

Technical Section G: Antivirals and Vaccines



Executive Summary - Antivirals

The purpose of this section is to describe the prioritization, distribution, dispensing, and tracking systems that Minnesota has in place, and the work that needs to continue, to achieve a response that for antivirals best serves the population of this state. Additionally, details related to this section can be referred to in the MDH State and Regional SNS Plan, which is an annex of the MDH All-Hazards Response and Recovery Plan.

The goals of antiviral use in a pandemic are to:

1. Limit mortality and morbidity,
2. Minimize disruption, and
3. Reduce economic impact.

Recent possible projections state that during a severe initial first wave lasting 6-8 weeks, 1,544,000 persons in Minnesota could become ill with pandemic influenza, 172,000 may require hospitalization, and 32,900 may die (see **Attachment G**). Judicious use of antivirals will be crucial in the course of a pandemic response where supplies of them may be either inadequate or slow to arrive.

The need for distribution and dispensing of antivirals will be present for all viral strains of any pandemic. However, for the purposes of this plan, we will refer to the current threat, the H5N1 viral strain, as we describe the specific strategies.

Antivirals are an important adjunct to prevention and control of influenza. Four antiviral drugs are used in the United States:

1. Rimantadine,
2. Amantadine,
3. Oseltamivir, and,
4. Zanamivir.

This plan will deal primarily with oseltamivir and zanamivir, due to their current effectiveness in treating and preventing H5N1 influenza.

The use of antivirals in the fight against a possible pandemic is based on the following critical assumptions:

- Antivirals will have two main uses: 1) treatment and 2) prophylaxis of priority groups.
- The use of oseltamivir or zanamivir will decrease the onset of pneumonia, hospitalization (by half), and mortality.
- The use of amantadine and rimantadine may be limited because of resistance to the drugs.
- Antivirals during a pandemic will primarily be available from stockpiles at the federal, state, or local level.
- Administration during the first 48 hours of symptoms is the most effective use of antivirals for treatment of influenza.
- The amount of antivirals to stockpile will be calculated by predetermining the size of priority groups and calculating expected illness within those groups.
- The amount of antivirals stockpiled or available at the beginning of the pandemic will indicate how many in the priority group can be covered.

Based on guidance from HHS, Minnesota must develop, and assist local and tribal entities to develop, plans that will:

1. Define priority groups and their size,
2. Develop strategies for identification of priority groups, and
3. Develop strategies for distribution of antivirals to the priority groups.

Antivirals will be procured and stockpiled at the state level and in private caches. They will be used for treatment by medical providers at hospitals or other healthcare facilities. In addition, LPH may, in some instances, participate in dispensing strategies. The state, with the guidance of HHS and public and private stakeholders, will define priority groups and strategies to implement the proper use of the antivirals.

Depending on the type and location of the antiviral stockpiles, distribution will vary from private internal distribution (as in a hospital which has stockpiled their own cache) to the use of some or all of the components of the Strategic National Stockpile program. Dispensing will take place in varied scenarios as well, ranging from the hospitals for treatment of inpatients to occupational health clinics for healthcare worker prophylaxis.

The MDH has utilized antiviral guidance from the CDC and developed additional guidance for the regional and local response. With the addition of the HHS Pandemic Plan's specific antiviral recommendations, this section will lay out the various aspects of the state's response.

Health and Human Services (HHS) Recommendations

Overview

The HHS recommendations regarding antivirals focus primarily on two overall response actions:

1. Allocate stockpiled antiviral drugs for use as treatment or prophylaxis in predefined high-risk groups and critical infrastructure groups.
2. Monitor antiviral distribution and adverse events, and assess safety and effectiveness.

In July of 2005, the National Vaccine Advisory Committee (NVAC) voted unanimously in favor of the antiviral drug use priority recommendations summarized in **Attachment Q**. The votes followed deliberations of a joint working group of two committees, which included representatives of public and private sector stakeholder organizations, ethicists, and academic experts. It was recognized that the recommendations will need to be reconsidered at the time of a pandemic when information on the available drug supply, epidemiology of the disease, and impacts on society are known.

Treatment with a neuraminidase inhibitor, oseltamivir or zanamivir, will likely be effective in decreasing the risk of pneumonia, hospitalization, and mortality. Antiviral dosing is evolving. Antiviral strategies may change as more cases are studied and results are compiled. Specific guidelines will be based on factors such as resistance to the drug, efficacy studies, and new science.

Planning Activities

Rationale

Antivirals are one tool in the pandemic response. Planning for their rapid and accurate distribution, use, and subsequent monitoring is dependent on flexibility and a multi-pronged approach described in this section. As more decisions and guidance are received from the federal level operational revisions will be made.

Legal Authority

Legislative support for the use of antivirals in an emergency response is available in federal and Minnesota statutes. As outlined below:

- A. The CDC has the authority to enact the Emergency Use Authorization (EUA) of Medical Products. In an event the DOD or HHS determines that HHS will issue the EUA to utilize a product (e.g., unlicensed medication) against label or prior to licensing. EUA was part of the BioShield Legislation and is codified in federal statutes at 21 U.S.C.A. § 360bbb-3.
- B. The All-Hazards Emergency Response Act, Minn. Stat. § 12.42 (2005) will allow persons with a license or permit from another state, Canada, or District of Columbia to come into the state and use their professional skills in accordance with the Governor's request.
- C. Minn. Stat. § 148.171 subdivision 15 states a registered nurse may delegate medical functions to other nursing personnel. Medication administration is delegated to others and supervised by an RN or monitored by an LPN.
- D. The Minnesota Nurse Practice Act, Minn. Stat. § 148.235, Sub 9, Prescription by Protocol, states that an RN may give a legend drug that has been predetermined and delegated when the condition falls within the protocol and the protocol specifies the circumstances under which the drug is administered.
- E. Pharmacy Statute, Minn. Stat. § 151.01, subdivision 30, describes dispensing to include the delivery of a drug in an appropriately labeled container, pursuant to a practitioner's order, for subsequent administration to or use by an individual.
- F. Minn. Stat. 144.4147 (2005) allows the Commissioner of Health to authorize others to dispense drugs in a local or declared state emergency.

Triggers

Interpandemic period

- Availability of four antivirals to providers

Pandemic alert period

- Antiviral stockpiling options available

Pandemic period

- Cases of H5N1 in hospitals
- Clusters of H5N1
- Widespread community transmission

Actions

Interpandemic period

1. Seasonal influenza planning

Pandemic alert period

1. Develop priority group antiviral allocation.
2. Develop guidance on rationing systems for identified priority groups and implementation strategies within healthcare systems.
3. Initiate stockpiling of antivirals.
4. Develop plans for distribution to all providers.
5. Develop dispensing guidance and plans with, and for, providers and health systems.
6. Develop antiviral tracking systems.

Detailed explanation of actions during the pandemic alert period

1. Develop priority grouping to allocate antivirals –
The MDH is convening a workgroup to review the HHS recommendations for priority groups and implementation strategies. The purpose will be to decide if they best fit the individual needs of Minnesota, and to revise them if necessary. This workgroup will examine the work and opinions of citizens, ethicists, public health, business, healthcare, and other private and public stakeholders. Their findings will be a compilation of the views and values of a cross-section of the state and will be used to make final recommendations on prioritizing antivirals when they are in limited supply.
2. Develop guidance on rationing systems for identified priority groups and implementation strategies within healthcare systems-
Defining and ranking the priority groups will allow the groups to identify and enumerate their members. Delivery strategies can then be developed to implement the plan.
3. Initiate stockpiling of antivirals by federal or state government and/or hospitals (Existing Private, State, and Federal Caches of Antivirals).
 - A. Private Caches
 - Some hospitals, clinics and other organizations have or will stockpile antivirals for their own patients and essential personnel. Institutional internal distribution plans should be in place for those caches.
 - B. State/Regional Caches
 - Currently, there are no state or regional caches; however, discussion is underway to consider purchase of antivirals (in particular, oseltamivir). In the event that Minnesota purchases a state cache of antivirals, it will be stored centrally or regionally. Minnesota already has regional pharmaceutical caches in all eight public health regions of the state that include antibiotics and SNS Chempacks. Distribution of state and regional antivirals will be discussed later in this document.
 - C. Federal SNS Caches
 - The federal government has stockpiled 5.5 million courses of Oseltamivir within the SNS Program and has ordered 1.5 million additional courses.

- The national goal is to stockpile enough to supply 25% of the population for distribution to the states via the SNS program. HHS has 1.75 million courses of zanamivir.
- D. Private Sector Capabilities
- Minnesota, or jurisdictions within, may be able to obtain antivirals from the private sector, e.g., from private distributors or from the manufacturers. In this event, the manufacturers and/or distributors may manage distribution of their products to hospitals and healthcare systems (yet to be determined). The MDH surveys hospitals annually for amounts of stockpiled drugs, including oseltamivir. Some hospitals have reported a small amount of antivirals stockpiled for seasonal influenza.
4. Develop distribution plans to providers.
- Antivirals will receive and distribute via private distribution or existing SNS programs to hospitals, clinics, LPH, or other healthcare facilities to dispense for treatment to priority groups, or to occupational health clinics, LPH, or other healthcare facilities for prophylaxis.
- The SNS plans in place at the state, regional and local levels are designed to ensure that a function (distribution and dispensing) can continue to exist in a devastating event when other systems are failing. Minnesota's SNS program is flexible and is committed to responding to the changing environment of antiviral procurement and distribution. As more information becomes available about the acquisition of antivirals, pandemic and SNS plans will adjust accordingly.
- A. Federal SNS Caches of Antivirals
- The Division of SNS is currently stockpiling antivirals and will distribute them to the states. Minnesota has plans for receipt, storage, staging, distribution, and dispensing of medical supplies or pharmaceuticals in the event of a natural or terrorist attack. The mass dispensing site (MDS) SNS plan is a collaboration of federal, state, and local assets, resources, and planning. Antivirals, in this case, may be delivered to the state to the receipt storage and staging (RSS) site. The RSS stages and transports the assets to the regional distribution node (RDN) or may send the assets directly to a provider (clinic and/or hospital). The following components of the MDS SNS plan may be utilized in a pandemic response:
- a. State Distribution Plan (includes federal or state caches of antivirals)
 - Receipt, staging, storage, security of antivirals at the RSS site
 - Distribution of antivirals from the RSS site to hospitals, clinics, LPH, and other providers
 - Transportation of assets
 - Security of assets in transit
 - Inventory management and tracking of antivirals at RSS site
 - b. Regional and local distribution plan
 - RDN
 - RSS and security of antivirals at the RDN
 - Distribution of antivirals from the RDN to hospitals, clinics, other providers
 - Transportation of antivirals
 - Security of antivirals in transit
 - Inventory management and tracking at RDN
- B. State Owned Caches of Antivirals
- A Minnesota-purchased cache of antivirals will be stored centrally or regionally, and distribution plans are in place either way. Central caches of antivirals will be distributed by the MDH using the following procedures:
- a. Metro

- Repackaging: If the antivirals are delivered in bulk form (bottle filled with many regimens) they will need to be repackaged. The drugs will be transported from the MDH central storage site to the metro Regional Distribution Node and will be repackaged at that site. Following repackaging, the antivirals will be distributed metro-wide using the existing metro SNS plan. This plan will use local law enforcement (if necessary) to secure the assets and transport them to the providers (LPH, clinics, and hospitals) that will dispense the antivirals. Any participating clinics and clinic systems will need to be added to the SNS distribution plan, which now only includes hospitals and mass dispensing sites.
- No repackaging: If antivirals are delivered in individual regimens (separately packaged for each person) they will be delivered from the MDH central storage site directly to providers (clinics and/or hospitals) using local law enforcement for transportation and security.
- b. Greater Minnesota
 - The State Patrol will escort the trucks that deliver antivirals from the MDH central storage site to regional cache sites.
 - Repackaging of bulk drugs may happen at the state storage site or at the regional cache sites (yet to be determined).
 - Distribution to providers will follow each region's pharmaceutical cache distribution plan.
- C. Regional Caches of Antivirals
 - a. If antivirals are stored regionally, distribution will follow the SNS Regional Pharmaceutical Cache Plan, which differs in each region.
- 5. Develop dispensing plans and guidance with and for providers and health systems
Various antiviral caches listed above will be distributed for the purposes of treatment and prophylaxis to the dispensing sites.
 - A. Treatment with antivirals
 - Treatment of priority group persons, who present with influenza symptoms within first 48 hours will take place at the following venues:
 - Hospitals – following MDH/HHS priority group recommendations and guidance
 - Primary care clinics - following MDH/HHS priority group recommendations and guidance
 - LPH mass dispensing sites
 - B. Prophylaxis of priority groups
 - Antivirals for prophylaxis will be dispensed to priority groups according to established plans, which will vary but may include:
 - Healthcare worker (HCW) clinics within hospitals: The hospital should have an internal plan for prophylaxis of staff that is included in the priority groups as well as for enumeration and a dispensing clinic.
 - HCW clinics within occupational health clinics: Hospitals may use an internal plan that includes prophylaxing priority groups in an occupational health clinic. The plan should include enumeration and a dispensing clinic.
 - HCW clinics at primary care clinics: Clinics should have internal plan that includes prophylaxing their priority groups, enumeration, and a dispensing clinic plan.
 - Priority group clinics at LPH sites for HCWs or contacts of patients: Regional and LPH “essential personnel” plans are in place or in development in the MDH SNS Plan.

- LPH sites (mass dispensing sites) dispensing antivirals to priority groups may be set up if the supply of antivirals is large enough. The size and scope would differ depending on the amount of antivirals available at each site.
 - See individual city/county plans for city/county MDS.
 - See SNS Regional Plans in MDH SNS Plan.
- 6. Develop antiviral tracking systems

With guidance from HHS and CDC, state tracking should include:

- Distribution inventory
- Appropriate use within priority groups
- Antiviral effectiveness
- Adverse events
- Antiviral drug resistance

MDH has various tracking systems in place or in some phase of development. Planning and strategizing will need to take place to identify the best way to obtain the information listed above. The following is a brief explanation of those tracking systems.

A. Minnesota Immunization Information Connection (MIIC)

- MIIC will be utilized to document, track, and assess antiviral administration and outcomes. ITIH influenza surveillance staff will summarize and analyze data as requested by the MDH Legal Unit and by staff involved in mass dispensing.
- MIIC is the best electronic reporting tool available for hospital- and clinic-based patient-specific reporting. MIIC is user-friendly, and ITIH IT staff can readily provide MIIC access to additional users. MIIC will be expanded to include data elements needed for antiviral administration reporting and tracking during an influenza pandemic. (Note: Independent of pandemic influenza planning, ITIH staff continues to promote MIIC, with the goal of enrolling all Minnesota clinics and hospitals statewide.)
- MIIC will also be modified to include fields specific to antivirals including: antiviral agent prescribed, duration of treatment (or prophylaxis, if available for that purpose), and reason antivirals were prescribed.
- Data entry options included in MIIC to address reasons antivirals were administered will be dependent upon antiviral availability, demonstrated effectiveness of and indications for specific antiviral agent(s) available, HHS/CDC guidance, and recommendations made by the MDH Pandemic Influenza Guidelines Group and the MDH Legal Unit, with input from the MDH Clinical Advisory group.
- ITIH influenza surveillance staff will summarize and analyze MIIC data as requested.

B. SNS Assets Management System (SAM)

- The tracking of state and local coverage will be done in association with the Behavioral Risk Factor Surveillance System (BRFSS). In addition, the Minnesota SAM, which is in development, may track coverage. The Inventory Management System will do the following tracking functions:
 - The number of antivirals sent to each dispensing site (whether MDS, hospital, clinic, or other) from the RSS or the nodes.
 - The number of persons receiving antivirals in a 24 hour period by inputting data at the dispensing site (MDS, hospital, clinic, or other). This information can be sorted by dispensing site, county, region, or state.

C. Behavioral Risk Factor Surveillance (BRFSS)

- The BRFSS is a cross-sectional telephone survey conducted by state health departments with technical and methodological assistance provided by the CDC. Every year, states conduct monthly telephone surveillance using a standardized

questionnaire to determine the distribution of risk behaviors and health practices among noninstitutionalized adults. The states forward the responses to the CDC, where the monthly data are aggregated for each state. The data are returned to the states, and then published on the BRFSS Web site. New questions can be added each year on approval of the CDC.

Pandemic period

1. Provide guidance to providers on identified priority groups.
2. Continue to coordinate, review, and revise distribution plans for antivirals.
3. Establish IND protocol until EUA is available.
4. Finalize tracking and monitoring processes and provide education.

Pandemic period

1. Provide guidance to providers of priority groups
 - Prioritization of stakeholder groups for antivirals will be completed and implementation strategies will have been developed. MDH will provide continual support and guidance to hospitals, clinics, and other healthcare systems as they implement the plans. Based on antiviral supply and surveillance and epidemiological data, the MDH will reprioritize as indicated. The MDH will continually communicate activities prioritization to the public, private sector, and healthcare systems regarding target groups and optimal antiviral use.
2. Continue to coordinate, review, and revise distribution plans for antivirals. See pandemic alert period.
3. Establish IND protocol until EUA is available.
 - Develop contingency plans for emergency distribution of unlicensed antiviral drugs using IND/EUA provisions, including strict inventory control and record keeping, completion of signed consent forms, and monitoring of adverse events as required by the FDA.
4. Finalize tracking processes and provide education.
 - Monitor coverage of priority groups, adverse events and antiviral drug effectiveness and resistance. See tracking section of pandemic alert period.
 - With guidance from HHS and CDC, state tracking should include:
 - Distribution inventory
 - Appropriate use within priority groups
 - Antiviral effectiveness
 - Adverse events
 - Antiviral drug resistance

Roles and Responsibilities

State and local roles and responsibilities are identified below. Regional roles are also identified when applicable. This is not an exhaustive list. Furthermore, although roles and responsibilities are listed, the MDH recognizes that the infrastructure to support these planning efforts is evolving and may not yet be in place.

Antivirals: State			
	Roles and responsibilities	Coordinating entity	Explanation
Development of priority group listing and state wide enumeration	Review the HHS priority groupings for antiviral use to identify appropriate recipients of antiviral treatment using HHS priority group guidance work with state and federal agencies to develop a stratified system for prioritization of state workers and estimations of the numbers. Coordinate with locals to estimate numbers of antivirals needed to prophylax and treat priority groups.	Primary MDH – IDEPC, OEP, District Team, RHRCs Contributor HSEM, State agencies Medical community	Enumeration of state and federal essential personnel will be done by the state. Enumeration at the local level will be compiled by locals for the state totals.
Procurement of Antivirals	Identify sources for antivirals to purchase, survey private sector for stockpiles, encourage local and private stockpiling and maintain strong a SNS program to facilitate any distribution aspect.	Primary MDH – IDEPC, OEP, DSNS Contributor Hospitals, LPH, HSEM	

Antivirals: State			
	Roles and responsibilities	Coordinating entity	Explanation
Coordination with Stakeholders	Coordinate with locals, state healthcare and other stakeholders to establish their buy-in to dispensing by priority groups, and the appropriate use of antivirals. MDH will coordinate with private entities that own antiviral caches to follow the state priority group guidelines of appropriate use of antivirals.	Primary MDH – OEP, IDEPC MAC Contributor HSEM, LPH Medical Community, Hospitals, Clinic System, MDSs	Communication and coordination of the priority grouping with the stakeholders will be key to acceptance and proper use of the prioritization. Rationale for priority groups and importance of appropriate use is critical.
Allocation of Antivirals	Identify the high risk groups and allocate based on antivirals available and continually recommend to the providers and LPH which antiviral priority group can be served based on the availability. The DSNS program will distribute the vaccine based MDH direction.	Primary MDH IDEPC - Epi MDH DSNS Program Contributor MDH – OEP, IDEPC, ITIH	High risk groups and the amount of antivirals available may vary t/o the response. Constant communication to the providers will be necessary.
Regional Caches	Coordinate distribution of regional pharmaceutical caches throughout the state to dispensing facilities such as hospitals, clinics or other sites.	Primary District Team, RHRCs Contributor MAC, Hospitals, clinics, LPH MDH SNS, OEP	

Antivirals: State			
	Roles and responsibilities	Coordinating entity	Explanation
Distribution of Antivirals	Maintain SNS system in which antivirals will be delivered from state and federal caches to health care providers in most instances, or to other sites if indicated.	Primary MDH – OEP, IDEPC Contributor HSEM, LPH Hospitals, Clinic System, MDSs	If there were large supplies of antivirals, other sites might be established to cover prophylaxis of a targeted “cluster”, HCW population, or possibly a public clinic to give treatment to early flu victims.
Public Information	Develop and coordinate statewide public information and risk communication regarding all aspects of distribution and use of antivirals. MDH will develop message vehicles with the Media for consistent and standardized public information throughout the state.	Primary MDH Communications, IDEPC Contributor Medical Community, MAC, LPH, District Team, Media, HSEM	Public understanding of the rationale for priority grouping and providers appropriately using antivirals is important message.
State/Federal Critical Worker Planning	Develop critical worker priority listing for state and federal workers and utilize the list for use in statewide priority grouping process.	Primary MDH – ITIH, DSNS, OEP Contributor MDH collaboration, NG, Fed Exec Board, VA Hospital	

Antivirals: State			
	Roles and responsibilities	Coordinating entity	Explanation
Monitoring & Data Collection of Drug Resistance	Work with the CDC and locals to monitor; 1) distribution of antivirals, 2) adverse events, 3) development of drug resistance, and 4) effectiveness of treatment.	Primary MDH – IDEPC Contributor Medical Community MDH SNS	MDH has the DSNS system to monitor the distribution. Will need to develop strategies to monitor the other system and coordinate with systems already in place in Minnesota.
Develop Medical Protocols for antivirals	Develop a medical protocol or template of a medical protocol for providers, LPH.	Primary MDH IDEPC	
Distribution of Antivirals	Receive, repackage and distribute SNS stockpiled antivirals at the regional distribution node (RDN) or directly to a point of dispensing site such as a hospital, physician clinic or LPH. Coordinate the receipt of antiviral from private distribution or private caches if necessary.	Primary LPH, District Team, MAC Contributor Hospitals, physician clinics MDH OEP/SNS Private distribution systems	Private caches of antivirals may exist in hospitals or other organizations. Regional caches exist, but do not have antivirals included at present.

Antivirals: State			
	Roles and responsibilities	Coordinating entity	Explanation
Identification and Enumeration of Priority Groups listing and state wide enumeration	Identify priority groups and numbers based on Minnesota recommendations and clinical guidance to develop stratification for antiviral use for treatment in healthcare facilities and for prophylaxis in HCWs or other groups. Minnesota recommendations will be determined partially by a stakeholder group consisting of ethicists, healthcare, business, professional groups and the public.	Primary Hospitals, physician clinics, occupational health clinics Contributor MDH – IDEPC, MDH OEP HSEM, State agencies, stakeholder groups	Enumeration at the local level will be compiled by locals and added to state totals. Stratification of types and numbers of antiviral recipients in the priority groups will be crucial to a rapid and accurate decision making at the provider level.

Antivirals: Regional			
	Roles and responsibilities	Coordinating entity	Explanation
Distribution Of Antivirals	Coordinate with MDH and Regional Distribution Node) or directly to a point of distribution site such as a hospital, clinic or LPH. Coordinate the receipt of antiviral from private distribution or private caches if necessary.	Primary Hospitals, clinics LPH, District Team, MAC Contributor MDH SNS, OEP Private distribution systems	Private caches of antivirals may exist in hospitals or other organizations.

Antivirals: Local			
	Roles and responsibilities	Coordinating entity	Explanation
Dispensing of Antivirals	<p>Coordinate with the MDH and the CDC on clinical guidelines for dispensing treatment at hospitals and physicians' clinics.</p> <p>Coordinate with the MDH and the CDC on clinical guidelines for dispensing prophylaxis at healthcare facilities.</p> <p>Utilize MDH guidance and recommendations via alternate venues, if needed.</p>	<p>Primary LPH, District Team, MAC, RHRCs</p> <p>Contributor Hospitals, Clinic systems</p>	<p>Antivirals will be dispensed for treatment at the patient point of contact, (hospitals and clinics) and for prophylaxis at clinics, occupational health clinics or worksites. Alternative sites (less probable) might be established to cover prophylaxis of a targeted "cluster", HCW population, or possibly a public health clinic to give treatment to early flu victims.</p>
Monitoring and Tracking of Antivirals	<p>Coordinate with the MDH and the CDC to monitor 1) distribution of antivirals, 2) adverse events, 3) development of drug resistance, and 4) effectiveness of treatment, and statewide coverage numbers.</p>	<p>Primary LPH, District Team Hospitals, Physician Clinics</p> <p>Contributor MDH OEP/SNS MDH</p>	<p>MDH has the DSNS system to monitor the distribution. Will need to develop strategies to monitor and coordinate with systems already in place in Minnesota.</p>
Public Information	<p>Coordinate with statewide public information and risk communication regarding all aspects of distribution and use of antivirals.</p> <p>Coordinate with MDH clinical recommendations for providers.</p>	<p>Primary MDH Communications, District Team, LPH, MAC, MDH IDEPC</p>	<p>Public understanding of the rationale for priority grouping and providers appropriately using antivirals is important message.</p>

Executive Summary - Vaccines

The purpose of this section is to describe the prioritization, distribution, dispensing, and tracking systems that the state has in place for vaccines and the work that needs to continue, to achieve a pandemic response that best serves the population of this state. Additional details related to this section can be found in the MDH State and Regional SNS Plan, which is an annex of the MDH All-Hazards Response and Recovery Plan.

The goals of vaccine use in a pandemic are to:

1. Limit mortality and morbidity,
2. Minimize disruption, and
3. Reduce economic impact.

Recent possible projections state that during a severe initial first wave lasting 6-8 weeks, 1,544,000 persons in Minnesota could become ill with pandemic influenza, 172,000 may require hospitalization, and 32,900 may die (see **Attachment G**). Judicious use of vaccines will be crucial in the course of a pandemic response where supplies may be either inadequate or slow to arrive.

The need for distribution and dispensing of vaccines will be present for all viral strains of any pandemic. However, for the purposes of this plan, we will refer to the current threat, the H5N1 viral strain, as we describe the specific strategies.

Vaccines may be arriving from different sources and will be distributed to numerous types of venues. Vaccine distribution and use scenarios are varied and depend on continued evolution of the pandemic. Minnesota has developed scenarios for vaccine use in collaboration with the CDC and HHS that mirror much of the MDH's emergency preparedness planning.

Following its development more than 50 years ago, inactivated influenza vaccine has long been considered the cornerstone of influenza prevention and control. Three categories of influenza vaccine may be administered in a pandemic:

- The current seasonal trivalent vaccine,
- The pre-pandemic influenza vaccine (H5N1) that is being stockpiled by the federal government, and
- The specific pandemic vaccine that is not being produced as yet, because the specific pandemic human-to-human strain has not been identified.

After identification of a pandemic-causing virus, the initial production of a specific vaccine will likely take 4-6 months.

The following are critical assumptions concerning use of pandemic vaccines within our healthcare and public health system:

- Vaccine production will be slow and will lag behind the demand. The likely need for two doses of vaccine may substantially decrease the amount that we receive and increase the timeframe in which we receive it.
- Vaccination of pre-identified high-risk groups will reduce mortality and morbidity. Although these groups will shift based on the epidemiology of the pandemic, they may initially include infants, the elderly, and those with underlying health conditions.

- A significant percentage of the workforce will become ill and may be absent from work during the pandemic. Absenteeism may be greater if there is fear of infection in those unprotected with a vaccine or antiviral medication.
- The healthcare system will be overwhelmed due to the large number of individuals requiring care.
- The preservation of critical infrastructure to maintain essential societal functions will be threatened by the possibility of widespread illness.

Based on guidance from HHS, the state must develop, and assist local and tribal entities to develop, plans that will:

- Define priority groups and their size,
- Develop strategies for identification of priority groups, and
- Develop strategies for distribution of vaccines to the priority groups.

Vaccine procurement, stockpiling, and distribution are under intensive review at the national level. Vaccine will be used for prophylaxis and when the supply is short, priority grouping and allocation will be necessary. Depending on the type and location of the vaccine stockpiles, distribution will vary from private distribution (from the manufacturer or a distributor) to the use of some or all of the components of the Strategic National Stockpile program. The dispensing function will take place in varied scenarios as well, ranging from occupational health clinics for healthcare worker prophylaxis to mass vaccination clinics for the general public.

The MDH has utilized vaccine guidance from the CDC and has developed additional guidance for the regional and local response. With the addition of the HHS Pandemic Plan's specific vaccine recommendations, this plan will lay out the various aspects of the state's response.

Health and Human Services (HHS) Recommendations

Overview

HHS vaccine recommendations focus on three response actions:

1. Administer pre-pandemic stockpiled vaccine to pre-defined groups critical to a pandemic response.
2. Allocate and administer pandemic vaccine to pre-defined priority groups once available.
3. Monitor coverage and track vaccine in order to recall vaccines for a second dose, if required.

In July of 2005, the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC) voted unanimously in favor of the vaccine priority recommendations summarized in **Attachment P**. The votes followed deliberations of a joint working group of two committees, which included representatives of public and private sector stakeholder organizations, ethicists, and academic experts. It was recognized that the recommendations will need to be reconsidered at the time of a pandemic when information on the available drug supply, epidemiology of the disease, and impacts on society are known.

Planning Activities

Rationale

Vaccines are the primary prevention tool in a pandemic response. Planning for their distribution and use, and subsequent monitoring in an equitable manner is dependent on flexibility and a multi-pronged approach. Additional decisions and guidance are expected from the federal level, which will generate operational revisions to this section.

Legal Authority

Legislative support for the use of vaccines in an emergency response is available in federal and Minnesota statutes. As outlined below:

1. The CDC has the authority to enact the Emergency Use Authorization of Medical Products (EUA). In an event the DOD or HHS determines that HHS will issue the EUA to utilize a product (e.g., unlicensed medication) against label or prior to licensing. EUA was part of the BioShield Legislation and is codified in federal statutes at 21 U.S.C.A. § 360bbb-3.
2. The All-Hazards Emergency Response Act, Minn. Stat. § 12.42 (2005), will allow persons with a license or permit from another state, Canada, or District of Columbia to come into the state and use their professional skills in accordance with the Governor's request.
3. Minn. Stat. § 148.171 subdivision 15 states a registered nurse may delegate medical functions to other nursing personnel. Medication administration is delegated to others and supervised by an RN or monitored by an LPN.
4. The Minnesota Nurse Practice Act, Minn. Stat. § 148.235, Sub 9, Prescription by Protocol, where an RN may give a legend drug that has been predetermined and delegated when the condition falls within the protocol and the protocol specifies the circumstances under which the drug is administered.
5. Pharmacy Statute, Minn. Stat. § 151.01, subdivision 30, describes dispensing to include the delivery of a drug in an appropriately labeled container, pursuant to a practitioner's order, for subsequent administration to or use by an individual.
6. Minn. Stat. 144.4147 (2005) allows the Commissioner of Health to authorize others to dispense drugs in a local or declared state emergency.

Triggers

Pandemic period

- EUA authorized at federal level
- Prepandemic vaccine available
- Pandemic vaccine available

Actions

Interpandemic/pandemic alert period

- | |
|--|
| 1. Seasonal influenza planning. |
| 2. Develop priority grouping to allocate vaccines. |

3. Use accepted prioritization; develop guidance on rationing systems and implementation strategies.
4. Initiate stockpiling of vaccine supplies by federal and state government, LPH, and healthcare systems.
5. Develop distribution plans for all points of distribution.
6. Develop vaccination guidance and plans with, and for, LPH, other providers and health systems.
7. Develop tracking systems.

Detailed explanation of the pandemic alert period

1. Plan for seasonal influenza
 - A. Annual “seasonal” flu Vaccine - three strains of influenza identified to match the circulating virus.
 - Vaccination action plan of Phase 1 and 2: Interpandemic Phase.
 - Continued distribution will be implemented via state and local public/private flu-shot programs through LPH, primary care clinics and private organizations.
 - If seasonal influenza is circulating during a pre-pandemic period, the two viruses could re-assort and cause human-to-human transmission, making seasonal flu shots a critical function of response.
 - Historically, the global system for manufacturing of seasonal flu vaccine has been fragile, and has exhibited severe problems regarding production and delivery of the vaccine to the providers.
 - Pneumococcal vaccination should be encouraged for those in the high risk groups identified in the ACIP recommendations.
2. Develop priority grouping to allocate vaccines
 - A. A workgroup is being convened to review the HHS recommendations for priority groupings and implementation strategies. The purpose will be to decide if they best fit the individual needs of Minnesota, and revise them if necessary. This workgroup will examine the work and opinions of citizens, ethicists, public health, business, healthcare, and other private and public stakeholders. Their findings will be will be a compilation of the views and values of a cross-section of the state and will be used to make final recommendations on the prioritization of vaccines in a situation where the resource is in limited supply.
3. Use accepted prioritization, develop guidance on rationing systems and implementation strategies
 - A. Defining and ranking the priority groups will allow target groups to identify and enumerate their members. Delivery strategies can then be developed to implement the plan.
4. Initiate stockpiling of vaccine supplies by federal and state government, LPH, and healthcare systems
 - A. The National Institute of Allergy and Infectious Diseases (NIAID) awarded two contracts to support the production and clinical testing of an investigational vaccine based on the prototype seed strain made available by WHO. Vaccine manufacturers, Sanofi Pasteur and Chiron Corporation, currently are producing H5N1 vaccine to be used prior to the production of the pandemic strain vaccine. The vaccine production

status is evolving. Allocation of pre and pandemic vaccine to the states is under development at the national level.

5. Develop distribution plans for all points of distribution

Distribution issues are evolving at the federal level, so therefore it is difficult to plan at the state and local level. CDC is forming workgroups to deal with the issues and the state is participating in this strategizing process.

Currently there are three systems of vaccine distribution in Minnesota:

- Private market system
- State, federal and private partnership
- SNS Program

A. Private Sector Capabilities

- Minnesota may obtain their vaccine from the private sector. Private vaccine manufacturers and distributors will distribute to the state, local jurisdictions or private organizations. This is how childhood vaccines are managed in Minnesota. Further guidance and planning is required to develop a vaccine distribution system for pandemic vaccine. Private, state and federal partnerships may be options for distribution.

B. SNS Program

- The Minnesota SNS Program plans for receipt, storage, staging, distribution, and dispensing of medical supplies or pharmaceuticals in the event of a natural or terrorist attack.
- Distribution and dispensing are two of the SNS functions utilized in any response, as well as a pandemic response. Vaccines may originate from varied sources, so flexibility and contingency plans in distribution and use will be necessary.
- The MDH SNS plan is a collaboration of federal, state, and local assets, resources, and planning. Federal assets such as vaccines may be delivered to the state at the Receipt Storage and Staging Site (RSS). The state re-assorts the assets for the regions at the Regional Distribution Node (RDN). The RDN then distributes the assets to the MDSs, clinics, or hospitals in the state.

a. State distribution includes:

- Receipt, Storage and Staging Site (RSS) - receipt of vaccine and ancillary supplies
- Staging, storage, and cold chain management of vaccine and ancillary supplies at the RSS site
- Security of vaccine and ancillary supplies at the RSS site
- Distribution of vaccine and ancillary supplies from the RSS site to the regions, including:
 - Transportation of assets
 - Security of assets in transit
 - Inventory management and tracking at RSS site

b. Regional & local distribution includes:

- Regional Distribution Nodes (RDN)
- Receipt of vaccine and ancillary supplies at the RDN
- Staging, storage, and cold chain management of vaccine and ancillary supplies at the RDN
- Security of vaccine and ancillary supplies at the RDN
- Distribution of vaccine and ancillary supplies from the RDN to hospitals, MDSs, clinics, other
 - Transportation of assets
 - Security of assets in transit
 - Inventory management and tracking at RDN

6. Develop vaccination guidance and plans with, and for, LPH, providers and health systems
 - A. Vaccination of Priority Groups
 - Administering vaccine for prophylaxis to identified priority groups through regional and local essential personnel plans will vary but these plans should include:
 - Healthcare worker (HCW) clinics within hospitals: The hospital should have an internal plan for prophylaxis of staff included in the priority group as well as for enumeration and a dispensing clinic.
 - HCW clinics within occupational health clinics: Hospitals may use an internal plan that includes prophylaxing priority groups in an occupational health clinic. The plan should include enumeration and a dispensing clinic.
 - HCW clinics at primary care clinics: Clinics should have internal plan that includes prophylaxing their priority grouping, enumeration and a dispensing clinic plan.
 - Priority group clinics at LPH sites for HCWs or contacts of patients: Regional and LPH “essential personnel” plans are in place or in development in the MDH SNS Plan.
 - See individual city/county plans for city/county MDS
 - See SNS Regional Plans in MDH SNS Plan
 - B. Mass Vaccination - Large scale public clinics (Mass Dispensing Sites)
 - a. Administering vaccine to priority groups and to the general public may happen at mass dispensing sites. The size and scope may differ depending on the amount of vaccine available to administer at that site.
 - City/County Mass Dispensing Sites – see individual county plans
 - Regional Mass Dispensing Sites – see SNS Regional Plans in MDH SNS Plan, Chapter K: Regional SNS Plans
 - b. Non-traditional vaccine delivery systems already established and used in the annual seasonal influenza programs.
 - Senior Centers
 - Homecare agencies
 - Retail flu clinics
7. Develop tracking systems

MDH has various tracking systems in place or in some phase of development. Planning and strategizing will need to take place to identify the best way to obtain the information listed above. The following is a brief explanation of those tracking systems.

 - A. Minnesota Information Inventory Connection (MIIC)
 - MIIC will be utilized to document, track, and assess vaccine and antiviral administration and outcomes. ITIH influenza surveillance staff will summarize and analyze data as requested by the MDH Medical/Legal team and by staff involved in mass dispensing.
 - The existing Minnesota Immunization Information Connection (MIIC) is currently the best electronic reporting tool available for hospital- and clinic based patient-specific reporting. MIIC is user-friendly, and ITIH IT staff can readily provide MIIC access to additional users; therefore, MIIC could easily be utilized by mass dispensing clinics as well. MIIC will be expanded to include data elements needed for vaccine administration reporting and tracking during an influenza pandemic, and for antiviral use and patient outcomes. (Note: Independent of

pandemic influenza planning, ITIH staff continues to promote MIIC, with the goal of enrolling all Minnesota clinics and hospitals statewide.)

- MIIC will be modified to include fields specific to antivirals including: antiviral agent prescribed, duration of treatment (or prophylaxis, if available for that purpose), and reason antivirals were prescribed.
- Data entry options included in MIIC to address reasons vaccine were administered will be dependent upon vaccine availability, HHS/CDC guidance, and recommendations made by the MDH Pandemic Influenza Guidelines Group and the MDH Legal Unit, with input from the Clinical Advisory Group.
- ITIH influenza surveillance staff will summarize and analyze MIIC data as requested.

B. MDH SNS Assets Management system (SAM)

- Tracking coverage will be done by the Minnesota SNS Assets Management system, which will be functioning by end of 2006. SAM will do the following tracking functions:
 - Track the number of vaccines sent to each dispensing sites (whether MDSs, hospitals, clinics or other) from the RSS or the nodes.
 - Track the number of persons receiving vaccines in a twenty-four hour period by inputting data at the dispensing site (MDSs, hospitals, clinics or other). This information can be sorted by dispensing site, county, region, or state.

C. Behavioral Risk Factor Surveillance (BRFSS)

- The BRFSS is a cross-sectional telephone survey conducted by state health departments with technical and methodological assistance provided by the CDC. Every year, states conduct monthly telephone surveillance using a standardized questionnaire to determine the distribution of risk behaviors and health practices among non-institutionalized adults. The states forward the responses to the CDC, where the monthly data are aggregated for each state. The data are returned to the states, and then published on the BRFSS Web site. New questions can be added each year on approval of the CDC.

D. Vaccine Safety Tracking

- Currently, the Vaccine Adverse Event and Reporting System (VAERS) is the process for vaccines. Additional collaboration and guidance with the CDC and DHS is forthcoming.

Pandemic period

1. Provide ongoing guidance to LPH and other vaccine providers on priority groups and supply and availability of vaccine.
2. Establish IND protocol until EUA is available.
3. Continue coordination, review, and revision of distribution plans for vaccine.
4. Continue coordination, review, and revision of vaccination implementation strategies for vaccine.
5. Finalize tracking processes.

Detailed explanation of the Pandemic Period

1. Provide guidance to providers of priority groups

- Prioritization of stakeholder groups for vaccines will be completed and implementation strategies will have been developed. MDH will provide continual support and guidance to hospitals, clinics and other healthcare systems as they implement the plans. Based on vaccine supply and surveillance and epidemiological data, reprioritize as indicated. Continually communicate activities prioritization to public, private sector, healthcare systems regarding target groups and optimal vaccine use.
- 2. Establish IND protocol until EUA is available.
 - Develop contingency plans for emergency distribution of unlicensed vaccines using IND/EUA provisions, including strict inventory control and record keeping, completion of signed consent forms and monitoring of adverse events as required by the FDA.
- 3. Continued coordination, review and revision of vaccination implementation strategies for vaccine.
- 4. Continue to coordinate, review, and revise distribution plans for vaccines.
- 5. Finalize tracking processes and provide education.
 - Monitor coverage of priority groups and adverse events. See tracking section of Pandemic Alert Period. Monitor the following with guidance from HHS and the CDC, state tracking should include:
 - Distribution inventory
 - Appropriate use within priority groups
 - Vaccines effectiveness
 - Adverse events

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Roles and Responsibilities

State and local roles and responsibilities are identified below. Regional roles are also identified when applicable. This is not an exhaustive list. Furthermore, although roles and responsibilities are listed, the MDH recognizes that the infrastructure to support these planning efforts is evolving and may not yet be in place.

Vaccine: State			
	Roles and responsibilities	Coordinating entity	Explanation
Development of priority group listing and state wide enumeration	Determine how the priority groups will be defined in Minnesota with assistance from local jurisdictions, size and the needs of these groups will be estimated.	Primary MDH IDEPC MDH OEP Contributor MDH District Team LPH Local EM Federal Executive Board	Enumeration of state and federal essential personnel will be done by the state. Enumeration at the local level will be compiled by locals for the state totals.
Coordination with Stakeholders	Work with locals, state healthcare and other stakeholders to develop state-based plans, and establish buy-in to the distribution, use (by priority groups), and monitoring of the vaccine.	Primary MDH OEP MDH IDEPC MDH District Team RHRCs Contributor HSEM LPH Hospitals Clinic Systems MDSs	Communication and coordination of the priority grouping will be key to statewide acceptance and proper use of the prioritization.

Vaccine: State			
	Roles and responsibilities	Coordinating entity	Explanation
Procurement of vaccine	Take direction/guidance from HHS and CDC on purchasing vaccine from private sector, or receiving vaccine via the SNS program.	Primary MDH IDEPC Contributor MDH SNS MDH OEP Distributors manufacturers	Prepandemic vaccine may be available via SNS program. No definitive direction is available as yet on the private sector purchase.
Distribution of vaccine	Distribute vaccine originating from CDC SNS to providers, clinics, hospitals or MDSs. Functions included in distribution are security, transport, storage, and cold chain management of the vaccine from state receipt until it is handed off to the local jurisdictions.	Primary MDH SNS Program Contributor MDH OEP MDH IDEPC MDH ITIH MDH District Team RHRCs CDC DSNS DOT HSEM NG State Patrol	Private sector distribution may be done by private systems already in place or may use the SNS distribution structure.

Vaccine: State			
	Roles and responsibilities	Coordinating entity	Explanation
Allocation of vaccine	Decide on what amount of vaccine goes where within the state. Based on amounts available, MDH Epidemiology staff will make allocation decision on where and what amounts are distributed. Appropriation of the vaccine done within the SNS program.	Primary MDH IDEPC, Epidemiology MDH SNS Program Contributor MDH OEP MDH IDEPC MDH ITIH	MDH Epidemiology will identify the disease type, high-risk groups and make the allocation decision as to where and how much vaccine is distributed. The SNS program will distribute the vaccine based on the resources available
Mass Vaccination Clinic Coordination	Coordinate statewide immunization clinics from the MDH ECC with communication with regional and local EOCs.	Primary MDH ITIH Contributor MDH OEP PHPCs LPH	Statewide coordination is necessary for distribution of limited assets, use of human resources, and monitoring statewide and local numbers and coverage.
Vaccination Training	Develop training or obtain resources for vaccination training. Coordinate training in regions if necessary.	Primary MDH ITIH Contributor MDH OEP MDH District Team	

Vaccine: State			
	Roles and responsibilities	Coordinating entity	Explanation
Prioritization, Summoning, & Identification	<p>Compile lists for individuals eligible for vaccine according to MDH and HHS guidelines and with guidance from HHS, develop summoning & identification system for general public when pandemic vaccine becomes available.</p>	<p>Primary MDH Communications MDH IDEPC MDH OEP Contributor PHPCs LPH HSEM DHS CDC</p>	<p>A public summoning for the general public should be a national directive and consistent everywhere. It will require a major public information campaign.</p>
Vaccine tracking	<p>Make revisions to MIIC to track vaccine information such as:</p> <ul style="list-style-type: none"> Tracking of vaccination recipients and second doses. Tracking priority status of vaccine recipients. <p>Work with the CDC to add questions to the BRFSS to include necessary data to track numbers and state coverage. Develop SNS Assets Management system (SAM) to track vaccine distribution and use.</p>	<p>Primary MDH MIIC MDH ITIH MDH SNS Program BRFSS Contributor LPH CDC</p>	<p>MDH will have to make the decision, based on recommendations, what must be tracked. MDH has a number of tracking tools that may be used</p>
Adverse Events Monitoring	<p>Utilize guidance from HHS to develop adverse event tracking system using VAERS or CDC revision. MDH will coordinate these programs with LPH and providers.</p>	<p>Primary MDH IDEPC Contributor DHS CDC Providers LPH</p>	

Vaccine: State			
	Roles and responsibilities	Coordinating entity	Explanation
Exercising of distribution and vaccination plans	Coordinate statewide exercises and assist in localized exercises to address following issues; 1) procurement, 2) storage, 3) cold chain management, 4) security, 5) transport, 6) distribution, 7) vaccination, 8)utilization of priority lists, 9) and 10) monitoring of vaccine safety.	Primary MDH OEP MDH ITIH Contributor LPH MDH District Team HSEM Other State agency SNS partners	SNS Exercising is ongoing with a full-functional planned for May 07.
Public Information	Develop standardized public directions and messaging, education, and signage necessary for effective vaccination clinic function throughout the state. Work with media to establish vehicles for consistent messaging.	Primary MDH Communication MDH ITIH MDH OEP Contributor Media	Federal agencies have stratified their essential personnel. State agencies must take on this task.
State /Federal Critical Worker Planning	Develop critical worker priority listing for state and federal workers. Develop an operational plan for vaccination of state agency and federal agency critical workers in Minnesota.	Primary MDH ITIH SNS MDH OEP Contributor MDH collaboration NG Fed Exec Board VA Hospital	

Vaccine: State			
	Roles and responsibilities	Coordinating entity	Explanation
Develop medical protocol for vaccine administration	Develop medical protocol for administering the primary and secondary dose of vaccine.	Primary MDH IDEPC	

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Vaccine: Regional			
	Roles and responsibilities	Coordinating entity	Explanation
Regional Distribution of Vaccine	<p>Set up and coordinate all activities at the Regional Distribution Node to receive, store and distribute vaccine to local sites; MDSs, LPH, private providers, clinics, and hospitals. Security, transportation, and cold chain management are key components of vaccine management.</p> <p>Coordinate with MDH on private sector distribution via systems already in place.</p>	<p>Primary LPH MDH District Team RHRCs county emergency management</p> <p>Contributor Hospitals clinics public safety county emergency management</p>	<p>Private sector distribution, SNS program, or a combination of the two may be utilized in the distribution of vaccine keeping in mind that evolving guidance from the federal level requires flexibility in state and local planning.</p>
Mass Dispensing	<p>Coordinate with mass dispensing sites in counties and at the regional level, including allocation of limited vaccine at the regional and local level, status of staffing needs, monitoring of local and regional vaccine coverage.</p> <p>Communicate data and information back to MDH for statewide status.</p>	<p>Primary District Team MAC LPH</p>	

Vaccine: Local			
	Roles and responsibilities	Coordinating entity	Explanation
Identification & Enumeration of Priority Groups	Identify and enumerate priority group numbers based on the HHS/Minnesota recommendations, definitions and rankings within the regions and counties.	Primary LPH District Team Contributor Hospitals clinics public safety	Minnesota recommendations are not yet developed. They will be determined via an ongoing process that includes stakeholder groups, such as ethicists, healthcare, business, professional groups and the public. Stratification of types and numbers of vaccine recipients in the priority groups will be crucial to a rapid distribution of vaccine as it becomes available. Although some of this work is done, additional work is necessary once the priority groups are completed.
Coordinate Priority Grouping with Stakeholders	Coordinate, communicate, educate with healthcare systems and other local stakeholders the distribution (by priority group), use and monitoring of the vaccine.	Primary LPH District Team RHRCs Contributor MDH IDEPC MDH ITIH Hospitals Clinic Systems	Statewide acceptance and proper use of the prioritization of vaccine is crucial and will depend on the buy-in achieved by stakeholder input.
Distribution of Vaccine	Set up and coordinate all activities to receive, store, and administer vaccine to mass dispensing sites, occupational health clinics, and other points of vaccine administration, keeping in mind security, transport and cold chain management of the vaccine.	Primary LPH District Team Contributor Private distribution systems MDH SNS	Private sector distribution, SNS program, or a combination of the two may be utilized in the distribution of vaccine

Vaccine: Local			
	Roles and responsibilities	Coordinating entity	Explanation
Dispensing for Critical Workers & Other Priority Groups	Activate essential personnel plans from the SNS Regional Plans to vaccinate the persons that are included in the Prophylaxis Priority Groups. These will include LPH clinics, and hospital or health system HCW clinics.	Primary LPH District Team Contributor Hospitals Clinic Systems	A variety of essential personnel plans are in place across the state which are dependent on the type of event. These plans will need to be customized to the Minnesota vaccine priority groupings.
Dispensing For the Public	Activate regional/local mass dispensing plan to vaccinate general public using state/HHS system of summoning and identification, which has yet to be developed. Utilize mass dispensing sites as well as alternate methods of distribution, if applicable, such as physician clinics, occupational health clinics, worksites, etc.	Primary LPH District Team Contributor MDH ITIH Hospitals Clinic Systems	The amount of vaccine available will dictate the site of vaccine administration, that is, MDSs, worksites, or physician clinics.

Vaccine: Local			
	Roles and responsibilities	Coordinating entity	Explanation
Public Information	Using standardized messaging from the state; coordinate the directives, messages, education, clinic signage within the regions and the counties to ensure effective vaccine information and MDS management.	Primary LPH District Team Contributor MDH Communications MDH IDEPC HSEM county emergency management	Mass dispensing site management demands public information to be consistent and accurate.
Coordination of Mass Dispensing Sites for Vaccination	Coordinate the regional or countywide MDSs. Coordination is necessary for distribution of limited assets, use of human resources, and monitoring regional and local numbers and coverage. All information will be shared with the MDH for their state wide coordination.	Primary District Team LPH Contributor MDH ITIH MDH OEP/SNS	
Monitoring and Tracking	Coordinate with MDH on the use of SNS Assets Management System (SAM) and MIIC system of recipient tracking and second dose tracking.	Primary LPH District Team Contributor MDH OEP MDH ITIH Hospitals healthcare systems	These options are strategies for tracking of vaccine. Further development of both options is needed.

Vaccine: Local			
	Roles and responsibilities	Coordinating entity	Explanation
Identify and Train staff on vaccination, and to staff local MDSs	Identify staff for vaccination, provide pre-vaccination training and develop just-in-time training program for other staff in MDSs. See Regional MDS Plans Assist or consult with hospitals for staff education.	Primary LPH District Team Contributor MDH ITIH Hospitals healthcare systems	SNS Plans have addressed Just in Time Training. Need event specific revisions.
Secure supplies for vaccination clinics	Provide clinic supplies for a rapid set up and activation of local mass dispensing sites. Stockpiling of ancillary vaccination supplies is acceptable, but it is anticipated that CDC will provide ancillary supplies, such as syringes, needles, gloves and alcohol wipes.	Primary LPH District Team Contributor Emergency Management MDH ITIH MDH OEP/SNS	

