

INTERIM DRAFT

NORTH DAKOTA COVID-19 VACCINATION PLAN

Updated December 11, 2020

Version 2.0



Significant changes from previous version:

- Information regarding ancillary supplies provided by federal government
- Additional tabletop exercises and other exercises
- Updated information regarding the data use agreement with CDC
- Tribal sovereignty to determine priority groups
- Redistribution guidance
- Vaccine finder inventory reporting
- Revised phases for vaccination based on ACIP meetings
- Long term care federal pharmacy partnership program
- Updated tribal preferences for federal or state allocations
- Federal pharmacies for Phase 2
- Updated ultra-cold freezer capacity
- Revised assumptions for vaccines A and B
- Federal government hold of second doses

Contents

Significant changes from previous version:.....	2
Acronyms	7
Introduction	8
Lessons Learned from H1N1	9
Response Goals for Pandemic Vaccination.....	11
COVID-19 Vaccination Planning Assumptions	12
Logistical Assumptions	13
Organizational Structure and Partner Involvement	14
Unified Command Planning Team.....	15
Internal COVID-19 Vaccination Planning Team.....	15
Internal/External COVID-19 Vaccination Planning Committee	15
CDC/HHS Microplanning	15
Tabletop Exercises	16
Current Unknowns and Contingency Planning	16
How persons who have tested positive for COVID-19 will be prioritized.....	16
Type of vaccine that will be available and cold chain requirements of vaccines.....	16
Potential adverse effects of a vaccine.	17
Vaccine amounts.....	17
Vaccine Timing.....	17
Use of adjuvant.....	18
Multiple FDA approved products with different specifications.	18
Packaging.....	18
Current Gaps	19
Provider Recruitment and Enrollment.....	20
Potential Providers	23
Vaccine Administration Capacity	24

Vaccination of Out-of-State Residents.....	25
Vaccine Prioritization and Critical Populations.....	26
Critical infrastructure workforce.....	26
People at increased risk for severe COVID-19 illness.....	26
People at increased risk of acquiring or transmitting COVID-19.....	26
People with limited access to routine vaccination services	27
Estimates of Priority Groups.....	27
Vaccination of Special and Dependent Populations.....	30
Homebound.....	30
Long Term Cares	30
Custodial institutions and special populations	33
American Indians.....	34
New Americans/Foreign Born/Immigrant Populations.....	35
Priority Vaccination of Infrastructure	36
Advisory Committee on COVID-19 Vaccination Ethics.....	37
Vaccine Allocation.....	37
Vaccine Ordering and Processing	39
Physical Vaccine Management and Cold Chain.....	39
Management of Priority Vaccine Unstable at Zero Degrees or Higher	39
Vaccine A:	39
Vaccine B:	40
Models for Distribution of Ultra-Cold Vaccine (Vaccine A)	40
Three Phase Distribution	41
Scenarios for Vaccine Distribution.....	44
Scenario 1 Background.....	45
Vaccine A: Ultra-cold with minimum quantity of 975 doses only.....	45
Phase 2 General Population	48
PHASE 3 Distribution with Reduced Uptake	48

Scenario 2	48
Vaccine B: Frozen vaccine only with minimum quantity of 100 doses.....	48
Scenario 3	49
Assumptions:	49
Distribution:.....	50
State Vaccine Storage.....	50
Local Vaccine Storage	52
State Warehouse Vaccine Processing	53
Vaccine Administration Fees	55
Vaccine Program Communication	56
Public.....	56
Healthcare Providers	58
Vaccine Hesitancy.....	59
Vaccine Administration Documentation and Reporting.....	59
Vaccine Transfers and Redistribution	61
Wasted and Recalled Vaccine.....	62
Vaccination Program Monitoring.....	63
IIS Data	63
CDC Data Use Agreement	63
SAS code for CDC data submission.....	63
Datamart	63
Public Data Dashboard	64
Non-Public Metrics.....	64
Gaps.....	64
Provider Enrollment Monitoring	65
Other Monitoring	65
Vaccination Second-Dose Reminders.....	66
Training	67

COVID-19 Vaccine Safety Monitoring	70
VAERS.....	70
v-safe.....	71
Security	72
Mass Vaccination Clinics Local Plans	73
Medical Waste	74
Infection Control and Social Distancing	74
Clinic Format Selection	75
Safety	76
Dry Ice	76
Local Safety Issues	76
Electronic Consent System	77
Vaccination Mandates.....	78
Regulatory Considerations for COVID-19 Vaccination.....	78
Appendix A: Known Ultra-Low Cold Chain Capacity in North Dakota	80
Appendix B: Organizational Structure	81
Unified Command Organizational Charts	81
Internal COVID-19 Vaccination Planning Committee Members:.....	82
Internal/External COVID-19 Vaccination Planning Committee	85
Advisory Committee on COVID-19 Vaccination Ethics	89
Appendix C: Anticipated COVID-19 Vaccine Availability in ND based on CDC Assumptions	91
Appendix D: North Dakota Tribal Allocation Preference and Estimates	92
Appendix E: NDIIS COVID-19 Vaccine Response Plan.....	93
Appendix F: Proposed Metrics for COVID Vaccine Power BI Dashboards	94
Public Dashboard Metrics.....	94
Non-Public Metrics.....	95
Appendix G: Alternative Models for Mass Vaccination	97

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 timely 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 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 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 vaccine at various temperatures. Some private entities have limited capacity for storing vaccine at ultra-cold temperatures. 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 vaccination methods (i.e., drive thru) 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 vaccination..

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
- 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 (975 doses) may complicate with reaching some high priority vaccines (e.g., rural healthcare workers), particularly with Vaccine A (Ultra-Cold).
- Ancillary supplies will be received along with the vaccine. Ancillary supplies will be packaged in kits and will be automatically ordered in amounts to match vaccine orders in VTrckS. For centrally distributed vaccines, each kit will contain supplies to administer 100 doses of vaccine. For vaccines that are shipped directly from the manufacturer, a combined kit will be included. Ancillary supply kits will not include sharps containers, gloves, and bandages. Additional personal protective equipment (PPE) may be needed depending on vaccination provider site needs.
- 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

A tabletop exercise for hospitals to assess their ability to vaccinate healthcare workers was distributed on November 6, 2020. A test of the NDDoH process for ordering vaccine and using the warehouse for distribution was conducted the week of November 2, 2020 using state-purchased influenza vaccine. The week of November 9, 2020, allocating COVID-19 vaccine for healthcare workers was exercised using various vaccine availability planning assumptions and Tiberius. North Dakota was one of ten states who participated in a mock end-to-end exercise for vaccine A.

Additional 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 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 975 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 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 has procured ultra-low cold chain capacity and transport freezers and thermometers. Additionally, the warehouse is procuring dry ice production capability. The items procured are being 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. North Dakota is unable to share identifiable data elements with CDC, so the data use agreement has been changed and accepted by both parties. Additionally, it is still unproven how federal systems, other state IIS will connect to the NDIIS. 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 has received minimal funding 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 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 (caring for patients, contact tracing, testing). It is estimated that the state will need an additional \$6.98 million for the COVID-19 vaccine response.
- This software is critical to obtaining online consent and managing satellite vaccination clinics. PrepMod will need to be tested using influenza vaccination prior

to being utilized for COVID-19 vaccine. PrepMod will need to be electronically connected to electronic medical records.

- 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.

CDC and the NDDoH will allow limited redistribution of COVID-19 vaccine within organizations. For instance, a health system may choose to receive vaccine and one central location and then redistribute it to clinic sites within the health system. The CDC redistribution agreement was 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. At this time the CDC's redistribution agreement will need to be signed by those facilities and additional education on reporting of doses, transferring doses in NDIIS 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. A 30-mile radius will be 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. COVID-19 vaccination providers will be required to report COVID-19 vaccine inventory daily using VaccineFinder. North Dakota intends to upload NDHS inventory into VaccineFinder on behalf of providers. All inventory should be managed in accordance with storage and handling requirements specific to each vaccine.

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.

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

- Providers must submit data to NDHS 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.

The CDC has authorized tribes to be able to determine their own priorities for COVID-19 vaccination. Language states the following:

"However, Tribal Health Program may deviate from CDC/ACIP prioritization groups to immunize under other priorities that meet the spirit of the CDC/ACIP designated priorities within allocations of COVID-19 Vaccine received. Records of any such prioritization decisions shall be maintained for at least three years, and be provided, upon request, to CDC, IHS, and the relevant jurisdictions."

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 \(HHS\)](#) authorized pharmacists, pharmacy interns and pharmacy techs to vaccinate against COVID-19 for individuals 3 and older. 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)
- Satellite 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 NDIIS, 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).

Upon enrollment, provider level throughput will be determined using reported influenza vaccination throughput for the previous year. Additionally, local public health has throughput estimates for points of dispensing. These throughputs are based on head of household dispensing model but flu dispense sites that have utilized the POD model shows that one person per lane per minute can be vaccinated if there is no information collected for billing or if no information is collected at the time of the vaccination. If billing or other information is collected at the time of the vaccination the throughput would be 10 minutes per person per lane. Throughput by provider will be dependent on the type of clinic (i.e., satellite, drive-thru), staffing and demand for vaccination. An average of 10 minutes per dose administered will be used for local planning purposes.

To accurately estimate possible throughput of the COVID-19 vaccine, data was pulled from the NDIIS 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 provider and by county.

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. This information will be used to adjust allocations accordingly. 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. Estimates by healthcare facility were also collected specifically from tribal health and IHS.

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 NDIIS data to identify priority groups and estimate vaccine coverage.

The federal government has provided 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 satellite 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 satellite 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.

Homebound individuals will likely be recommended for vaccination in phase IB.

Long Term Cares

LTC includes skilled nursing, basic and assisted living facilities. Long term care staff and residents will likely be prioritized for vaccination during phase 1A.

LTC staff will either be invited to satellite 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 satellite vaccination clinic off site. LTC residents will be vaccinated by local public health, by the LTC facility, or by a pharmacy.

Pharmacy Partnership for Long-term Care (LTC) Program:

North Dakota plans to participate in the pharmacy partnership for LTC Program coordinated by CDC. CDC's Pharmacy Partnership for LTC Program for COVID-19 Vaccine will provide on-site vaccine clinics for residents of long-term care facilities (LTCFs) and any LTCF staff. National pharmacies chosen for this program were CVS and Walgreens. Because North Dakota has limited CVS and Walgreens, the federal government also contracted with Thrifty White. The Pharmacy Partnership for Long-term Care Program provides end-to-end management of the COVID-19 vaccination process, including close coordination with jurisdictions, cold chain management, on-site vaccinations, and fulfillment of reporting requirements. The program will facilitate safe and effective vaccination of this prioritized patient population, while reducing burden on facilities and jurisdictional health departments. This program is free of charge to facilities. The pharmacy will:

- Schedule and coordinate on-site clinic date(s) directly with each facility. Three visits over approximately two months are likely to be needed to administer both doses of vaccine and vaccinate any new residents and staff.
- Order vaccines and associated supplies (e.g., syringes, needles, personal protective equipment).
- Ensure cold chain management for vaccine.
- Provide on-site administration of vaccine.
- Report required vaccination data (approximately 20 data fields) to the local, state/territorial, and federal jurisdictions within 24 hours of administering each dose.
- Adhere to all applicable CMS requirements for COVID-19 testing for LTCF staff.

If interested in participating, each facility must sign up and indicate their preferred partner from the available pharmacies.

- Skilled nursing facilities (SNF), basic care, and assisted living facilities will indicate which pharmacy partner (one of two large retail pharmacies or existing LTC pharmacy) their facility prefers to have on-site (or opt out of the services) between October 19 – November 6.
 - SNFs will make their selection through NHSN beginning October 19.
 - An "alert" will be incorporated into the NHSN LTCF COVID-19 module to guide users to the form.
- ALFs will make their selection via online REDCap sign-up form.
- The online sign-up information will be distributed through ALF and SNF partner communication channels (email, social media, web).

- After November 6, 2020, no changes can be made via the online forms, and the facility will have to coordinate directly with the selected pharmacy provider to make any changes in requested vaccination supply and services.
- Indicating interest in participating is non-binding and facilities may change their selection (opt-out) if needed.

CDC will communicate preferences to the pharmacy partners and will attempt to honor facility preferences but may reassign facilities depending on vaccine availability and distribution considerations, and to minimize vaccine wastage. CDC expects the Pharmacy Partnership for Long-term Care Program services to continue on-site at participating facilities for approximately two months. After the initial phase of vaccinations, the facility can choose to continue working with the pharmacy that provided its initial on-site clinics or can choose to work with a pharmacy provider of its choice.

LTCs may need to receive vaccine directly or work with an independent pharmacy, private healthcare provider or LPH for vaccination. 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. LTCs would need freezers in order to store COVID-19 vaccine on-hand for subsequent vaccination. 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.

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. Adult group homes are considered long term cares and included in phase 1A. Corrections and homeless may be included in phase 1B or in phase 2. Group home healthcare workers or healthcare workers who work in corrections could be included in phase 1A with other healthcare workers.

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 coordinating 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. The Tribes will have populations that fall into priority groups for phases 1A and 1B. Since the federal government has yet to determine priority groups, it has not yet been determined if Tribes as a group will be prioritized for COVID-19 vaccine.

All reservations have worked on vaccination clinics and have successfully participated in 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 tribal health/IHS will provide vaccination as part of clinical services; however, not all reservation-based American Indians choose tribal health/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. North Dakota does not have urban tribal health facilities. 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 or 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. Since the federal government has yet to determine priority groups, it has not yet been determined if NFI as a group will be prioritized for COVID-19 vaccine.

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

Current planning assumptions assume critical infrastructure could be recommended for vaccination in phase 1B. Health care workers are phase 1A.

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) should retain documentation 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. Tiered priorities by phase will be posted on the NDDoH COVID-19 vaccine [website](#).

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. Additionally, North Dakota will use excel to allocate vaccine equitably using formulas.

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 975 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 is being discussed by the [Advisory Committee on COVID-19 Vaccination Ethics](#).

The NDDoH does not plan to release locations of where vaccine is allocated to until vaccine is publicly available. During phase 1A, when vaccine is only available for healthcare workers and LTC residents, allocations by facility will not be publicly available. This is to ensure security of vaccine and because the public will not have access to the vaccine. Starting in phase 1B, vaccine availability will be publicly available on [vaccinefinder.org](#). COVID-19 vaccine doses allocated to the state will be publicly available on the NDDoH COVID-19 vaccine website.

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 -80 DEGREES C)

- Minimum Quantity: 975 doses
- Doses per Vial: 5
- Time Allowed in Refrigerator: 5 days (120 hours)
- Can be stored in shipping container if dry ice replenished

Vaccine B:

- Frozen vaccine (-15 DEGREES C to -25 DEGREES C)
- Minimum Quantity: 100 doses if direct shipment to user
- Doses per Vial: 10
- Time Allowed in Refrigerator: 30 days

Current storage requirements for both vaccines make it difficult for some 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.

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 facilities who have ultra-cold freezers and can be stored for up to six months.
2. 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.
3. A container of ultra-cold vaccine that arrived in a target area would be opened to supply each clinic (satellite 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.
4. 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..

5. 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. Redistribution also refers to a limited number of health systems and district health units who have been approved to move vaccine within their organizations. 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 1A, large, urban areas will hold satellite clinics for outreach to eligible groups (e.g., healthcare workers, LTC workers, EMS) in addition to supplying vaccine to health systems and long-term care facilities. Redistribution or transfer may not be needed for Vaccine B, as it will be shipped in smaller quantities to providers (minimum of 100 doses). Vaccine A will be redistributed or transferred to smaller clinics that can be held proximal to high risk populations (e.g., rural health care workers). Some pharmacies may assist with vaccinating LTCs. This information will be captured upon enrollment. LTC residents will likely be recommended for vaccination during this phase. LTC residents will be vaccinated either by a CDC-contracted pharmacy, independent pharmacy, local public health, private health care provider, or administer vaccine on their own. The Division of Immunizations (Mass Immunization Group) will pair each LTC up with a vaccinator.

During Phase 1B, vaccination will be expanded to other essential workers. People at high risk and those 65 and older will be vaccinated during phase 1C. Additional satellite clinics will occur for eligible populations. Vaccine will also be allocated to providers who are responsible for vaccinating these populations.

Other congregate settings (i.e., corrections, shelters) will likely be vaccinated during phase 1C. 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.

It may not be possible to widely engage the private clinic system during Phase 1 unless vaccine B is available or if vaccine A 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., White Shield, ND population 336). Reaching small populations without redistribution may not be possible.

North Dakota would rely heavily on PrepMod to pre-register vaccines 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 vaccines 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 will be available for the general population. Continued vaccination of phase 1 priority groups will also need to continue. 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. Satellite 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 satellite clinics (e.g., targeted outreach to schools, colleges and workplaces in addition to homebound and “hard to reach” populations).

In addition, people that have not yet had their second dose will need to be targeted for reminder/recall. 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.

North Dakota plans to participate in the federal direct allocation to pharmacy partner strategy coordinated by CDC. The vast majority of pharmacies in North Dakota are participating in this program. Vaccine will be allocated and distributed directly to select pharmacy partners from the federal government. Direct allocation opportunities will be provided to retail chain pharmacies and networks of independent and community pharmacies¹ (those with a minimum of 200 stores). All partners must sign a pharmacy provider agreement with the federal government. Once the list of federal partners has been finalized, CDC will share the list with jurisdictions.

On a daily basis, pharmacy partners must report to CDC, the number of doses of COVID-19 vaccine a) ordered by store location; b) supply on hand in each store reported through VaccineFinder, and c) number of doses of vaccine administered to individuals in each state, locality, and territory. Pharmacy providers will be required to report CDC-defined data elements related to vaccine administration daily (i.e., every 24 hours). CDC will provide information on these data elements and methods to report if stores are not

¹Pharmacy services administrative organizations, or PSAOs

able to directly provide data to jurisdiction IISs. All jurisdictions participating in this program will have visibility on number of doses distributed to and administered by each partner store. Jurisdictions will be given contact information for each partner participating in this program if they have any questions or concerns related to distribution of vaccine to stores in their jurisdiction.

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 satellite vaccination clinics have become low yield, public health would shift to usual vaccination activities. NDHS would be able to provide county level estimates for vaccination rates. 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 continue to be placed on completing vaccination of those who have not yet received their second dose.

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 975 doses only

Priority populations:

PHASE 1A:

Healthcare workers and LTC residents

Phase 1A tiers are posted on the NDDoH COVID-19 vaccine [website](#).

PHASE 1B: (PLANNING, NOT YET VOTED ON BY ACIP)

Essential workers (i.e., police, fire, teachers)

PHASE 1C: (PLANNING, NOT YET VOTED ON BY ACIP)

People 65 and older and those at high risk (i.e., underlying health conditions, living in congregate settings)

PHASE 1A Healthcare workers and Long Term Cares

TIER 1A: REFERRAL HOSPITALS

Most referral hospitals have ultra-cold freezers. Vaccine would be shipped directly from the manufacturer to each of the four cities with referral hospitals. If a hospital can accept 975 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 state warehouse and packaged into smaller quantities and delivered to the facilities.

TIER 1A: CRITICAL ACCESS HOSPITALS AND COMMUNITY HEALTHCARE WORKERS

Most of these facilities do not have ultra-cold freezer storage. Vaccine would continue to be shipped directly to facilities who are receiving the minimum shipping quantities. The state warehouse would breakdown shipments for those receiving less than the minimum federal shipments.

Option A: Hospitals and local public health are allocated a number of doses according to number of consents/registrants in priority group and doses are used within 5 days (refrigerator stability). This option is more convenient for HCWs 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 shipping container and removing some of the vaccine. Dry ice must be

replenished within 24 hours of receipt, then every 5 days after that for a total of three times. On day 15, vaccine must be moved to the refrigerator for a maximum of 120 hours (5 days). 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 satellite 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.)

TIER 1B: ADDITIONAL HEALTHCARE WORKERS AND LTCs

Vaccination of HCWs would continue similar to Tier 1A. Allocations would be equitably distributed throughout the state based on number of HCWs per facility/county. Facilities allocated the minimum federal shipping quantities, would receive vaccine directly. Others would receive vaccine from the state warehouse. LTCs would be allocated doses for staff and residents. In order to start the [federal pharmacy partnership program](#) for LTC, the state needs at least 50% of doses that would be needed for staff and residents. LTCs not participating in this program, or their vaccinating designee (independent pharmacy, LPH), will be equitably allocated vaccine at the same time as the LTCs participating in the federal program.

Option A (Redistribution method): Vaccine is repackaged into certified shippers with dry ice or into certified, ultra-cold freezers at the warehouse. A shipper with the allocation for each recipient location is prepared. Upon local arrival, recipient health care institutions must have a representative to receive their allocation and use it during the viable period. 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 satellite clinics and health care institutions. Representatives of final recipients would pick up the vaccine, refrigerate and use within five days.

Option C (Federal Pharmacy Partnership Program): Many LTCs have opted-in this program. The NDDoH will allocate vaccine to this program for vaccination of LTC staff and residents. This program will only vaccinate in LTCs up to three times. Additional planning is needed to ensure continued vaccination of new staff and residents.

TIERS 2, 3, 4, AND 5:

Continued vaccination of healthcare workers similar to above. As uptake slows, providers should move on to Phase 1B to avoid wastage of vaccine.

Phase 1B: Essential Workers

The ACIP has not yet voted on phases beyond 1A. The following is for planning purposes only and is subject to change. In this scenario, Phase 1B is a combination of continued Phase 1A outreach and public vaccination. Vaccine will be equitably distributed throughout the state. Essential worker estimates have been identified by county and will be divided amongst applicable providers in the county. Providers who are allocated the minimum shipping quantity from the federal government will receive vaccine directly. Others will receive redistributed vaccine from the state warehouse. Vaccination will occur at workplaces by pharmacies or local public health, at satellite vaccination clinics, or through private healthcare providers.

Phase 1C: 65 and older and others at high risk

The ACIP has not yet voted on phases beyond 1A. The following is for planning purposes only and is subject to change. In this scenario, phase 1C is a combination of previous phases plus people 65 and older and others at high risk (i.e., underlying health conditions, living in congregate settings). Vaccine will be equitably distributed throughout the state. Estimates for 65 and older and people at high risk have been identified by county and facility (if applicable) and will be divided amongst applicable providers in the county. Providers who are allocated the minimum shipping quantity from the federal government will receive vaccine directly. Others will receive redistributed vaccine from the state warehouse. Vaccination will occur at pharmacies, local public health, satellite vaccination clinics, or through private healthcare providers. Vaccination will also need to occur at other congregate settings (i.e., corrections, homeless shelters, group homes). Some congregate settings are able to vaccinate themselves (i.e., state corrections). Others do not have healthcare staff. Each congregate setting in the state will be paired with a vaccinator.

Phase 2 General Population

Given the greater population designated for vaccination in Phase 2, it is expected that most, if not all, larger North Dakota cities will be able to use at least 975 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 shipping containers can hold temperature for 15 days, the community will be able to time vaccine clinics within a window of several days.

Many health systems can store ultra-cold vaccine and would be able to supply clinics with limited supplies for patients, as scheduled.

The NDDoH warehouse will continue to breakdown shipments for more rural areas for mass vaccination clinics.

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 A](#)). Since the original container would necessarily be accessed multiple times, dry ice remaining in the shipper would have to be monitored. Larger cities should be able to manage 975 dose increments if dry ice is maintained. This might require supplemental dry ice being supplied to these areas from the warehouse. Smaller cities and rural areas 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.

Tier 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, public health, 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 vaccines 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 satellite clinics would be shipped in full cases directly to LPH in larger cities. For rural areas, vaccine would be broken down into smaller quantities at the NDDoH warehouse and redistributed to more rural areas. The viability period is likely to be only 30 days in the refrigerator.

PHASE 2: GENERAL

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 30 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 satellite clinics.

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 extend 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). When possible, vaccine B will be prioritized for rural areas and smaller providers due to smaller minimum shipments and longer stability in the refrigerator.

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.
 - b. The state warehouse may receive some frozen vaccine and repackage 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 or can use the vaccine within 30 days.

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 975-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 Praxair 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.

The federal government will supply the initial replenishment of dry ice for Vaccine A's shipping container. Providers will need to order subsequent dry ice from the warehouse if they want to use the shipping container to store vaccine A.

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 A](#) 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 Praxair in Bismarck, ND. They have the capacity of producing approximately 300 pounds per hour. Praxair 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 has procured supplies 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 data 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 contracted, 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 NDHHS 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.

Supplies required for vaccination will be supplemented by supplies from the NDDoH 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. Enrolled providers will be allowed to bill administration fees for COVID-19 vaccine. On October 28, 2020, the Centers for Medicare and Medicaid Services announced a [plan](#) for payment of COVID-19 vaccine administration fees.

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 encourage 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 NDIIS 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. Communication messages will need to be tailored to specific priority groups for vaccination and address vaccine hesitancy concerns.

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 Public Good Project provides weekly reports showing common vaccine-related topics being discussed on social media. 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 EUA 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, tribal health clinics are 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 NDIIS, the vaccine dose has not been administered. This is already being done with VFC vaccine.

When necessary, entry of data into NDIIS 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 NDIIS 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 NDIIS is not great in any case.

PrepMod adds a substantial number of fields that can be pre-populated by potential vaccines 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 NDIIS can be used to record administration without collection of additional information.

If the NDIIS user interface was unavailable due to unplanned system outages, provider EHRs and PrepMod can continue to send data to the NDIIS electronically through their interface. Providers can capture vaccine administration information on paper to be entered into the NDIIS once it is available. If the NDIIS 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 NDIIS 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

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](#)). North Dakota is unable to share identifiable data with CDC per North Dakota Century Code (N.D.C.C.) §§ 23-01-05.3 and 23-07-20.1, and N.D.C.C. ch. 23-01.3. The data use agreement with CDC was amended to reflect that North Dakota will only be sharing county of residence and year of birth but will not be sending any other demographic information. Although identifiable data will not be shared with CDC, there are concerns that certain aggregate data could be identifiable in some rural areas of North Dakota that have very small populations. This concern has been discussed with CDC.

Planning is underway to encrypt and de-identify data prior to sending it to CDC in the future, which would alleviate concerns regarding sharing of data.

SAS code for CDC data submission

NDIIS Manager has written SAS code that adheres to CDC's specifications and data dictionary for record-level data submissions. NDIIS Manager has also submitted two test data files to validate formatting. 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 asking for three 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](#)). 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

The federal government will hold second doses for facilities who receive first doses. The second doses will be sent at the appropriate interval after the first doses. People who receive first doses should be prioritized for receiving second doses over starting the series for others. Doses should be administered as close to the minimum interval as possible. Providers are encouraged to schedule second doses at the time of first doses. If patients do not present for second doses, then the doses should not be wasted and should be used for first doses. Providers are not expected to track first and second dose inventories separately.

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 NDHHS 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.

[v-safe](#), CDC's post-vaccination safety monitoring system, will also send reminders for second doses to vaccines who opt-in to the program. Individuals will be provided education regarding v-safe upon vaccination.

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 vaccines are brought back for second doses. This may vary substantially by area and vaccinator. Individual vaccinators 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. NDHS 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 VAERS

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.

v-safe

CDC will implement v-safe, a new smartphone-based tool that uses text messaging and web surveys to check in with vaccinated individuals for adverse events after a COVID-19 vaccination. v-safe will also provide second-dose reminders (if needed) and live telephone follow up by CDC if vaccinated individuals report a medically significant event during a v-safe check-in. v-safe asks questions that help CDC monitor the safety of COVID-19 vaccines. Medically significant events will be identified if the vaccinated

individual reports that they missed work, were unable to complete normal daily activities, or had to seek care from a health provider or healthcare professional. The information will be used to analyze common side effects (soreness in the arm, muscle aches, etc.) and to detect unexpected, serious health problems if they occur.

CDC will create a v-safe information sheet that contains background on the v-safe program and instructions for enrolling. Healthcare professionals and healthcare facilities that are giving COVID-19 vaccines are asked to provide printed hard copies of the v-safe information sheet to each vaccinated individual and counsel them on the importance of enrolling in v-safe. The v-safe information sheet and counseling script are in development and will be made available electronically when completed. It is critically important for vaccine safety monitoring and assessment that healthcare professionals give each patient a v-safe information sheet at the time of vaccination and encourage patients to enroll.

The federal government has additional 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 destination 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 vaccines. 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.

DRAFT

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

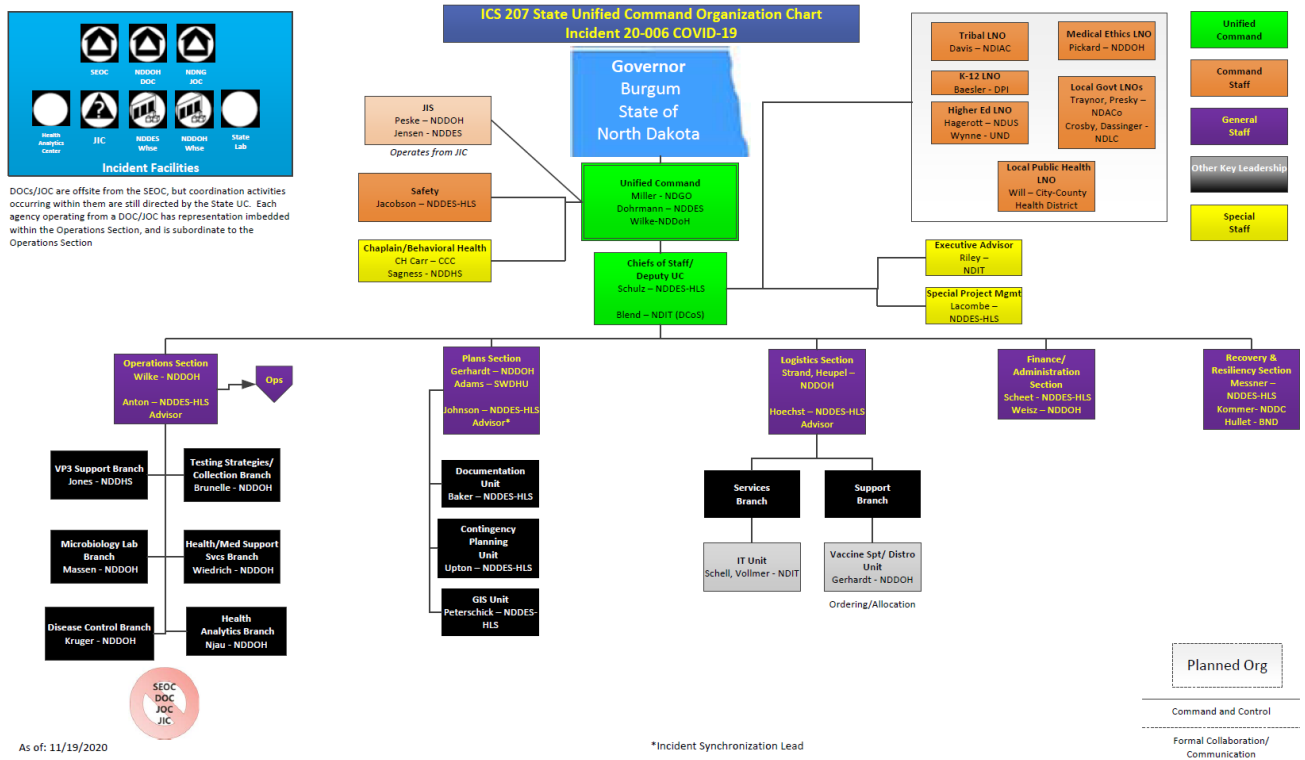
Note: Cold chain capacity being collected through the healthcare provider enrollment process. Additional ultra-low cold chain capacity may be available.

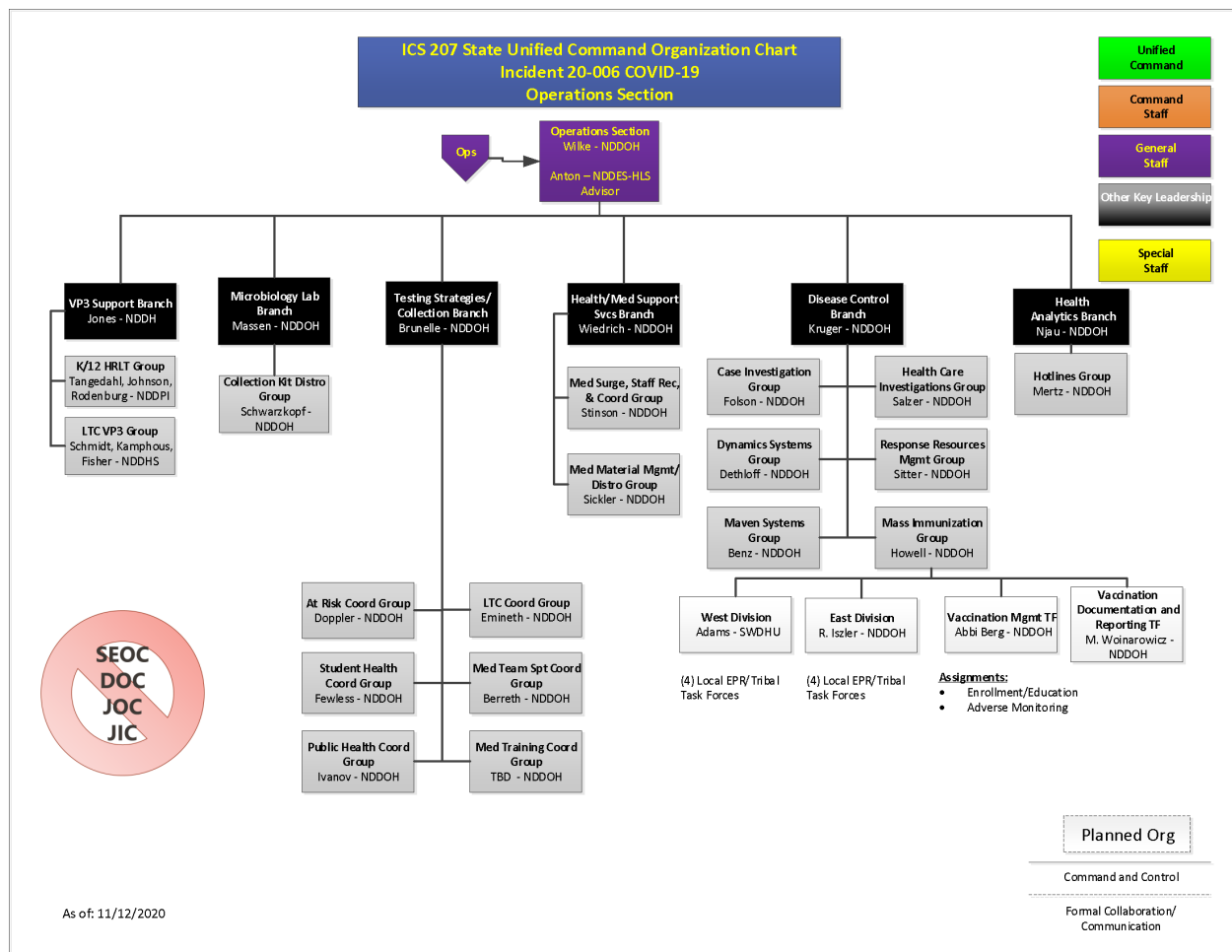
Redacted

DRAFT

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 HIS
Andrea Polkinghorn	Sanford Health Systems
Angie Strand	ND Department of Health
Arlene Krulish	Spirit Lake HIS
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
Renae 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.

DRAFT

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

Pfizer COVID-19 Vaccine			
Month	Total US doses	ND Doses	ND Individuals
December	22,500,000	47,019	23,510

Moderna COVID-19 Vaccine			
Month	Total US doses	ND Doses	ND Individuals
December	18,000,000	37,615	18,808

Appendix D: North Dakota Tribal Allocation Preference and Estimates

Affiliation	Tribe	Facility Name	Distribution Method
IHS	Standing Rock	Cannon Ball Health Station	Federal
IHS	Turtle Mountain	Dunseith Health Location	Federal
IHS	Standing Rock	Fort Yates Hospital	Federal
IHS	Three Affiliated	Mandaree Health Station	State
IHS	Turtle Mountain	Quentin N Burdick Memorial Health Facility	Federal
IHS	Spirit Lake	Spirit Lake Health Center	State
IHS	Three Affiliated	Twin Buttes Health Station	State
IHS	Three Affiliated	White Shield Health Station	State
IHS	Sisseton-Wahpeton	Wahpeton Health Center	Federal
Tribal	Three Affiliated	Elbowoods Memorial Health Center	State
Tribal	Three Affiliated	Parshall Clinic	State
Tribal	Turtle Mountain	Trenton Community Clinic	Federal
Tribal	Three Affiliated	Sage Coulee	State
Tribal	NA	United Tribes Technical College	State

Appendix E: NDIIS COVID-19 Vaccine Response Plan



NDIIS COVID
Vaccine Response Plan

DRAFT

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 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 graph showing weekly coverage rates by priority group (as identified by CDC/ACIP).
 - Graph will only show the most current weekly rates.
 - A graph showing weekly coverage rates by race and ethnicity.
 - Graph will only show the most current weekly rates.
 - A graph showing weekly coverage rates for healthcare workers.
 - Graph will only show the most current weekly rates.
 - A 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 Mondays and will be sent to the NDITD data lake or analyzed by NDIIS staff.
- The non-public dashboard metrics will be updated by 9am Tuesdays.

Appendix G: Alternative Models for Mass Vaccination



Alternative Models
for Mass Vaccination

DRAFT