	58
Vaccine Transfers and Redistribution	60
Wasted and Recalled Vaccine.....	61
Vaccination Program Monitoring.....	62
IIS Data	62
CDC Data Use Agreement	62
SAS code for CDC data submission.....	62
Datamart	63
Public Data Dashboard	63
Non-Public Metrics.....	63
Gaps.....	63
Provider Enrollment Monitoring	64
Other Monitoring	64
Vaccination Second-Dose Reminders.....	65
Training	67

COVID-19 Vaccine Safety Monitoring	70
Security	71
Mass Vaccination Clinics Local Plans	71
Medical Waste	72
Infection Control and Social Distancing	73
Clinic Format Selection	74
Safety	74
Dry Ice	74
Local Safety Issues	75
Electronic Consent System	76
Vaccination Mandates	76
Regulatory Considerations for COVID-19 Vaccination	77
Appendix A: Known Ultra-Low Cold Chain Capacity in North Dakota	78
Appendix B: Organizational Structure	79
Unified Command Organizational Charts	79
Internal COVID-19 Vaccination Planning Committee Members:	80
Internal/External COVID-19 Vaccination Planning Committee	83
Advisory Committee on COVID-19 Vaccination Ethics	87
Appendix C: Anticipated COVID-19 Vaccine Availability in ND based on CDC Assumptions	89
Appendix D: North Dakota Tribal Allocation Preference and Estimates	90
Appendix E: NDIIS COVID-19 Vaccine Response Plan	91
Appendix F: Proposed Metrics for COVID Vaccine Power BI Dashboards	92
Public Dashboard Metrics	92
Non-Public Metrics	93
Appendix G: Alternative Models for Mass Vaccination	95

Acronyms

AAR – after action report

ACIP – Advisory Committee on Immunization Practices

BCBSND – Blue Cross Blue Shield of North Dakota (NDIIS vendor)

CDC – Centers for Disease Control and Prevention

CISA – Cybersecurity and Infrastructure Security Agency

COP – Common Operating Picture

DHS – Department of Human Services

DNA – deoxyribonucleic acid

DOC – Department Operations Center

DUA – Data Use Agreement

EHR/EMR - electronic health/medical record

EMS – Emergency Medical Services

EUA – Emergency Use Authorization (by the FDA)

FDA – Food and Drug Administration

GIS – Geographic Information System

HCF – health care facility

HCW – health care worker

HHS – U.S. Department of Health and Human Services

HIPAA – Health Insurance Portability and Accountability Act

HRSA – Health Resources and Services Administration

IHS – Indian Health Services

LPH – local public health

LTC – long term care

mRNA – messenger ribonucleic acid
ND – North Dakota
NDDoH – North Dakota Department of Health
NDIIS – North Dakota Immunization Information System
NFI – New Americans/Foreign Born/Immigrant Populations
NVAC – National Vaccine Advisory Committee
POD – points of dispensing
PPE – personal protective equipment
PrepMod – mass vaccination software
SIRVA – Shoulder injury related to vaccine administration
SNS – Strategic National Stockpile
VA – Veterans Affairs
VAERS – Vaccine Adverse Event Reporting System
VAMS – Vaccine Administration Management System
VAR – vaccine administration record
VFC – Vaccine for Children Program
VIS – Vaccine Information Statement
VTrckS – Vaccine Tracking System

Introduction

A safe and effective COVID-19 vaccine(s) will be critical to preventing and reducing morbidity, severity, and mortality associated with COVID-19 in North Dakota. When a large proportion of the population has immunity to a virus (community immunity), a virus is less likely to spread. The safest way to achieve community immunity is through vaccination.

There are many COVID-19 vaccines being developed and it is currently unknown when a COVID-19 vaccine will be available and what the safety and efficacy of COVID-19 vaccine(s) will be.

Benefits of a safe and highly effective COVID-19 vaccine that is accepted by a majority of the population above and beyond reductions in morbidity and mortality could include:

- Less visitor restrictions at long term care (LTC) facilities;
- Students attending school in-person with less interruptions;
- Reduced use of personal protective equipment (PPE);
- Reduced need for testing;
- Reduced need for masking;
- Reduced need for contact tracing;
- Increased social interactions, including large gatherings;
- Economic resiliency and improvement.

Ultimately, COVID-19 vaccination will hopefully lead to a better, safer, and healthier future for all North Dakotans.

At the time of this writing, many issues related to COVID-19 vaccination remain undefined and will not be defined until closer to the time that vaccination is scheduled. Although this plan will require updates as new information is available, creation and partial implementation of this plan are needed now for resource acquisition, resource allocation and population testing of vaccination methods across the entire jurisdiction.

North Dakota gained extensive experience with mass vaccination during the response to the H1N1 influenza pandemic in 2009. Knowledge of many of the approaches used and lessons learned have been retained by personnel present during the H1N1 influenza response, after action documents and plan revision after the event. That knowledge has been applied to this plan.

Lessons Learned from H1N1

- Vaccine storage was capacious and reliable.

The warehouse could have handled far more vaccine than it did during the H1N1 influenza vaccination campaign. Additional cold storage for cold packs was needed and acquired.

- Inventory tracking was efficient.

Software for inventory tracking worked well but has been further upgraded since H1N1.

- Communications with partners was consistently excellent and necessary.

Regular video conferencing for both updates and training was the primary tool used, supplemented by written material (e.g., health alerts, emails) or phone calls when needed.

- The NDDoH warehouse was able to manage temperature control and redistribute very well.

Recurrent testing and retesting led to improvements in temperature monitoring using both data loggers and a change in real-time monitoring while vaccine was in cooler.

- Need to use temperature-controlled transport for redistribution

Attempts to maintain temperature control using commercial shippers failed except when using certified shippers. These worked if pre-cooled before use. However, they were expensive to ship and had a small payload. Use was limited to reaching distant corners of the state with vaccine. The better method for most of the state was using temperature- controlled vehicles with vaccine refrigerators.

- Carrying vaccine into destinations in appropriate transport container.

Movement of vaccine into the destination needed to use an appropriate cooler even if it went directly into onsite storage. This was a visual issue more than a functional issue.

- Recurring vaccine management training in warehouse plus just-in-time training.

Warehouse staff needed to routinely ship vaccine and be trained in shipping vaccine. In addition, for any unique vaccine situations, they needed just-in-time training.

- No regional management of distributed vaccine

An attempt to allow regional public health in two regions to redistribute vaccine locally worked in one region and not the other. Vaccine was adequately protected, but it created friction with vaccine recipients in the region. This will be disallowed in the future.

- Identification of best method for routing

Extensive trials of Toursolver in 2013 were failures. The models were too inflexible because horseshoe shaped distribution routes are inefficient for rural areas. Information of tests was sent to developers, but the warehouse found that distant regional circuits (lollypop) worked well and could be planned on a map quickly and efficiently without software. This was a function of the relatively small number of destinations possible per route due to distances traveled.

- Improvements in software for vaccination management

Some functions were still carried out by paper during H1N1. Scanning of vaccine administration records into the North Dakota Immunization Information System (NDIIS) created significant data quality issues. In addition, NDIIS had substantial management gaps for pandemic situations. Since 2009, the vast majority of providers now report electronically to the NDIIS, so scanning won't be needed. Pandemic functionality and reports have since been added to NDIIS.

- Changes to hotline to include triage and transfer.

Many of the calls to the hotline could not be dealt with by the hotline and needed to be immediately transferred to other responders or referred to medical providers. The hotline for COVID-19 has worked well and been consistently effective since changes were implemented.

Response Goals for Pandemic Vaccination

- To maximize uptake of vaccine by the population; the unified command goal is for 70% of the eligible population to be vaccinated;
- To ensure that those persons determined to be at highest priority for vaccination are vaccinated first;
- To ensure that all persons receive a vaccine that is approved (licensure or Emergency Use Authorization (EUA) by the Food and Drug Administration (FDA) for their cohort (e.g., age);
- To ensure people receive second doses of vaccine, when indicated;
- To minimize the amount of time from receipt of vaccine in the state to administration while maximizing efficiency;
- To maintain the cold chain and security of the vaccine;
- To have vaccine allocation which is ethical and transparent;
- To be able to track where all COVID-19 vaccine is at all times;

- To ensure that potential adverse events associated with vaccine administration that are of moderate or greater severity are captured and investigated as indicated;
- To minimize risk of disease transmission associated with mass vaccination procedures.

COVID-19 Mass Vaccination Planning Assumptions

(See the [CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#))

- Vaccine for pandemic will eventually be administered to the entire population that is willing to be vaccinated.
- Earliest vaccine delivery date is likely to be fall or winter of 2020.
- Initially, sufficient quantities of vaccine will not be available to vaccinate all interested persons. Vaccine will arrive in batches as it becomes available. Size of batches will depend on the specific vaccine since production is being combined with phase III clinical trials for some vaccines.
- Resources for storing large quantities of vaccine do not exist locally; however, the state warehouse has capacity to store large quantities of either refrigerated or vaccine frozen to zero degrees. The state warehouse has little capacity to store vaccine at either minus 20 degrees C or minus 70 degrees C except in its original containers; however, more capacity is being acquired. Private entities may have limited capacity for storing vaccine. This will be assessed at the time of enrollment. See [Appendix A](#).
- Many of the parameters for vaccination will be pre-determined by the federal government and communicated to the state. Allocation to the state will occur through the Centers for Disease Control and Prevention (CDC).
- The groups to which the vaccine will be prioritized will be designated by the federal government; selection will be based on risk information available at the time the vaccine becomes available. Since sufficient vaccine will not be available to vaccinate all persons in priority groups, subgroup prioritization will be required and left to the state to determine. (See below: [Vaccine Prioritization and Critical Populations](#))
- COVID-19 vaccine will most likely not be available (at least at first) for children or pregnant women.
- Receipt of vaccine into the state will be generally in proportion to the state population (about 0.2% of the US population) but may not consider persons crossing over into North Dakota from other states.

- COVID-19 is contagious prior to symptom onset. This will make exclusion of all contagious individuals from vaccination clinics impossible; consequently, vaccination methods will have to minimize transmission risk. A plan for alternate vaccination strategies has been produced that is a supplement to points of dispensing (POD)-based vaccination plans.
- Vaccine may arrive during cold weather. This will complicate shipment and make some mass vaccination methods difficult or impossible.
- More than one dose will be required for most vaccines because the first dose will not provide full immunity; however, the extent to which any immunity will be provided by the first dose cannot be known at this time. The vaccine will not protect a person exposed at the time of vaccination.
- More than one round of vaccination may be required. At the time of this writing dozens of vaccines are in development. The first available vaccine may not be as effective or provide protection from infection that is as durable as vaccines that are available subsequently.
- The degree to which the security of the vaccine will pose a problem will depend on circumstances at the time vaccine is being administered. If North Dakota is dealing with a large wave associated with great loss of life, the vaccine may be at some security risk. Likewise, public opposition to vaccine could pose a risk.
- Routine immunization for other diseases will need to continue at the same time. Gaps in vaccination have expanded among some populations (e.g., children) which must be made up. In addition, influenza vaccination will be added to necessary vaccinations this fall.
- Response to COVID-19 will have to continue at the same time. This includes testing and contact tracing. Some pullback by local public health (LPH) personnel from activities related to COVID-19 control may be necessary to free up time for mass vaccination; however, the National Guard will continue to be active in testing and Emergency Medical Services (EMS) has been recruited to assist with testing.

Logistical Assumptions

- Multiple vaccines will be in use. Current planning assumptions provide information for two vaccines. Vaccines labeled A (Ultra-Cold) and B (Frozen) are the initial vaccines expected. See [CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#).
- Priority groups for vaccination have not been determined; however, at the current time they will mostly likely include:

- LTC staff and residents
 - Others living in congregate settings
 - [People with underlying health conditions who are at higher risk for COVID-19 complications](#)
 - Health care workers
 - [Essential workers and critical infrastructure](#)
 - Older persons
 - National security infrastructure
 - Communities of color
- Many of the proposed groups are large with many sub-sections. For example, essential worker sub-sections have been previously identified to include communications, commercial, manufacturing, chemical, security, water, food/agriculture, government, nuclear, financial, technology and research, transportation and healthcare/public health.
 - Limited cold chain stability of vaccine and large minimum shipments (1,000 doses) may complicate with reaching some high priority vaccinees (e.g., rural healthcare workers), particular with Vaccine A (Ultra-Cold).
 - Ancillary supplies will be shipped with vaccine including some personal protective equipment (PPE). Additional supplies for mixing vaccine with adjuvant will be included if indicated.
 - Sites (e.g., federal facilities and some pharmacies) may receive vaccine directly from the manufacturer or McKesson (CDC contractor).
 - Communications materials will be forthcoming from CDC, but specifics are not available.
 - Federally produced information for training and education related to vaccine will be forthcoming, but specifics are not available.

Organizational Structure and Partner Involvement

COVID-19 vaccination planning falls under the planning section of the Unified Command. After approved, most aspects of this plan fall under the Operations Section, within the Disease Control Branch in the Mass Immunization Group. [Molly Howell](#), immunization director for the North Dakota Department of Health (NDDoH), is the lead for the Mass Immunization Group. The state warehouse falls under Logistics. The Joint Information System will be responsible for all communications. See [Appendix B](#) for the ND Unified Command Organizational Chart.

Unified Command Planning Team

A unified command system planning meeting occurs weekly on Thursday afternoons. All members of unified command are encouraged to attend and provide input into planning for the COVID-19 response, including vaccination. This team was routinely updated on the COVID-19 vaccination plan and assisted in the overall planning process, including the estimating of vaccine priority groups and tabletop exercises.

Internal COVID-19 Vaccination Planning Team

Throughout the COVID-19 response (since May 2020), an internal planning team has been meeting to plan for COVID-19 vaccination. Members include unified command planning leads and NDDoH Division of Immunization staff. This team used the North Dakota pandemic influenza vaccination plan as a template and updated it when information became available for COVID-19 vaccine. See [Appendix B](#) for expertise of the internal planning team.

Internal/External COVID-19 Vaccination Planning Committee

A planning committee (See [Appendix B](#)) for COVID-19 vaccine has been established and includes key external stakeholders, including LTC, corrections, private health care providers, LPH, emergency managers, pharmacy stakeholders, Tribes/Indian Health Services, university system, communications, information technology, various state agencies, etc. The committee meets Wednesday mornings. This committee was used to inform planning and implementation of COVID-19 vaccine. As needed, the NDDoH met with a smaller subset of stakeholders to discuss specific planning issues in greater depth. In the future, this committee will be used to modify plans as additional information becomes available regarding COVID-19 vaccine and distribution.

CDC/HHS Microplanning

North Dakota was one of five sites selected for enhanced microplanning for COVID-19 vaccination with CDC and other federal partners. Internal and external stakeholders participated in a two-day meeting August 11 and 12, 2020. Various COVID-19 vaccination planning topics were reviewed and discussed including, prioritization, allocation, storage and handling, distribution, role of pharmacies, communications, technology, and Tribal vaccination. Lessons learned and strengths from the H1N1 influenza pandemic were discussed. This meeting was mutually beneficial; information and feedback obtained from this meeting has been used to write North Dakota COVID-19 Vaccination Plan and CDC's COVID-19 Vaccination Program Playbook.

Tabletop Exercises

A series of tabletop exercises were completed October 5, 2020 in preparation of finalizing the immunization plan. Target audience included COVID-19 Vaccination Planning Committee members (see [Appendix B](#)), Unified Command, hospitals, LTC facilities, pharmacies and other stakeholders. Areas covered during the tabletop exercises included storage of vaccine, security, patient prioritization, provider enrollment, vaccine acceptance, etc. An after action report (AAR) was completed after the tabletop exercises. This document identified strengths and weaknesses in the current plan. Changes were made to the plan accordingly. Some gaps are still being addressed and [listed](#) in this plan. The following dates and the target audiences for tabletop exercises are listed below.

- COVID-19 Vaccination Planning Committee: September 30, 2020
- LPH statewide response team: September 30, 2020
- Unified Command: October 1, 2020
- Medical providers (LTCs, hospitals): October 5, 2020

Additional tabletop exercises will be conducted as needed when new information regarding COVID-19 vaccine and distribution become available.

Current Unknowns and Contingency Planning

At the time of this writing, certain things cannot be known. These include:

How persons who have tested positive for COVID-19 will be prioritized.

The extent to which COVID-19 infection imparts immunity and the duration of that immunity are not known. In the unlikely event that COVID-19 imparts life-long immunity (such as occurs for measles), these persons will not require vaccination. More likely, these persons will have some immunity which should be boosted by vaccination, but which will make vaccination less urgent.

Type of vaccine that will be available and cold chain requirements of vaccines.

Different vaccines will have different cold chain requirements and cold chain capacity must be sufficient to manage the vaccine delivered regardless of required storage.

- Some vaccines are formulated as a liquid that requires storage around 4° C.
- Some vaccines are formulated as a freeze-dried preparation requiring reconstitution. These may be maintained around 4° C or may be frozen. These vaccines arrive with

diluent in glass vials with rubber stoppers that require no refrigeration, but the vials must not be frozen.

- Some vaccines must be kept frozen. New messenger ribonucleic acid (mRNA) vaccines in development will likely need to be frozen. They tend to be unstable and may require freezing at temperatures not widely available in most local health agencies or hospitals. RNA vaccines have not been used in large scale vaccination
- New deoxyribonucleic acid (DNA) vaccines in development may be room temperature stable. DNA vaccines have not been used in the past for large scale vaccination.

Potential adverse effects of a vaccine.

All vaccines are associated with some risk of adverse events. At the time of planning for COVID-19 vaccine, the safety profile is unknown. Even after EUA or FDA approval, monitoring of adverse events will need to continue. A vaccine that causes more adverse effects than expected could seriously impair uptake by the population, even if safe for the vast majority of people.

Vaccine amounts.

H1N1 influenza vaccine arrived during the winter and quantities arrived in very small quantities for many weeks. A similar situation may occur for COVID-19. On the other hand, concurrent testing and production may create quantities of vaccine sufficient for the entire population which the state could store but only at zero degrees or above given currently available cold storage management capabilities at the state warehouse. For estimates of vaccine quantities and timeframes see [Appendix C](#).

Vaccine Timing.

If the vaccine arrives in the winter, it will have to be stored with influenza vaccine in available cold storage space at the state and local level. Furthermore, if the vaccine arrives during a pandemic surge, private providers, who traditionally provide a large percentage of the vaccination services in North Dakota may not have time to vaccinate. What vaccine is not administered by the private health care sector will need to be administered by public health, pharmacies or some non-traditional vaccine providers (e.g., contract vaccinators, employee-based clinics).

Use of adjuvant.

An adjuvant (an ingredient used in some vaccines that helps create a stronger immune response in people receiving the vaccine) is expected with some vaccines. Several different adjuvants are present in current vaccines, especially in some newly formulated vaccines. It is now expected that an adjuvant will have to be mixed with the COVID-19 vaccine at the time of the vaccine administration for some vaccines. (That would prevent use of pre-filled syringes containing vaccine and slow vaccine administration.)

Multiple FDA approved products with different specifications.

During H1N1 mass vaccination, many companies provided FDA approved products. Some of these products were approved for young children, some for pregnant women and some for older adults. Substantial overlap occurred and different vaccines were delivered to North Dakota in different weeks. This may occur with COVID-19 vaccine. This could be further complicated if different adjuvants are used in different preparations. Delivery of second and subsequent doses should be with the same vaccine/adjuvant used for the first dose. These multiple vaccine products complicate allocation and vaccine use by providers.

Packaging.

During H1N1, vaccine came in a variety of package formats including multi-dose vials, single dose pre-filled syringes and single dose nasal vaccine. The pharmaceutical industry has increasingly moved toward single dose formats. The primary impact of the dosage form on vaccine management is the amount of cold chain space required to store and transport the vaccine, since single dose packaging is much bulkier. A marked increase in the amount of vaccine received in single dose containers could pose a storage problem at some local sites. It is however anticipated that the first vaccines will be in multidose vials that require use the same day that they are punctured, which may increase wastage for the vaccine if left unused.

Vaccine will be shipped in minimum quantities of 100 doses for some vaccines and 1,000 doses for Vaccine A. Due to frozen and ultra-low cold chain requirements, it may be logistically difficult to breakdown these packages further for redistribution, however, early on in the campaign, this may be necessary. When possible, vaccine should be direct shipped from the manufacturer or distributor directly to the provider.

Current Significant Gaps

The following are gaps that have been identified in the planning process and through tabletop exercises that have yet to be resolved.

- The state warehouse is in the process of procuring ultra-low cold chain capacity and transport freezers and thermometers. Additionally, the warehouse is procuring dry ice production capability. The items procured will have to be tested before being used. The CDC has advised against states purchasing ultra-low cold chain capacity. However, the state is currently procuring these items. As a rural state, it may be necessary to repackage vaccine into smaller quantities and redistribute to rural areas.
- The CDC released the data elements that will be required to be reported within 24 hours of vaccine administration. Some of the data elements are identifiable, so additional data use agreements and non-disclosure agreements will be needed (identifiable data elements will not be sent to CDC but will be de-identified prior to reaching CDC). Additionally, it is still unproven how federal systems, other state IIS will connect to the ND IIS. Many of these connections have yet to be tested. It is also likely that CDC will post de-identified data to their website regarding vaccine coverage rates. It is possible that CDC and state data/dashboards will not match due to different data sources and timing. Priority group is not one of the required fields for data reporting, so it will be difficult to determine which priority group each individual who is vaccinated is included in, making it difficult to report coverage rates by priority group.
- Limited resources and funding are available for COVID-19 vaccination. The state is receiving less than \$400,000 for COVID-19 vaccination planning and operations. This funding is not adequate to sustain a vaccination campaign of this magnitude. Additional funding will be needed to cover staffing, redistribution, LPH travel expenses and mass vaccination clinics, driving vaccine to various locations throughout the state, information technology project management, media campaigns, etc. Additionally, resources for vaccination response at the state and local level are competing with other COVID-19 response activities (contact tracing, testing).
- Procurement, customization and implementation of PrepMod (mass vaccination software) has been delayed. North Dakota's instance of PrepMod will be delivered mid-October. This software is critical to obtaining online consent and managing mass vaccination clinics. PrepMod will need to be tested using influenza vaccination prior to being utilized for COVID-19 vaccine.
- Uptake of COVID-19 vaccine in North Dakota is unknown and difficult to estimate. [National estimates](#) report only about half of Americans being willing to accept COVID-19 vaccine. The allocation process for vaccine needs to balance vaccine availability and uptake. The process also needs to balance expediting vaccination

with risks of wastage if uptake is low. Pre-consent or pre-registration for vaccination will also assist.

Provider Recruitment and Enrollment

The first step in the vaccination process will be provider recruitment. Recruitment will be advertised through various provider associations (North Dakota Medical, Pharmacy, LTC, and Hospital Associations), immunization list serv, and the NDDoH website. While CDC provided most of the language for provider enrollment documents, some additions are expected at the state level (see below). Enrollment with the state will be required to receive COVID-19 vaccine; even providers already enrolled as a Vaccines for Children (VFC) Program provider will have to enroll specifically to receive COVID-19 vaccine. Enrollment will be conducted electronically using Qualtrics. Qualtrics is an online survey tool that is used annually for VFC enrollment. An enrollment cutoff date will be given, but as a practical matter, late enrollment will likely be allowed. Since vaccination will almost certainly be strongly targeted to older adult populations rather than children and pregnant women, problems recruiting specialized providers are not anticipated early in the process; however, eventually, the state may need to vaccinate pregnant women and children.

Facilities are required to provide license numbers for all prescribers who may order or administer COVID-19 vaccine. As is done annually and quarterly for new providers in the VFC program, all licenses included in the provider enrollment will be verified to ensure they have valid in-state (or valid out of state for federal facilities) licenses that are in good standing and are not included on the federal exclusion list. This is done through purchasing licensing information from licensing boards in North Dakota and comparing this information to the most recent version of the federal exclusion database (https://oig.hhs.gov/exclusions/exclusions_list.asp). For any names on the provider enrollment that do not fall into one of the licensing data sets or match on the federal exclusion listing, follow up with the facility with occur. This may affect a facility's ability to receive COVID-19 vaccine.

The state will provide education to providers, including pharmacies, clinics, LTC facilities, hospitals and LPH, using webcasts and training videos (see [Training](#) section).

Information will be sent through multiple communication channels (e.g., email, health alert network contacts, professional associations) about the enrollment process. Since enrollment will be the only means for providers to acquire the vaccine, it is thought that

nearly all eligible vaccine providers will choose to enroll, as they did for H1N1. Enrollment will occur exclusively via website.

This means for large health systems, which make up the bulk of health care providers in North Dakota, multiple enrollments would be necessary, one for each delivery point. Specific information required for shipping will be collected at the time of enrollment and populated into a lookup table in the CDC vaccine ordering software. The enrollment site will also provide a contact who will receive emails when COVID-19 vaccine has been ordered for their facility and will be the point of contact for delivery of COVID-19 vaccine.

In the future a separate redistribution agreement may be offered to LPH, pharmacies and large health systems. In order to make the determination of who would be eligible to be a COVID-19 vaccine redistribution site, the facilities will need to complete enrollment and provide information on populations they plan to vaccinate along with storage and handling capabilities. A COVID-19 redistribution agreement was provided by the CDC with the provider enrollment documents but there is still more clarification from the CDC on what is needed for the COVID-19 vaccine redistribution agreements. Redistribution agreements will not be approved in very early stages of Phase 1 when vaccine is extremely limited. However once vaccine is more readily available, the NDDoH will work with LPHU, pharmacies and large health systems to elicit their interest and ability to redistribute to their secondary sites. At this time the CDC's redistribution agreement will need to be signed by those facilities and additional education on reporting of doses and inventory will need to occur.

Upon receipt of an enrollment request, the NDDoH Division of Immunization (Mass Immunization Group) will look up the provider site in NDIIS to ensure that that site is using NDIIS. If not, the provider will be contacted and required to enroll in NDIIS before they can become a vaccine recipient site. At this time, nearly all private providers are enrolled and use NDIIS through one mechanism or another. All COVID-19 vaccine doses will be required to be in NDIIS, whether through direct data entry, an electronic connection to their facility's Electronic Medical Record (EMR) or by using PrepMod that will be connected directly to the NDIIS.

Providers will be asked to estimate the number of people in certain risk groups that they intend on vaccinating. Some risk group data is available using statewide data; however, some risk groups are not available so it will be gathered at the provider level during enrollment. This information will be used to help determine allocation. Provider

estimates along with estimates of priority groups by county will be used to determine which providers are allocated vaccine by priority group. This is discussed below under [vaccine allocation](#).

Provider enrollment will be mapped to ensure access to COVID-19 vaccine by priority group and geography. For the VFC Program, a radius of 30 miles is utilized.

Additional requirements set by CDC for vaccine eligibility included agreement to meet vaccine storage specifications, a limited vaccine administration fee, and agreement to abide by the prioritization of vaccine to the high-risk groups as specified by CDC.

Correct storage and handling of COVID-19 vaccine is of the utmost importance and not all facilities that will enroll to receive COVID-19 vaccine will be VFC enrolled providers. The CDC language in the provider agreement requires health care providers to store COVID-19 vaccine according to the vaccine package insert and the [CDC's Vaccine Storage and Handling Toolkit](#). Providers are also required to monitor storage unit temperatures at all times using equipment and practices that comply with guidance located in the CDC's Vaccine Storage and Handling Toolkit and follow protocols set by their jurisdiction's immunization program on how to handle temperature excursions. The division of Immunizations provided education on how the importance of correct storage and handling during the first required COVID-19 vaccine provider enrollment webinar. Enrolled facilities are asked to send in data logger temperature logs on a monthly basis. Division of immunization staff will do their best to follow up with facilities who will receive COVID-19 vaccine allocations but have not yet sent in temperature logs. If facilities do not send in temperature logs this may affect their ability to receive COVID-19 vaccine. Monthly submission of data logger temperature charts is required for participation for all VFC enrolled facilities. This will be a new requirement for non-VFC enrolled facilities.

In addition to requirements of provider enrollment identified by CDC, the following requirements will be added by the state:

- Providers must submit data to NDIIS within 24 hours.
- Providers must, at least weekly, update an online site (i.e., [vaccinefinder.org](#)) that lists the availability of vaccine in their clinic, identifies when clinics will be held to administer the vaccine, and identifies population groups eligible to receive the vaccine.

Enrollment information will be sent to the CDC twice weekly, Mondays and Thursdays. At the same time this information is sent to the CDC it will be disseminated to LPH through email. This will allow for LPH to know which facilities are requesting direct allocations for COVID-19 vaccine in their jurisdictions and will also allow for planning with facilities (LTC, group homes, jails, etc.) who may need assistance vaccinating their populations. The Division of Immunizations will match up all congregate living facilities with vaccinators (LPH, pharmacy, private provider) in their area.

Failure by providers to comply with enrollment requirements may impact fulfillment of COVID-19 vaccine orders.

Potential Providers

In North Dakota various types of providers are eligible to vaccinate. Registered nurses and LPNs may vaccinate. [Health and Human Services \(HHS\)](#) recently authorized pharmacists to vaccinate against COVID-19 for individuals 3 and older. Pharmacy techs are unable to vaccinate in North Dakota but are eligible for vaccination in other states. Dentists are unable to vaccinate in North Dakota but are eligible to vaccinate in other states. EMS providers can provide influenza vaccine starting at age 18; a state health officer order would be needed to include COVID-19 vaccine or change the age of vaccination. Upon enrollment, providers will be asked which priority groups they would vaccinate. Potential providers to recruit for vaccination and the populations they may vaccinate include:

- Hospitals: staff, patients
- Clinics, including rural health clinic and federally qualified health centers: staff, patients, essential workers
- LPH departments: all priority groups
- Pharmacies: staff, patients, workplaces, LTCs
- LTCs: staff and residents
- Correctional facilities: staff and residents
- Group Homes: staff and residents
- University health centers: staff and students
- Occupational health: essential workers, other workers
- Emergency Medical Services: staff and other priority groups (as needed)
- Mass vaccinators: all priority groups
- Dialysis Centers: staff and patients
- Indian Health Services (IHS) and/or tribal health: all priority groups

North Dakota has two U.S. Air Force Bases. The Department of Defense will receive vaccine directly from the federal government for personnel and dependents. Veterans Administration will receive vaccine from the federal government for staff and patients.

Vaccine Administration Capacity

According to the NDHHS, for the 2019-2020 influenza season, 293,500 doses of influenza vaccine were administered in North Dakota and reported. This is most likely an under-representation of actual doses administered due to limited doses being entered by LTCs, Veterans Affairs (VA), etc. The vast majority of doses for adults are administered by the private sector (40.5%), followed by pharmacies (20.7%), LPH (15%), and then various other provider types. The influenza vaccination coverage rate for the 2019-2020 season was 56.5% for people 6 months and older (National Immunization Survey and Behavioral Risk Factor Surveillance System).

To accurately estimate possible throughput of the COVID-19 vaccine, data was pulled from the NDHHS to analyze influenza vaccine administration for the 2019-2020 flu season. Following analysis, it was found that the largest weekly number of influenza vaccine doses administered was 42,255 during the week of October 13 - October 19, 2019. Further data was pulled in order to determine administration location by county and vaccine provider. These figures will be instrumental in determining vaccine allocation as well as anticipating doses needed.

It is assumed that initial COVID-19 vaccine will be approved for administration to adults age 18 and older, thus these calculations will not include North Dakotans under age 18. Using population estimates from the 2019 U.S. Census, the following table was calculated to anticipate time needed to administer first dosages and completion of the vaccine series, anticipating a 4-week interval between doses. This table assumes availability of vaccine for all adults wishing to be vaccinated, as well as those receiving the first dose of vaccine will comply with receiving a second dose. This table also doesn't take into consideration ramping up of vaccination by adding additional providers or prioritizing vaccination over other activities/services.

Vaccine Coverage Rate	Number of ND Adults Vaccinated	Number of Weeks Needed for One Dose	Number of Weeks Needed for Two Doses
100	580,640	14	18
90	522,576	12	16
80	464,512	11	15

70	406,448	10	14
60	348,384	8	12
50	290,320	7	11
40	232,256	5	9
30	174,192	4	8
20	116,128	3	7
10	58,064	1	5
0	0	0	0

The table above is also available by county.

Throughput by provider will be dependent on the type of clinic (i.e., mass, drive-thru), staffing and demand for vaccination. An average of 10 minutes per dose administered can be used for local planning purposes.

Vaccination of Out-of-State Residents

Because health care is provided for many out-of-state residents within North Dakota cities, no distinction will be made between out-of-state and North Dakota residents for COVID-19 vaccination. It is not expected that CDC will make any adjustment to allocation based on cross border vaccination. No agreement will be sought with border states for reimbursement of vaccine. During the enrollment process, providers will be asked to estimate the number of out-of-state residents that they serve in an effort to inform allocation. COVID-19 vaccine will not be distributed to sites outside of North Dakota.

Vaccine Prioritization and Critical Populations

Additional detail is expected from CDC regarding priority groups to be vaccinated. The [National Academy of Medicine, Engineering and Sciences](#) has finalized a Framework for Equitable Allocation of COVID-19 Vaccine to use as a guide for determining priorities. Nonetheless, North Dakota will have to make decisions regarding how specific doses are allocated. That is, for any shipment, the number of doses to be allocated to any particular institution of population group will have to be determined. For instance, because of their greater burden of COVID-19 care, referral hospitals may be allocated a larger share of hospital-designated vaccine than rural hospitals. These decisions will be referred to an [Advisory Committee on COVID-19 Vaccination Ethics](#) established

specifically for COVID-19 vaccination. The group will be advisory and work by consensus (obtaining unanimity when possible).

Critical infrastructure workforce

- Healthcare personnel (i.e., paid and unpaid personnel working in healthcare settings, which may include vaccinators, pharmacy staff, ancillary staff, school nurses, and EMS personnel)
- Other essential workers (see additional guidance from the [Cybersecurity and Infrastructure Security Agency \[CISA\]](#))

People at increased risk for severe COVID-19 illness

- Long Term Care (LTC) residents (i.e., nursing home, assisted living, independent living facility residents)
- People with [underlying medical conditions](#) that are risk factors for severe COVID-19 illness
- People 65 years of age and older

People at increased risk of acquiring or transmitting COVID-19

- People from racial and ethnic minority groups
- People from tribal communities
- People who are incarcerated/detained in correctional facilities
- People experiencing homelessness/living in shelters
- People attending colleges/universities
- People who work in educational settings (e.g., early learning centers, schools, and colleges/universities)
- People living and working in other congregate settings

People with limited access to routine vaccination services

- People living in rural communities
- People with disabilities
- People who are under- or uninsured

Estimates of Priority Groups

Estimates of priority groups by state, county, city and facility (i.e., congregate settings, hospital staff) have been calculated and will be used in conjunction with provider enrollment to determine allocations once vaccine is available. Estimates of priority

groups by health care provider (including staff by facility) will be obtained through the COVID-19 enrollment process.

Below are statewide estimates for priority groups that may be the first priority for vaccination. There is likely overlap amongst the priority groups (i.e., healthcare workers who also have an underlying health condition, people 65 and older who also reside in a LTC facility). People may be vaccinated according to the first priority group that they fall under.

PRIORITY GROUP	TOTALS
HEALTHCARE_WORKERS:	
HEALTHCARE_PERSONNEL	62576
EMERGENCY MEDICAL SERVICES	5915
LOCAL PUBLIC HEALTH	373
TOTAL_HEALTHCARE	68864
INCREASED RISK:	
LICENSED_LTC	11248
INTERMEDIATE CARE FACILITIES	108
AGE_65+	116237
OBESITY	202361
COPD	34564
HEART_DISEASE	38814
DIABETES	55679
CHRONIC KIDNEY DISEASE	15761
SELF_IDENTIFIED_DISABILITY	77207
TOTAL_INCREASED_RISK	551979
ESSENTIAL_WORKERS:	
UTILITY	2580
EDUCATION	22311
FIRE	4603
LAW_ENFORCEMENT	1409
ENERGY	3047
TOTAL_ESSENTIAL_WORKERS	33950

In order to obtain estimates of priority groups for COVID-19 vaccine, a variety of data sources have been consulted including U.S. Census data and state, regional and local

entities. By utilizing the NDDoH and ND Department of Human (DHS) services data, licensed bed counts were obtained for congregate living facilities such as skilled nursing homes, assisted living, senior living, and group home settings. A challenge presents in identifying the number of direct healthcare workers employed by each facility, however. While staffing ratios are in place due to patient acuity in healthcare settings, this does not capture the number of staff employed at a facility. Congregate setting staff estimates will be collected upon enrollment to receive COVID-19 vaccine and/or through a survey of these facilities. Staff working at healthcare facilities will also be collected upon enrollment.

The ND Department of Corrections was able to provide data for the state correctional system for the number of staff and inmates. The ND University System provided estimates for the number of students living in dorms or Greek housing (congregate settings), as well as faculty and staff numbers.

Identifying the location and number of [critical infrastructure/essential personnel](#) in non-healthcare settings has presented an additional challenge in vaccine-planning. While some labor data (ND Job Service) is available, due to the small populations in certain North Dakota counties, this information has been unable to be released to the NDDoH. Additionally, some occupational organizations have not been agreeable to providing data regarding employee numbers. Local emergency managers have assisted in calling various facilities to get estimates of the number of employees. The ND Department of Public Instruction and DHS were able to provide estimates for the number of school employees and licensed childcare workers. The NDDoH intends to post an employer interest survey on the COVID-19 vaccine website, where employers can submit their interest to receive information and request COVID-19 vaccination. Information about employers interested in COVID-19 vaccine will be sent to LPH and used for planning.

Data points such as race and ethnicity, health conditions, 65 and older, and rural populations by county have been identified via state level and U.S. Census data. However, a limitation with this data is the self-reported nature of this surveillance as well as the ability to provide a complete data picture in areas of low survey response.

Tribal population estimates have been identified through U.S. Census data, for population of American Indians living within reservation areas. As many American Indians (40%) in North Dakota do not live on reservation lands, additional data has been taken from county level data to obtain information regarding race.

Due to North Dakota's robust testing efforts throughout the COVID-19 pandemic, established points of contact for designated groups such as universities, tribal nations, private healthcare systems, and local public health (LPH) are already in place. These contacts have been instrumental in providing estimated counts and identifying possible barriers to vaccination within their populations. The electronic system used for test registration collects underlying health conditions, race, ethnicity, address, age, and occupation for all individuals tested. The NDDoH is currently exploring the possibility of matching testing data with NDHIS data to identify priority groups and estimate vaccine coverage.

The federal government will provide access to the Tiberius platform, which will assist in estimating priority groups and allocating vaccine. "Tiberius integrates data sources from Federal agencies, State and Local partners, private sector partners, and open data providers to create a comprehensive Common Operating Picture ("COP") for the COVID-19 vaccine planning, distribution, and administration effort."

North Dakota is having internal discussions about using Geographic Information System (GIS) or Microsoft Power BI to map priority groups, provider enrollment, and later vaccine uptake. Dashboards are currently being developed and are discussed in the [IIS Data Section](#).

Vaccination of Special and Dependent Populations

The approach to vaccination of special and dependent populations will vary from one LPH to another but is similar to plans developed for SNS drug distribution.

Homebound

During H1N1, vaccination of homebound persons was expected to occur after mass vaccination clinics largely completed general population vaccination. This reflected the somewhat lower risk of infection of persons who are not mobile, the lower risk to older persons posed by H1N1, and especially the low efficiency of reaching the population compared to mass clinics. Given the high risk of elderly to COVID-19, LPH and other partners who serve homebound individuals will need to raise the priority of these recipients. Although their risk is somewhat reduced by lower public contact, they are not fully isolated from the virus. Vaccination of homebound individuals will combine routine provider office visits, visiting nurse services and home visits by LPH personnel.

No "list" exists in communities of persons who are homebound. Many of these people will have family helping them to keep critical provider appointments which potentially

offers an opportunity for vaccination. Vaccination can be provided to some homebound through LPH and/or home health nursing if those services have been requested, but a substantial portion of this population may not be served by either of these. A large percentage of additional homebound individuals can be identified through churches, particularly in rural areas where the number of churches is small, and through home meal services. Currently, the NDIIS does not have the capability of flagging NDIIS records by risk group (such as homebound) that would allow rapid identification of persons not yet reached by vaccination.

Long Term Cares

LTC includes skilled nursing, basic and assisted living facilities. The federal government is contracting with two large pharmacy chains to vaccinate residents of LTCs. North Dakota does not have many chain pharmacies, so it is likely that many LTCs may need to receive vaccine directly or work with an independent pharmacy or LPH. Some LTC facilities vaccinate their own staff and residents while others have relationships with private providers, local pharmacists or LPH. LTCs have limited storage capacity, especially for frozen vaccine. Consent for vaccination for staff and residents will need to occur prior to vaccination. Vaccine clinics at the facility will then have to be scheduled and vaccine provided based on prior consent. LTC facilities will need to ensure vaccination of new staff and new residents after vaccination has already occurred in a LTC facility and communicate their need for additional vaccine to the state, LPH or their usual pharmacy. The NDDoH Division of Immunizations (Mass Immunization Group) will ensure that each LTC facility in the state is either able to vaccinate themselves (through redistribution/transfer of vaccine) or is paired with LPH, private provider or pharmacy for vaccination.

LTC staff will either be invited to mass vaccination clinics held by LPH or will be given supplies of vaccine (redistribution/transfer) to vaccinate their own staff. Uptake of vaccination amongst staff will be greater if staff are vaccinated on site, opposed to having to travel to a mass vaccination clinic off site.

Policies in LTC related to mandatory vaccination of staff at this time will be dependent on individual facilities. While strongly encouraged, residents could refuse vaccination like any other medication. It is highly unlikely that facilities would eject patients for refusing vaccination for COVID-19; however, it may be possible to get LTC facilities to include it as part of admission criteria. COVID-19 vaccination in LTC settings may reduce

the need for routine testing of staff and residents. It may also lead to lifting of visitor restrictions. These may be incentives for staff and residents to be vaccinated.

Ongoing communication with LTC facilities will occur during bi-weekly LTC webinars that have been ongoing throughout the COVID-19 response.

Custodial institutions and special populations

This includes state and local corrections, group homes, and homeless. Delivery of vaccine to institutions that have custodial responsibility for the health of their population will require a visit by LPH vaccine providers or pharmacists unless the institution has its own medical staff capable of providing vaccination (collected upon enrollment). State corrections has historically done a good job of vaccinating its residents; however, most local corrections do not vaccinate and require outside assistance.

Good progress has been made in homeless outreach in recent years and for COVID-19 testing. LPH traditionally vaccinates for influenza at homeless shelters.

Some group homes have medical staff who are able to provide vaccines on site. Others may require LPH or other vaccinators to vaccinate. Staff and residents in these facilities may have increased interest in COVID-19 vaccination due to the need for increased testing and visitor restrictions in these facilities. Group homes may request vaccination from a chain pharmacy similar to LTCs. Group homes not within the radius of a chain pharmacy may need assistance from LPH or an independent pharmacy.

Early consent or assessment of interest in vaccination will be needed to ensure that the appropriate number of doses are allocated in these settings and vaccine is not wasted. Even once vaccinated, custodial institutions will have population turnover for both staff and residents. These institutions will need to track gaps in vaccination and notify LPH of the need for additional vaccination.

The NDDoH Division of Immunizations (Mass Immunization Group) will ensure that each group home, correctional facility and homeless shelter in the state is either able to vaccinate themselves (through redistribution of vaccine) or is paired with LPH or a pharmacy for vaccination.

American Indians

The North Dakota Indian Affairs Commission is leading the communications with Tribes and Tribal stakeholders. Planning has included members from all Tribes, tribal health, IHS, tribal colleges, urban American Indian Organizations, and other tribal stakeholders.

On September 24, 2020, the Tribes were notified by Health and Human Services that they could express a preference for whether to receive vaccine directly from the federal government or through the state's allocation. [Appendix D](#) outlines each North Dakota Tribe's preference. Regardless of the Tribes' decision, the state will provide assistance to Tribes to ensure COVID-19 vaccination effectively reaches this population.

Tribes receiving vaccine through the state's allocation will receive equitable amounts of vaccine in accordance with other enrolled healthcare providers in the state. The [ND Advisory Committee on COVID-19 Vaccine Ethics](#) may choose to utilize CDC's vulnerability index when allocating vaccine, which may ensure equity in the number of doses Tribal healthcare providers receive.

All reservations have worked on mass dispensing and have successfully participated in mass testing for COVID-19 on reservations. The Tribes have already identified potential locations (gyms, community centers) for vaccination. They also have experience in finding individuals who may need transportation assistance or are home bound. Use of reservation-based clinics is anticipated that will be collaborative efforts by LPH, IHS and Tribes. In addition, persons on reservations may seek vaccination at the nearest public health venue off reservation. For Spirit Lake and Turtle Mountain reservations, and for many people at MHA Nation these services will be close to the reservation. Standing Rock is the most distant from LPH services. Standing Rock also crosses the South Dakota border, so many Tribal members may go across state lines for vaccination.

It is expected that IHS will provide vaccination as part of clinical services; however, not all reservation-based American Indians choose IHS as their primary health care. Some reservation residents have medical care through health systems in nearby cities and would receive vaccination through them like any other ND resident. Similar to other provider types, there is no ultra-low cold chain storage at IHS.

Only about 60% of ND Native Americans live on a reservation. A substantial segment of the Turtle Mountain Chippewa population lives on non-reservation trust land. About half of Turtle Mountain Chippewa live on or near the Turtle Mountain reservation. Chippewa Trust Lands with small rural populations of Chippewa Indians are scattered through

Western ND. It is likely that this population will be well-served by usual outreach methods. Most non-reservation American Indians live in cities, especially Bismarck/Mandan and Devils Lake. Access to urban American Indian populations will depend on LPH outreach and venues for vaccination proximal to high American Indian population areas in cities. Community health centers and traditional healthcare providers will also play a role in vaccination of urban American Indians.

Communicating with American Indians may be culturally and logistically different than communicating with other populations in the state. The joint information system will provide culturally appropriate educational information. Radio transmission capacity on at least some reservations will be available to notify and educate the population that is likely to be more isolated from usual data sources than much of the rest of the population.

New Americans/Foreign Born/Immigrant Populations

This population has been disproportionately affected by COVID-19 illness and therefore may be prioritized for vaccination. In urban areas there are community health centers that typically see a large portion of NFI along with LPH. In more rural areas reaching immigrant populations will primarily be a LPH function with methods similar to those used to reach non-reservation American Indians. Many urban areas with immigrants have developed local leadership and informal civic groups that can facilitate access. At this point, it is not clear how much additional outreach will be required for these groups beyond what is needed to reach the general population, although certainly capturing illegal immigrants will be challenging.

Cultural and language barriers may be significant for some communities and communication will need to be facilitated through trusted community leadership. The ND NFI Advisory Board will be utilized to ensure appropriate communication and stakeholder engagement in the COVID-19 vaccination program.

Priority Vaccination of Infrastructure

Guidance at this point suggests that states will have some latitude in deciding when and if to step outside CDC guidance for vaccination of priority groups (e.g., for needs unique to the state). North Dakota expects to adhere tightly to CDC and the rationale for any deviation will be clearly documented and defensible.

At this time, CDC has released general, but not specific, information related to selection of priority groups. Regardless, of guidance, specific allocation will be up to North

Dakota. That is, if North Dakota receives 10,000 doses in a single month, the decisions for allocating those doses will be up to unified command informed by recommendations from the [Advisory Committee on COVID-19 Vaccination Ethics](#).

Based on first wave experience with the COVID-19 pandemic, sufficient damage to infrastructure to warrant widespread priority vaccination of critical infrastructure may not occur. Nonetheless, current guidance suggests allocation of some priority vaccine to key infrastructure groups. Specific infrastructure groups to receive vaccine are only partially defined at this time. How much of this decision will be left to the state is unknown.

Local (e.g., institutional) prioritization may be necessary. For example, hospitals receiving vaccine for health care workers may not have sufficient vaccine arrive at one time to vaccinate all employees. Institutions will have to determine internally which persons in the institution will receive vaccine in what order. Guiding principles for prioritization will be provided to facilities to inform decision making. Prior planning documents developed by hospital emergency managers for pandemic influenza and modified for coronavirus provide some guidance based on expected exposure risk and criticality of function (e.g., ER and ICU personnel first—see below). An alternative approach could be based on persons at highest disease risk (i.e., comorbidities associated with poor outcome among all patient care staff). Similarly, other institutions and non-institutional health care worker (HCW) at the community level would require prioritization (e.g., LTC, EMS, LPH). Prioritization decisions will be referred to the [Advisory Committee on COVID-19 Vaccination Ethics](#) established for immunization planning.

Entities that administer prioritized vaccine (e.g., hospitals, LPH) will need to document how each dose is allocated. It is expected that nearly all doses delivered until vaccine becomes highly available will reflect some risk priority group. Since during a pandemic, people would be expected to become seriously ill or die due to vaccine shortage, the entities allocating vaccine within their system would need to be able to defend the appropriate use of the vaccine at a later date (e.g., vaccine was not diverted away from high priority groups to lower priority group with more authority).

Advisory Committee on COVID-19 Vaccination Ethics

An [Advisory Committee on COVID-19 Vaccination Ethics](#) made up of five individuals, including the state health officer (or designee), executive director of human services (or designee), ethicist, healthcare provider, and a local health representative, will advise unified command of vaccine priorities. The committee will be coordinated by [Dr.](#)

[Stephen Pickard](#). A listing of members and their experience is listed in [Appendix B](#). The committee will be needed when vaccine is limited and priorities above and beyond the priorities of the Advisory Committee on Immunization Practices (ACIP) have to be determined. This committee will be open to the public and applicable public notices be distributed.

Vaccine Allocation

Vaccine allocation will attempt to distribute vaccine fairly across the state according to the extent that vaccination providers have access to prioritized populations. Priority groups specified by the ACIP and the North Dakota [Advisory Committee on COVID-19 Vaccination Ethics](#) will provide recommendations if prioritization among those recommendations are necessary. Priority population estimates will be provided through statewide data sources (see [Vaccine Prioritization and Critical Populations](#)) and by healthcare facilities at the time they enroll for COVID-19 vaccine. These population estimates will be vetted to the best of ability according to county census data and known data sources. North Dakota intends to use the federal Tiberius platform, which will provide data from a variety of sources to inform allocation decision making and monitor the impact of allocations.

When North Dakota receives COVID-19 vaccine allocations, the vaccine will be allocated to providers based on their population estimates for the targeted population (e.g., front line health care workers or LTC staff) and will be apportioned out according to the number of doses that are allocated to the state and package quantities. Any orders that are in 100 dose increments (or 1,000 dose increments for ultra-low cold chain vaccines) will be ordered and sent to the CDC's ordering system to be distributed through McKesson. Vaccine orders that are not able to be sent in 100 dose increments will be ordered through CDC's vaccine ordering system and delivered to the NDDoH Emergency Preparedness warehouse for breakdown and redistribution. For more information on the technical aspect of the vaccine allocation and ordering process please see [Appendix E](#) (NDIIS COVID-19 Vaccine Response Plan).

Vaccine allocated to each provider will be tracked on a cumulative basis with calculation of expected vaccine coverage for risk groups in specific geographical areas. Adjustments will be made to the allocation of vaccine based on these estimates. Allocation will also be based on doses administered and inventory. If a provider is not using and/or reporting vaccine, then subsequent doses will not be allocated to that provider. Vaccine

coverage rates and uptake based on data from the NDIIS will also be used to determine which providers in which locations need vaccine.

To the extent possible, the NDDoH Division of Immunization (Mass Immunization Group) would attempt to provide the same vaccine to a provider consistently rather than giving them whatever vaccine is available. If providers must track the indications of many different vaccines, they are likely to make errors and deliver vaccine to individuals for whom the vaccine available is not approved. This effort to create some consistency for providers would have to be balanced with the need to fairly distribute vaccine to the entire population. That is, if no shipment of the vaccine that the provider previously received is expected soon, they would be allocated a different vaccine so that the patients served by that site could have access to vaccine.

The [National Academy of Science, Engineering and Medicine](#) suggests using the [CDC social vulnerability index](#) to ensure areas at higher risk receive extra vaccine in the allocation process. This topic can and should be discussed by the [Advisory Committee on COVID-19 Vaccination Ethics](#).

Vaccine Ordering and Processing

In very early stages of vaccine allocation, the NDDoH Division of Immunization (Mass Immunization Group) will allocate based on the process discussed in the previous section of this plan. However, to decrease wastage and to best use very limited supplies, facilities who will be receiving allocations of COVID-19 vaccine will be emailed and given 24 hours to respond to whether or not they are able to use their full potential allocation. Facilities will be encouraged to have staff or patients pre-register for COVID-19 vaccine in an effort to estimate uptake. If the facility wants the allocation, their vaccine will be ordered, if they are not able to safely store the number of doses, are having a lower uptake of vaccine or don't yet need more doses their allocation will be given to another facility who is more in need. This process may delay vaccine orders by one day but will reduce wastage of vaccine that goes unused due to uptake being less than anticipated.

Once vaccine is more plentiful COVID-19 vaccine will be allocated out automatically based on population estimates, doses available and doses of COVID-19 vaccine administered based on NDIIS data. Once vaccine supply meets or exceeds demand, facilities will have the ability to order doses as needed in NDIIS. For more information on the ordering process see [Appendix E](#).

Provider information will be manually updated in NDIIS in the vaccine ordering/wastage/return module based on what is completed in the provider agreement. When changes are made in this module those changes are automatically uploaded to the CDC's ordering system, Vaccine Tracking System (VTrckS). Once providers are placing their own orders for COVID-19 vaccine, if they update contact, address or business hours in this module, it will automatically be uploaded to VTrckS.

Physical Vaccine Management and Cold Chain

Management of Priority Vaccine Unstable at Zero Degrees or Higher

Current information suggests that two vaccines are likely to arrive early with markedly different requirements. See [CDC COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#) for Vaccine Scenarios.

Vaccine A:

- Ultra-Cold Vaccine (-60 DEGREES C to -90 DEGREES C)
- Minimum Quantity: 1,000 doses
- Doses per Vial: 5
- Time Allowed in Refrigerator: 5 days

Vaccine B:

- Frozen vaccine (-20 DEGREES C)
- Minimum Quantity: 100 doses if direct shipment to user
- Doses per Vial: 10
- Time Allowed in Refrigerator: 14 days

Current storage requirements for both vaccines make it difficult for providers to store unused doses for second doses.

Models for Distribution of Ultra-Cold Vaccine (Vaccine A)

Based on current information, once vaccine is moved from dry ice to refrigerator conditions, it must not be frozen again. The vaccine cannot be refrozen and remain viable. If vaccine can be off-loaded to freezer conditions (-20 C), it should remain frozen until ready for use. (Off-loading ultra-cold vaccine to a freezer would almost certainly extend its viability compared to refrigerator conditions, but the state has received no indication of how long it would be viable for at -20 degrees C instead of -70 degrees C.)

The following are potential models for vaccine management. The specific model(s) depend on additional information and situational assessment at the time of vaccination.

1. Ultra-cold vaccine would be shipped to the designated use area and vaccination clinics can be scheduled for the same day or the subsequent five days throughout the area. If splitting up the shipment, representatives from vaccinating entities would pick up their allocation early in the morning and expect to use the vaccine within 5 days.
2. A container of ultra-cold vaccine that arrived in a target area would be opened to supply each clinic (mass clinic or institution) within the area. The ultra-cold chain container may only be opened twice per day, so clinics must be scheduled based on that limitation. The remaining vaccine would stay in the original container on dry ice with the volume of dry ice monitored over time and recharged as necessary.
3. An ultra-cold container would be received by the state warehouse and redistributed to a number of pre-cooled certified shippers for each of many smaller jurisdictions. Each shipper would be filled with dry ice and the repackaged containers would be distributed to the target areas. The vaccine would need to be used before the dry ice sublimated away, although it may be possible to periodically supply many jurisdictions with extra dry ice contained in certified shippers to use for re-charging.
4. Ultra-cold vaccine would be carried to multiple locations and off-loaded from dry ice or from ultra-cold portable freezers to refrigerator. Local entities would have 5 days from the time the vaccine was off-loaded until use.

Three Phase Distribution

For purposes of this discussion redistribution refers to receipt of vaccine at the NDDoH central warehouse with repackaging of the vaccine into thermostatically controlled refrigerator/freezers or certified shippers with appropriate coolant and transport to individual local destinations using temperature-controlled vehicles. Transfer refers to local receipt of vaccine with movement of some of the vaccine to multiple nearby locations and institutions. Transfer may also refer to vaccine received at the central warehouse or regional site and carried in the original packaging to up to two destinations in a single day at which some of the vaccine is removed.

CDC has designated three phases of vaccination. Phase 1 represents low availability with priority vaccination. Phase 2 represents high availability and vaccination of all population groups. Phase 3 represents high availability and slowing demand.

During **Phase 1**, large, urban areas will hold mass clinics for outreach to eligible groups (e.g., healthcare workers, essential workers) in addition to supplying vaccine to health systems and long-term care facilities (if targeted by prioritization as expected). If vaccine can be redistributed or transferred, then smaller clinics can be held proximal to high risk populations (e.g., rural health care workers, areas with urban American Indian populations or elderly housing) or carried by vaccinators into homes of the homebound. (This will depend on cold chain requirements of available vaccine). If vaccine can be redistributed, then use of ancillary vaccinators such as pharmacies should be possible. Some pharmacies will assist with vaccinating LTCs. This information will be captured upon enrollment.

It may not be possible to widely engage the private clinic system during Phase 1 unless vaccine can be redistributed. A few large clinics in the state could reach high priority recipients, but the number of vaccines administered using “vaccination opportunities” during office visits would be small for any one provider. Again, this is highly dependent on the cold chain requirements, minimum shipment quantities and ability to pre-register patients. If clinic providers can be engaged during this stage, they will be since their ability to identify and vaccinate persons with secondary conditions will be high.

The greatest challenge will be to moving small amounts of vaccine to widely scattered locations during Phase 1 since only a small percentage of the small population will be eligible for the vaccine. For example, the Southwest District Health Unit has a population of 45,000 people with a central city of 23,000. The remainder of the population is scattered over 10,000 square miles, mostly in cities of less than 1,000 and rural farmsteads. It has three hospitals, two of which are more than a one-hour drive from the central city over two-lane road, plus eight LTC facilities up to 1.5 hours from the central city. Similar problems would be faced reaching reservation American Indian populations since reservation populations are small and rural, and reservation officials want to hold multiple small clinics in scattered small communities (e.g., While Shield, ND population 336). Reaching small populations without redistribution may not be possible.

North Dakota would rely heavily on PrepMod to pre-register vaccinees and obtain consent. Shipments of vaccine would preferably be limited to the number of people with advance consent (preferably breaking down larger quantities at the central warehouse for redistribution but reaching sites through regional transfer may be possible.). For instance, in a hospital with 500 eligible vaccinees if only 75% signed a consent in advance, then vaccine allocation would be limited to 375 doses at that time.

During **Phase 2**, when vaccine becomes more widely available, vaccine distribution to large urban areas will first emphasize targeted vaccination outreach to priority groups such as ancillary health care workers and unvaccinated infrastructure workers in addition to other high-risk members of the general population. Additional congregate settings (group homes, corrections) will need to be vaccinated. Some have the capability to vaccinate themselves, but others will require assistance from LPH, a pharmacy, or a mobile vaccination team. Upon enrolling to receive COVID-19 vaccine, the Division of Immunizations (Mass Immunization Group) will pair each congregate setting up with a vaccinator. Focused public health efforts would shift entirely to other high priority groups (elderly, minority populations, persons with underlying conditions) as uptake among any higher priority infrastructure workers diminishes. The assumptions provided indicate that throughout this period, vaccine would be plentiful and available to the general public including those not listed in a priority group. While any person presenting for vaccination would be vaccinated, intense public health efforts to reach a high percentage of the non-prioritized population would wait until resources were available after reaching priority populations.

Since the largest vaccinating entity in the state is normally private providers, moving vaccine in appropriate quantities to clinics would be high priority but would likely require redistribution preferably with a vaccine with non-rigorous cold chain requirements. Pharmacies would be leveraged as mentioned under Phase 1. Mass clinics would continue to be held to reach those less likely to be reached by clinic providers and pharmacies (e.g., younger populations), but local outreach is likely to be emphasized as much or more than mass clinics (e.g., targeted outreach to schools, colleges and workplaces in addition to homebound and “hard to reach” populations).

In addition, it is likely that a substantial number of people that have not had their second dose will need to be targeted. Personalized letters, texting and phone calls will be possible, but mass communication may also be necessary. In addition, provider contact may be very helpful in ensuring persons with only a single dose to complete their vaccination series (e.g., automated callback and emails), so providers will be urged to make contact with their patients who have not completed the series.

During **Phase 3**, when vaccine is widely available, but demand is reduced, emphasis will be on private health care providers and pharmacies continuing to use vaccination opportunities. A provider recommendation for COVID-19 vaccine will be critical. Assuming mass vaccination clinics have become low yield, public health would shift

most resources to trying to reach high-risk populations that have not yet been reached. NDIIIS would be able to provide county level estimates of priority group coverage (other than homebound which cannot at this time be flagged in NDIIIS). Leveraging local community leaders will likely be necessary to gain vaccination participation by the undecided in these population subsets.

If a level of coverage is achieved that reduces COVID-19 cases to low levels, uptake by low risk populations will almost certainly become small, but convincing high-risk individuals to be vaccinated may still be possible. Emphasis will also be placed on completing vaccination of those who have not received their second dose as mentioned under Phase 2.

Scenarios for Vaccine Distribution

Priorities for vaccination are dependent on pending ACIP recommendations. The following scenarios are based on information provided in the COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations. In the scenarios below, vaccination begins with health care workers as the first outreach target, then progresses to other Phase 1 recipients. The next group is the general public and any other critical populations that have yet to be vaccinated as listed in Phase 2. In Phase 2, vaccination offered to anyone who is willing to be vaccinated does not exclude prioritizing those at greatest risk. Note that actual vaccination priorities might deviate from the imagined scenarios below. Scenarios present alternatives that use or do not use redistribution methods. Scenarios must include rural areas, which make up a large percentage of the state population and include both a high percentage of elderly and much of the American Indian population. It is not acceptable to not distribute vaccine to these areas.

Scenario 1 Background

Vaccine A: Ultra-cold with minimum quantity of 1,000 doses only

Priority populations:

PHASE 1A

Stage 1: Health care workers: COVID-19 providers in referral hospitals

Stage 2: Health care workers: Tier 2 and 3 hospitals COVID -19 workers, LTC providers in all areas.

Stage 3: Other health care workers (vaccinators, dialysis, EMS, etc.), LTC residents, direct care public health workers

Stage 4+: Second dose administration continues until all initially vaccinated persons have received second dose. Any extra vaccine is used to extend coverage to “Stage 3” target populations and begin Phase 1B target populations.

PHASE 1B:

High priority infrastructure, ancillary HCW, vulnerable populations with underlying conditions, older age and any other population at increased risk of illness or adverse outcome from illness.

Scenario 1 PHASE 1 Distribution

TIER 1 CITIES (FARGO/WEST FARGO, BISMARCK/MANDAN, GRAND FORKS, MINOT) IN PHASE 1.

Vaccine would be shipped directly from the manufacturer to each of the four cities with referral hospitals. If a hospital can accept 1,000 doses and equitable allocations allows for that amount, then the entire shipment will be sent directly to the hospital. If vaccine shipments need to be separated into smaller quantities, then vaccine will be received by the regional emergency preparedness coordinator.

Option A: A brief vaccination period (few days) is agreed upon by all hospitals in each city. Hospitals are allocated a number of doses according to number of signed consents in priority group and the entire 1,000 doses is used within 5 days. The vaccine container is not opened until all vaccine is ready for allocation. This option is more convenient for HCW to be vaccinated on site and may increase the uptake of vaccine. This option is more complicated for storage and handling of ultra-cold chain vaccine. It assumes that health care facilities will have difficulty releasing HCW to attend central clinics.

Option B: Different vaccination dates or multiple vaccination dates are accommodated by opening the container and removing some of the vaccine. Dry ice is replenished if needed. The vaccine container is optimally only opened once in the morning and never more than twice in a single day.

Option C: LPH holds a closed mass vaccination clinic for health care workers in the city. Workers would have to leave the health care facility if on-duty to come to the clinic. This option streamlines vaccine management but increases the difficulty of HCW accessing the vaccine, potentially reducing uptake.

If necessary, leftover vaccine could be used for lower priority recipients. (e.g., if a hospital completes highest priority recipients, it would use any remaining vaccine to vaccinate lower priority recipients in the facility.)

If 1,000 doses are shipped to each primary city in week one, coverage of HCW within health systems in larger cities (e.g., Bismarck, Fargo) is likely to be substantially behind coverage in Minot and Grand Forks at the end of the week. If available, higher vaccine quantities may be directed to those cities if institutions anticipate ability to fully administer 2,000 doses or more. Staffing estimates are being collected with enrollment to receive COVID-19 vaccine.

TIER 2 CITIES (DICKINSON, WILLISTON, JAMESTOWN, DEVIL'S LAKE) IN PHASE 1

Option A (Redistribution method): Shipping containers go to state warehouse. Vaccine is divided and repacked into certified shippers with dry ice and allocated doses are carried to institutions in Tier 2 cities. Health care facility (HCF) allocation is determined by number of signed consents. Either option A or B listed under Tier 1 cities may be used.

Option B (Transfer method): At the beginning of a series of days allocated for vaccine use, an original container of 1,000 doses is carried to two recipient Tier 2 cities (Dickinson and Williston or Jamestown and Devils Lake), arriving in the first of the couplet at LPH at earliest reasonable hour and at the second LPH as soon thereafter as possible. (e.g., Dickinson at 7:00 am and Williston at 9:30 am). The vaccine allocated to that city is removed from the original shipping container and held at refrigerator or freezer temperature. Recipient institutions must have a representative present at the LPH at the anticipated time of vaccine arrival. Each institution will receive a cooler with ice packs for administration of vaccine within the period of time of vaccine viability. The institution would move the vaccine from the temporary cooler to stationary vaccine storage on arrival. All vaccine must be used within five days.

Option C: LPH holds a closed mass vaccination clinic for health care workers in the city which may need to draw from a substantial geographical area to reach regional HCW.

TIER 3 CITIES (ALL OTHER CITIES) IN PHASE 1

Tier 3 receiving locations are designated statewide, usually in LPH primary or satellite offices, but other locations could be used as long as public health personnel are present to receive and allocate vaccine.

Option A (Redistribution method): Vaccine is repackaged into certified shippers with dry ice or into certified, ultra-cold refrigerators at the warehouse. A shipper with the

allocation for each Tier 3 recipient locations is prepared. Upon local arrival, recipient health care institutions must have a representative to receive their allocation and use it during the viable period; alternatively, LPH can send vaccine to a cluster of institutions. This might require several vehicles. A combination of the two approaches is also possible. Vaccine can remain in a certified shipper on dry ice at the LPH unit for a few days such that all destinations do not have to receive vaccine on the same day but vaccine should be distributed quickly so that recharging the container with dry ice would not be needed. Vaccine sent in ultra-cold freezers would transfer to refrigerators and would have to be used within five days.

Option B (Transfer method): A regional site (e.g., Dickinson) would receive the original shipping container and carry the vaccine to up to two destinations in single day. On arrival in a local area, enough vaccine would be offloaded, that it could go to multiple local sites such a mass clinics and health care institutions. Representatives of final recipients would pick up the vaccine, refrigerate and use within five days.

Phase 2: General Public Added to Phase 1 Target Populations

ASSUMPTIONS:

1. Ultra-cold vaccine can be refrigerated for up to five days before administration.
2. Recruitment of HCW and LTC residents is necessary to increase uptake.
3. The [Advisory Committee on COVID-19 Vaccination Ethics](#) approves first vaccine for referral hospital personnel who are bearing the brunt of COVID-19 care.
4. The exact sequence of groups in Phase 1 would not substantially change distribution methods for this scenario since all groups are institutional.
5. Any allocated vaccine that must be used by the end of a day may given to lower priority recipients who can be accessed quickly to ensure vaccine is not wasted.
6. Tier 2 cities and Tier 3 cities will not have sufficient target populations in Phase 1 to guarantee complete usage of 1,000 doses. Methods for split distribution are reviewed in the scenario.
7. The regional emergency preparedness coordinator acts as vaccine recipient for all shipments to the region/large urban areas. Shipments to local (as opposed to regional) destinations go to LPH directors.
8. Whenever possible, vaccine leaving dry ice or ultra-cold refrigerators is moved to frozen conditions rather than refrigerators, but vaccine must not be allowed to thaw then be refrozen since this has not been shown to be safe for vaccine viability. Lower temperatures should slow the rate of degradation.

9. The state uses ultra-cold portable refrigerators and dry ice acquired from the only state vendor located in Bismarck or made in the NDDoH warehouse if successfully acquired. If recharging certified shippers with dry ice is anticipated, the warehouse would deliver certified shippers containing only dry ice. The dry ice would be redistributed into certified shippers containing vaccine as needed.
10. All original containers are dated at the time they arrive in the state.
11. If the frequency of adverse reactions (even if minor) is sizable, health care institutions will not want to vaccinate all workers at the same time since this may impair their ability to staff their facility.

Scenario 1 PHASE 2 Distribution

In this scenario, Phase 2 is a combination of continued institutional outreach and public vaccination. This discussion is focused on public vaccination since institutional vaccination would continue as above—reaching HCW not considered high priority in during Phase 1.

TIER 1 AND TIER 2 CITIES

Given the greater population designated for vaccination in Phase 2, it is expected that most, if not all, Tier 1 and Tier 2 cities will be able to use at least 1,000 doses in large scale public vaccination during the period that vaccine is viable at refrigerator temperatures. Given greater limitations on moving vaccine into rural areas, large scale clinics will advertise and draw from surrounding counties.

Vaccine will be shipped directly to each city for large scale vaccination. Since the containers can hold temperature for more than a week, the community will be able to time vaccine clinics within a window of several days.

Option A: Clinics plan to administer all the vaccine during the viable period. If demand falls short, back up plans for rapid vaccine administration will be used. In that case, a vaccine would be diverted from a clinic early enough for targeted vaccination of localized groups such as group homes, jails, homeless shelters and hospitals in nearby Tier 3 cities. This option is suitable for providing some vaccine to alternate public vaccinators (e.g., pharmacies).

Option B: Vaccine in the original container is removed in quantities needed for mass vaccination clinics. This might also involve limited removal for clinics or pharmacies. The original container would not be accessed more than twice in a single day. Repeated access to original shipping container over several days will require monitoring dry ice

remaining. Containers can be recharged, or alternatively complete use of vaccine can be accelerated in the absence of replacement dry ice; however, the warehouse is prepared to make and ship dry ice at need. This option would be suitable for providing vaccine to alternate vaccinators. Frequent allocation of vaccine from the dry ice container could be made to representatives of alternate vaccinators in quantities certain to be used while viable.

TIER 3 CITIES

The same methods and options used for moving vaccine to institutions in low population areas would be used for public vaccination (see Tier 3 Cities under Period 1);

RESERVATIONS

The following options are if a Tribe chooses to receive COVID-19 vaccine from the state and not through direct federal allocation.

Option A (Redistribution method): Vaccine is carried to a reservation in a certified shipper packed with dry ice to hold only as much vaccine as could be administered in a few days. This shipper could come from the warehouse (or carried to the reservation by the applicable LPH agency). A designated responsible party would receive and manage the vaccine on the reservation. This could be a person from IHS, a tribal representative or a person assisting from LPH. Vaccine would be removed from the shipper sequentially as needed but no more often than twice per day. In addition to use in a public clinic, vaccine could be allocated to the IHS outpatient area for administration to patients. As long as dry ice remains in the certified shipper, the vaccine could continue to be accessed over multiple days but must be used within 5 days after thawed.

Option B (Transfer method): An original shipper is taken from a regional site to the reservation and vaccine is offloaded to refrigerators or freezers. The entire vaccine quantity would need to be used during the days of viability. In addition to public clinics, mobile vaccination may target homebound in communities around the reservation. Since reservations have decided to hold multiple smaller clinics in various communities around the reservation; refrigerated vaccine would need to be moved around the reservation of the few days of viability.

Scenario 1 PHASE 3 Distribution with Reduced Uptake

If large quantities of vaccine are available, but all of it ultra-cold, rapidly using the vaccine would be difficult if it had to be held at refrigerator temperatures. Allocating vaccine on multiple occasions from the original container would be necessary without opening the container more than twice a day. Some areas have permanent ultra-cold

chain storage which could be used to store vaccine for prolonged periods of time (See [Appendix B](#)). Urban areas receiving direct shipments would need to allocate to alternate vaccinators (e.g., pharmacies) frequently in addition to holding mass clinics and targeted clinics. Since the original container would necessarily be accessed multiple times, dry ice remaining in the shipper would have to be monitored. Tier 1 and Tier 2 cities should be able to manage 1,000 dose increments if dry ice is maintained. This might require supplemental dry ice being supplied to these areas from the warehouse. Tier 3 cities would receive vaccine as described above in smaller quantities.

Scenario 2

Vaccine B: Frozen vaccine only with minimum quantity of 100 doses

This scenario is similar to Scenario 1. Changes are specific to distribution and management of a frozen vaccine.

Priority populations:

PHASE 1A

Stage 1: HCW: COVID-19 providers in referral hospitals

Stage 2: HCW: Tier 2 and 3 hospitals COVID -19 workers, LTC providers in all areas.

Stage 3: Other HCW, LTC residents, direct care public health workers

Stage 4+: Second dose administration continues until all initially vaccinated persons have received second dose. Any extra vaccine is used to extend coverage to "Stage 3" target populations and begin Phase 1B target populations.

PHASE 1B:

Tribes, high priority infrastructure, ancillary HCW, vulnerable populations with underlying conditions, older age and any other population at increased risk of illness or adverse outcome from illness.

Scenario 2 PHASE 1 Distribution

If vaccine quantities are very limited, only large health care institutions would be able to receive full cartons of vaccine. During the initial week or weeks only referral hospitals may be eligible to receive vaccine if they are prioritized over smaller community hospitals. Subsequently, because of limited number of doses available, small health care institutions (hospitals, LTC) may have to receive partial cases through transfer as described under Scenario 1 or through redistribution if allowed. Even if vaccine is available, sites with more than 100 potential vaccinees would not likely be able to use an

exact multiple of 100 doses (e.g., a facility that confirms it can vaccinate 150 health care workers would need 1.5 cases).

Vaccine for mass clinics would be shipped in full cases directly to LPH in Tier 1 and Tier 2 cities. For rural areas, vaccine would be shipped to regional sites for transfer (see options from Scenario 1) to local communities in quantities that can be used during the viable period. The viability period is like to be only two weeks for many local sites since having little or no frozen vaccine storage space is common. Small cities that could potentially use a full case over a two week period may not be able to receive full cases in order for the state to reach all areas of the state with limited vaccine.

PHASE 2: GENERAL PUBLIC ADDED TO PHASE 1 TARGET POPULATIONS

ASSUMPTIONS:

1. Frozen vaccine is substantially easier to manage, but frozen storage at many local sites is limited or absent.
2. Health systems and LTC have identified HCW willing to receive vaccine and have obtained consent. Consent would be obtained for lower priority HCW at the same time as higher priority groups.
3. LTC have identified residents willing to receive vaccine and obtained consent.
4. Recruitment of HCW and LTC residents is ongoing to convert initial refusals.
5. The [Advisory Committee on COVID-19 Vaccination Ethics](#) approves first vaccine for referral hospital personnel who are bearing the brunt of COVID-19 care.
6. The exact sequence of groups in Phase 1 would not substantially change distribution methods for this scenario since all groups are institutional.
7. If the frequency of even minor adverse reactions is sizable, health care institutions will not want to vaccinate all workers at the same time since this may impair their ability to staff their facility.
8. Shipments of full cases to individual vaccination sites would depend on the amount of vaccine available.

Scenario 2 Phase 2 Distribution

Distribution during Phase 2 would be almost entirely by direct shipment of 100 dose cartons to vaccinators that had frozen storage and those without frozen storage that had high enough throughput to use vaccine in 14 days (based on enrollment and pre-registration). This would exclude some small pharmacies, small clinics and LPH entities in low population jurisdictions. These would continue to receive partial cartons through

transfer or redistribution. After approved for a shipment, vaccinators would need to use the entire allotment before being resupplied except in the instance of mass clinics.

Scenario 2 Phase 3 Distribution

As use begins to taper, both state and LPH would need to be aware particularly of recipients who are not administering enough vaccine to use full cartons. This would initially be small jurisdictions but will extent to larger sites as use declines further. Increased use of transfer or redistribution will be necessary as public health and clinics reach out to underserved populations and persons who have not completed the series.

Scenario 3

Scenario 3 is the same as Scenario 1 except two vaccines are available: Ultra-cold and frozen (vaccines A and B).

Assumptions:

As far as can be known at the time of vaccination, the two vaccines are equivalent in efficacy and their respective side effect profiles.

Distribution:

1. Distribution of ultra-cold vaccine will use the same methods described in Scenario 1. Ultra-cold vaccine will be preferentially sent to larger urban areas where it can be more easily used. If ultra-cold is approved first, it may be available in substantially greater quantities than frozen vaccine. To prevent any discrepancy in vaccine access, ultra-cold vaccine may still need to go to sites other than large cities.
2. Frozen vaccine will preferentially be distributed to smaller communities when supply is limited.
 - a. Direct shipment of vaccine from McKesson to larger clinics may still occur if the clinic is allocated at least 100 doses, but the state may have greater needed for the frozen vaccine in rural areas where the large number of destinations, small population size and greater difficulty holding a vaccine at ultra-cold temperatures make use of ultra-cold vaccine complicated. Consequently, the state may not approve many large clinics for direct shipment of frozen vaccine until frozen vaccine becomes available in large quantities. Instead, transfer methods (or redistribution if permitted) would be used as described above.
 - b. If redistribution is allowed, the state warehouse may receive some frozen vaccine and sort it for distribution using the methods outlined in the vaccine plan for vaccine handling. Shipment to locals will be by circuit route using

- temperature- controlled vehicles and portable freezers. Vaccine will be moved from the portable freezer to local vaccine storage. Repackaged vaccine would be distributed from the warehouse to all destinations (LPH, health care institutions, pharmacies, self-vaccinating congregate settings, private clinics). Distribution by LPH would not be necessary.
- c. When frozen vaccine is abundant, many clinics statewide may be approved to receive full cases of 100 doses directly from McKesson as long as the local site has sufficient frozen cold space for storage and can use the vaccine within two weeks. (Allocating clinics larger quantities than can be used in two weeks may create storage problems, and, depending on vaccine availability, more vaccine would be sent to those with faster throughput.)

Scenario 4

Scenario 4 is similar to Scenarios 1 and 2 (depending on available vaccine) except that priority groups change so that initial priority groups are not institutional but public. This is equivalent to Phase 1B in Scenario 1 occurring before Phase 1A. Alternatively, priority groups may be mixed such that some institutional and some public vaccine is approved for highest priority use. Methods will be similar.

Scenario 5

Scenario 5 is similar to Scenario 1; however, it is assumed in this case that ultra-cold vaccine is allocated largely to many difficult to reach populations including group homes, homeless, immigrant, urban American Indians but not to other larger population entities. The certainty of reaching large number of people within these populations at any one time will make it imperative that the ultra-cold vaccine is repackaged in certified shippers on dry ice at the warehouse and moved to many local areas. Sites would not receive large quantities but be resupplied from the warehouse with additional vaccine as it is used. Allocation would be limited so that dry ice recharge was not necessary although it could be done if necessary.

State Vaccine Storage

It is likely that North Dakota will request and receive vaccine through the CDC-authorized contractor (McKesson). Ultra-cold vaccine (vaccine A) will ship directly from the vaccine manufacturer. It is expected that CDC will authorize the direct shipment of full cases (100-dose or 1,000-dose increments) to providers authorized by the state to receive that much vaccine at one time. CDC advises against redistribution of frozen and

ultra-low cold chain vaccine, so every effort to utilize direct shipment will be made. Nonetheless, it is unlikely that North Dakota will be able to fully meet the need of rural areas and Tribes without repackaging some of the vaccine. If vaccine is released slowly, relatively few providers will be allocated full cases by direct shipment. In that case, a high percentage of the vaccine early on may need to be received by the NDDoH warehouse and re-apportioned into smaller quantities for shipment to specific sites. Redistribution of ultra-cold vaccine would be avoided, if possible. Frozen vaccine could be moved in portable freezers since the temperature expectation is -4 degrees F (-20 degrees C).

Storage capacity that is part of the state medical cache and located at the warehouse consists of walk-in cooler and freezers as well as four upright ultra-cold freezers with 28 cubic feet of storage capacity in each, 14 transport refrigerators, 13 transport freezers and 9 ultra-cold freezers these are able to be powered by 110 AC volts or 12 volt DC voltage provided by a port located in the vehicle or a battery back-up that goes with each at the time of transport, each transport device has a dedicated data logger that records the temperature of each device, each datalogger has an audio and visual alarm that alerts when going out of range and also reports by wifi to the NDDoH and alerts staff if any device goes out of range. The walk-in cooler and freezer also have data loggers that sound an audio and visual alarm at the warehouse or through a wifi connection to NDDoH, also in the warehouse are 354 certified shippers that can be used with either dry ice and refrigerated or frozen gel packs to maintain the required temperature, dry ice is provided through an agreement with Prax Air to supply a minimum of 5,000 pounds of dry ice per week that will bridge the need until a dry ice manufacturing plant can be installed at the warehouse.

Mass shipment of vaccine with specific cold chain requirements can be problematic during winter months because of the need to protect the vaccine from both moderate warmth and severe cold. During H1N1, the only methods proven to be reliable were shipping in controlled temperature environments (i.e., portable refrigeration units in temperature-controlled vehicles) and certified shippers, which had a small payload for the shipping weight making them an expensive and inefficient distribution option except in select circumstances (e.g., sites a long distance from Bismarck).

During H1N1, shipments from the vendor were packed in large Styrofoam containers that did not have thick walls. No temperature data loggers were included in the shipments. NDDoH found that even containers with much thicker walls could not

reliably prevent freezing during harsh winter conditions for the lengths of time that commercial shipping companies kept the vaccine containers out-of-doors. Vaccine shipping from the CDC contractor could be more restricted during very cold weather than it was during H1N1. In that event, retrieval of vaccine from the vendor would default to use of a temperature-controlled aircraft sent from North Dakota.

Local Vaccine Storage

Local vaccine storage may not be sufficient for both COVID-19 vaccine and influenza vaccine; however, NDDoH is not planning a push to increase local storage. If COVID-19 vaccine is available in November or later, than most influenza vaccine will have already been administered. Vaccine will not be shipped to a provider unless the provider is able to adequately store vaccine. In the very early allocation process providers will be contacted prior to any vaccine orders being placed. This will allow for the facility to report if they have adequate storage space for their existing and potentially additional doses being ordered. They can also report if they have the need for the vaccine. COVID-19 vaccine inventory is tracked in NDIIS even if the vaccine has been transferred. Vaccine will generally be shipped directly from CDC's distributor or the vaccine manufacturer. If needed, the state warehouse can act as a vaccine repository and allocate quantities of vaccine that are within the storage capacities of local receiving entities. Vaccine storage capacity by type and by provider will be collected upon enrollment.

The NDDoH Division of Immunization (Mass Immunization Group) is currently in the process of determining where ultra-low cold chain storage capacity is available in the state. The facilities identified to have the capability to store ultra-cold vaccine will be used for emergency storage or could be allocated this type of vaccine to store for their own healthcare facilities. See [Appendix B](#) for ultra-low cold chain capacity in North Dakota. At this time, North Dakota does not anticipate leveraging these sites for storage except in an emergency. In the future if other vaccines are available, these sites could be prioritized for vaccine A. Dry Ice is only manufactured in one location in the state this is by Prax air in Bismarck ND, they have the capacity of producing approximately 300 pounds per hour. Prax Air also supplies dry ice to their facilities in North Dakota these facilities are in Fargo, Grand Forks, Minot, and Dickinson. Supply in each location would be limited on production and demands of other cities. The only other location of large amounts of dry ice in ND is at Continental Carbonic Products in Fargo ND, this company gets a shipment of 40,000 pounds of dry ice on a weekly basis but this amount is again limited by the demand in that location and the demand of other locations

supplied by the manufacturing plant that is located out of state. There are several small scale producers of dry ice in the state but these are usually labs and only capable of producing small amounts of dry ice at a given time.

State Warehouse Vaccine Processing

Vaccine will be shipped directly from the manufacturer or the distributor to providers who are able to accept the minimum shipment. Vaccine that needs to be redistributed in smaller quantities will be broken down by the state warehouse. The state is currently procuring supplies in order to redistribute frozen and ultra-low cold chain vaccines.

Procedures for vaccine management of frozen and refrigerated vaccine would be similar to those used during H1N1 (as outlined below) but will require modification based on:

- Type of vaccine and required cold chain
- How shipment is received
- Advance notification from shippers
- Frequency of shipments

Training for management of vaccine is conducted annually for warehouse staff and this would be updated with any additional information about the specific vaccine just before the state begins to receive shipments. Refrigerated or frozen vaccine received by warehouse, likely via commercial carrier, will be transferred into alarm-monitored, walk-in refrigerators or freezers. Ultra-cold vaccine received at the warehouse will remain in original containers until distributed or repacked in ultra-cold freezers or certified shippers with dry ice.

Allocation schedules will be created as packing slips produced by NDIIS prior to actual receipt of the vaccine. Packing slips will be electronic rather than paper as was used in H1N1. For additional details on the NDIIS packing slip, see [Appendix E](#). Additional vaccinators, such as pharmacies, will need to receive their vaccine allocation through LPH. All the designated recipient sites for the vaccine will be plotted on a map and cluster routes defined for delivery. Certified shippers or other shippers with higher payloads may be used for single destination transport. Transport media will be tested before it is used for vaccine delivery. The method selected will be an incident command decision.

The vaccine will be sorted by provider and route, and routing sheets will be created. Vaccine for each route will be put into a holding container (basket) in the refrigerator or

freezer for loading at 6:00 am the next morning. The next morning, all the vaccine in a single container will be placed in a portable refrigerator/freezer.

Continuous, certified/calibrated data loggers (with the appropriate probe based on the temperature) will be used instead of the glycerin thermometers used in H1N1. The loggers have an external alarm different from that of the refrigerator and transmit alarm information to the NDDoH as well. These will be periodically re-calibrated. One route sheet will be put on a clipboard with route instructions and another route sheet attached to the top of the portable refrigerator. Each refrigerator/freezer will be numbered, and the number added to the routing sheets.

Drivers may be contract, re-assigned NDDoH personnel or emergency preparedness and response temporary hires. It is expected that ND Department of Transportation, Civil Air Patrol or National Guard drivers will be used as back-up only. The drivers will leave the warehouse in time to arrive at the first destination after the site has opened to receive vaccine (usually 8:00am). The route driver will call the recipient contact for each site a few minutes before arrival. If the contact cannot be reached, the driver will call the Department Operations Center (DOC) and request the DOC to make contact with the destination. The NDIIS contains primary and secondary contacts that will be provided to Logistics.

On arrival at the site, all the vaccine for that site will be removed from the refrigerator/freezer to a cooler and carried into the building, where it will be transferred into the refrigerator or freezer. If the site has any coolers or shippers to return to the warehouse, these will be picked up by the driver.

Routes will be designed to be no longer than 12 hours. To keep the length of the routes down, far distant destinations (e.g., Divide County) will receive their allocation by certified shipping containers delivered by commercial carrier (depending on vaccine being shipped and its cold chain requirements). Certified shipping containers must be pre-cooled before loading. The vaccine recipient site will ship the certified shipping containers back to the warehouse once emptied.

Vaccine refrigerators and freezers do not need to be plugged in unless there is an overnight stay. They will hold temperature over the course of the delivery route. Batteries will re-charge overnight. It is not intended that the driver stay overnight with any vaccine but return to the warehouse to report-in that same day. If a driver has to stay overnight, the driver will take the vaccine refrigerator into the hotel room and plug

it in. If the driver is unable to deliver all the vaccine (e.g., the recipient site refuses the vaccine because they have all they want), the vaccine will be returned to the warehouse and reallocated for the next shipment.

Most clinics will make provisions to receive vaccine after hours if they are notified to expect it. Any vaccine recipient who cannot receive vaccine after hours will need to designate an alternate receiving site such as a hospital or long-term care facility with sufficient cold space to accommodate the vaccine. All VFC sites already have an alternate delivery site designated.

During H1N1, NDDoH attempted to receive, route, pack and deliver vaccine it received within 24 hours of receiving it. Although the policy facilitated vaccine access, it placed considerable strain on resources both in immunizations and the warehouse. In order to reach a greater number of sites directly from the warehouse, this process will be altered. Since several hundred sites may need to be accessed, transport to all sites may occur over several days.

Ancillary supplies will be received along with the vaccine. Supplies required for vaccination will be supplemented by supplies from the medical cache as needed. Required supplies will be picked and packaged based on the amount of vaccine for a given location and delivered with the vaccine. Supplies will be tracked using the state's inventory system. See the transportation annex for complete description of the process.

Vaccine Administration Fees

Providers will be unable to charge for the cost of the COVID-19 vaccine, as it will be provided at no cost. It is expected that enrolled providers will be allowed to bill administration fees for COVID-19 vaccine. The cap for administration fees is unknown at this time.

The fee will help to finance the vaccination campaign but may pose an additional administrative burden on clinics. An administration fee will be necessary for private provider and pharmacy participation since the vaccine will not be charged for otherwise.

Patients who are unable to afford the administration fee must still be vaccinated. According to the [Health Resources and Services Administration \(HRSA\)](#), providers may submit a claim for reimbursement to cover costs for patients who were unable to pay.

Insurance is required to cover the COVID-19 vaccine at the first dollar, meaning at no cost to the patient, including co-pays and deductibles. It is possible that some providers may be out-of-network for certain patients. For example, most health systems are self-insured and only cover vaccination of staff at in-network providers. The NDDoH has had conversations with the two largest insurers in the state, Blue Cross Blue Shield of North Dakota and Sanford Health Plan to encourage in-network coverage of COVID-19 vaccine at a LPH clinic.

The North Dakota Insurance Department met with private insurance companies to ensure coverage of the COVID-19 vaccine administration fee. The North Dakota Medicaid Services Division has approved coverage of the administration fee for its recipients.

Vaccine Program Communication

Public

A vaccine section was added to the [NDDoH COVID-19 website](#). Heavy dependence on a COVID-19 vaccine website to communicate the needed information may tend to limit access for some people to this information; however, the information is complex and changes often, so other easily accessible statewide alternatives are not apparent. Alternatives such as reverse 911, mass text messages through Amber Alert, large clinic reverse 911 systems and National Weather Service alerts all have serious potential problems. The Governor's press conference each week receives significant media attention and will be used to communicate up-to-date information about COVID-19 vaccine. Social media use may be successful but would have similar limitations to a stand-alone website but may be more successful reaching younger populations. Local communications (newspaper, public access channels) can reach local populations with provider specific messages about availability and may be the best option but would need to be employed by local public information providers. LPH could be asked to be responsible for collecting and communicating vaccine availability within their jurisdiction, but many LPH are small, have competing priorities and may have reduced staff due to illness-related absenteeism.

The ND COVID-19 hotline will be utilized to answer questions from the public regarding COVID-19 vaccine. The hotline is staffed Monday through Saturday. Vaccination-specific scripts are currently being developed for the hotline and will be revised and amended as

needed throughout the campaign. Questions received on the hotline are tracked and will be used to inform needed public education and messaging.

In the COVID-19 vaccine enrollment agreement North Dakota will require facilities to post vaccine availability to vaccinefinder.org or a similar vaccine locator website once vaccine is publicly available. Provider enrollment data that is submitted to the CDC twice weekly will also prepopulate vaccinefinder.org with healthcare facility information. Once vaccine is widely available for the general public, the Division of Immunizations will also have an interactive, county-level map showing which providers in North Dakota have COVID-19 vaccine based on their NDHHS vaccine inventory.

PrepMod has the capability for anyone who is interested in receiving COVID-19 vaccine to preregister for the vaccine. The user will go onto the website and complete an online form giving basic contact information and list a high risk/priority group, if applicable. This information can then be used by the vaccine provider to plan their vaccination clinics. Given that COVID-19 vaccine will come in multi-dose vials that will need to be use within a few hours after they are punctured, it will be important to know how many people plan on attending vaccination clinics. Education will be done with the public on the PrepMod preregistration capabilities and the link will be posted to the NDDoH COVID and Immunization websites.

A media campaign to promote and educate about COVID-19 vaccination will be developed. It is anticipated that CDC and other partners will also have media campaigns. The joint information system will be used to develop the campaign. As needed, external stakeholders will be consulted regarding communications.

The need to evaluate communication with the public will be monitored over the course of the vaccination campaign. If more detailed information is needed related to gaps, evaluation questions may be added to websites listing clinic times or added to the COVID-19 call line procedures. Evidence of inadequate communication will include the following: the wrong people showing up at clinics, failure to come to mass clinics prepared (e.g., ID, face covering, loose clothing), increased public misinformation and evidence of low coverage or reduced coverage of certain populations. It may be possible to elicit specific reasons for failures as well (e.g., time and place of vaccine availability, concerns about cost or side effects). Calls to the hotline will also be monitored to determine the need for specific education.

The Unified Command Joint Information System can be called upon at anytime (24/7) to rapidly disseminate messages through social media, media list serves, etc. This has been exercised throughout the COVID-19 pandemic.

North Dakota has a low percentage of non-English speaking persons generally, but substantially higher in some areas. Approaches vary depending on the percentage of the population that is not English speaking. In areas with relatively higher numbers of non-English speakers (e.g., Fargo area), interpreters will be available within clinics for common languages. For areas with low numbers of non-English speakers (as well as for languages that are spoken by few persons in all parts of the state) telephone-based interpretative services will be provided with the help of designated persons assigned to assist those with special needs in the clinic. The utilization of CDC-translated resources may also be available. When this is not readily available, NDDoH has software that can translate documents into several different languages.

Healthcare Providers

Communication with healthcare providers will need to be extensive and repetitive. Providers need to 1) be encouraged to offer the vaccine to all eligible recipients during office visits and know how to convert refusals, 2) know how to handle ultra-cold vaccine, 3) know how to mix vaccine and adjuvant, 4) be re-educated about vaccine administration to avoid patient injury, 5) know how and when to contact patients for revaccination, 6) know current priority groups to vaccinate 7) be reminded of enrollment requirements (e.g., data, maintenance of Vaccine Finder), and 8) be encouraged to report to Vaccine Adverse Event Reporting System (VAERS).

A vaccine section for healthcare providers has been added to the current [NDDoH COVID-19 website](#). Information posted here will include enrollment, educational materials, vaccine information statements, NDIIS information, and webinars.

Information will be sent through professional associations (medical, hospital, pharmacy, LTC), emails and when necessary, phone calls. Upon enrollment, two contacts at each COVID-19 provider will be collected and added to a list serve. Training will be primarily conducted through webcasts/webinars which will be archived so that providers can be directed to the information if they miss the initial trainings. The NDDoH Division of Immunizations will schedule "office hours" once per week for providers in an effort to answer any COVID-19 vaccine-related questions.

The North Dakota State University Center for Immunization Research and Education is developing a curriculum for healthcare providers regarding COVID-19 vaccine and patient communication. This education will be made available to all healthcare providers in the state. Continuing educational credits for medical professionals will be offered.

Vaccine Hesitancy

It is anticipated that there may be increased vaccine hesitancy related to COVID-19 vaccine. North Dakotans are generally accepting of vaccines; however, the current climate, lack of transparency of clinical trials, and plethora of negative social media information may make acceptance much lower than is usually seen in the state. A contractor is currently surveying North Dakotans regarding their intention to receive a future COVID-19 vaccine. Results of that survey are intended to be available in mid-October. However, without safety and efficacy information regarding COVID-19 vaccine, it is understandable for the public to be hesitant. Educational materials about the safety and efficacy of the vaccine will be needed for the public and providers. Transparency about vaccine development and anticipated outcomes is critical. It is anticipated that CDC and other credible organizations will have patient materials, however, some North Dakota-specific materials will be needed. Vaccine spokespeople (trusted individuals who have been vaccinated and healthcare providers with immunization and infectious disease experience) will be used to promote vaccination to others.

A process for monitoring vaccine hesitancy and concerns is being developed. North Dakota Information Technology is able to monitor social media for vaccine hesitancy. Additionally, the National Governor's Association plans to work with the Public Good Project to understand trends in social media regarding vaccines and provide state-level data. It will likely not be necessary to have statistically valid information about vaccination barriers, attitudes and experiences. Anecdotal evidence, formal or informal focus groups, attention to media reports and social media and questions added to the hotline may be sufficient to identify potential problems which can be verified when necessary.

Vaccine Administration Documentation and Reporting

(See NDIIS COVID-19 Vaccine Response Plan in [Appendix E](#))

All providers must agree to submit the data to NDIIS within 24 hours of administration if they wish to become COVID-19 vaccine providers. The NDDoH Division of Immunizations (Mass Immunization Group) will be responsible for training providers to

use the NDIIS. The NDIIS has emergency preparedness functionality that includes the ability for users to document the administration of both a vaccine antigen and adjuvant (if required) and to track administration to established high-risk groups. PrepMod is expected to be fully implemented before mass vaccination is needed and will be available for all North Dakota healthcare providers to use during mass vaccination clinics.

PrepMod will allow for members of the public to preregister for COVID-19 vaccine online. This will include electronic registration, consent to vaccination, consent to receive immunization reminders via text message, review the Vaccine Information Statement (VIS) or other fact sheet, report their high risk/ priority group and to find the vaccination clinic nearest to them. Healthcare providers using PrepMod will be able to set up clinics and control the appointment times and number of patients per appointment to allow for social distancing. PrepMod will also document all required fields for vaccine administration then report to the NDIIS in real-time. This system will allow for a paperless vaccination clinic and no waiting in the clinic to complete forms. PrepMod will be made available to any healthcare provider in ND who would like to use it for vaccination clinics, not just COVID vaccination.

With the adoption of electronic health records (EHRs) by many health systems, data from the EHR can automatically document the vaccine record in NDIIS in real time. As of the time of this writing, about 80% of records were going into NDIIS electronically by EHRs. NDIIS currently has processes in place for monitoring data quality coming from provider EHRs and has functionality to remove both duplicate patient and duplicate dose records. Pharmacies and long-term care facilities account for most of the remaining vaccine information that is not transmitted by EHR. Additionally, IHS is not yet electronically submitting vaccination data to the NDIIS. Those without EHR direct transfer of data will default to paper-based data collection and manual data entry into the NDIIS. Some of these (e.g., LTC facilities) may need help with data entry. Forms for data collection may be locally developed or sites can use the NDIIS vaccine administration record (VAR). PrepMod may also be used and would reduce the need for entry directly into NDIIS.

To encourage getting data into NDIIS, the proposed policy is not to ship additional vaccine to a site which does not account in NDIIS for administration of all the doses previously sent (that is, every dose is accounted for by administration to a specific individual). Failure to enter data into NDIIS would limit the ability of that provider to

receive more vaccine; the assumption will be if the data is not in NDIIIS, the vaccine dose has not been administered. This is already being done with VFC vaccine.

When necessary, entry of data into NDIIIS from a paper vaccine administration record has not proven to be problematic; matching to the correct person for data updating appears to be quite good. Time requirements for data entry into NDIIIS for persons without existing records is not expected to be a serious problem since nearly 100% of children and over 90% of adults in North Dakota already have a record in the system. The time required to setup a new record in NDIIIS is not great in any case.

PrepMod adds a substantial number of fields that can be pre-populated by potential vaccinees when signing up for a clinic over the Internet. If a person does not sign up using PrepMod, the record administrator at the clinic can update information in PrepMod or the NDIIIS can be used to record administration without collection of additional information.

If the NDIIIS user interface was unavailable due to unplanned system outages, provider EHRs and PrepMod can continue to send data to the NDIIIS electronically through their interface. Providers can capture vaccine administration information on paper to be entered into the NDIIIS once it is available. If the NDIIIS EHR interfaces are unavailable due to unplanned system outages, messages will queue on the interface and are processed once the outage has ended. Additionally, EHR systems are able to access their messaging logs and resubmit any messages that did not process so no data will be lost. PrepMod also has the ability to extract a data file for administered immunizations that could be loaded into the NDIIIS once the system is available.

Vaccine Transfers and Redistribution

For ultra-cold and frozen vaccine, approaches to vaccine distribution and usage will attempt to minimize vaccine transfers or redistribution at the local level. During the early phases of the vaccination, when vaccine is limited, preregistration and signed consent forms will guide the amount of vaccine that can be sent to particular locations.

Nonetheless, it may occur that some doses of vaccine are left after persons selected for vaccination have been vaccinated. The first recommendation will be to extend vaccination to persons who may be outside the immediate target group (e.g., non-front line health care workers) to ensure the vaccine is used, assuming immediate usage is necessary to ensure that the vaccine is not wasted (e.g., a punctured vial or ultra-cold vaccine with rapid administration requirements). Mass clinics may redirect some of the

vaccine late in the day to institutions that can rapidly use it or to targeted outreach (e.g., infrastructure).

As vaccine becomes more plentiful and larger numbers of persons are eligible for vaccination, complete use of available vaccine may become less of a problem. Shipment amounts would still be limited to try to avoid leftover vaccine, especially for ultra-cold vaccine. Extra refrigerated vaccine may be transferred between health units. For example, a small rural area near a large city may send excess vaccine to a large city clinic. Vaccine transfer would occur in portable freezers/refrigerators which are available in regional locations. When needed, the state would facilitate transfer between health units or health care institutions. Distributed vaccine would not be returned to the warehouse once it is released to local management

COVID-19 vaccine inventory will also need to be monitored in the NDIIS. This will require any vaccine being transferred or redistributed be documented in the NDIIS using the vaccine inventory transfer functionality. For additional details, see COVID-19 Vaccine Response Plan in [Appendix E](#).

If COVID-19 vaccine is transferred from one provider to another, the transferring provider must obtain approval from the NDDoH Division of Immunization (Mass Immunization Group) prior to the transfer. Transferring lot numbers in NDIIS is required so that all doses of COVID-19 vaccine can be accounted for. Division of Immunization (Mass Immunization Group) staff can access all transfer information in NDIIS at any time, regardless if permission was given. All providers must use appropriate cold chain measures including qualified transport coolers and digital data loggers to track temperatures for the entire time the vaccine is being physically transported. Frozen or ultra-cold vaccine transferring between providers is not allowable under any circumstance.

Wasted and Recalled Vaccine

Some wastage of vaccine is inevitable. Wastage may be higher for COVID-19 vaccine due to limited stability (6 hours) once the multidose vial is punctured. Wastage also may be higher due to unknown uptake of vaccine and limited refrigerator stability. Currently vaccine wastage is reported to NDDoH through the NDIIS (see [Appendix E](#)). The NDDoH Division of Immunization (Mass Immunization Group) is responsible for training providers on how to use the NDIIS vaccine return/waste system. If vaccine is recalled, NDIIS will be able track who received the specific vaccine that was recalled in order to

make contact with the provider to quit using the vaccine. Additional information regarding what to do with wasted or expired vaccine is forthcoming from CDC.

Vaccination Program Monitoring

IIS Data

CDC Data Use Agreement

North Dakota has a fully executed data use agreement (DUA) that allows the NDDoH to send de-identified, record-level NDIIS data to CDC. The DUA with CDC includes language that specifies weekly data will be submitted from the NDIIS in the event of a pandemic. The DUA specifies an end date for data submission of July 31, 2024 so de-identified data captured for COVID-19 vaccine can be sent to CDC under the current DUA through 2024. The DUA also provides the ability for North Dakota to submit ad hoc aggregate data to CDC as requested. The Division of Immunizations has a current secure FTP in place to submit data to CDC and the NDIIS Manager has access to the secure portal in CDC's SAMS system to submit COVID data.

CDC has released their list of required IIS data elements for daily reporting COVID-19 vaccine which include identifiable, patient-level data (See CDC's [COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations](#)). A new DUA will be needed before North Dakota can provide identifiable data for CDC required data elements. The Division of Immunizations (Mass Immunization Group) cannot send identifiable patient data to CDC without a fully executed DUA. Even with a DUA, there are major concerns with the sharing of identifiable data with CDC. There are also concerns that certain aggregate data could be identifiable in some rural areas of North Dakota that have very small populations. Planning is underway to encrypt and de-identify data prior to sending it to CDC, which would alleviate concerns regarding sharing of data.

SAS code for CDC data submission

NDIIS Manager and NDIIS Coordinator have written SAS code that adheres to CDC's standard data dictionary for record-level data submissions. NDIIS Manager and NDIIS Coordinator also have SAS code written to pull aggregated influenza data that can be quickly modified to pull aggregated COVID-19 vaccine data if needed. The NDIIS staff are proficient at writing SAS code to generate record-level data files as well as calculate aggregate data as needed.

Datamart

The NDIIS has a datamart that allows immunization staff to extract data directly from the NDIIS database. All members of the Division of Immunizations have access to the NDIIS datamart. All demographic and vaccination data elements captured in the NDIIS can be included in a data extract through the datamart. The Senior Software Developer at Blue Cross Blue Shield of North Dakota (BCBSND) is able to help immunization staff write complex SQL code when needed. The datamart will be used to generate daily data reporting for CDC and to send data to the NDITD data lake to populate the public and non-public COVID-19 vaccine dashboards for North Dakota. If Division of Immunization staff are overwhelmed, the Office of the State Epidemiologist will assist in analysis of immunization data. The NDSU Center for Immunization Research and Education also has experience analyzing NDIIS data.

Public Data Dashboard

The NDIIS Manager, in collaboration with members of the NDDoH, has defined metrics for a public-facing COVID Vaccine Dashboard. The NDIIS manager will be working with an ND Information Technology contractor to build the dashboard in Microsoft Power BI®. The public dashboard will be published to the [NDDoH COVID-19 Vaccine website](#). See [Appendix F](#) for the metrics and schedule.

Non-Public Metrics

In addition to the public data dashboard, there are additional metrics for COVID-19 vaccine that the NDDoH will need for internal decision making. A non-public dashboard will also be created in Microsoft Power BI® and will be provided to the Unified Command, NDDoH Leadership and the Governor's office. See [Appendix F](#) for metrics and schedule.

Data will be reviewed weekly to inform changes in COVID-19 vaccine allocation, distribution, and communication efforts.

Gaps

CDC is requiring vaccine administering provider suffix. This is not a data element currently captured in the NDIIS or PrepMod. The Division of Immunizations has asked CDC for further clarification on the need for this data element. If it will be required, it will have to be added to the NDIIS user interface and to PrepMod.

CDC is also asking for four optional data elements that are not captured in the NDIIS. Comorbidity status could be inferred if a patient is flagged as part of the priority group

for individuals with underlying health conditions. However, the NDIIS may not be able to capture 100% of priority group information (see Gaps section of NDIIS plan in [Appendix E](#)). Missed appointments is not something traditionally reported by providers and would only be captured if patients were required to pre-register for a vaccine appointment. Initial phases of vaccination may focus largely on mass vaccination events that may not require patient's to pre-register. Serology results would only be captured in the NDIIS if having a positive serology meant the patient did not need to be vaccinated. In that case, the NDIIS would want this information entered as a history of disease exemption. There are challenges to the NDIIS capture of vaccine exemptions (see Gaps section of NDIIS plan in [Appendix E](#)). The NDIIS does not capture vaccine refusals. Providers can capture this information in their EHRs but not all EHRs send this information in their HL7 message. The NDIIS only captures exemptions if a patient or their parent/guardian is making a permanent refusal to vaccinate based on medical or personal belief reasons. The NDIIS does not capture one-time refusals or requests to delay vaccination.

Provider Enrollment Monitoring

As facilities enroll to receive COVID-19 vaccine, NDDoH Division of Immunization (Mass Immunization Group) staff will work with other state partners to map enrolled facilities by physical location, type and populations they plan on vaccinating. Through mapping we will be able to identify disparities or access issues to vaccine based on geography or priority groups being vaccinated. NDDoH Division of Immunizations (Mass Immunization Group) staff will also work to recruit facilities if disparities are found.

Other Monitoring

For many years and through multiple disaster responses including H1N1, North Dakota has been highly successful in using video conferencing to monitor progress during a disaster. Regular video conferencing is currently being used for management of the COVID-19 response, including regular meetings with external partners (LPH, health systems and LTC) and internal planning and management meetings. Updates on vaccination have been included in these meetings. Vaccination specific video conferencing will be initiated soon with increasing frequency as COVID-19 vaccination is initiated. Separate video conferencing will be held with LTC, health systems, pharmacies and LPH. Content will include:

- Review of updated information on vaccine availability, adverse events, and policy
- Data review re: progress in reaching priority groups
- Vaccination venues and methods in use by local vaccine providers

- Lessons learned
- Problems being encountered
- Resource needs and resource availability

Video conferences are recorded and archived, plus notes are taken by state organizers. Information obtained from meetings will be reviewed regularly by the core planning group currently working on the broad range of vaccination planning and problem solving. Needed changes in response to current problems, changing coverage and changing vaccine availability will be discussed and actions assigned.

The budget, staff and supplies for COVID-19 vaccination will be tracked by the Finance and Administration Section of Unified Command. This information is reported weekly during Unified Command meetings. Additionally, the immunization program manager will track spending and sign off on purchase orders related to COVID-19. The NDDoH Division of Accounting sends monthly accounting reports that are also reviewed by the immunization program manager.

Vaccination Second-Dose Reminders

At this time, it is not clear how vaccine needed for second doses should be handled. Further guidance is expected from CDC. Options include:

- Making completion of second dose the highest priority for any new vaccine received whenever sufficient time has elapsed for vaccinees to receive it.
- Making first dose administration the highest priority.

It is likely that the option that CDC recommends will depend, at least in part, on the level of immunity provided by the first dose. If that is small, the second dose will get priority over the first dose.

It is expected that multiple methods for recall would be needed.

- Non-patient specific message sent through Everbridge (autodialer).
- The use of PrepMod for texting and email recall which requires consent at the time of the first dose.
- The use of an autodialer (automated calling system) which requires consent at the time of the first dose.
- Generation and distribution of lists of patients needing second dose specific to the provider who gave the first dose and specific to the vaccine the provider is

scheduled to receive (to facilitate provider contact to patients with appropriate vaccine availability information).

- Verbal and written communication (e.g., information sheets, vaccination cards) to patients at the time of vaccination regarding when they will need to be revaccinated combined with methods for notifying the public when vaccine is available. This would primarily depend on provider updating of a federal vaccine finder database.
- Use of postcards to mail patients reminders: more costly but used regularly in North Dakota and effective for other vaccines.

NDIIS can generate reminder and recall notifications for persons who received the initial dose of pandemic vaccine once the required time between doses has elapsed. See NDIIS COVID-19 Vaccine Response Plan in [Appendix E](#). The system can produce line lists to upload to a mass notification system (e.g., Everbridge) which could deliver a generic message to persons needing to return to the clinic by voice, email, or text. Messages sent by a mass notification system would have to be Health Insurance Portability and Accountability Act (HIPAA) compliant. Contact information would be obtained from the person at the time of the vaccination along with authorization to contact the person. A list generated by NDIIS would be uploaded into an autodialer or texting system and a generic message would be attached. If HIPAA-sensitive information needs to be passed on to the recipient, the message could advise them to contact the NDDoH and after positive identification is made, that sensitive information would be communicated. PrepMod is also capable of sending reminder notices for second doses.

A more specific message would be better than what can be provided by mass notification systems, especially since it is assumed that a person's second dose must be exactly the same vaccine (e.g., type, manufacturer) as the first dose. In that case, just because sufficient time had elapsed for the person to receive the second dose would not mean the specific vaccine would be available in their community or at their usual care provider office. It might prove difficult for the patient to show up at the right place and time to get the correct vaccine, even if they knew what vaccine and adjuvant they needed. A reminder letter could be generated locally when the vaccine the person needed was available to them locally, but this would be expensive, and likely impractical during a pandemic when hundreds of thousands of persons are receiving two doses of vaccine. Furthermore, by the time the letter is received, the vaccine the person needed might already have been used. However, many provider offices have reminder recall systems set up by phone or email that could be used based on provision to the provider

of a list of people who would be eligible to receive the second dose of a vaccine about to be delivered to the provider.

One of the primary options for patients to know when and where vaccine is available is use of the [Vaccine Finder](#) website that will be set up by CDC. The NDDoH required its use, once vaccine is publicly available, in the enrollment agreement. Providers keeping this up-to-date will be the primary limitation, even though doing so will be a requirement of the agreement they sign to obtain vaccine.

Training

Multiple trainings will be needed before vaccination. These include:

- PrepMod—These will be conducted by the vendor. Not all users will by any means need to know all of the content of PrepMod, which is extensive. While use of PrepMod will not be required in all cases, for early priority vaccine, especially for ultra-cold vaccine, pre-registration will be required before the state will approve vaccine shipment. The state must determine that the vaccine quantity shipped is no more than can be reliably and quickly administered based on signed consents.
- NDIIS—NDIIS training tip sheets and videos are available on the Division of Immunizations NDIIS website and cover all aspects of the NDIIS. These trainings can be accessed by any NDIIS user at any time. Compliance with data entry timeliness and data completeness will be monitored. Additional vaccine will not be shipped unless all doses are accounted for. Problems with data will be addressed one on one with providers.
- Vaccination—Even experienced vaccinators should be updated on vaccination technique. Adverse outcomes from vaccination including shoulder injuries related to vaccine administration (SIRVA) and nerve injury, in addition to failure to get the vaccine into the muscle which is prone to occur with obese persons and may lead to vaccine failure. It is not expected that re-training of approved vaccinators will be required, but NDDoH Division of Immunization (Mass Immunization Group) will examine adverse event reporting for signs of vaccine administration injury and discuss with LPH occurrence of suspected cases whether in public or private clinics. It is not expected that vaccine administration areas will be more common with this vaccine, only that the consequences may include loss of public confidence in vaccine safety.

- Management of COVID-19 vaccine—Issues related to cold chain, storage, distribution, types of vaccine, adjuvant mixing and second dose administration will be needed for all vaccinators. Attendance can be taken at the time of webcasts and archived webcasts can require registration to allow tracking of use by those who missed available webcasts. It is not necessary that all persons in all clinics be trained in vaccine management, rather key personnel need to be trained and take responsibility for vaccine management. If key providers are not trained, they will be contacted and told to complete training in order to receive vaccine.
- Drawing up Vaccine—LPH will be encouraged to designate specific individuals who will be trained to draw up vaccine and adjuvant. These persons will not need to be vaccinators although vaccinators who rotate out of that role may fill this function. Monitoring for this function is the same as that for vaccine management.
- Second Dose Recall—This training would include the following: methods and resources for reaching patients for second dose, differences in intervals for second dose for different vaccines and prioritization of first or second dose from available supply of vaccine. This training is focused on necessity and methods for second dose recall. The success of this training will be determined by data showing how well first time vaccinees are brought back for second doses. This may vary substantially by area and vaccinator. Individual vaccinator who are falling behind on second dose administration will be contacted to determine reasons and seek solutions.
- VAERS Reporting – All providers need to know how and when to report clinically significant adverse events to VAERS. In monitoring progress of vaccine administration, anecdotal reports from LPH, other providers or the public can be followed up to ensure that VAERS reporting occurs for all moderate or severe adverse outcomes.
- Vaccine Finder—All vaccine providers need to know how to update Vaccine Finder and necessity of making frequent updates. Recipients of vaccine will need to have updated information in Vaccine Finder. If that information is missing, contacts to providers may be needed to remind providers of the necessity and encourage them to set up systems to ensure updating is automatic whenever new vaccine is received.
- Opportunities for vaccination and communication to refusals—Private health care providers in particular will need to recognize the need to encourage all patients eligible at the time of visit to be vaccinated. Physicians in particular can have a powerful impact on patient willingness to accept vaccine. It will not be possible to directly monitor this, but it will be indicated by data showing lower coverage of key target groups. Missed opportunities for vaccination are an old problem, but

recurring education and assistance from professional societies should help. Missed opportunities in private practices may be made up in part by public health mass clinics and targeted community vaccination efforts.

- Eligibility Criteria—Criteria for who is eligible will change over the course of the vaccination effort. Updating all providers on who they need to target will be part of periodic scheduled training. Documentation of reasons why each priority vaccination was given can be monitored both from data and anecdotal report investigation. Vaccination that is occurring substantially outside of established priority groups may threaten provider access to the vaccine.

The NDDoH Division of Immunization (Mass Immunization Group) will have web-based trainings available for providers prior to COVID-19 vaccine availability. NDIIS trainings are already available [online](#). Trainings will be promoted using applicable associations (LTCA, NDPhA, NDMA, NDHA, NDAAFP).

For required trainings there will be an online post-test that each facility will have to complete attesting that they have completed the required trainings that are outlined in the COVID-19 provider agreement. NDDoH Division of Immunization (Mass Immunization Group) staff will have access to the posttest and will track facilities who have completed the trainings. Those that do not complete the trainings will not be fully enrolled until they do.

Required COVID-19 Vaccine Enrollment presentations were offered on October 5th, 6th and 7th, 2020 via Microsoft Teams. The presentations were duplicated but had a live question and answer session. Providers only needed to attend one presentation but were welcome to view others. An archived version of the presentation was posted to the COVID-19 vaccine health care provider [website](#).

An additional required training was offered October 14th, 2020 during the standard Division of Immunizations Lunch and Learn time. This time slot is reserved monthly for immunization education and is well attended. The topic for the Lunch and Learn is SIRVA (should injury related to vaccine injury) and safe vaccination practices. After the conclusion of the SIRVA training an online survey will be posted to the COVID-19 vaccine health care provider [website](#) where facilities will attest to completing the training. Division of Immunization Staff (Mass Immunization Group) will track who completed the survey and stated that their facility had completed both required trainings.

Once more is known about the vaccine that will be first be sent to North Dakota healthcare facilities an additional required webinar will be completed via Microsoft Teams and archived. All training webinars have been catered to requirements outlined in the CDC's COVID-19 Vaccination Program Interim Playbook for Jurisdiction Operations.

COVID-19 Vaccine Safety Monitoring

Most vaccines are rarely associated with serious side effects, but any vaccine or drug given to enough people will cause serious adverse reactions in rare instances. The addition of adjuvant to the vaccine, even if very safe, will increase the risk of adverse reactions. The NDDoH currently recommends and will continue to recommend that providers directly report adverse events using an [on-line form](#) to VAERS. A link to VAERS is available upon entry into NDIIS. Direct VAERS reporting in NDIIS could be turned on; however, this is unlikely since the data cannot be electronically uploaded to VAERS. The NDDoH Division of Immunization (Mass Immunization Group) has designated five employees to have access to receive vaccine adverse events for North Dakotans from VAERS weekly.

It is likely that serious reactions will come to the attention of physicians since patients are likely to seek care. NDDoH will strongly encourage physicians and other providers to report all moderate and severe vaccine adverse reactions to VAERS. Healthcare providers will be educated about VAERS upon enrollment and routinely through the vaccination campaign. In addition to physicians, other recipients of vaccine reports will be those who provided the vaccination including public health (state and local) and pharmacies. These entities will be able to report directly to VAERS.

Any serious adverse reaction should be reported to the NDDoH Division of Immunization (Mass Immunization Group) immediately, which would notify CDC. If an investigation is warranted, CDC will direct it. This may include assignment to the state which will trigger data collection by the NDDoH Division of Immunization (Mass Immunization Group) that would be reported to the CDC VAERS team. (For very serious adverse reactions, especially one not previously reported, CDC may elect to send investigators into the field to try to confirm that the reaction was vaccine related and not preventable.)

NDDoH will receive weekly VAERS data from the federal government. This data will be compiled and reported on an internal dashboard. The NDDoH Division of Immunization

(Mass Immunization Group) will monitor SIRVA reports and provide education to involved healthcare providers. It is likely CDC will report de-identified vaccine adverse events data publicly.

The federal government has processes and methods for additional vaccine safety monitoring.

Security

Redacted

Mass Vaccination Clinics Local Plans

Mass vaccination can be a function of LPH, health institutions or ancillary providers. LPH, Tribes and health institutions across the state have plans designed for multiple locations to be used for dispensing/vaccinating. These plans are reviewed by the federal government and the state on a periodic basis to ensure that they meet the minimum requires for efficient and safe delivery of medical countermeasures.

Content of plans include the following:

- Service population description
- Selection of physical location and MOU for use
- Receipt and storage of countermeasure material
- Equipment
- Activation procedures
- Setup and orientation
- Security

- Safety
- Crowd and traffic control
- Incident command structure
- Staffing and calldown
- Job Action Sheets
- Policies (e.g., minors, hours, authority of safety officer, staff management)
- Volunteer recruitment and management
- Data and inventory management
- Communications: technical
- Communications: public
- Serving reservations
- Training
- Demobilization

COVID-19 response requires some modification of procedures for vaccine handling and social distancing. Local entities are testing methods that work for their jurisdictions in order to modify their plans.

The ND National Guard has limited medical capacity. All available medical capacity is currently being utilized for testing efforts. The ND National Guard may be able to assist with facilitating mass vaccination clinics (i.e., consent, security, flow). It is unknown at this time if assistance will be needed. Based on [vaccine administration capacity](#), it is likely that ND National Guard assistance will not be utilized.

Additionally, the NDDoH has hired a group of nurses to assist with COVID-19 testing sites and supplement care at LTC facilities. These nurses could be deployed to certain areas needing assistance with mass vaccination clinics.

Medical Waste

NDDoH has acquired the materials needed for safe containment of large amounts of medical waste. Individual public health units have their own local arrangements with providers of services for disposal or destruction of the waste material. During a pandemic it is possible that there will be some problems with managing large amounts of sharps generated by mass vaccination within the capacities of existing disposal companies. If necessary, LPH will store the waste in sealed containers in locked rooms until the capacity of disposal companies is sufficient to receive and destroy the excess medical waste material.

Infection Control and Social Distancing

Public health workers routinely administer vaccines and are trained in universal and bloodborne pathogen precautions. The current course of the pandemic does not suggest that a substantial public health worker shortage would be anticipated. If other vaccinators must be used (approved through executive order), ensuring that these employees are adequately trained in infection control will be the responsibility of the vaccinating entity.

Worker PPE protection would depend on the specific role of the worker, whether cold, warm or hot zone, as defined by clinic protocols. PPE would not need to be changed between patients except an outer layer of gloves used by the vaccine administrator. Doffing of PPE would result in a change of PPE or a careful process for PPE conservation would be followed depending on PPE availability at the time of vaccination.

A pandemic vaccine clinic may increase the risk of exposure to the population. Since the specific vaccine is unknown, the degree to which the vaccine will provide protection after a single dose is not known; however, receiving the vaccine will not provide immediate protection against disease, so any infection transmitted during a mass clinic would not be prevented by vaccination regardless of the efficacy of the vaccine.

There are several approaches that may be used to minimize the adverse social distancing:

- Exclusions of ill patients from clinics
- Separate clinic times for persons at heightened risk from COVID-19.
- Universal covering of the nose and mouth – Masking appears to be at least somewhat effective in limiting the droplet spread of a person who is sneezing or coughing, even if its effectiveness at preventing another person from inhaling the droplets is less clear. Although sufficient surgical masks may not be available to put on every person, clinics will need to require every person to have their nose and mouth covered with a mask or a cloth at all times.
- Education – Continuous education of those who enter the clinic regarding respiratory etiquette, avoiding touching surfaces, frequent hand washing, not touching the face with one's hands, and maintaining a distance between families of at least six feet will be needed even though the distancing requirement may slow the pace of the clinic and require a larger area for people to line up in an area not exposed to inclement weather, and larger places to complete forms.

- Alternative clinic models for vaccine administration are provided in the plan “Alternative Models for Mass Vaccination.” (See [Appendix G](#)). These depend on a variety of alternate protocols including vehicle queuing instead of person queuing, ushering of persons to and from vaccination areas to avoid contact, “no touch” vaccine areas, separation of vaccine areas from other use areas, screened vaccination stations, multiple building entrance and egress points. However, some vaccine models usable in moderate weather will have to be abandoned in cold weather. As flu vaccination gets underway, LPH are testing various models for safe vaccine clinics. The intensity of flu vaccine is likely to be lower and less risky than for COVID-19 vaccination but provides an opportunity to see which models work in different jurisdictions.

Clinic Format Selection

Vaccination at the LPH may be logistically easier than points of dispensing (POD)-based vaccination, when the number of doses to be administered is small. It will be the option of LPH to determine when the number of doses is so large that transition to POD-based vaccination would be more efficient. The details of POD-based operations are contained within local POD planning documents which are part of the Strategic National Stockpile (SNS) documentation at the local level. However, even with a small number of doses, LPH agencies may seek a method for vaccine delivery that uses space outside the LPH offices for vaccine administration.

Cold chain has to be maintained at the vaccination site. Sites distant from the LPH generally rely on portable refrigerators and vaccine managers to allocate vaccine to vaccine stations.

LPH does not at this point anticipate the need for state assistance teams to supplement clinic staff. Such assistance may be needed in reservation areas.

Safety

Dry Ice

Requirements for managing expected vaccines introduce a new safety concern—dry ice handling. Ultra-cold vaccine will be shipped from the manufacturer to multiple North Dakota destinations in certified shippers packed with dry ice. Both the dry ice in the package and the vaccine in the package will be cold enough to cause burns. Dry ice can be handled with leather or cloth gloves (e.g., oven mitts). Vaccine will need to be allowed to warm to at least -18 C (zero degrees F) before handling and allowed to warm

above freezing before being mixed for administration. It takes about 30 minutes for Vaccine A to thaw.

In addition to burns, carbon dioxide is mildly toxic at concentrations of around 0.5% because it disturbs pH balance in the body. As carbon dioxide concentration increases, it displaces oxygen which can lead to suffocation. This is most likely to occur when the containers are left in closed spaces subsequently entered by a person.

Because of its intense cold, it can break plastic or glass containers. If sealed in containers not intended to tolerate high pressures, it will cause rupture or explosion. It must be allowed to off-gas and, when disposed of, must be placed in a secure, well-ventilated space.

In anticipation of ultra-cold vaccine, the warehouse has special gloves available for handling dry ice. These gloves will be accessible to all providers in the state.

Local Safety Issues

Every vaccinating entity is strongly encouraged to have a safety officer present during each clinic as well as assisting incident command with safe design and procedures between clinics.

The safety issues associated with dry ice use will not be limited to the state. Local entities that handle packages with ultra-cold vaccine packaging will need to be educated in its safe use. Recipients of packages containing dry ice include clinics, hospitals, LTC, LPH and pharmacies.

Additional safety issues arise during local mass clinics depending on the circumstances.

- Some models for mass vaccination (e.g., drive-thru, drive-by –see [Appendix G](#)) require people to mix in the same space as vehicles. This includes vaccinators reaching vehicles and pedestrians reaching clinics. A safety officer locally will need to assist with clinic design and monitor during clinics to prevent injuries.
- Some models require working outdoors. These models are not suitable for very cold weather but may occur in circumstances cold enough to pose a threat to workers who are exposed to cold too long.
- Safe vaccination technique is not as much an issue for a safety officer as a professional issue for routine re-training, particularly in light of the frequency with which shoulder joint injuries and nerve injuries can occur. The other primary

vaccination risk, sharps management, is well known but should be under surveillance by a local safety officer.

- High exposure to the public poses an infection risk to both staff and vaccinees. Models for preventing infection during clinics are discussed above but ensuring that procedures are followed is an active duty of a local safety officer.

Electronic Consent System

As mentioned previously PrepMod allows for online registration, electronic consent, VIS review and vaccine administration entry during a mass vaccination clinic. PrepMod will be made available to any healthcare provider in ND that wants to use it for their mass vaccination clinics. Three separate consent questions will be asked of people preregistering or registering at the time of a vaccination clinic with PrepMod. They will be asked if they would like PrepMod to notify their provider, employer or school of their vaccination information. Vaccination information will only be shared with these parties if the person consents to it and the provider, school or employer registers with PrepMod to receive these notifications. The next consent field is consent to receive vaccination. The third and final is to receive text notifications for recall of second doses for COVID-19 vaccine. All of the consent language was reviewed and approved by the Attorney General's office and the Chief of Staff for the NDDoH.

The CDC is working with a private vendor to produce the Vaccine Administration Management System (VAMS). This product is currently under development and should be available for use by facilities during Phase 1 COVID-19 vaccine administration. Many of the capabilities are similar to PrepMod but lack a few functionalities that we gain with PrepMod. Also, North Dakota has been interested in purchasing an electronic registration system for facilities to use for all vaccinations including back to school and influenza. VAMS will only be used for COVID-19 vaccine administration. VAMS may be used by providers in North Dakota once it is available but most likely facilities will use their own systems or PrepMod.

Vaccination Mandates

It is not expected that the state will enact any mandates requiring vaccination for COVID-19. However, specific institutions or businesses may choose to mandate the vaccination of employees as a condition of employment. A requirement that health care workers and long-term care workers have mandated vaccination should be discussed by applicable institutions. Many institutions have mandates in place for influenza

vaccinations. It is unknown at this time what impact COVID-19 vaccination will have on the need for ongoing testing and use of PPE, but it is anticipated that vaccination may lessen the requirements for testing, visitor restrictions, and use of some PPE. Therefore, there may be incentives that will encourage COVID-19 vaccination. COVID-19 vaccines distributed under EUA cannot be mandated.

Regulatory Considerations for COVID-19 Vaccination

The provisions of an EUA requires that persons receiving the vaccine know that the vaccine has not completed full approval, but that it is being offered due to an emergency. Potential recipients would need to know the risks and benefits of receiving the vaccine or of refusing the vaccine, any alternatives that they have to the vaccine, and an assurance of their right to refuse the vaccine. In the event that NDDoH needed to administer vaccine under an EUA, the agency would expect to receive substantial information from Department of Health and Human Services detailing the following:

- Target recipients;
- FDA conditions for use;
- Information regarding risk and benefit of use;
- Additional information to be collected (in addition to contact information and information collected as part of the vaccination process for a non-EUA vaccine);
- Guidance regarding enhancements to adverse event reporting and case investigation that would need to be implemented as additional safeguards.

NDDoH would provide web-based training of all persons who would be administering vaccine under an EUA. Specific documents for EUA would be posted to the NDDoH website. They would also be printed for providers and included in PrepMod for online consent.

Appendix A: Known Ultra-Low Cold Chain Capacity in North Dakota

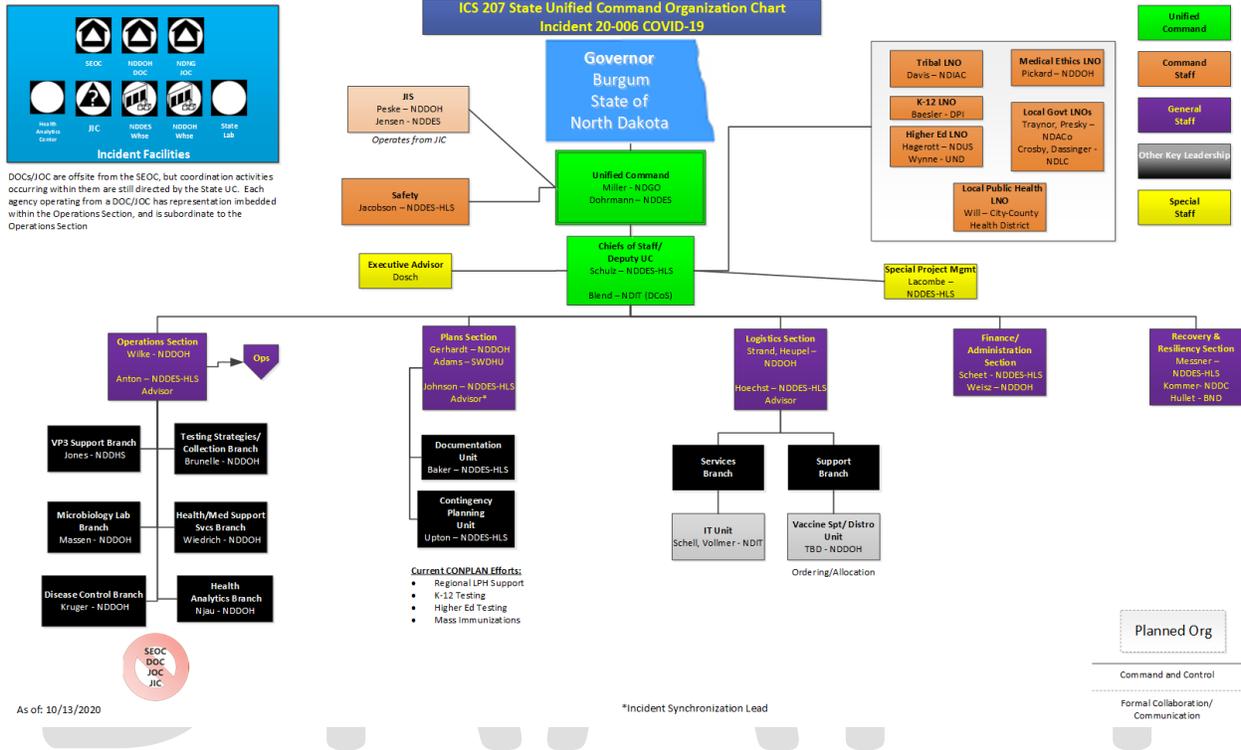
Note: Cold chain capacity being collected through the healthcare provider enrollment process. Additional ultra-low cold chain capacity may be available.

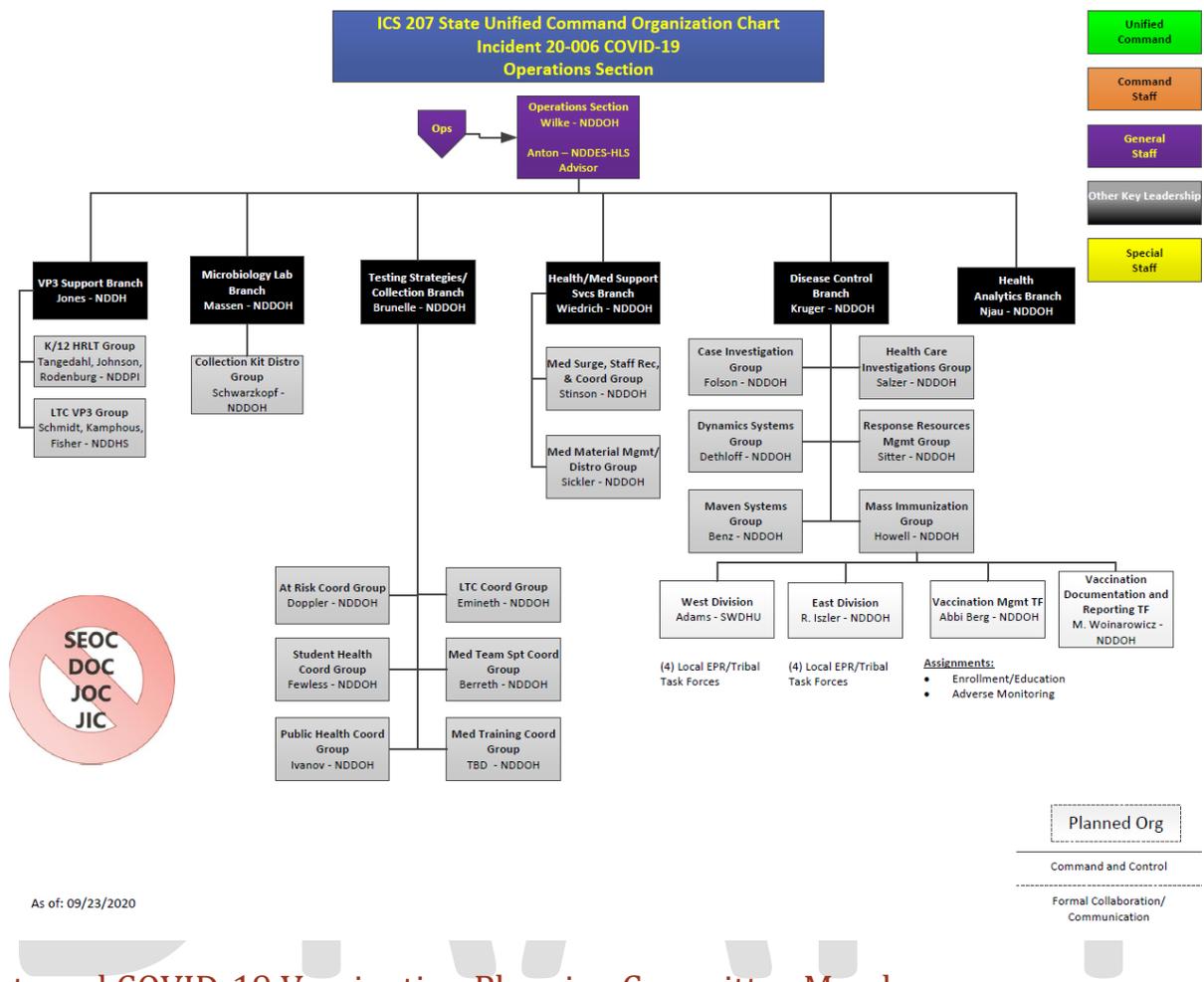
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Appendix B: Organizational Structure

Unified Command Organizational Charts





Internal COVID-19 Vaccination Planning Committee Members:

Molly Howell:

Molly Howell is currently the Immunization Director at the NDDoH. Molly has worked in the field of immunizations for the past 17 years. She led the vaccination response during the H1N1 influenza pandemic in 2009. Before working at the NDDoH, she worked as an intern in infectious disease surveillance at the Lincoln-Lancaster County Health Department in Lincoln, Nebraska.

Molly has a Bachelor of Science degree in biology from the University of Nebraska – Lincoln, and a Master of Public Health degree from the University of Massachusetts – Amherst. She has previously published immunization and infectious disease-related articles in *Public Health Reports*, *the American Journal of Preventive Medicine*, *Travel Medicine and Infectious Disease*, *Morbidity and Mortality Weekly Report*, and the *New*

England Journal of Medicine. Molly is currently an executive committee member of the Association of Immunization Managers and previously served as Chair of the organization. She was appointed to the National Vaccine Advisory Committee (NVAC) in January of 2020.

Dr. Stephen Pickard:

Dr. Stephen Pickard obtained his medical degree from the University of Louisville in 1982. He completed his internal medicine training at the University of Alabama Birmingham Hospitals and the University of Louisville Hospitals and is board certified in internal medicine. He joined the USPHS in 1985. He worked six years with the Indian Health Service, and after completing EIS (Class of 91), worked 24 years for CDC. He was assigned to North Dakota as a Career Epidemiology Field Officer (CEFO) in 2002, and retired from the USPHS in 2015 with the rank of Captain. In the Spring of 2020, the NDDoH asked for his assistance with the COVID-19 response and has since served the agency as an advisor and planning strategist.

Sherry Adams:

Sherry Adams is a Registered Sanitarian/Registered Environmental Health Specialist working at Southwestern District Health Unit, in Dickinson since 2004. She became the as Administrator/CEO for the health unit in 2009. She has worked in Emergency Preparedness and Response for sixteen years, is certified in Homeland Security. She is also certified by FEMA and the State of ND as an Incident Command instructor. She became a part of State IMAT (Incident Management Assistance team), as a Safety Officer, in 2009, and as an Incident Commander in 2012. Sherry has responded to numerous incidents including the Dickinson Tornado of 2009, H1N1 Pandemic flu of 2009, Flooding/Evacuation of 2009 and 2011, DAPL (Dakota Access Pipeline) in 2016/2017. During the H1N1 pandemic, Sherry was Incident Commander for all of the Mass Vaccination clinics throughout her 8-county region. In March of 2013, Sherry was part of a team of 5 that was sent to Ghana, Africa to teach Incident Command to their government. The team returned again in March of 2014, and April of 2015. The team returned to Togo, Africa in September 2015, to also start the training process, and returned both Togo, as well as Benin Africa in June of 2016. She returned to Benin in February of 2018, and Togo in February of 2019. Sherry became a certified Chaplain in 2013, and is also trained in Critical Incident Stress Management. Sherry was recently deployed to assist with Hurricane Harvey, and worked in the State Operation Center in September of 2017. Sherry was able to spend 3 weeks in Hawaii helping with both

volcano and Hurricane response in August of 2018. Sherry has worked as one of the Planning Chiefs for the NDDOH throughout the COVID-19 pandemic.

George Gerhardt:

George Gerhardt is the North Dakota State Strategic National Stockpile Coordinator and is also a Public Health Emergency Preparedness and Hospital Preparedness Program Representative in these roles he has been involved in reviewing and updating plans of many facilities and organizations throughout the state of ND. He was the on scene medical incident commander during the Dakota Access Pipeline protest and has extensive training and experience in the Incident Command System. He received and associates of applied Science Paramedic Technology from Bismarck State College and a Bachelor of Science in Business Management from the University of Mary in Bismarck ND. He has been a EMT Paramedic for the past 30 years and was a field Paramedic for 25 years during that time he was heavily involved in emergency preparedness and planning. He has also responded to several emergencies across the united states in support of the local jurisdictions which included hurricanes in Texas and Louisiana and flooding in ND.

Mary Woinarowicz:

Mary Woinarowicz is the NDIIS Manager and has been with the NDDoH Division of Immunizations managing the NDIIS for the past 9 years. She is a Subject Matter Expert in the IIS community, serves as co-chair for the American Immunization Registry Association (AIRA) Standards and Interoperability Steering Committee (SISC), and is a member of the AIRA Board of Directors. She also previously worked on the EHR team for a private healthcare provider in North Dakota.

Mary has a Master of Arts Degree in Sociology with a focus in Educational Foundations and Research from the University of North Dakota.

Abbi Berg:

Abbi Berg is the Vaccines for Children/ Quality Improvement Manager. She was heavily involved in planning for H1N1 vaccine and was in charge of allocating H1N1 vaccine during the pandemic in 2009. She also oversees the annual influenza vaccine prebook and allocation process.

Abbi has a Bachelor of Applied Science degree in Community Health Education from the University of Minnesota Duluth, and a Master of Public Health degree from the State University of New York at Buffalo.

Internal/External COVID-19 Vaccination Planning Committee

Name	Organization
Abbi Berg	ND Department of Health
Amy Anton	ND Department of Health
Amy Simon	Spirit Lake IHS
Andrea Polkinghorn	Sanford Health Systems
Angie Strand	ND Department of Health
Arlene Krulish	Spirit Lake IHS
Avis Little Eagle	Standing Rock
Barb Frydenlund	Rolette County Public Health
Brad Darr	ND Department of Transportation
Bradley Hawk	Indian Affairs
Brandon Hoechst	ND Department of Emergency Services
Brian Phillips	Thrifty White Pharmacy
Bridget Weidner	Director of Health Facilities
Brenda Vossler	ND Department of Emergency Services
Brook Kirkeide	Lake Region District Health EHP/Emergency Preparedness and Response
Bryan Delage	University of North Dakota
Callie Stein	ND National Guard
Carmen Martinez	ND Department of Health
Chantel Hillius-Kramlich	Mid Dakota Clinic
Courtney Koebele	North Dakota Medical Association
Crystalynn Kuntz	SC Emergency Preparedness and Response Region
Daphne Clark	NW Emergency Preparedness and Response Region
Darko Draganic	United Tribes Technical College
Dayle Knutson	Great Plains Area Indian Health Service
Dee Pritschet	ND Department of Health
Dirk Wilke	ND Department of Health
Dixie Omen	Spirit Lake Indian Health Services
Doug Murphy	SE Emergency Preparedness and Response Region
Dr. Amber Tincher	Standing Rock Sioux Tribe
Dr. Anita Martin	Elbowoods Memorial Health Center

Dr. John Hagan	North Dakota Department of Corrections
Dr. Paul Carson	North Dakota State University Center for Immunization Research
Dr. Stephen Pickard	ND Department of Health, Advisor
Dr. Terry Dwelle	Advisor
Duane Schell	ND Information Technology
Elizabeth Skoy	North Dakota State University
Eric Hieb	North Dakota Health Information Network
Eric Jensen	Public Information Officer
Faye Salzer	ND Department of Health
Frank Balak	Central Valley Health District Emergency Preparedness and Response
George Gerhardt	ND Department of Health
George Walker	IHS Standing Rock Sioux Safety and Infection Control Officer
Grace Doppler	ND Department of Health
J Faulks	Thrifty White Pharmacy
James Driving Hawk	Aberdeen area Indian Health Services
Jan Kamphius	ND Department of Human Services
Jana Gipp	Standing Rock Sioux Tribe
Jenny Galbraith	ND Department of Health
Jesse Bradley	ND Department of Health
Jessica Graves	ND Department of Human Services
Joe Vetter	ND Department of Health
Joe Wanner	SW Emergency Preparedness and Response Region
Jordan Laducer	ND Department of Health
Jose Estrada	NC Emergency Preparedness and Response Region
Juli Sickler	ND Department of Health
Kathy Laxdal	ND Department of Health
Katie Bentz	Developmental Disabilities
Katie Fitzsimmons	North Dakota University System
Kayla Briggs	North Dakota State University
Kimberly Iron Road	Standing Rock Sioux Tribe
Kim Mertz	ND Department of Health
Kris Vollmer	ND Information Technology
Kylie Hall	North Dakota State University Center for Immunization Research
Lauren Dybsand	North Dakota State University Center for Immunization Research

Lawrence Lee	Great Plains Area Indian Health Service
Lori Brierly	ND Department of Health
Lori Dumke	Community Health Association of the Dakotas
Lori Thomas	Community Health Association of the Dakotas
Lorraine Davis	ND Native American Development Center
Lorna Meidinger	ND National Guard
Lt Luke Gardiner	Bismarck Police Department
Lynde Monson	Spirit Lake Indian Health Services
Major Tom Iverson	North Dakota Highway Patrol
Mandi Peterson	University of North Dakota Center for Rural Health
Marcus Lee	NE Emergency Preparedness and Response Region
Mark Hardy	North Dakota Board of Pharmacy
Mary Hoffman	Community Health Association of the Dakotas
Mary Woinarowicz	ND Department of Health
Melissa Fetting	Minot State University
Melissa Reardon	North Dakota State University
Mike Benz	ND Department of Health
Mike Gill	Civil Air Patrol
Mike Kisse	ND Department of Transportation
Mike Schwab	Pharmacy Association
Miranda Baumgartner	ND Department of Health
Molly Howell	ND Department of Health
Nathan Davis	Turtle Mountain Band of Chippewa Indians
Nathan Leedahl	Sanford Health
Nick Thomas	Standing Rock Sioux Tribe
Nicole Brunelle	ND Department of Health
Nicole Peske	ND Department of Health
Nola Taken Alive	Standing Rock
Patrick Cote	Evangelical Lutheran Good Samaritan
Phil Peterschick	ND Department of Emergency Services
Rachel Goebel	ND Department of Health
Rebecca Baron	Mid Dakota Clinic
Rena Henderson	Rolette County Public Health
Red Fox Sanchez	MHA Nation
Richard Vetter	Essentia Health
Roseanne Schmidt	Department of Human Services
Russ Korzeniewski	ND Department of Health
Rusty Dahlin	ND Information Technology
Ruth Ivanov	ND Department of Health

Samantha Plemons	Grand Forks Air Force Base
Sara Decoteau	Sisseton Wahpeton Oyate
Sara Hanson	Essentia Health
Scot Mickelson	CHI - Primecare
Scott Davis	Indian Affairs Commission
Scott Satermo	Mandan, Hidatsa and Arikara Nation
Sean Johnson	ND Department of Emergency Services
Seth Fisher	ND Department of Human Services
Shannon Hansen	Altru Health
Shelly Peterson	North Dakota Long-Term Care Association
Shelly Ten Napel	Community Health Association of the Dakotas
Sherrie Meixner	ND Department of Health
Sherry Adams	Southwest District Health Unit
Shila Blend	ND Department of Health
Stephanie Jay	Turtle Mountain Band of Chippewa Indians
Theresa Fewless	ND Department of Health
Thomas Mah	New American/Foreign Born/Immigrant Advisory Board
Tim Blasl	North Dakota Hospital Association
Tim Wiedrich	ND Department of Health
Tom Malley	Minot Air Force Base
Tracy Charboneau	Spirit Lake Nation
Tracy Miller	ND Department of Health
Vanessa Raile	North Dakota Long-Term Care Association
Vern Dosch	ND Department of Emergency Services
Viola Lafontaine	Trenton Community Clinic

Advisory Committee on COVID-19 Vaccination Ethics

Steven Mitchell, MD is a neuroradiologist practicing at Sanford Medical Center in Fargo, ND. He is the co-chair of the ethics committee at Sanford in Fargo as well as co-chair of the Sanford Enterprise Ethics Committee. His training in ethics includes summer intensive courses at Harvard Medical School and Georgetown. He also earned a graduate certificate in health care ethics at University of Mary/National Catholic Bioethics Center. Earlier this year, he helped develop the Sanford ventilator allocation guidelines in response to the Covid-19 pandemic. He subsequently formed triage teams for ventilator allocation as well as the Moral Distress Team and coordinated an expanded Palliative Care team to work with the Covid-19 health care team.

Dirk Wilke JD, MBA is the Chief Operating Officer for the North Dakota Department of Health and is currently serving as the Acting State Health Officer. He obtained his law degree from the University of North Dakota School of Law and his MBA from the University of Mary.

Caleb Pickard completed his bachelor's degree at the University of Nebraska - Lincoln and his PhD in Philosophy at the University of Colorado, Boulder. He specializes in applied ethics with a focus on contemporary issues in bioethics, business ethics, consumption ethics, and the ethics of emerging technologies. He is currently an instructor at the University of Colorado, Boulder teaching classes remotely from St. Louis, MO.

Seth Fisher serves as a State Regional Coordinator with the North Dakota Department of Human Services and works on the governor's VP3 (Vulnerable Patient Protection Plan) taskforce. Prior to this COVID response, he was most recently the Director of Nursing Services at Knife River Care Center in Beulah. He has served in various roles within the long-term care community over the past 12 years, including: Director of Nursing, MDS Coordinator, and RN-Charge Nurse. He also provides consultation services and subject matter expertise for various long-term care facilities across the state. Seth received his Bachelor of Arts in Nursing from Concordia College in Moorhead, MN and is currently pursuing his Doctorate of Nursing Practice through the University of Mary in Bismarck which he will obtain this April.

Barbara Frydenlund, RN is Administrator and Director of Nursing for Rolette County Public Health. This health agency includes the entirety of the Turtle Mountain Indian Reservation.

Facilitator (Non-Voting Member)

Stephen Pickard MD obtained his medical degree from the University of Louisville in 1982. He completed his internal medicine training at the University of Alabama Birmingham Hospitals and the University of Louisville Hospitals and is board certified in internal medicine. He joined the USPHS in 1985. He worked six years with the Indian Health Service, and after completing EIS (Class of 91), worked 24 years for CDC. He was assigned to North Dakota as a Career Epidemiology Field Officer (CEFO) in 2002, and retired from the USPHS in 2015 with the rank of Captain. In the Spring of 2020, the NDDoH asked for his assistance with the COVID-19 response and has since served the agency as an advisor and planning strategist.

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Appendix C: Anticipated COVID-19 Vaccine Availability in ND based on CDC Assumptions

Month	Assumed doses for ND (0.23% of U.S.)	Total US doses	Scenario 1 Vaccine A
November	23157	10,000,000	
	46313	20,000,000	
December	46313	20,000,000	
	69470	30,000,000	
Month	Assumed doses for ND	Total US doses	Scenario 2 Vaccine B
November	23157	10,000,000	
December	34735	15,000,000	
Vaccine A			
Month	Assumed doses for ND	Total US doses	Scenario 3 Vaccine A and B
November	23157	10,000,000	
	46313	20,000,000	
December	46313	20,000,000	
	69470	30,000,000	
Vaccine B			
Month	Assumed doses for ND	Total US doses	
November	23157	10,000,000	
December	34735	15,000,000	
Total			
Month	Assumed doses for ND		
November	46,313		
	69,470		
December	81,048		
	104,205		

Appendix D: North Dakota Tribal Allocation Preference and Estimates

Affiliation	Tribe	Facility Name	Population	Distribution Method
IHS	Standing Rock	Cannon Ball Health Station	950	State
IHS	Turtle Mountain	Dunseith Health Location	0	Pending
IHS	Standing Rock	Fort Yates Hospital	8500	State
IHS	Three Affiliated	Mandaree Health Station	888	State
IHS	Turtle Mountain	Quentin N Burdick Memorial Health Facility	14,550	Pending
IHS	Spirit Lake	Spirit Lake Health Center	4560	State
IHS	Three Affiliated	Twin Buttes Health Station	400	State
IHS	Three Affiliated	White Shield Health Station	730	State
NULL	Sisseton-Wahpeton	Wahpeton Health Center	0	Pending
Tribal	Three Affiliated	Elbowoods Memorial Health Center	2122	State
Tribal	Three Affiliated	Parshall Clinic	753	State
Tribal	Turtle Mountain	Trenton Community Clinic	4000	Pending
Tribal	Three Affiliated	Sage Coulee	1500	State

Appendix E: NDIIS COVID-19 Vaccine Response Plan



NDIIS COVID
Vaccine Response PI

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Appendix F: Proposed Metrics for COVID Vaccine Power BI Dashboards

Public Dashboard Metrics

- State-wide doses administered
 - A trend line showing the total number of doses of COVID vaccine administered by all providers in North Dakota per day.
 - A bar graph showing the cumulative total number of doses of COVID vaccine administered by all providers in North Dakota compared to number of doses allocated to North Dakota.
- County-level doses administered
 - A map showing cumulative weekly total doses administered by county (based on patient county of residence).
- State-wide coverage rates for dose 1 and dose 2
 - A trend line showing overall weekly coverage rates by week.
 - A trend line showing weekly coverage rates by age group.
 - Age groups will be broken out as:
 - 19-29 years
 - 30-39 years
 - 40-49 years
 - 50-59 years
 - 60-69 years
 - 70-79 years
 - 80 years or age and older
 - A bar graph showing weekly coverage rates by priority group (as identified by CDC/ACIP).
 - Graph will only show the most current weekly rates.
 - A bar graph showing weekly coverage rates by race and ethnicity.
 - Graph will only show the most current weekly rates.
 - A bar graph showing weekly coverage rates for healthcare workers.
 - Graph will only show the most current weekly rates.
 - A bar graph showing weekly coverage rates for long-term care residents and staff.
 - Graph will only show the most current weekly rates.
- County-level coverage rates for dose 1 and dose 2
 - A map showing overall with coverage rates (based on patient county of residence).

- State-wide coverage rates for people who previously tested positive
 - This metric will only be included if this is part of the ACIP recommendation for COVID vaccine.
- State-wide exemption rates
 - A bar graph showing overall personal belief exemptions for COVID vaccine.
 - Data for exemptions may be limited, especially in early phases of vaccination. This metric may not be included in the public dashboard until vaccine is widely available for the general public. The Division of Immunizations may track this as a non-public metric during the first phases of vaccination.

Timeline

- The public dashboard will be updated once per week.
- Weekly data will consider data from Sunday through Saturday.
- Data for the previous completed week will be extracted from the NDIIS datamart on Mondays by noon and will be sent to the NDITD data lake.
- The public dashboard will be updated after the NDIIS data has been submitted to the NDITD data lake and the updates will be published to the COVID-19 Vaccine website by 9am Tuesdays.

Non-Public Metrics

- Daily state-wide and county-level doses administered.
- Provider-level doses administered
 - Cumulative weekly totals by provider
 - Compare to number of allocated doses
- Provider-level vaccine wastage
 - Cumulative weekly total number of doses wasted by provider
 - Compare to number of allocated doses
- Provider-level coverage rates
- Vaccination rates on reservations
 - based on patient zip code
- Doses administered to out-of-state residents
 - State-wide totals by week
 - Show percent of weekly doses administered to ND vs. non-ND residents
- Vaccine adverse events reported after COVID-19 vaccination
 - Based on data North Dakota will receive from VAERS weekly.
- Adult opt-outs in NDIIS
 - Trend line showing increase by week.

- Timeliness of data entry
 - A trend line showing the time between date of COVID vaccine administration and date of entry into NDIIS by week.

Timeline

- NDIIS staff will run the daily state-wide and county-level doses administered Monday through Friday and will include all doses administered the previous day. Data for Saturdays and Sundays will be included in Monday's analysis.
 - This data will be provided to the Director of the Division of Immunizations by 9am.
- Data for the rest of the non-public metrics will be updated once per week.
- Weekly data will consider data from Sunday through Saturday.
- Data for the previous completed week will be extracted from the NDIIS datamart by noon on Tuesdays and will be sent to the NDITD data lake or analyzed by NDIIS staff.
- The non-public dashboard metrics will be updated by 9am Wednesdays.

Appendix G: Alternative Models for Mass Vaccination



Alternative Models
for Mass Vaccination

DRAFT