Vaccine Management Plan

North Dakota Department of Health

Scope

This plan represents a complete revision and consolidation of prior NDDoH plans related to vaccine management. Because a moderate or severe influenza pandemic puts the greatest stress on vaccine management, that will be the base scenario for development of this plan. Other scenarios to which this plan may apply are bioterrorism (anthrax, smallpox), community-based vaccination for a localized outbreak (e.g., meningitis) and seasonal influenza in which vaccine shortages are substantially impacting vaccine coverage of the population.

Response Goals for Pandemic Vaccination

- To maximize uptake of vaccine by the population;
- To ensure that those persons determined to be at highest priority for vaccination are vaccinated first;
- To ensure that specific population subgroups (e.g., age) receive the correct, FDA approved vaccine;
- To minimize the amount of time from receipt of vaccine in the state to administration;
- To maximize second dose administration as soon as possible after completion of the required interval after the first dose;
- To maintain the cold chain and security of the vaccine;
- To have vaccine allocation which is ethical and transparent;
- To ensure that adverse events associated with vaccine administration are captured and investigated as indicated;
- To minimize disease transmission which will arise from aggregating persons in vaccination clinics during a pandemic.

Assumptions For Pandemic Influenza Vaccination

- Vaccine for pandemic influenza will be administered to the entire population that accepts it.
- Vaccine which is specific to the pandemic strain will not be available until many months after the pandemic is identified, and once it becomes available, quantities will not be initially available to vaccinate all persons.
- Pandemic vaccine will be prioritized either to 1) high risk groups first, or 2) to high risk groups and critical infrastructure, depending on the nature of the pandemic.
- Receipt of vaccine into the state will be in proportion to the state population (about 0.2% of the US population), but may not take into account persons crossing over into North Dakota from other states.
- Initial vaccine dose will provide little, if any, protection against infection[1];
- Influenza is contagious during the 24 hours prior to symptom onset (making exclusion of all contagious individuals from vaccination clinics impossible) and vaccination clinics potentially have a strong anti-social distancing effect which, if not neutralized, may increase morbidity and mortality;
    - Anti-social distancing effect will be minimized by vaccination between waves.

[1] This assumption was not true for the H1N1 pandemic because the population already had some inherent immunity to H1N1, but it will remain as a planning assumption for most pandemics since it is likely to be true for many potential influenza pandemics (H5N1).

    - Some types of clinics (e.g., drive-through) are expected to minimize any anti-social distancing effect.
    - For indoor clinics, infection control procedures (screening for ill, cough hygiene, distancing between families) will be needed to minimize disease transmission.
- If vaccine for mass vaccination arrives during the first wave, rapid administration of the vaccine may not be possible in the face of high absenteeism among public health and health care staff.
- Second dose vaccination, if needed to secure immunity, will, in almost all circumstances, take precedence over first dose administration. That is, completion of immunity which is protective is more important than initiating immunity which is not protective. However, doses will not be held from a shipment to provide the second dose to persons who are not yet eligible to receive the second dose.
- Within NDDoH, the lead role for vaccine management policy will be taken by the Immunization Program of the Division of Disease Control. The Immunization Program will function as part of incident command under the Operations Section of the DOC, but will not be relocated to the DOC.
- The roles for the Immunization Program and the DOC in vaccination management will be different.
    - Immunization Program roles will include provider registration, vaccine ordering, allocation to registered sites, management and analysis of NDIIS, vaccine adverse events coordination, and communication with CDC Immunization Program.
    - DOC roles will be logistical management (including vaccine receipt, cold chain and distribution), public information and policy.
- In a moderate or severe pandemic for which vaccine is perceived as lifesaving, the vaccine may pose a security risk.

Refer to planning documents relevant to specific diseases (e.g., anthrax, smallpox) for assumptions for those conditions.

Background

Many factors that cannot be known prior to a major event will potentially affect vaccine management. These include the nature of the event (severity, public reaction to the pandemic and to the vaccine, impact on infrastructure), the characteristics of the vaccine (quantity available, timing, release rate, doses required, adjuvant required, toxicity, mode of administration, cold chain requirements and FDA approvals) and the response of the health care system. Each of these factors is discussed below.

<u>Nature of the Event</u>

In a pandemic setting, it is assumed that the entire population will be at risk and that the intent of the vaccine delivery process will be to reach every person with the vaccine. In an anthrax, smallpox or meningitis scenario, it is assumed that the vaccine will be targeted toward a much narrower part of the population actually at risk for illness; however, public and political pressure may result in broader use of the vaccine than is actually indicated (and broader adverse consequences). During a pandemic, the amount of public fear of the illness will likely be the strongest factor determining the extent of public uptake of the vaccine and the amount of political pressure.

In an influenza pandemic, it is expected that several months will elapse from the time the specific organism (clade) is typed to the time that vaccine becomes available, and all vaccine will not become available at the same time. This will result in prioritization of the vaccine. In the event of small impact on the national infrastructure, the vaccine will be targeted toward risk groups at highest risk of adverse outcome (e.g., pregnant women). If the pandemic is causing serious impacts on infrastructure, substantial portions of the vaccine will be directed toward persons responsible for maintaining the infrastructure. CDC plans call for this infrastructure allocation to extend to all critical sectors of the economy (e.g., transportation, energy production, communications) and not just the health care or emergency response sector. (See Attachment C.)

In a moderate or severe pandemic, timing of mass vaccine delivery would logically be impacted by concerns about the anti-social distancing effect of vaccination clinics. Mass vaccination during a pandemic wave, particularly for a vaccine which requires two doses to be protective, may actually increase the mortality rate. That is, providing the initial, non-protective dose in an anti-social distancing environment may increase illness rates while providing no protection. In some pandemic settings, waiting until after the wave is over to begin vaccination may be the best option for improving outcome, albeit an option of questionable political viability. Some regions of the state are prepared to deliver vaccine by drive-through clinics to minimize the anti-social distancing impact, but it is not clear that this could be done on a scale large enough for rapid vaccination of most of the population, and some regions have never exercised this approach[2].

Vaccine Characteristics

In an influenza pandemic, it is likely that two doses will be needed to achieve adequate protective antibodies. This might be altered by the use of an adjuvant. If a chemical (adjuvant) can be added to the vaccine when administered to increase the body's immunological reaction to the disease agent, less vaccine or fewer injections may be required. Mixing and matching of antigen and adjuvant at point of care may be required. Matching an antigen and adjuvant type from the first dose at the time the second dose is given may be needed. The exact combination of antigen and adjuvant administered for the first dose may also be needed for administration of the second dose. Introduction of adjuvants may cause public distrust of the vaccine since adjuvants have not previously been used in this country.

Influenza vaccine is currently being developed primarily using chicken embryos as the cell culture medium. This process is slow. During the H1N1 pandemic, the vaccine was released late and in a trickle. By the time substantial amounts of the vaccine were available, much of the public appeared to be "over it," particularly since the pandemic was mild and the initial wave was on the decline in many states. Cell culture-produced vaccine is now appearing

[2] It is not clear what the relative throughputs for drive through clinics and walk-in clinics are. However, an additional barrier is availability of venues for drive-through vaccination which are protected from the weather, have sufficient space and flow for many lanes and can safely handle vehicle exhaust.

which could decrease the wait time after the identification of a pandemic to vaccine availability, although it still may take several months to produce vaccine.

A transition to intradermal vaccination may result in improved vaccine coverage when quantities of the antigen are limited, since intradermal vaccination requires less antigen to achieve the same level of immune response now seen with intramuscular vaccination. Some vaccine for intradermal is now available but represents only a small fraction of the influenza vaccine in use.

If the influenza subtype is known in advance of the pandemic (e.g. H5N1), the U.S. government may have developed vaccine to the subtype which is not clade specific. That is, the vaccine would not offer substantial protection to the recipient, but may be quite adequate as a priming dose to improve response to the clade-specific vaccine. It is unlikely that generic subtype vaccine would be available to vaccinate a large percentage of the population, but may be sufficient to start the vaccination sequence for certain high risk subgroups or for infrastructure personnel.

Vaccines vary substantially in risk of adverse events. Influenza vaccine is very safe, but if given to millions of people, a few serious adverse events are inevitable. Some persons take this information and miscalculate their relative risk of receiving the vaccine versus not receiving the vaccine and refuse vaccination. Alternately, smallpox carries a higher risk of adverse events of the available vaccines. For this reason, and because smallpox spread can be quite effectively controlled using ring vaccination techniques, the preference of public health will be to avoid mass vaccination. However, fear of smallpox with political pressure to vaccinate everyone may make this impossible. People will tend to overestimate their risk of illness relative to the risk of the vaccine and demand vaccination[3]. This is not likely to be as big a problem with anthrax since the disease is not contagious, but a larger group than is actually exposed may demand prophylaxis. In the case of both smallpox and anthrax, unlike pandemic influenza, sufficient vaccine should be available immediately for all persons who need it.

Another characteristic of influenza vaccine that makes mass vaccination complicated is the number of different manufacturers and formulations with varying FDA approvals. Some products will be approved for infants, toddlers, pregnant women, immunocompromised persons, persons with egg allergy or persons over 65; however, a typical product will be approved for some of these categories but not for all. During H1N1, as vaccine trickled in, the specific products had to be allocated to specific providers according to the type and number of patients they expected to vaccinate who were eligible to be vaccinated with the vaccine that was available. This not only made allocation complicated, but was confusing to

[3] Just because people demand vaccination is not sufficient reason to provide it, any more than people demanding a narcotic should be given a prescription in the absence of a medical indication for treatment with a narcotic. Political mandates can alter public health action by taking the decision to vaccinate or withhold vaccination away from public health.

providers[4]. To the degree possible, Disease Control tried not to give many different vaccines to the same provider over time.

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 due to higher safety. 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; however, the NDDoH warehouse is expected to have sufficient space to maintain the vaccine that it receives for re-distribution.

Health Care System Response

The health care system currently provides the vast majority of vaccinations; for influenza this is estimated at around 80%[5] of the doses given (exact number is pending). However, during seasonal influenza, a large percentage of the population does not request influenza vaccination. During the 2012 – 2013 flu season, only 48.9% of North Dakotans were vaccinated[6]. During a pandemic, more people will be requesting vaccine, more doses will be needed and the health care system may be overwhelmed by clinical care. Not only may the private health care system be unwilling to pick up the large number of extra vaccinations which need to be provided, they may not even have the resources to vaccinate the patients they would have vaccinated during a normal influenza season. What vaccine is not administered by the private health care sector will need to be administered by public health, pharmacies, long term care facilities or other non-traditional vaccine providers (e.g., contract vaccinators, employee-based clinics).

Physical Vaccine Management and Cold Chain

For a bioterrorism related outbreak, vaccine would likely come to the state via the SNS. For all other circumstances, NDDoH would request and receive vaccine through CDC's authorized contractor which in recent years has been [redacted] for North Dakota shipments). During H1N1, CDC authorized the direct shipment of full cases (100-dose increments) to providers authorized by the state to receive that much vaccine at one time. Because vaccine was released slowly, relatively few providers could be allocated full cases. Consequently, a high percentage of the vaccine had to be received by the NDDoH warehouse and re-apportioned into smaller quantities for shipment to specific sites. During the H1N1

[4] For example, a provider needing to vaccinate a seven year old child may have been able to do so with vaccine provided to his or her office one week but not with vaccine provided the following week with vaccine only approved for children eight and older. Keeping track of which vaccine can be given to which people and which vaccine the clinic has could be very difficult. During a normal influenza season the provider would have ordered only vaccine that he or she was familiar with.

[5] The percentage of H1N1 vaccine provided by various provider types has not been calculated, but it is believed that LPH provided a substantially larger percentage of the H1N1 vaccine than it normally provides of seasonal influenza vaccine.

[6] CDC Fluvax View: http://www.cdc.gov/flu/fluvaxview/reports/reporti1213/reporti/index.htm

pandemic, shipments of vaccine went to well over 100 public and private destinations, although not all these destinations would receive vaccine from every shipment.

Most vaccines, including influenza, are expected to be received as liquid that must be stored between 35º and 46º Fahrenheit (2º – 8º Celsius)[7]. Vaccines for some conditions (e.g.., smallpox) have traditionally shipped frozen and need to remain frozen. Mass shipment of influenza vaccine during winter months proved to be difficult due to the need to protect the vaccine from moderate warmth and severe cold[8]. The only methods proven to be reliable by trial and error 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, NDDoH had concern about the [redacted] shipments that it received. The shipments were packed in large Styrofoam containers which did not have thick walls. No temperature 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 which commercial shipping companies kept the vaccine containers out of doors[9]. In the event that forecasted temperatures dropped so low that [redacted] refused to ship, NDDoH developed plans for retrieval of vaccine from [redacted] directly using a temperature controlled aircraft. It never became necessary to implement this plan during H1N1. Substantial changes in federal shipment practices could occur for the next pandemic, but are not expected at this time.

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[7] Vaccine removed from refrigeration to a warm environment does not instantly reach ambient temperature and 46º is not a firm number above which the vaccine loses potency. Vaccine can likely tolerate periods (days to weeks) of moderate temperatures above 46º without substantial loss of potency (the warmer the temperature, the faster it will degrade), but this varies by vaccine and the temperature stabilizers added to the vaccine. At least one study found insignificant degradation of influenza vaccine after two weeks at room temperature (see abstract at http://www.ncbi.nlm.nih.gov/pubmed/16150515). Another study found no loss of influenza vaccine potency for live attenuated vaccine after three freeze-thaw cycles (see abstract at http://www.ncbi.nlm.nih.gov/pubmed/22341195). However, even if vaccine can stand freezing, it is typically packed with rubber stoppered bottles of diluent (e.g., sterile water). If the bottle diluent freezes, the stopper is forced part way or entirely out of the bottle so that it is no longer guaranteed to be sterile and must be discarded.

[8] Vaccine leaving the warehouse by commercial shipper during the winter would be packed in a warm room, be picked up by the commercial carrier where it might remain outside in an unheated truck overnight, be transferred to the cargo hold of a plane (variable temperature), again spend time on a truck, go to a warehouse belonging to the shipping agent, go back into a plane, go back on a truck and finally arrive at its destination where it may or may not be moved immediately to a refrigerator.

[9] It is not clear that this concern has been fully addressed at the federal level. Although NDDoH never proved that any Xxxxxxxx material froze, temperature monitoring was not present in the periphery of the containers near the walls.

Provider Recruitment

During H1N1

The first step in the vaccination process during H1N1 was provider recruitment. This was initiated upon CDC instructing to the states to begin; CDC also provided most of the language for enrollment documents. NDDoH held a series of video/webcast sessions to educate providers, including pharmacies, clinics, long term care facilities, hospitals and local public health. This was followed by a memo sent through multiple communication channels (e.g., email, HAN contacts, professional associations) providing information about the enrollment process. Since enrollment was the only means for providers to acquire the vaccine, it is thought that nearly all eligible vaccine providers chose to enroll. Enrollment occurred over a website; a paper enrollment option was not provided in order to eliminate data entry.

Enrollment was by vaccine delivery site. This meant 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 was collected at the time of enrollment and populated into a lookup table in the CDC vaccine ordering software. This information was used by both [redacted], to ship directly to providers, and by the warehouse for direct delivery. The registration site also provided a contact who could be called to ensure that someone would receive the vaccine when it arrived at the door.

Another action initiated by enrollment was ensuring providers where signed up and prepared to use NDIIS. Upon receipt of an enrollment request, the Immunization Program looked up the provider site in NDIIS to ensure that that site was using NDIIS. If not, the practice was contacted and required to enroll in NDIIS before they could become a vaccine recipient site.

The final action initiated by enrollment was a request to providers to estimate the number of each risk group that they believed they could vaccinate, so this information could be used as part of allocation. This is discussed below under allocation. To help providers make this estimate, they were provided with information from orders made during regular flu vaccination seasons.

No specific guidance was given to providers about accounting for out-of-state residents coming to North Dakota to get vaccinated. For Grand Forks, Fargo, Wahpeton and the western edge of North Dakota substantial numbers of people flow into the state for health care services. That is, the number of doses provided to out-of-state residents by North Dakota would substantially exceed the number of North Dakota residents who got their vaccination out of state. (No allocation adjustment was made by CDC for this during H1N1.)

The vaccine was provided free of charge, but vaccine providers were permitted to charge an administration fee up to a maximum set by CDC. The administration fee could be collected from insurance or out of pocket from the recipient, but providers were not allowed to turn anyone away for inability to pay[10]. Additional requirements set by CDC for vaccine eligibility

[10] No mechanisms were in place during H1N1 to ensure that non-pay patients weren't turned away, but anecdotal reports of this were not received by the state so attempting to monitor this is not needed unless a problem becomes evident.

included agreement to meet vaccine storage requirements (which may include continuous monitoring[11]), and agreement to abide by the prioritization of vaccine to the specified high risk groups CDC specified. The NDDoH required use of the NDIIS for vaccine administration documentation.

During H1N1 in two regions of the state, the local public health unit was allowed to become the local vaccine recipient and redistribution point for vaccine within that regional area. This was done at the request of those local public health units. While it had the advantage of decreasing the number of distribution points for NDDoH, it also created a substantial number of problems including provider complaints (e.g., unfair allocation, lack of transparency, excessive control, increased delay), primarily from one of the two areas. Having an additional drop-off and redistribution point, also created another opportunity for a break in cold chain.

Provider Recruitment for Future Pandemic

The process used for provider recruitment during H1N1 worked well. No substantial change is anticipated in the method unless changes imposed by CDC require it. It was not necessary during H1N1 to recruit additional providers after the initial enrollment due to the large percentage of providers who chose to enroll. In a future pandemic, if insufficient numbers of providers of specific types (e.g., pediatricians, obstetricians) are initially enrolled, these needed groups will be targeted specifically with enrollment messages. An enrollment cutoff date would be stated to try to get all providers on-board and trained before mass vaccination was needed, but in practice, enforcement of the cut-off date would be unlikely.

Non-traditional vaccinators (e.g., pharmacies, other private vaccination groups) received their allocations relatively late during H1N1. This was due to an incident command decision to preferentially direct vaccine toward providers providing longitudinal care of patients, and due to greater numbers of persons in clinics with influenza risk factors. If a future pandemic is more severe, the anticipated large gap in vaccination by clinic-based vaccination providers would have to be filled by public health and non-traditional vaccinators. Current law allows pharmacists to vaccinate against influenza down to age five. The greater need for vaccinators during a more severe pandemic may make an executive order allowing pharmacists to vaccinate young children advisable.

Future policy related to local redistribution will default to a strong no; however, it is possible that some compromise might have to be reached. If that becomes necessary it is proposed that LPH must:

- Obtain the consent of all provider recipients in the area; and,
- Develop and provide to NDDoH for approval a vaccine allocation and redistribution plan which addresses:
    - Communications;
    - Allocation algorithm including fairness and optimal use of vaccine;
    - Security;
    - Cold chain and storage;

[11] Many providers who have implemented continuous monitoring are finding substantial problems with vaccine storage which is necessitating replacing vaccine storage equipment.

- Timeliness;
- Transportation;
- Documentation (NDIIS); and,
- Transparency.

If these criteria could not be met, the vaccine would be distributed directly to providers by NDDoH.

Procedures for Vaccine Ordering by the State

During H1N1

A set amount of vaccine was allocated to the state by CDC as the vaccine became available; however, the state still had to order the vaccine. A computer program provided by CDC used for the ordering process during periods of non-pandemic was also used during H1N1. To complete the ordering process, the Immunization Program had to:

1) Populate the recipient lookup table which included the names and addresses of all registered vaccination sites eligible to receive vaccine (i.e., registered). This information was obtained from the data generated by the registration website, but had to be manually transferred into the ordering software.
2) Examine the specific vaccine (how supplied, manufacturer, quantity) which had been allocated to the state (provided daily by spreadsheet from CDC, even if no new vaccine was allocated during the previous 24 hours). From this information, the specific amounts of each vaccine to go to each provider were input into an excel spreadsheet.
3) Adjust quantities to try to reach full boxes for those destinations near that level, so that vaccine at least would not have to be repackaged and shipped from the NDDoH warehouse. This adjustment had to be done in a manner which was not unfair to smaller volume vaccinators who would never get enough vaccine at one time to make a full carton.
4) Orders were then entered into CDC's vaccine ordering system on behalf of providers. Orders had to be in 100-dose increments by vaccine type. Orders for providers receiving less than 100 doses by vaccine type were aggregated and ordered to be sent to the NDDoH warehouse for redistribution.
5) Update the allocation information into NDIIS (manual entry) and generate a packing slip for the warehouse in NDIIS which would describe the specific vaccine, quantity and destination. These packing slips were then sent to the warehouse by email or fax.
6) Populate a website where providers could look up how much of each vaccine they had been allocated.
7) For those sites which used a local regional health broker, the warehouse shipping point was ultimately different from the data in NDIIS (i.e., actual provider who administered the vaccine), so that information had to be corrected.

Vaccine Ordering for Future Pandemic

CDC is now using new vaccine ordering software, VTrcks, which should allow direct uploading of spreadsheets rather than manual entry. Additionally, NDIIS now has a vaccine ordering system where providers can enter orders for vaccine directly and then the orders are reviewed by Immunization Program staff, and if approved, electronically uploaded to VTrcks. The Immunization Program will be responsible for training providers as to how to use the NDIIS vaccine ordering system. During a pandemic, Immunization Program staff may have to

enter orders into the NDIIS on behalf of providers. A substantial burden of data entry would be expected, so Disease Control would work with the DOC to pre-plan additional assistance in the Immunization Program. Whether these needs would be filled by existing NDDoH staff redirected to emergency response or whether by temporary employees would be determined at the time.

One option for ordering in a pandemic would be to tell the local provider how much vaccine their site was allowed to order, but require the provider to go in and order the vaccine. The ordering system allows all vaccine orders from within the state to be reviewed and approved by NDDoH before the order goes to CDC for processing. The state would need to ensure that providers did not order a greater quantity of vaccine from the state allocation or order a different type of vaccine then they were told they could have. Vaccine orders in excess of the state allocation would mean that someone at the federal level would determine who would or would not receive vaccine in the state. To avoid this, the state will need to stay within its allocation limit.

An additional change that would streamline the ordering process would be a modification to NDIIS to improve its handling of spreadsheet data without manual re-entry of information. However, this would take a financial investment that is not available at this time.

The NDIIS ordering system does give providers a vaccine shipment tracking number, so they are able to track vaccine shipments, however, providers receiving vaccine from the NDDoH warehouse would not receive this tracking number. Also, if orders are directly entered into VTrcks, providers would not see this tracking number in NDIIS. A method would need to be developed to notify providers of vaccine shipments.

Vaccine Prioritization and Allocation

During H1N1

Prioritization of vaccine during H1N1 followed CDC guidelines; however, NDDoH did attempt to sub-prioritize CDC authorized risk groups to ensure that those at very highest risk were vaccinated first. This created some confusion on the part of the public re: who was eligible be vaccinated, and inconsistency between local sites with some vaccine providers moving on to vaccinate other sub-groups while others were still waiting for sufficient vaccine to reach the highest priority groups. Because the H1N1 pandemic did not threaten infrastructure, no infrastructure allocation was necessary other than the targeting of health care workers.

The allocation process during H1N1 was awkward and time consuming. Disease Control would determine number of vaccine doses of what type had been allocated to the state and assign each dose to a provider based on the best estimate of population need and provider ability to reach high risk groups. This would be input into the ordering system. When the vaccine arrived, Disease Control would use the NDIIS to generate a packing slip in NDIIS and transmit this to the warehouse by fax or email where it would be used to pack the right amounts and types of vaccine for each destination.

For allocation, Disease Control relied heavily on provider estimates of how many people in each risk group the site could vaccinate. After Disease Control received the vaccine quantity request, the amounts sometimes required adjustment. For instance, if the sum of providers serving a catchment area were ordering quantities believed to exceed likely ability to reach

persons needing vaccine, estimates were adjusted down. One local public health broker site that ordered enough vaccine for the entire population in their region had their allocation adjusted down, since this would not be achieved and was substantially out of line with estimates from other sites. (Sites estimating high tended to receive vaccine faster relative to the population size than sites which estimated low.)

As each provider was allocated vaccine, this was tracked on a cumulative basis with calculation of expected vaccine coverage in that area. Adjustments were made to the allocation of vaccine based on these estimates. Even with these adjustments, substantial unevenness in vaccine availability across the state appeared to exist. To some extent this was unavoidable, but better methods for determining how much vaccine to allocate to each provider were needed.

As vaccine come in which was suitable for specific risk groups, it was allocated to all providers who reporting being able to vaccinate that risk group. One problem with this was that it meant a provider might have to deal with many different vaccines with different approved indications rather than vaccines the provider was familiar with.

Priority Vaccination

The current plans for prioritization of vaccine are dependent on the severity of the pandemic and the potential for the pandemic to impact infrastructure. CDC has provided some planning guidance for covering critical infrastructure sectors including health care, transportation, energy production, community utility, community services (e.g., grocers) and others. The prioritization would not ignore high risk groups like pregnant women, but a substantial quantity of the early vaccine would be directed away from adverse outcome-based allocation to cover infrastructure. This would not happen in a milder pandemic in which damage to infrastructure was not expected to be substantial. DES has maintained lists of critical infrastructure which could be used to help make the allocation.

For the health care and public health sector, NDDoH has also planned for within sector prioritization. Hospitals especially would determine internally who received vaccine first in order to preserve its internal infrastructure. Generally ER and ICU personnel would be highest priority followed by other direct care providers, but portions of the support infrastructure (e.g., dietary, housekeeping, maintenance) would have be vaccinated reasonably early. For guidance on how within sector prioritization would occur and be documented, refer to the pandemic influenza plan re: prioritization and to attachments A and B.

Entities which received vaccine which required population prioritization (e.g., hospitals) would need to document how each dose was allocated. 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).

During priority vaccination only, a local vaccine broker may be used. A vaccine broker is a partner institution at the local level which has agreed to receive vaccine and administer it

according to state and federal guidance. Only local public health units (LPHU) and hospitals are designated as eligible vaccine brokers in current plans[12]. Only a vaccine broker would be designated as a ship-to site during priority vaccination.

The roles of the vaccine broker include:

- Receipt and storage of vaccine, including maintenance of cold chain;
- Security of the vaccine;
- Administration of the vaccine to those authorized to receive it;
- Maintaining documentation of administration and reason for vaccination priority, and providing that documentation on request;
- Ensuring that persons given their initial dose receive an appropriately timed second dose;
- Allocation of vaccine to end user organizations (duty of LPHU only);
- Establishing clinics or PODs for mass vaccination (duty of LPHU only), and;
- Splitting vials of vaccine among priority recipient groups (duty of LPHU only).

For additional details related to roles during priority vaccination, see Attachment C.

Vaccine Prioritization and Allocation during a Future Pandemic

The NDIIS can calculate where (provider) people routinely go to get vaccinated. This could provide a reasonable estimate of how much each destination should expect to receive, but would still have to be modified by provider input since the percentage of the vaccination burden that will be left to LPH or other vaccinators may vary from provider to provider. For instance, Hettinger Clinic would need to plan to vaccinate substantial portions of Bowman, Slope, Hettinger, Grant and Adams Counties, and could receive an allocation based on the percentage of people it normally vaccinated from each county in its catchment area. This might result in a substantially better algorithm than that based on provider estimates of coverage alone. An allocation module in the registry would have the potential to improve the allocation process, but creating it would likely be expensive and no funds have been identified for this at this time. Another possible resource is SAS code written in Tennessee intended to assist with the allocation process. This software has not been evaluated in North Dakota to date.

[12] One problem that has developed since the H1N1 vaccinations is the rapid population growth in Western North Dakota and shortfall in health and public health services for the population. In this area of the state at least, it may be necessary to encourage employers to register to receive and administer vaccination, if they have the capability to do that. Employer-based vaccination would still be required to follow risk-group prioritization requirements and would need to provide estimates of how many of each risk group they could vaccinate. Estimates from NDIIS would not be available to help allocate vaccine to employers.

To the extent possible, Disease Control 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 which 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 which 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 use of adjuvant would provide a new challenge to vaccine management. It will not be known whether one or more adjuvants will be used or how they will be managed or administered until the event. Some additional training will be required for providers, but that is not expected to pose a substantial problem. NDIIS is being setup to manage data related to adjuvant. This is discussed further in the section allocation of vaccine for second vaccination.

During H1N1, traditional vaccination providers (clinic-based) providing longitudinal care and local public health were given allocation priority over pharmacies or contract vaccine providers in the allocation process. Although this was felt to be advantageous at that time, it would be less likely to be advantageous in a situation in which outpatient care was being overwhelmed with sick patients. This would remain an incident command decision during a future pandemic. Allocation will also need to consider special destinations like state penitentiary and other custodial care institutions and cross border vaccinees in how vaccine will be allocated. Consideration may rest heavily on the epidemiology of the virus (e.g., susceptibility to serious disease outcomes). For instance, H1H1 has not had a propensity to cause epidemic illness in long term care facilities, so allocation to LTC was less urgent during the last pandemic. See section on vaccination of vulnerable population for additional discussion.

Example:
In county X with a population of 5,000 of which 1,000 are children, 50% of adults (2,500) and 50% of the child population (500) usually get an annual influenza vaccine, of which 30% of the vaccinations provided to children in the county are done by Clinic A (150), 50% by Clinic B (250), and 20% by LPH (100). For adults 50% are provided by Clinic B (1,250), 10% by Clinic C (250) and 40% by LPH (1,000). If Clinic A reports that it will attempt to vaccinate any children presenting for vaccination (guess maybe 40% of child population or 400 children) and Clinics B and C expect to only vaccinate the number of people they would normally vaccinate in a typical influenza season, that is B (250 + 1,250) and C (250 adults). If 90% of the population is expected to be vaccinated with pandemic vaccine, that leaves 250 children ((1,000*0.9) – 650=250) and 2,100 adults ((4,000*0.9)-2,500=2,100) that LPH or other non-traditional vaccinators would vaccinate in that county. If two doses are required, the total allocation to that provider for that county would be double the number of people that they would expect to vaccinate. Each provider would also receive an allocation for each of the other counties they served.

Communication to the Public and to Providers

During H1N1

On a single instance early in the vaccine delivery process, part of a shipment of vaccine was thought to have possibly frozen. The vaccine was administered before a determination was made that it should be discarded. NDDoH decided to report the vaccine loss in the media and ask that those who received the vaccine be re-vaccinated. Other states also froze some vaccine but NDDoH was the only one known to have reported it to the media. The NDDoH response was consistent with DOC policy of media transparency during a disaster.

Information about influenza and vaccination were communicated through the media by weekly press conferences, radio and TV ads. This was in addition to information which was coming from CDC through the media. The hotline was open and received calls, but many callers were looking for clinical information (e.g., about care of an individual) that the hotline was not able to provide.

Although the amount of information flowing to the public was large, misinformation remained a problem. For example, as the pandemic progressed it became increasingly difficult for the state to give a uniform message about who was eligible for vaccination. Initially all local providers were targeting the same high risk groups, and it was intended that local areas not progress to vaccinating new groups until the DOC notified them that the entire state would begin to vaccinate the same new groups. In part because vaccine availability and demand were uneven, some local areas began to run out of eligible and willing vaccinees before they ran out of vaccine, so they moved to new target groups without consulting the DOC. Rumors about low vaccine safety were also common nationwide although the extent to which that impacted vaccine uptake was not known.

Communicating local vaccine availability to the public during H1N1 was a challenge that was never fully solved. The vaccine delivered to a particular provider could be provided by NDDoH because NDDoH made the allocation decision, but local clinic-specific information which the public needed to know to seek out vaccination could not be updated by the state. This included eligibility, how many doses the clinic had for what age or risk groups and when vaccination clinics were being held. Although local providers (e.g., LPHU) may have used methods specific to their area, the primary method used by the state was the Flu-Finder website.

The intent was that each provider or clinic would update this information in Flu-Finder as the information changed, but this was not done consistently. The only incentive offered to providers was the ability to get information to their patients and to decrease the number of phone calls to the office. Substantial pressure was applied by the federal government to the states related to this issue, but that did nothing to alleviate the problem[13]. The website was adequate, but the updating was not, and NDDoH did not control the updating.

Communication during a Future Pandemic

[13] DHHS went so far as to call state governors to complain about problems with up-to-date vaccination information in Flu Finder without first consulting with state health agencies. This created a firestorm of protest.

The communication of general information about the pandemic and vaccine worked reasonably well, particularly with federal investments in nationwide education, and is unlikely to be greatly different in a future pandemic. However, communication about the specifics of vaccine availability at local sites needs to improve (see below).

During a moderate or severe pandemic, some issues will be difficult to communicate to the public such as declining quality of care and allocation of ventilators. Priority vaccination may be one of these issues since it may be viewed as inherently unfair by some persons. Priority vaccination is about valuing the protection of some people over others. This not likely to be as much a problem for vaccination of high risk group as it will be for vaccination of priority infrastructure, particularly those outside of health care. Since the recommendation for priority infrastructure vaccination will come from the federal level, the federal level is also likely to take the lead in justifying it to the public.

A couple of methods may be useful for getting provider offices to update the Flu-Finder website. A requirement to update Flu-Finder can be included in the initial registration agreement signed by the provider as a condition of receiving vaccine, as well as requiring contact information for one or more persons in each office who were assigned the responsibility for updating. Incentives may be helpful but have not been identified. Yet, as long as it is left to the providers' initiative to update this information, gaps will occur.

A more reliable approach would be for NDDoH to assume responsibility for updating the website. This would require incident command to collect this information from provider offices, probably by daily or every other day phone calls to all registered provider offices. This information would then be posted by NDDoH to the Flu-Finder website. Taking on this task would require additional personnel time, either by using additional NDDoH non-EPR staff in the response or by hiring temporary employees. In a moderate or severe pandemic, additional personnel time to make phone calls to provider offices may not be available due to high absentee rates.

Heavy dependence on a 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. Some alternatives include reverse 911, mass text messages through Amber Alert, large clinic reverse 911 systems or National Weather Service alerts. Problems with these systems include 1) triggering the use of several of these would require that the information had a substantially higher urgency than was the case in H1N1, and 2) complex information which is locally specific and changing frequently would be a barrier for these methods. Social media use may be successful but would have similar limitations to the Flu-Finder website. Local communications (newspaper, public access channels) can reach local populations with provider specific messages about availability and may be the best option, but one better employed by local public information providers. Local public health could be asked to be responsible for collecting and communicating vaccine availability within their jurisdiction, but many local public health units are small and may have very thin staff due absenteeism. Complete loss of public health services in some local jurisdictions is possible due to absenteeism since staff depth is so small.

No mechanism was in place to evaluate the success of communication systems in H1N1, but anecdotal information suggests a substantial problem. In a future pandemic, it would be helpful to determine if alternative communication strategies being employed were meeting the information need. Although not without bias, one simple approach would be the addition of a pop-up survey on the Flu-Finder website and questions asked of callers to the hotline. The BRFSS could be used with less bias, but is more difficult to alter and would have a substantial delay (e.g., one or more months until prior months data became available).

Warehouse Vaccine Processing

During H1N1

During H1N1, the warehouse received cases of vaccine which had to be split among multiple delivery points. These arrived in large Styrofoam containers delivered by commercial carrier. The vaccine was transferred into alarm-monitored, walk-in refrigerators. Allocation schedules were received as packing slips produced by NDIIS prior to actual receipt of the vaccine and faxed or emailed to the warehouse by Disease Control. All the designated sites were plotted on a map and eight cluster routes were defined for delivery[14]. The vaccine was sorted by provider and route and routing sheets were created. Vaccine for each route was put into a holding container (basket) in the refrigerator for loading at 6:00 am the next morning.

The next morning, all the vaccine in a single container was placed in a portable refrigerator, a glycerin thermometer with lead wire was placed among the vaccine and the lead wire was attached to the external temperature display of the thermometer. One route sheet was put on a clipboard with route instructions and another route sheet was attached to the top of the portable refrigerator. Each refrigerator was numbered and the number was added to the routing sheets.

The drivers would leave the warehouse in time to arrive at their first destination after the site had opened to receive it (usually 8:00am). The route driver called the recipient contact for each site a few minutes before arrival. If the contact could not be reached, the driver called the DOC and requested the DOC to make contact with the destination. On arrival at the site, all the vaccine for that site was removed from the refrigerator to a Styrofoam cooler and carried into the building, where it was transferred into the refrigerator. If the site had any coolers or shippers to return the warehouse, these were picked up by the driver. Routes were intended to be no longer than 12 hours. To keep the length of the routes down, far distant destinations (e.g., Divide County) received their allocation by certified shipper shipped by commercial carrier. The vaccine recipient shipped the certified shippers back to the warehouse once emptied.

It was not intended that the driver stay overnight with any vaccine, but return to the warehouse to report-in that same afternoon. If a driver had to stay overnight, the driver would take the vaccine refrigerator into the hotel room and plug it in. If the driver was unable to deliver all the vaccine (e.g., the recipient site refused the vaccine because they

[14] In large rural areas like North Dakota, cluster routing in which routes look like lollipops on a stick are more efficient that loop routes that look like a horseshoe.

had all they wanted), the vaccine was returned to the warehouse and reallocated for the next shipment.

Several problems had to be overcome (during and after the pandemic) until final procedures were established. These included:

- Non-certified shippers could not always maintain temperature during extreme weather. Shipping switched to controlled temperature refrigerators in temperature controlled vehicle cabins, and certified shippers.
- Refrigerators initially used were hard to set and did not reliably hold temperature. The refrigerator could be plugged into the cigarette lighter, but did not have battery backup. They were replaced with vaccine refrigerators with battery backup.
- Drivers were not initially instructed to carry vaccine into the destination building in coolers. This upset some recipients so procedures were changed.
- Attempts to use SNS software called TourSolver v. 2 were not successful. The faster way to route was by hand which proved to be quite adequate for this state. Many iterations of TourSolver have been released since then, but it may not be valuable for this purpose in this state.
- Disposable temperature monitors were not found to be reliable enough and could not be externally monitored. The disposable thermometers had a plus or minus two degree margin of error. Glycerin thermometers had a plus or minus one degree margin of error and could be externally monitored.
- DOT drivers "wore out" over the course the outbreak. The DOC switched to a contract service to transport the vaccine to its destination. This worked well.
- Certified shippers needed to be pre-cooled before loading to help them maintain the correct temperature. This resulted in a procedure change.
- Although no frozen vaccine was used during H1N1, it was used in other vaccination projects. Vaccine refrigerators can manage frozen vaccine. Packing frozen vaccine in shippers is problematic since there is no reliable source of dry ice in Bismarck.
- Two vaccine refrigerators can be run off the cigarette lighter of a truck, but not in a smaller vehicle due to insufficient amperage.
- If a refrigerator is unable to keep temperature and the time to route completion lengthy, the vaccine can be dropped off at a LPHU (if so directed by the DOC) until the problem is solved. I reality, the vaccine is not so sensitive to a modest temperature rise that that should be necessary, but the freeze-thaw threshold for that vaccine should not be crossed.

Communications between the warehouse, the DOC and Disease Control evolved over the course of the pandemic and seemed to work well during most of the course of the response. Communication from providers to the DOC or Disease Control did not always work as well. Often the first indication NDDoH got that a particular provider had all the vaccine that that clinic wanted was when the vaccine was refused at the door. Most clinics would make provisions to receive vaccine after hours if they were notified to expect it. After hour delivery was an occasional problem for private providers, but a bigger problem for some small local public health units. Communications from NDDoH to providers improved over the course of the H1N1 response. The next allocation of vaccine was posted on the FluFinder website for each provider including when to expect delivery. The only place substantial problems remained was in one of the areas which was managing vaccine allocation for its region. Substantial provider complaints were received from that region.

Warehouse Vaccine Processing during Future Pandemics

A future pandemic would follow the procedures outlined above except:

- Data loggers (with probe in glycol) which can be externally monitored and have an alarm (different from the refrigerator alarm) have replaced glycerin thermometers. These are periodically re-calibrated.
- Vaccine refrigerators 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.
- During H1N1, NDDoH attempted to receive, route, pack and deliver vaccine it received within 24 hours of receiving it. Although the policy prevented vaccine from sitting in the warehouse when it was needed by vaccine providers, it placed considerable strain on resources both in Disease Control and the warehouse. Whether to continue this policy would be an incident command decisions. In a serious pandemic when personnel resources become stretched and tired, this may be unreasonable.
- Additional contacts other than the primary contact for each destination are held in NDIIS; this information needs to be transmitted to the DOC.
- For shipped vaccine, recipients have had a hard time learning how to read the temperature log. More training is required and is being undertaken by Disease Control. Recipients must look at the logger at the time of vaccine receipt to ensure the vaccine is still good.
- Transportation capacity may be impaired in a severe pandemic. This may result in less frequent shipments and possible use of a greater combination of transportation resources to move vaccine.
- Higher volume of vaccine may cause a problem for certified shippers, but portable vaccine refrigerator capacity should not be taxed.
- Having all vaccine for a single destination inside a single, breathable container (e.g., laundry mesh bag) inside the refrigerator would prevent driver errors in selecting vaccine for each destination. This was not perceived to be a serious problem during H1N1, but occasionally errors were made.
- Destination will sign for the vaccine when they receive it.
- Sites which may have difficulty having someone available after hours to receive the vaccine need to make arrangements with an alternate recipient such as hospital or LTC facility which would be able to store the vaccine until it could be picked up by the vaccine provider.

Vaccine Documentation

During H1N1

Data from the vaccine recipient (vaccinee) was collected at the clinic site on a form designed for that purpose. The form could be scanned using an appropriate fax machine which would upload it into NDIIS.

- Persons completing the form often made little effort to write into the designated scannable boxes on the form.
- The program reading the forms did not perform adequately. This lead to data being dropped or scanned in as gibberish, including some critical information.
- Information required before the data could go into NDIIS was often unreadable or unavailable. There was no way to ensure that all the information needed was collected

at the time of the encounter. Mandatory fields had to be removed in order for the data to go in.
- Form scanning was often delayed.
- It was not possible for the person scanning the form to know of the form had been successfully transmitted or not.
- Data going into the registry often duplicated individuals rather than merging with existing individuals, mostly due to the poor data quality from the scan.

Eventually data was redirected to the DOC where manual data correction occurred.

Vaccine Documentation during Future Pandemics

Collection of all vaccine administration data during a pandemic will be important, and data needs to be available as soon as possible to permit assessment of coverage and reminder recalls for second dose administration. Consequently, all providers must agree to submit the data into NDIIS if they wish to become vaccine providers. The Immunization Program will be responsible for training providers as to how to use the NDIIS.

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 60% of records were going into NDIIS electronically by EHRs. One of the limitations of EHR is inflexibility of the systems that generate the data for NDIIS. That is, if a new field is wanted in NDIIS, the EHR cannot easily be altered to capture the information. Pharmacies and local public health account for most of the remaining vaccine that is not transferred by EHR. Few vaccinations given in LTC facilities are currently being entered into NDIIS so that data is being lost (a new grant has been received to bring LTC into NDIIS). Additionally, IHS is not yet electronically submitting immunization data to the NDIIS.

It is assumed that all or nearly all mass vaccination records will need to be collected on paper forms for later entry into NDIIS, and a very substantial portion of the vaccines given in a pandemic could take place in mass clinics. Those forms blanks would be created by Disease Control at the time of the pandemic with content adjusted to the specific pandemic situation. 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 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 delivered. This is already being done with Vaccines For Children (VFC) vaccine. (Whether this could actually be enforced during a pandemic would depend on the circumstances.) Another alternative to ensure timely entry of data into NDIIS would be for the paper records to be sent to NDDoH for entry here. Substantial numbers of temporary staff would be needed to accomplish this. Forms would be destroyed once the data is entered.

Entry of data into NDIIS from a paper 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 NDDoH for persons without existing records is not expected to be a serious problem since about 80% of all North Dakotans already have a record in the system.

NDIIS can generate recall reminders for persons who received the initial dose of pandemic vaccine once the required time between doses had elapsed. The system can produce line lists to upload to an autodialer which could deliver a generic message to persons needing to return to the clinic[15]. A more specific message would be better, especially if it is determined that to be important that a person's second dose be exactly the same vaccine (e.g., type, manufacturer) as the first dose, or at least the same adjuvant. In that case, just because sufficient time had elapse for the person to receive the second dose would not mean the specific vaccine would be available in the community. 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 when the vaccine the person needed was available to them locally, but this would be labor intensive and expensive, and likely impractical during a pandemic when hundreds of thousands of persons were receiving two doses of vaccine. Furthermore, by the time the letter was received, the vaccine the person needed might already have been used.

Adverse Event Reporting

Influenza 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, although the risk profile of the vaccine will depend on specific adjuvant used with it. The NDDoH currently recommends that providers directly report adverse events using an on-line form to VAERS (www.vaers.org). Previously, providers reported adverse events using the NDIIS. Since these events are not able to be electronically submitted to VAERS, the immunization program changed this process. During a pandemic, VAERS reporting in NDIIS could be turned back on. During H1N1, CDC pushed states to receive adverse events and investigate those that were unexplained and serious. CDC is likely to do this again during the next pandemic. Not all vaccines are quite as safe as influenza vaccine, and some are substantially less safe.

Wasted and Recalled Vaccine

Some wastage of vaccine is inevitable. Currently this is reported to NDDoH through the NDIIS. The Immunization Program 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.

Security

In the event of a serious pandemic in which many otherwise healthy persons are dying because insufficient vaccine is available to protect them, vaccine security may become a substantial problem. In that event, security will be handled as outlined in the SNS for other types of materials distribution.

Mass Vaccination Clinics

Medical Waste

[15] Use of autodialers in North Dakota is currently against the law; however, this could be altered during a pandemic by executive order.

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 expected 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, LPHU 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, including influenza, and are trained in universal and bloodborne pathogen precautions. It is possible that a public health worker shortage might lead to vaccine administration by some workers who are not normally allowed to administer vaccine, but could do so under circumstances of a Governor-declared disaster. Ensuring that these employees are adequately trained in infection control will be the responsibility of the vaccinating entity.

Prevention of transmission of influenza during a pandemic vaccination clinic is a serious concern, since presence in a pandemic vaccine clinic may increase the risk of exposure but receiving the vaccine will not provide immediate protection against disease. In other words, a vaccination clinic will have a potentially powerful anti-social distancing effect. There are several approaches that may be used to minimize the adverse social distancing:

- Universal covering of the nose and mouth – Masking appears to be at least somewhat effective a 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 may 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 three feet may be needed.
- Use of outdoor space or drive through clinics – Not all local sites have exercised drive through clinics which should more effectively limit spread between families, but many of the large jurisdictions in the state have exercised it. Throughput would likely be a problem for large scale vaccination is needed quickly.
- Clinic intensity – Lower clinic throughput may decrease the risk of transmission; if is not likely that if this will be known although if it permits greater distance between families coming in for vaccination, it should be partially effective. Lower than expected throughputs may also be necessary if an acute shortage of public health workers makes staffing large clinics impossible.

Logistics

Vaccination at the LPHU may be logistically easier than POD-based vaccination when the number of doses to be administered remains small. It will be the option of LPHU 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 SNS documentation at the local level.

Local POD plans[16] encompass both drug distribution and mass vaccination. Initial plans were developed for antibiotic prophylaxis, but have been modified to address vaccine specific issues. Issues unique to vaccination, when compared to mass dispensing of oral medication include:

- Workforce vaccinators and person drawing up vaccine/adjuvant– Even though an executive order by the Governor made under the state disaster act would provide opportunity to use providers to give vaccines who don't normally give vaccinations, the availability of providers who will be capable of administering an injection will be limited. In addition the greater physical demand of the work compared to pill dispensing will place more limitation on the number of hours a vaccinator can work without rest.
- Cold chain – Mass vaccination sites may have limited refrigeration capacity which will require LPHU to transport the vaccine from the storage site to the mass vaccination site and maintain the vaccine within temperature at the clinic site. Requirement for cold chain maintenance may limit the amount of vaccine that can be brought to the vaccination site at any one time.
- Number of persons to be treated – Unlike antibiotic dispensing which provides multiple courses of medication to the head of household, vaccination clinic will have to reach all persons.

Vaccination of Special and Dependent Populations

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

- Homebound – Vaccination of homebound will take place after mass vaccination clinics have largely completed general population vaccination. This reflects the somewhat lower risk of infection of persons who are not mobile, but more especially the low efficiency of reaching the population compared to mass clinics. In most LPHU, this will involve home visits by public health personnel.
- Outreach to custodial institutions – Delivery of vaccine to institutions which have custodial responsibility for the health of their population, when health care personnel are not on-staff to provide the vaccine, will require a visit by public health vaccine providers. Generally, public health personnel will be dispatched to go on-site after mass vaccination is completed, but institutions may be prioritized for earlier vaccination based on risk assessment. Some institutions will be able to vaccinate their own residents. These would include hospitals and clinics, long term care, some schools (if operational at that time), state penitentiaries.
- Language barriers - 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 which 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 which 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.

<u>Vaccination of Reservation Populations</u>

Some reservations have PODs which may be able to vaccinate. Otherwise, persons on reservation will need to seek vaccination at the nearest public venue off reservation. For both Spirit Lake and Turtle Mountain reservations, these venues are likely to be close. Fort

[16] Each of the 62 local POD plans includes an MOU and points of contact for both site command structure and building access including multiple access numbers. The plans are located in the secure document library of NDDoH.

Berthold is likely to be able to vaccinate locally since they have had the most stable POD structure. Standing Rock has not been able to sustain a POD in the past across changes in tribal leadership. Because of the large distance to the nearest substantial city (Mandan), and accessory transportation plan has been drafted and may need to be activated. Standing Rock is trying to re-establish a POD at this time. The NDIIS should provide the ability to track vaccine coverage among American Indians.

Emergency Use Authorization 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 DHHS 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 which would need to implemented as additional safeguards.

NDDoH would provide training of all persons who would be administering vaccine under an EUA. Training would be provided using video conferencing over Stagenet and BTWAN (hospital network), as well as by web-casting if needed to reach additional entities not tied into the videoconferencing system.

Investigational New Drug Protocol

IND protocols require specific information collection, especially related to adverse events, a detailed consent signed by each recipient and patient follow-up. Because of its high burden of documentation, investigational new drug protocols would be impossible to implement on a mass scale; however, implementation within a narrowly targeted population could be feasible. Should IND vaccine use be necessary, NDDoH will look for additional guidance specific to the vaccine being used under IND including vaccine recipients to be targeted, additional documentation requirements and reporting. The NDDoH IRB would be prepared to review the protocol on a priority basis. Prior to use of the IND protocol, NDDoH would ensure that it had:

- FDA site approval for administration;
- IRB approval by the NDDoH IRB (or a CDC IRB which NDDoH has recognized as a substitute IRB);
- A designated principal investigator. Since the vaccine would be administered under the authority of NDDoH, the State Health Officer would likely be the PI.
- A research protocol which incorporated FDA requirements for data collection and patient follow-up and to which no changes would be made without IRB review and approval.
- A reporting pathway defined for adverse event communication back to DHHS.
- State training of all persons who would be administering vaccine under an IND protocol including informed consent requirements, record keeping and reporting. Training would be provided using video conference over the Stagenet (IT backbone for state) and BTWAN (hospital network), as well as by web-casting if needed to reach additional entities not

tied into the videoconferencing system. State software used to register for and track training would be used to confirm participation in training for each site before the IND protocol could be used.

Until the time of the event, it will not be known what the extent of the utilization of a vaccine would be under an IND protocol. Once this is known, vaccine would be allocated to specific sites and duplicated consent form/protocols (duplicated through central duplication services of the state) would be distributed through the SNS system along with POD materials for clinic setup.

ATTACHMENT A
HOSPITAL PREPAREDNESS PROPOSAL FOR PANDEMIC INFLUENZA VACCINE DISTRIBUTION PRIORITIES

At this time, NDDoH is expecting that direct care providers in hospitals will be first line recipients of pandemic influenza vaccine. It is likely that initial vaccine shipments will not be sufficient to vaccinate all direct care providers; consequently, establishing a priority system for vaccination pre-event is necessary. At this time, no guidance is available for development of such a system.

Hospital preparedness representatives to the four regional HPP meetings were asked to describe a priority system for allocating the expected small numbers of vaccine doses which would initially be available to distribute to health care workers. Prioritization does not include other personnel who may be assigned vaccine outside the health care sector such as critical community infrastructure and public health.

To divide health care personnel into priority groups, the hospital planning committees were asked to only consider prioritization based on their perceptions of the approach that would save the most lives. In keeping with that overarching goal, it was recommended that they consider 1) whether the person had specialized skills which were necessary for patient care and difficult to replace (e.g., ventilator management); and 2) the level of exposure that the employee would likely have to persons infected with the pandemic strain. Since in smaller hospitals, many of the staff serve multiple roles, it was decided that the prioritization level of any individual would be based upon their highest level of priority. For example, a nurse covering both the floor and the ER would be considered ER for purposes of prioritization, since it was at a higher priority level.

PRIORITIZATION RECOMMENDATION

The following prioritization schedule represents a consensus of the hospital preparedness representatives. Tier 1 is numerically ordered with each numerical group being completed with two doses before starting the next numerical group. Lower tiers are not subdivided. If insufficient doses are available to vaccinate an entire tier (e.g., Tier 2A) or category (Tier 1 Category 1) that was eligible for vaccination, it would be up to the health care institution to decide who within the tier or category would receive the vaccine. It is expected that facilities would attempt to vaccinate some persons from across the categories represented within a tier in order to maintain all functions to the degree possible.

Tier 1

1. Critical Care Staff [ICU, ER, and Specialty Physicians (ICU, ER, and Infectious Disease)
2. Hospital designated urgent care staff (walk-in/triage area to minimize traffic in ER)
3. Primary Care Nursing Staff (RN, LPN, CNA)
4. Emergency Medical Services staff
5. Incident Commanders
6. Radiology Staff
7. Respiratory Therapy staff
8. Primary care physicians
9. General Surgeons

10. Laboratory/phlebotomy staff
11. Anesthesia
12. Inpatient pharmacy

Tier 2A

- All other physicians, nurses, CNAs
- Admitting staff
- Housekeeping
- Bio-medical staff
- Dietary staff
- Laundry staff
- Incident Command staff
- Chaplain staff

Tier 2B

- Medical records staff/ward clerks
- Central Supply staff
- Long term care staff
- Home health staff
- Social Workers/Discharge/Case managers
- Psychiatry staff/mental health providers
- General Incident Command Staff
- Security staff

Tier 3

- Purchasing staff
- Maintenance staff
- Information technology staff
- Rehab Therapy
- Admin Support
- Finance staff

Tier 4

- Any other staff without direct patient contact
- Family members of Tier 1 hospital staff

ALLOCATION

It is expected that when NDDoH receives the first shipment of vaccine, the Department Operation Center (DOC) would determine the percentage of vaccine that would go to several different domains (e.g., local public health, state public health, health care, first responders, municipal workers, and disaster management). The relative allocations between these groups will be an incident command decision guided by the situation in the state when the initial vaccine is made available and any CDC requirements. It is expected that the vast majority of doses would be allocated to health care. Based on the number of doses of vaccine available for allocation to that domain, recipient institutions would be asked to supply the number of persons who fall into each Tier 1 category. Incident command would designate which categories were eligible for vaccination, and recipients would have to agree to abide by these eligibility criteria in order to receive vaccine. For the purposes of this discussion, community

health care staff (within minimum care facilities) will be considered for vaccination based on their assigned role, as if they were hospital staff.

The available doses would be divided proportionate to the number of personnel in each of the categories that could be covered. It is the intent of NDDoH that the vaccine would be sent to destinations within 24 hours of receipt by the state. Facilities receiving vaccine would be asked to provide the vaccine to staff within 24 hours of receipt, keeping careful records of who received the vaccine and why. The receiving facility would need to provide for the security and storage of the vaccine including maintenance of cold chain.

If insufficient vaccine is available to vaccinate an entire priority group (e.g., ICU and ER), the hospital would need to decide how to allocate the vaccine. The decision needs to be logical and ethical. It could be by lottery, epidemiological risk (e.g., age), professional risk (e.g., assignment to care for pandemic patients specifically), availability to work through the pandemic or any other defensible method. The method chosen should be documented and as each person is vaccinated, it should be documented why that person was vaccinated and not someone else. These records would be made available to NDDoH on request, which would only be likely if questions were raised about ethical allocation. Given that vaccine receipt may determine whether certain persons live or die, public inquiry may occur after the pandemic.

PUBLIC HEALTH PANDEMIC INFLUENZA VACCINE PRIORITIZATION

Once the world enters into pandemic influenza, an effective vaccine is not expected to be available for several months. Although it is not possible to know how the situation will unfold, we are expecting that as vaccine is produced, it will be released to states in small quantities, and into the public sector (NDDoH) rather than the private sector. Past experience suggests that it will be up to states to determine how the vaccine will be allocated within their states within broad guidelines supplied by CDC. At this time, it is anticipated that two doses would be required by each vaccine recipient in order to acquire any protective immunity. Persons who had received one dose would be given a second dose (assuming sufficient time had elapsed) before an unvaccinated person was given their first dose.

It is expected that when NDDoH receives the first shipment of vaccine, the Department Operation Center (DOC) would determine the percentage of vaccine that would go to each of six domains as follows: local public health, state public health, health care, first responders, municipal workers, and disaster managers (listed in no particular order) in addition to any risk categories designated as high priority by CDC. The relative allocations between these groups will be guided by the situation in the state when the initial vaccine is made available. That is, different shipments of vaccine might be divided among the domains differently based on the situational assessment. It is anticipated that the largest quantity of vaccine in each shipment would be allocated to the health care domain.

The NDDoH Department Operation Center would designate which categories were eligible for vaccination and potential recipient institutions would be asked to supply the number of persons who fall into each specific eligible category. Recipients would have to agree to abide by these eligibility criteria in order to receive vaccine.

Priority
The tier table below represents the recommendation of local public health for vaccine prioritization. The final decision on eligible categories would be made by the NDDoH Department Operation. In the recommendation below, each tier and each numbered category within each tier below represents a higher priority level than the tiers or categories below it. Vaccination would be completed in the highest level tier or category before moving on to a lower category or tier. Regardless of category or tier, provision of second dose to those already having received their first dose takes precedence over provision of any first dose, assuming sufficient time as elapsed since the first dose was given.

<u>TIER 1:</u>

1. Nursing Staff
2. Public Health Officer (with direct patient contact)
3. Field Surveillance Workers

<u>TIER 2:</u>

1. PH staff at-risk of exposure*
2. Incident Command Staff

- Incident Commander
- Business Manager
- PIO
- Community members filling these functions
- EPR Coordinators

4. IT Staff

TIER 3:

1. Program Staff
2. Janitor
3. Board of Health Members
4. Primary and secondary POD people/managers
5. Families of Tier 1

* Persons having direct patient contact other than those listed above.

Local Vaccine Brokers

A local vaccine broker is a partner institution at the local level, typically a local public health unit or hospital, which has agreed to receive vaccine and administer according to state guidance and federal guidance. The role of the vaccine broker would include:

- Receipt and storage of vaccine including maintenance of cold chain;
- Security of the vaccine;
- Administration of the vaccine;
- Allocation of vaccine to end user organizations;
- Maintaining documentation of administration and reason for vaccination priority and providing that documentation on request;
- Ensuring persons receiving their initial dose receive an appropriately timed second dose, and;
- Setting clinics or PODs for mass vaccination.

Only a vaccine broker would be eligible to receive and administer the vaccine for priority vaccination of infrastructure. This would not be true of priority vaccine for demographic risk groups. All domains which were allocated doses would have to report to the vaccine broker in order to have the vaccine administered. If both a hospital and local public health unit were designated vaccine brokers, it is expected that in most cases, the local public health unit would be the primary broker responsible for splitting vials among domains and administering those doses.

ATTACHMENT C

Vaccine Management and Administration Roles During Priority Vaccination

Local Public Health Roles

By its nature, vaccination is considered to be primarily a local public health function. Local public health assumes this duty under legislative mandate and contract with NDDoH. The following are the anticipated roles of local public health:

- Receiving vaccine and signing for receipt (chain of custody)[17];
- Administering vaccine to all non-hospital priority recipients;
- Ensuring that vials which need to be split between two different groups are appropriately divided. This includes splitting vials for hospital employees when only part of the vial is allocated to hospital personnel. Those hospital employees receiving vaccine from a split vial will need to go to the LPHU to be vaccinated, unless other arrangements have been made with the LPHU.
- Ensuring that vaccinees receive their second dose as soon as possible after they become eligible for the second dose;
- Maintaining records for all priority recipients which include the reason why the person was selected for priority vaccination;
- Providing whole vials to institutions which agree to 1) perform self-administration and 2) maintain required vaccination records. (See section on custodial care.)
- Maintaining the vaccine between 35°and 46° at all times, and provide documentation of cold chain records;
- Maintaining refrigeration space in excess of daily, non-pandemic requirements sufficient to hold a local allocation equivalent to one dose per person – Given the uncertainty of potency of the vaccine and hence the number of vials of vaccine which might be received at any time, it is difficult to know with certainty the amount of refrigeration space required.
- Maintaining cold chain transportation from vaccine storage sites to public health operated clinics. That is, vaccine will be received at the LPHU; however, POD sites, one or more per region, may be at a different location. This will require transporting the vaccine from the LPHU to the vaccination site and storage of the vaccine at the site. (Vaccine which is released to other institutions for self-vaccination will also have to be kept cool, but this is the responsibility of the receiving institution. LPH would need to take care that it does not release vaccine to an entity which is packaging it for cold chain transport;
- Setting up and operating vaccine clinics of sufficient capacity to administer expeditiously the quantity of vaccine ready for administration. When vaccine quantities are small, vaccinations will occur at LPHU offices with transition to POD sites for large volume administration. The point of transition from office to POD will be at the discretion of local public health;
- Establishing hotlines which can receive reports of vaccine adverse events and forwarding adverse event reports to NDDoH;
- Entering data into the North Dakota Immunization Information System (NDIIS);
- Providing public communication in cooperation with regional and state public information officers.

Hospital Roles

[17] The receiving agent for vaccine within each local public health unit is the designee of the incident commander for the institution. NDDoH will make direct contact with the agency operations center for notification of vaccine shipments and signing custody transfer forms.

- Receiving shipments of vaccine from manufacturer or shipping agent and maintaining security and cold chain[18];
- Administering vaccine to own employees and volunteers, unless arrangements have been made specifically with local public health to complete this;
- Selecting individuals for priority vaccine within the guidelines provided by the state;
- Ensuring that employees due a second dose receive it in a timely manner;
- Maintaining records for all employees given priority vaccination including the reason why the person was selected for priority vaccination;
- Entering data into the North Dakota Immunization Information System (NDIIS);
- Receiving reports of adverse reactions caused by the vaccine and reporting that to NDDoH.

NDDoH Roles

- Designating the priority recipient groups based on pre-determined state and federal guidelines provided (responsibility of incident command in the DOC);
- Determining shipment allocations;
- Providing to the federal shipping agent the list of ship-to sites and the quantities to be shipped to each destination for each shipment;
- Receiving shipments from the manufacturer or their shipping agents and re-packaging vaccine for shipment to smaller geographic areas as necessary.
- Approving redistribution of vaccine if indicated -- If all persons within the approved priority groups in the jurisdiction of a LPHU have been vaccinated, but vaccine remains, the LPHU will call the Department Operations Center (DOC) of NDDoH which will determine whether to permit use at the local site or to re-allocate vaccine to another LPHU jurisdiction for use with priority designees in the approved groups (unlikely unless quantity of vaccine remaining unused is large). NDDoH will coordinate the transfer of the vaccine between the public health units if this becomes necessary.
- Reviewing adverse reactions to identify those of high severity or of an unusual nature which require investigation to assess the likelihood that the reaction was vaccine-related, or identify any reasons why reaction occurred (e.g., presence of a relative contraindication or absolute contraindication to vaccination). See section on adverse event reporting for additional detail.
- Providing aggregate reports to CDC in the manner requested by CDC. NOTE: In some circumstances, shipment sites will differ from administration sites (e.g., multiple PODs within the jurisdiction of a single health unit);
- Providing oversight to the NDIIS system and coordinating system changes with Noridian (Blue Cross/Blue Shield of North Dakota) which administers the software;
- Analyzing results from the NDIIS system to provide estimates of coverage, identification of local areas which appear to be experiencing barriers to rapid completion of vaccination, identification of individuals substantially overdue for second dose vaccination and identification of number of persons ready for second dose vaccination (for purposes of vaccine allocation);
- Taking the lead in working with the PIO for public communications about priority vaccination. It is expected that not all persons will willingly understand why they or their family members were not selected for priority vaccination. NDDoH will attempt to provide transparency to the process through media messages.
- Ensuring staff at the state level who are to receive priority vaccination are vaccinated. (State personnel prioritized for vaccination will be vaccinated through their local public health unit in the same way as priority vaccinees of other infrastructure institutions.)

[18] The receiving agent for vaccine within each hospital is the designee of the incident commander of the institution. NDDoH will make direct contact with the agency operations center for notification of vaccine shipments and signing custody transfer forms.

ATTACHMENT D

Prioritization of Infrastructure

Summarizing information for critical infrastructure recommendations other than the above from The Prioritization of Critical Infrastructure for a Pandemic Outbreak in the United States Working Group

www.dhs.gov/xlibrary/assets/niac/niac-**pandemic**-wg_v8-011707.pdf.

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Tier 1	Law enforcement personnel Fire services personnel Key government leaders
Tier 2	Electricity sector personnel Natural gas personnel Communications personnel Water sector personnel Critical government personnel Community suppt. & emergency mgt. (e.g. Red Cross
Tier 3	Transportation sector personnel Food and agriculture sector personnel Banking and finance personnel Pharmaceutical sector personnel Chemical sector personnel Oil sector personnel Postal and shipping personnel Other important government personnel

Sector	**Tier 1 Functions**	**Tier 2 Functions**	**Tier 3 Functions**
Financial	• Federal funds, foreign exchange, and commercial paper; • U.S. Government and agency securities; • Corporate debt and equity securities. • Sufficient critical personnel to operate and maintain minimum cash availability to the public through the ATM network (1 ATM per bank branch office).	• Obtain cash on a broader basis through the ATM network • Maintain electronic payment systems (checking, wire transfer, ACH, retail lockbox, credit/debit card) throughout a pandemic.	

Chemical	50% of critical • Production and plant first-line management; • Production, plant and system assemblers and operators; • Material recording, scheduling, dispatching, and distributing; • Industrial machinery mechanics and machinery maintenance workers; • Transportation and material moving workers; and • Healthcare and safety and occupational health providers	Other 50% of critical personnel	
Commercial facilities	50% of the most critical • Lodging • Real estate • Retail maintenance • Media	Other 50% of critical personnel	
Communications	% of criticals • Wireless service providers; • Wireline service providers; • Other communications service providers; • Manufacturers, suppliers and vendors; • Networking companies; • Information Technology companies that characterize themselves as having a communications infrastructure or provider-related role; • Communications-related system integrators; • Owners/operators of infrastructure used within the sector including cable systems, other operators and broadcasters; • Trade and other associations representing sector members; • Infrastructure owners who have national assets used in the Emergency Alerting Systems		
Emergency Services	• Fire • EMS • Law Enforcement • Emergency Management • Local Jail/Corrections Officers • Dispatch		

Electricity	• Transmission System Operators • Distribution System Operators • Power Plant Operators • Outage Response Line Mechanics • Substation Operators • Substation Technicians • SCADA Technicians	• Maintenance Line Mechanics • Power Plant Maintenance Mechanics • Customer Service Representatives • Substation Maintenance Mechanics • Material Handlers, Management, Finance and Accounting • Regulatory Affairs, Engineers	• All remaining power plant personnel • Line mechanics • Substation mechanics • Dispatchers • Supply chain • Customer service • Finance • Accounting
Oil and Natural Gas	Mission criticals for: • Oil and Natural Gas Extraction • Petroleum Manufacturing • Petroleum Merchant Wholesalers • Gasoline Stations • Pipeline Transportation (Natural Gas)	Business criticals for: • Oil and Natural Gas Extraction • Petroleum Manufacturing • Petroleum Merchant Wholesalers • Gasoline Stations • Pipeline Transportation (Natural Gas)	
Food and Agriculture	None identified		
Health Care	See Above		
IT	Those providing onsite presence to customer support.		
Nuclear			
Postal and Shipping (Public sector)	10% of critical employees in • Field processing • Movement and delivery	20% of criticals for maintenance of service	
Postal and Shipping (Private sector)	5% of criticals in • Aviation • Truck delivery • Warehouse and material management	15% of warehouse and management	

Transportation	Criticals in • Aviation air traffic controllers and critical specialty commercial pilots; • 50 percent of maritime crew members and the most critical port workers, such as crane operators; • Some critical skilled maintenance workers • 50 percent of the most critical railroad locomotive engineers, operators, and maintenance workers; • 50 percent of total drivers and support personnel for critical specialty cargos and vehicle types.	Remaining 50% of criticals	
Water and Waste Water	Not defined		