Draft

Missouri Department of Health and Senior Services

Pandemic Influenza Plan

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ANNEX K.1.
PANDEMIC INFLUENZA

DHSS Department Situation Room (24 hours a day, 7 days a week)

Director, Missouri Department of Health and Senior Services

Deputy Director, Missouri Department of Health and Senior Services

Director, Division of Community and Public Health

Director, Division of Regulation and Licensure

Director, Division of Senior and Disability Services

Administrator, Section for Communicable Disease Prevention

Administrator, Office of Surveillance

Center for Emergency Response and Terrorism

Medical Consultant

State Epidemiologist

Director, State Public Health Laboratory

Interim Director, Center for Local Public Health Services

Chief, Office of Public Information

Chief, Office of General Counsel

PANDEMIC INFLUENZA

Purpose:

To provide an effective response to Pandemic Influenza resulting from natural causes or a terrorist release. This response will reduce the impact on public health (i.e. reduce illness and save lives) and maintain essential services, minimizing economic loss.

Definition:

Pandemic influenza is a global influenza epidemic. It is characterized from a usual outbreak of influenza by: 1) the presence of a novel influenza virus exhibiting an "antigenic shift; 2) high population susceptibility worldwide; 3) evidence of high person-to person transmissibility; 4) widespread illness in multiple geographic areas with unusually high rates of morbidity and mortality due to the virulence of the viral infection.

Background:

Epidemics of influenza occur annually in the United States and the Department of Health and Senior Services has an ongoing program of education, surveillance, control and prevention in place to minimize the effects of these epidemics. In general the primary disease prevention strategy for epidemic influenza includes:

- Targeted vaccination* and anti-viral usage toward high-risk populations to minimize the effects of expected outbreaks.
- Public information and education.
- Enhanced surveillance.
- Isolation, quarantine, public facility closures and other control measures.

If new novel strains of influenza develop for which vaccines are not available and these strains are associated with causing epidemics or a pandemic then:

- Implementation of the DHSS Pandemic Influenza Annex as a part of the State's Emergency Response Plan would occur. **
- Notification of a pandemic influenza would come from CDC in phases.

If an unexpected epidemic should occur as a result of a known circulating strain of influenza, parts of the pandemic flu plan would be implemented to minimize the outbreak. The parts that would be implemented would depend upon the specifics of the outbreak and would be determined in consultation with CDC, DHSS experts, local public health agencies, and local and state elected officials.

(*see Appendix A for a discussion of Vaccine Delivery)
(**see Appendix B for a discussion of the integration of the Pandemic Annex with the DHSS Emergency Response Plan)

Pandemic Influenza: How Does an Influenza Pandemic Start?

There are three main types of influenza viruses: A, B, and C. Influenza C causes only mild disease and has not been associated with widespread outbreaks. Influenza types A and B, however, cause epidemics nearly every year. Influenza A viruses are divided into subtypes, based on differences in two surface proteins: hemagglutinin (H) and neuraminidase (N). Influenza B viruses are not divided into subtypes. During an influenza flu season, usually one or more influenza A subtype and B viruses circulate at the same time.

A pandemic is possible when influenza A virus makes a dramatic change (i.e., "shift") and acquires a new H or H+N. This shift results in a new or "novel" virus to which the general population has no immunity. The appearance of a novel virus is the first step toward a pandemic. However, the novel influenza A virus also must spread easily from person to person (and cause serious disease) for a pandemic to occur. Influenza B viruses do not undergo shift and do not cause influenza pandemics.

The reservoir for Type A influenza viruses is wild birds, but influenza A viruses also infect animals such as pigs and horses, as well as people. The last two pandemic viruses were combinations of bird and human influenza viruses. Many persons believe that these new viruses emerged when an intermediate host, such as a pig, was infected by both human and bird influenza A viruses at the same time. A new virus was created. Events in Hong Kong in 1997, however, showed that this is not the only way that humans can become infected with a novel virus. Sometimes, an avian influenza virus can "jump the species barrier" and move directly from chickens to humans and cause disease.

Since, by definition, a novel virus is a virus that has never previously infected humans, or has not infected humans for a long time, it is likely that almost no one will have immunity, or antibody to protect them against the novel virus. Therefore, anyone exposed to the virus--young or old, healthy or weak--could become infected and get sick. If the novel virus is related to a virus that circulated long ago, older people might have some level of immunity. It is possible that the novel virus may be especially dangerous to some age groups that are not usually at risk of severe illness or death from annual influenza (such as healthy young adults). Such widespread vulnerability makes a pandemic possible and allows it to have potentially devastating impact. ***(Source CDC)***

Assumptions in Planning

This plan is based on assumptions derived from known evidence and expert opinion. These are not predictions, but reflect historical circumstances and current trends. These assumptions are necessary for scaling the plan to some workable format. However, adjustments may be made (and can be made) within the response if certain of the assumptions prove to be false.

Assumptions Concerning the Origins of a Pandemic

- A new pandemic will be due to a new subtype of influenza A
- Emergence of new influenza A viruses is inevitable
- A new virus may be a re-emerging previously known human virus subtype which has not recently been in circulation, or a virus of avian origin, emerging either through stepwise 'adaptation' conferring greater affinity for humans or through a process of genetic 'reassortment' between the genes of an avian and human virus.
- From time to time, avian influenza viruses will infect people directly exposed to infected poultry (as has been occurring mainly in the Far East since 1997) but may not necessarily evolve into potential pandemic viruses
- Such a strain could first emerge anywhere, including Missouri, but it is most likely to emerge in the Far East—the birthplace of recent pandemics—because:
    - The close proximity of humans, ducks, other poultry and domestic pigs in farming communities in South East Asia and China facilitates mingling of human and animal viruses which may then exchange genetic material, resulting in a new 'reassorted' strain
    - Viruses may directly transfer from birds (or animals) to humans and adapt to become genetically more likely to infect people
    - Viruses may re-emerge from unrecognized or unsuspected reservoirs
    - For H5N1 there is already wide dissemination of H5N1 infection in poultry, domestic fowl and wild birds
- Whenever a new or novel influenza virus is isolated from an infected person, its potential to spread directly from person to person and cause outbreaks of illness needs to be assessed
- False alarms are likely, but until it is known whether a new virus has resulted in person-to-person transmission, its pandemic potential must remain under consideration and investigation
- Vaccine for the novel influenza virus will not be available in Missouri before the virus reaches the state
- Initial distribution of vaccine to Missouri will be extremely limited and must be prioritized to maximize effectiveness
- Effective antivirals will be in limited supply and must be prioritized to maximize effectiveness
- Education, public health interventions, and "social controls" must be relied upon initially to slow the spread of the disease within Missouri

The Phases of a Pandemic

The phases described have been summarized from the World Health Organization (WHO) global influenza preparedness plan published in 2005. It is important to understand that actual spread of the virus may or may not be described by these phases.

Interpandemic Period:

Phase 1: No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection may be present in animals. If present in animals, the risk of human infection or disease is considered low.

Phase 2: No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.

Pandemic Alert Period:

Phase 3: Human infection(s) with a new subtype, but no human-to-human spread, or at most rare instances of spread to a close contact.

Phase 4: Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.

Phase 5: Large cluster(s) but human-to-human spread still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).

Pandemic Period:

Phase 6: Pandemic; increased and sustained transmission in general population.

*********Note of Explanation Related to the Checklists and Phases**********

The Phases and assignment of responsibilities within the plan based on these phases are products of the planning assumptions. As such, the checklists begin with Phase 4 (as the current pandemic status as of August 2005 is Phase 3) based on the assumption that the virus will appear in the Far East and enter the United States and Missouri as a human disease spreading human to human. However, the possibility remains that the novel virus could emerge within the United States, or even in Missouri, rather than internationally. If a circulating animal virus subtype appears in Missouri (most likely as a High Pathogenic Avian Influenza in poultry), especially if human infections with this subtype occur (essentially Phases 2 and 3 developing in state), this will precipitate a full-scale emergency response by DHSS and associated LPHAs, the Missouri Department of Agriculture, federal health and agricultural agencies, and impacted industries.

Emergency Responsibilities:

1. The Department of Health and Senior Services (DHSS) has primary responsibility to safeguard the health of the people of the state and all its subdivisions and will respond in the event of Pandemic Influenza to limit the impact on public health. In so doing, these actions will limit the impact on the social and economic infrastructure of the state. DHSS will serve to support the local public health agencies (LPHAs) in this effort, and lead the response of a coordinated multitude of federal, state, local, and private organizations and agencies.

2. The following pages lay out the specific responsibilities for both DHSS and coordinated agencies and organizations during the Phases of Pandemic response.

3. The attached flowchart outlines these responsibilities and activities in graphic form. (flowchart under revision at this time)

Organization:
Department of Health and Senior Services Responsibilities

Director – Department of Health and Senior Services

Pandemic Alert Period: Phase 4

- Will be notified by Director of DCPH of Phase shift
- After briefing will consult with key staff and direct appropriate actions

Pandemic Alert Period: Phase 5

- Will be notified by Director of DCPH of Phase shift
- After briefing will (as necessary):
    - Notify Governor's Office
    - Declare a Public Health Emergency
    - Request Deputy Director to identify staff not working on pandemic flu and reassign and to develop work schedule
    - Activate the Department Situation Room in conjunction with the CERT Director

Pandemic Period: Phase 6

- Will be notified by Director of DCPH of Phase shift
- After briefing will:
    - Maintain the declaration of Public Health Emergency
    - Update the Governor's Office on anticipated actions
    - Have Deputy Director reduce programmatic functions to maintenance operations and designate available staff to assist in data entry, surveillance, vaccinations, medication distribution, etc.

Director – Division of Community and Public Health

Pandemic Alert Period: Phase 4

- Will be notified by State Epidemiologist of the Phase shift
  - Direct DCPH staff to assess and prepare response
- Notify Daily List (Daily List is: Director and Deputy Director of DHSS, Director of CERT, SPHL, DRL, DSDS, and CLPHS, Chief of the Office of Public Information, General Council, Medical Advisors and State Epidemiologist)
- Lead briefing discussions. *(Briefing will be set up by CERT)* Provide overview of ongoing DHSS activities with Daily List.

Pandemic Alert Period: Phase 5

- Will be notified by State Epidemiologist of the Phase shift
  - Direct DCPH staff to assess and prepare response
- Notify Daily List
- Lead briefing discussions. *(Briefing will be set up by CERT)* Provide overview of ongoing DHSS activities with Daily List.
- Project effects of the novel influenza outbreak
- Discuss major elements of enhanced surveillance
- Discuss vaccine/antiviral plan
- Recommend priority vaccination and antiviral distribution
- Discuss communication strategies for LPHAs, Hospitals and Public

Pandemic Period: Phase 6

- Will be notified by State Epidemiologist of the Phase shift
  - Direct DCPH staff to assess and prepare response
- Notify Daily list
- Provide updates and briefings

Director - Center for Emergency Response and Terrorism

Pandemic Alert Period: Phase 4

- Will be notified by State Epidemiologist of the Phase shift
- Set up briefing for Director of DCPH
- Communicate with internal and external staff by issuing a Health Alert

Pandemic Alert Period: Phase 5

- Will be notified by State Epidemiologist of the Phase shift
- Set up briefing for Director of DCPH
- After briefing – Notify SEMA
- Stand-up DSR, as directed by the Director of DHSS
- Communicate with internal and external staff by issuing a Health Alert

Pandemic Period: Phase 6

- Will be notified by State Epidemiologist of a Phase shift
- Set up briefing for Director of DCPH
- Notify SEMA
- Communicate with internal and external staff by issuing a Health Alert

State Epidemiologist

Pandemic Alert Period: Phase 4

- Will be notified by CDC of Phase shifts
- Notify the Director of DCPH of the change in alert status
- Notify the Director of CERT of the change in alert status
- Participate in briefings
- Carry out normal duties as they apply to outbreaks
- Monitor bulletins and events related to influenza and engage in vigorous proactive communications with CDC related to the novel influenza virus

Pandemic Alert Period: Phase 5

- Monitor bulletins from CDC regarding virologic, epidemiologic and clinical findings associated with new variants isolated within and outside of the United States.
- Notify the Director of DCPH of the change in alert status
- Notify the Director of CERT of the change in alert status
- Participate in conference calls
- Continue to carry out duties as they apply to outbreaks

Pandemic Period: Phase 6

- Notify the Director of DCPH of the change in alert status
- Notify the Director of CERT of the change in alert status
- Continue to carry out duties as they apply to outbreaks

Chief – Office of Public Information

Pandemic Alert Period: Phase 4

After briefing by Director of DCPH will:

- Coordinate and control public information
- Develop key messages for media and general public
- Coordinate message with the Office of the Governor
- Reexamine prepared media releases
- Update media releases if needed
- Review and be prepared to use Public Information Emergency Communications Plan
- Check availability of key spokespersons
- Brief key spokespersons as necessary
- Finalize communications strategy with Daily List
- Consult with Department experts if needed
- Prepare for media and public inquiries
- Participate/arrange media release and press briefings
- Schedule media informational workshops in several locations throughout the state.
- Ensure web site information is updated routinely
- Be prepared to expand hotline to10 lines and additional DHSS call handlers

Pandemic Alert Period: Phase 5

After briefing by Director of DCPH will:

- Continue in coordinating and controlling information as above
- Develop new messages in accordance with changes in the outbreak

Pandemic Period: Phase 6

After briefing by Director of DCPH will:

Continue as above

Administrator – Section for Communicable Disease Prevention

Pandemic Alert Period: Phase 4

After instruction from Director of DCPH will:

- Instruct the Immunization section to:
  - Review Appendix A
    - Vaccination/drug plan
    - Prioritize target group
    - Determine Points of Dispensing (POD) (hospitals, LPHAs)
    - Coordinate with SPHL on testing
    - Monitor staffing/workload gaps
    - Work with CERT in the preparation of Health Alerts

Notify the Local Public Health Agencies to:
- Implement their pandemic flu plans
- Communicate updates

Pandemic Alert Period: Phase 5

After instruction from Director of DCPH will:

- Brief new employees assigned to work on pandemic influenza
- Evaluate resources available to vaccinate and manage the outbreak
- Communicate to Immunization Section
- Work with CERT in the preparation of Health Alerts
- Provide updates to the Director of DCPH

Pandemic Period: Phase 6

After instruction from Director of DCPH will:

- Continue as above in addition to other Emergency Response duties

Administrator – Office of Surveillance

Pandemic Alert Period: Phase 4

After instruction by Director of DCPH will:

- Coordinate heightened surveillance efforts, including:
    - BT and Passive Surveillance, Sentinel Providers
    - Daily monitoring of hospitals
    - Communicate with LPHA's
    - Communicate with surveillance sites
    - Analysis of data
- Coordinate with the Administrator of SCDP
- Provide updates to the Director of DCPH

Pandemic Alert Period: Phase 5

After instruction by Director of DCPH will:

- Continue the Coordination of heightened surveillance efforts (as above), and (if necessary):
    - Monitor non-hospital related deaths
    - Monitor adverse events related to vaccines and anti-virals
- Coordinate with the Administrator of SCDP
- Provide updates to the Director of DCPH

Pandemic Period: Phase 6

After briefing by Director of DCPH will:

- Continue the Coordination of heightened surveillance efforts (as above)
- Coordinate with the Administrator of SCDP
- Provide updates to the Director of DCPH

Section For Health Standards and Licensure

Pandemic Alert Period: Phase 4

After briefing from Director of DCPH will:

- Ask hospitals to determine availability of critical equipment and medicines

Pandemic Alert Period: Phase 5

After briefing from Director of DCPH will:

- Update POD Hospitals, Providers, Missouri Hospital Association.
- Activate local response plans

Pandemic Period: Phase 6

After briefing from Director of DCPH will:

- Update POD Hospitals, Providers, Missouri Hospital Association.
- Continue as above

Director – State Public Health Laboratory

Pandemic Alert Period: Phase 4

After briefing from DCPH Director will:

- Enhance surveillance for the novel virus throughout the state by supplying such information on sample submission and protocols as necessary to LRN laboratories by Health Alerts formed in cooperation with SCDP and CERT and by other communication means if needed

- Increase communications with CDC to ensure the best information regarding strain typing, reagent specifics, and other such information related to the novel virus is available to the SPHL and associated network of partners

- Redirect staffing, inspect equipment, monitor supplies, and other such steps as needed in preparation for testing the novel virus

- Communicate, in an expeditious manner to the Director of DCPH, any confirmation of the novel virus within the state

- Coordinate, with LPHAs, in providing technical consultation, necessary sampling kits, and other assistance as may be needed in surveillance for the novel virus

Pandemic Alert Period: Phase 5

After briefing from DCPH Director will:

- Continue as above in coordination and communications with DCPH, LRN, LPHAs, CDC, and so forth.
- Update, in conjunction with SCDP and CERT, Health Alerts modifying (by prioritization of regions, details of sample submission, etc.) the enhanced surveillance effort for the novel virus
- Communicate, in an expeditious manner to the Director of DCPH, trends and movement of the novel virus within the state

Pandemic Period: Phase 6

After briefing from DCPH Director will:

- Continue as above

Director-Center for Local Public Health Services

Pandemic Alert Period: Phase 4

After Briefing from DCPH Director will**:**

- Maintain communications with the Administrator of SCDP
- Maintain communications with the DSR (once activated)
- Maintain communications with LPHA Administrators
- Poll LPHAs to determine needed doses of vaccine and antivirals for identified high priority populations
- Coordinate with the Administrator of SCDP on vaccine and antiviral information
- Interpret DHSS guidance for LPHAs, provide advice, maintain relationships, answer questions, and make referrals
- Assist in the assessment of capacities and capabilities of the LPHAs
- Serve as a conduit of information flow between DHSS and the LPHAs
- Redirect staff and resources within CLPHS as necessary
- Maintain knowledge of the deployment level of the LPHA workforce
- Recommend LPHA representatives for providing local input
- Work with DCPH Director to consider easing routine contract work of LPHAs to free staff for the pandemic effort

Pandemic Alert Period: Phase 5

- Continue as above

Pandemic Period: Phase 6

- Continue as above

Responsibilities of Partnered Agencies and Organizations

Centers for Disease Control

Pandemic Alert Period: Phase 4

- Publish bulletins re: virologic, epidemiologic, and clinical findings about new variants isolated within or outside of the United States
- Notify the State Epidemiologist that a Phase shift has occurred
- Supply the State Public Health Lab with appropriate reagents to detect & identify the novel strain when they become available
- The National Vaccine Program Office will convene it's pandemic flu working group

Pandemic Alert Period: Phase 5

- Publish weekly (or as needed) bulletins regarding virologic, epidemiologic, and clinical findings associated with new variants isolated within or outside of the United States
- Notify the State Epidemiologist that a Phase shift has occurred
- Activate electronic mail distribution lists to provide influenza activity information to State Program Managers (State Epidemiologist, Director DCPH, Care Prevention Unit or designees at DHSS will receive these messages)
- Schedule regular conference calls with State Program Managers to update them on Global pandemic activity and to ensure coordination of programmatic activities

Pandemic Period: Phase 6

- Supply vaccine and antivirals as appropriate to State
- Notify the State Epidemiologist that a Phase shift has occurred

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Local Public Health Agencies

Pandemic Alert Period: Phase 4

After briefing by Administrator of CDP will:

- Activate Heightened Surveillance
- Communicate updates to POD local hospitals etc. and work with them to determine availability of critical equipment/medications

Pandemic Alert Period: Phase 5

After briefing by Administrator CDP will:

- Implement Pandemic Flu Plans
- Activate Heightened Surveillance
- Communicate updates to POD local hospitals etc., and work with them to determine availability of critical equipment/medications

Pandemic Period: Phase 6

After briefing by Administrator CDP Unit will:

- Work with local hospitals & immunization section in implementing vaccine distribution
- Activate drug distribution
- Full activation of plan

State Emergency Management Agency

Pandemic Alert Period: Phase 4

- Will be notified of the Phase shift by CERT
- Assess resources
- Provide communication linkages

Pandemic Alert Period: Phase 5

- Will be notified of the Phase shift by CERT
- Outline program initiatives by DHSS
- Consider formation of a Joint Public Information Center
- Consider activation of partial SEOC

Pandemic Period: Phase 6

- Will be notified of the Phase shift by CERT
- Consider full activation of SEOC

Appendix A: Vaccine Delivery

Vaccine Delivery:

Vaccine Delivery
- Continue to distribute and control use of vaccines and antivirals
- Modify distribution system as needed to ensure optimal coverage
- Assess supply status and any imminent needs
- Prepare report assessing vaccine delivery response

B. VACCINE DELIVERY

1.Introduction
The annual distribution and administration of vaccine for each winter's predicted strain of influenza is an "institutionalized" process involving both the public and private sectors. For this annual vaccination effort, the vaccine type is predicted by the Centers for Disease Control and Prevention (CDC) approximately 18 months before the anticipated influenza season. In recent years, manufacturers have predicted that 90-100 million doses would be available over a six- to eight-month period.

Except for some children 8 years of age and younger, effective immunization is generally achieved with a single dose of vaccine. Approximately 90 percent of the vaccine is administered by the private sector and is directed toward high-risk individuals as defined by Advisory Committee on Immunization Practices (ACIP). The next pandemic will pose a number of threats to this existing vaccine delivery and immunization process. Critical factors that will affect the current system of vaccine distribution include the following:

- The time period for the identification, production, and distribution of vaccine to prevent influenza will be greatly shortened, placing considerable burdens on all existing processes and procedures.
- Because time frames for planned production, distribution, and administration may be shortened, significant shortages and delays in vaccine availability will likely arise.
- Limited allotments of vaccine will be shipped to states, probably on a weekly basis.
- In all likelihood, the target population for vaccination coverage will be extended well beyond the typical high-risk populations, with a potential goal of vaccinating the entire population.
- The influenza virus encountered during a pandemic will represent a new strain, with new hemagglutinin (HA) and/or neuraminidase (NA) antigens. Thus, to maximize vaccine efficacy, a second dose of vaccine given approximately 30 days after the initial administration may be necessary.

As a result of these concerns and considerations, state and local public health providers must develop a strategic plan for the management of vaccine delivery and administration during a pandemic. That plan must ensure that the distribution and allocation of available vaccine is completed in an organized and coordinated manner in order to maximize the public's health and safety.

2. Assumptions

When considering the challenges that must be addressed to ensure a smooth and efficient distribution of available vaccine, the state of Missouri has accepted CDC guidance and has based its plan for making vaccine available on the following assumptions:

a. Supply

Based on guidelines issued by the CDC, it is understood that in the event of a pandemic, the total vaccine supply will initially be under the control of the federal government. This suggests that Missouri will be assigned an "allotment" of vaccine and that all distribution efforts will be based on that allocation.

b. Distribution Activity

Actual distribution activities cannot begin until the CDC, in cooperation with manufacturers, can offer an expected date for delivery of vaccine.

c. Shortages

The vaccine allotment may not be adequate to meet the state's entire need for vaccine. That is, vaccine shortages are expected. These shortages may be so extensive that the vaccine supply would not be adequate to protect all individuals identified as having a critical role in managing the crisis.

d. Costs

The state of Missouri and local communities will need to absorb the "up-front" costs associated with the purchase, delivery, and administration of vaccine. The CDC anticipates that national resources *may* be able to offset costs, although the exact level and nature of such resources is not yet determined. Federal resource assistance may include such items as federal contracts for the purchase of vaccine, grants, or reimbursement activities to subsidize the costs associated with vaccine distribution. However, at a minimum, the state and its local public health communities should expect to absorb the costs associated with the redirection of personnel and should expect to use other financial resources to meet immunization objectives.

e. Liability

Any activity related to liability issues and concerns that may be associated with instances of adverse reactions to vaccine administration will be the responsibility of the federal government. For inclusion in this federal liability coverage, the medical provider must ensure there is adequate and accurate documentation regarding the vaccine administration process and be able to identify vaccine recipients. This information must be entered into the state's electronic immunization registry.

f. Centralized Control

Activity to properly manage the distribution and allocation of available vaccine will begin as soon as is reasonably possible. However, excessively short implementation periods, limited supply, or the emergence of a highly incapacitated infrastructure may require the state's executive leadership to issue a state of emergency. An Executive Order from the Governor will be needed for the deployment and use of state personnel, supplies, equipment, materials, and facilities: this intervention would facilitate access to and use of expanded resources to meet vaccination objectives.

3. Interpandemic Infrastructure

As a base for disaster planning associated with vaccine delivery issues, Missouri intends to rely to a large extent on the strength of its current distribution system, which is based in the Department of Health and Senior Services' Section for Communicable Disease Prevention and the contract vaccine distributor. That infrastructure is currently used to efficiently distribute childhood vaccine. In 2004, an average of 76,500 doses of childhood vaccine was distributed each month. This distribution program has the systems, policies, and procedures, and these processes can be adapted to assist the state in its pandemic vaccine distribution goals and objectives. Specifically, the current distribution system includes:

- A contract pharmacy warehouse for management of a state distribution system.
- Adequate coolers and back-up power for proper storage of vaccine.
- Adequate supplies for repackaging vaccine as necessary.
- Established protocols and lines of communication.
- An existing communications infrastructure, which includes phone and fax accessibility for the community.
- An existing computer system for tracking inventory receipt and shipping.
- Trained professional and support staff, who are capable of preparing shipments for up to 35 different sites per day, with shipments averaging 6,000 doses per day, for shipment 3 days per week.
- Experience with providing rapid, accurate service with the ability to complete and ship orders within two to three days of receipt.

4. Pandemic Vaccine Supply and Distribution

a. Supply Needs versus Allocation

Missouri had approximately 5.7 million residents in the year 2003. Faced with a novel influenza virus, estimates suggest that Missouri could need over 11 million doses of vaccine, with adequate lead-time, to fully immunize its population. However, due to anticipated shortages and delays in acquiring vaccine, the actual distribution will, in most likelihood, be substantially less than the amount needed for full population immunization.

b. Ordering and Distribution

Assuming that the need will exceed vaccine availability, Missouri will submit its order to the CDC for the maximum allocation of vaccine. The CDC will assume responsibility for ensuring that the manufacturer ships the vaccine to Missouri's contract vaccine distributor. If the manufacturers and the CDC allow multiple shipping sites, local public health agency or its previously identified community partner in selected large counties

will be targeted for direct shipment. In order for counties to be considered for direct receipt of vaccine, the following conditions must be met:

- The local public health agency must have adequate storage capacity to safely accept direct shipments.
- The epidemiology of the disease suggests that faster access to vaccine is needed in that community.
- The local public health agency has developed a clear community-based plan to ensure vaccine will be quickly and properly redistributed throughout the county.

The contract vaccine distributor estimates it would be able to store one million doses of influenza vaccine at any one time. This amount is in addition to the other vaccines and biologicals normally stored in its facilities. Temporary relocation of some existing inventory would be considered if capacity storage greater than one million doses is needed. Current activities are underway to identify the state's partners, such as local hospitals, that would be able to assist with these short-term emergency storage needs.

The Section for Communicable Disease Prevention and the contract vaccine distributor staff will focus on redistributing the flu vaccine as quickly as possible to local communities.

5. Local Public Health Agency Activity

For the majority of Missouri's 115 counties, the local vaccine storage site will be based at the local public health agency. These facilities have the experience and resources to properly store and secure vaccine as well as track its receipt and redistribution. As local storage sites, each local public health agency will be responsible for developing a local plan that conforms to the priorities set forth below. Specifically, local public health agencies will be required to:

- Educate the local community in advance of a pandemic.
- Identify the maximum amount of vaccine that can be accepted under emergency conditions for short-term storage.
- Define procedures to assure the biological safety and physical security of the vaccine within the local public health agency.
- Identify the community partners who will work with the heath department to administer vaccine to targeted populations.
- Define procedures to accurately document the receipt and re-distribution of vaccine. This documentation should, at a minimum, indicate the amount and date the vaccine is received, as well as the amount, date, and method of redistribution to the identified community partner. (Note: The immunization program in EHCDP is currently working with the SNS Program Manager (and awaiting further guidance from the CDC) to determine the most expeditious manner of vaccine distribution documentation).
- Develop a system for notifying those partners with as much advance notice as possible. Notice will include timing for the local availability of vaccine for delivery or pick-up.

- Assure that the redistribution of vaccine will occur prior to receiving the next capacity shipment so that no vaccine is lost because of storage shortages. In some counties, where large provider groups can accept direct shipment of large amounts of vaccine, additional local distribution sites may be added. These additional shipping sites should be identified and included in the local public health agency's plan. Examples of sites that local communities should consider for direct shipment from the contract vaccine distributor include:

    - Hospitals and medical centers.
    - Tertiary care centers with extensive outreach clinics and services.
    - Large provider practices serving over 1,000 persons per month.
    - Large residential facilities with over 500 beds serving elderly, disabled, or other dependent populations.

The contract vaccine distributor will continue shipments of vaccine to local public health agency and other identified community sites as necessary to address community needs. Shipments may occur weekly or monthly depending on vaccine supply and usage. If local public health agencies need additional staff to manage excessively large shipments or to continue vaccine management and shipping activity for extended hours or over non-traditional workdays, staff from DHSS will be recruited. When developing a redistribution plan, local public health agencies should consider the following provider groups as potential partners for vaccine redistribution and administration:

- Federally funded health care centers and clinics
- Private medical providers, coordinated through the local medical society
- Urgent care centers, walk-in clinics, or managed care organizations
- Hospitals with outpatient services and clinics
- Hospital emergency facilities
- Nursing homes and assisted living facilities
- Paramedics and emergency management personnel
- School health clinics, including colleges and universities
- Commercial health care vendors (e.g., home health agencies)
- Local emergency response and support agencies, such as the Red Cross

The recruitment of community partners will depend on the resources available to the community. In addition, the actual coordination with community partners may be further refined based on the populations that are targeted for actual disease management during a pandemic. In working with community partners that will administer vaccine during a pandemic, local public health agencies must ensure that these partners understand their roles and the expectations associated with this partnership. Specifically, the community partner must be prepared to accept and store their allotment of vaccine and must ensure that vaccine administration is properly documented for accountability purposes, and in the event that reimbursement becomes available. Finally, the personnel resources devoted by community partners should be considered a public health contribution to the community, rather than a cost-reimbursable or profit-making activity.

During a pandemic, communities who believe they are not receiving their fair share of vaccine, or community members who believe they are not receiving the full cooperation of the local public health agencies, will be directed to contact the Department of Health and Senior Services, Section for Communicable Disease Prevention. That office will assume responsibility for managing calls and requests from the community to consider amendments to the allocation, distribution sites, and shipment allotments.

6. Targeted Recipient Groups

a. Establishing Target Recipient Groups

In view of the likely vaccine shortage, the United States Public Health Service, in conjunction with various advisory committees has formulated *draft* recommendations for a rank-order list of high priority target groups for vaccination. The order of these groups is based on a number of factors including the need to maintain those elements of community infrastructure that are essential to carrying out the pandemic response plan. Other factors include limiting mortality among high-risk groups, the reduction of morbidity in the general population, and the minimization of social disruption and economic losses. The draft rank-order list is subject to change – potentially on short notice - depending on the epidemiological and clinical features exhibited by the actual pandemic strain. Plans based on these draft recommendations should contain a great deal of flexibility in order to be responsive both to the final recommendations and changing conditions during the pandemic.

b. Rank-Order List of High-Risk Groups

- Health-care workers and public health personnel involved in the distribution of vaccine.
- Persons responsible for community safety and security, e.g., police, firefighters, paramedics, military personnel, National Guard, “local responders” not included in first priority group (e.g., ambulance drivers).
- Other highly skilled persons who provide essential community services whose absence would either pose a significant hazard to public safety (e.g., nuclear power workers) or severely disrupt the pandemic response effort (e.g., persons who operated regional telecommunications or electric utility grids). Members of these groups are likely to vary widely from community to community and are highly influenced by local circumstances.
- Persons traditionally considered being at increased risk of severe influenza illness and mortality, as currently defined by the Advisory Committee on Immunization Practices.
- Persons of any age with high-risk medical conditions.
- Pregnant women.
- Persons in nursing homes and other long-term care facilities.
- Persons age 65 or older without identified high-risk medical conditions.
- Infants between the ages of 6 to 23 months, if supported by epidemiological and clinical data.

- Persons who, in the judgment of state and local health officials, provide critical community services (e.g., utility workers, funeral services personnel, persons involved in the transport of essential goods such as food).
- Household contacts of persons with high-risk medical conditions and household contacts of persons in the first three groups.
- Pre-school age children (especially those attending day-care-centers).
- Healthy persons between the ages of 18 and 64.
- Healthy school-age children (the population least likely to have severe illness).

c. Reporting Adverse Events to Vaccination

Suspected adverse events to vaccination can be reported by providers, vaccine recipients, or anyone with responsibility for the health care of vaccine recipients. They can be reported to the Vaccine Adverse Event Reporting System (VAERS) on the web at http://www.vaers.org/, by mail using the VAERS form, which is attached, or by calling 800-822-7967. The designated VAERS coordinator at the Missouri Department of Health and Senior Services can obtain information on all reporting of adverse events by calling 866-628-9891.

d. General Considerations

Both the public and private sector will be mobilized to administer whatever vaccine is available. The exact proportion of vaccine to be purchased and administered through the public versus the private sector is yet to be established. However, it is likely that the public sector will take responsibility, at a minimum, for vaccinating health care workers, other "local responders," certain essential community servants, the poor, and the uninsured. The actual organization of the vaccination program, in both the public and private sectors, will have to be customized for each community and target group and will depend on the extent and availability of the available infrastructure and resources. Success of the pandemic vaccination program will be determined in large part by public confidence in the benefits of influenza vaccination and the strength of state and local planning.

d. References

[complete references to come]

C. ANTIVIRAL AGENTS

1. Introduction

The current situation with antiviral agents presents numerous challenges to their effective use in pandemic flu planning and hence in the event of a pandemic. Currently there are four agents. The two standard antiviral agents for years have been amantadine and rimantadine. These drugs can be used for treatment if available early enough in the clinical course of a patient, or for prevention, but are effective against influenza type A only. These agents also have side effects, including effects on the central nervous system, which can make their long-term use a problem in people with key leadership or technical roles. The new classes of drugs are

neuraminidase inhibitors that were originally approved for treatment use only, but one has recently received approval for prevention as well. These are effective against influenza types A and B. There may be other agents with varying recommended uses available in the future. Certain conditions would have to change in order for antivirals to become a reliable and consistent part of any pandemic influenza planning:

A. A centralized supply of a sufficient amount of these agents would have to be available for controlled distribution in any kind of planned effort.

B. Guidelines for effective use in a community setting for a pandemic situation would have to be further defined with accepted standards.

C. Cost effectiveness of preventive versus therapeutic use should be analyzed for anticipated use in pandemic conditions.

Currently none of these assurances is available. While these questions are being Studied, the lack of definitive information or direction creates uncertainty surrounding the appropriate use of these agents in an influenza pandemic.

2. Assumptions

A sufficient quantity of these agents would have to be available to the Central Pharmacy or to specific local public health agencies in order for any planned effectual use of these medications to take place.

3. Infrastructure and Distribution

A similar method to that described in the vaccine delivery part of this plan would be used to distribute antiviral medications. Key to any distribution plan in determining where the priorities are for places to distribute the medications would be specifics as to the exact ways the antivirals are recommended for use.

While the primary focus of the state's plan is on the distribution of vaccine for the prevention of a novel influenza virus, the CDC anticipates that a limited amount of antivirals will be available for the treatment of the disease. Their estimates suggest that nationally, adequate antiviral stock will be available to treat from 500,000 to 3 million persons per month. In addition to the anticipated limited supply, the administration of antivirals as either a prophylaxis or treatment regimen is rigorous, requiring approximately 60 doses per month to prevent illness and approximately 10 doses for therapeutic intervention. Therefore, the contract pharmacy warehouse will control distribution and use of Missouri's allocation of any antivirals. The Department of Health and Senior Services and the executive committee involved in implementing this plan shall identify those individuals and groups of individuals who shall be eligible to receive these agents. In general, use of antivirals shall be reserved for the highest priority groups with consideration given to maintaining the integrity of the healthcare community and the leadership and persons responsible for the safety and security of the communities most effected by the novel virus.

4. Targeted Recipient Groups

Special consideration needs to be given to the decisions made for who receives the probably limited supply of antivirals. The most appropriate use would result in combination of risk groups, those in most need of amelioration of their disease and while at the same time most critical to continuation of health and community

services. While this might be the most effective use of these limited supplies, this will also encounter controversy as use in this way would make available antivirals to certain key individuals who are seriously ill or with predisposing conditions and not make it available to other individuals who are similarly ill with comparable predispositions. In addition, because of the anticipated limited supply, a formula for distribution is challenging in these terms because of special case considerations. This means that certain key locales would have to serve as distribution points in any effort.

Annex B:

Integration with the Department's Emergency Response Plan:
Preparing for, responding to, and recovering from pandemic influenza has many similarities to other disease outbreaks, be they naturally occurring or resulting from terrorist action. The goals of prevention and control of these outbreaks, and the time honored public health activities to lessen the impact on morbidity and mortality, namely, education, vaccination, prophylaxis, isolation/quarantine, and the closure of public facilities remains in many respects very similar, despite the particular disease of concern. In addition, clear, concise communication to the public, within the DHSS, and with other agencies remains a critical component, as does the ability of the involved agencies to achieve collaboration and coordination.

DHSS has Emergency Response Plans in place that have been tried, tested, and exercised relating to all aspects of response and recovery, including those mentioned above relating to disease surveillance, investigation, and control. Where necessary, details or public information templates unique to pandemic influenza have been added into the existing plan and this annex, and this annex outlines the pandemic mechanics from the federal level and lists pandemic specific job duties for DHSS staff and the roles of partnered agencies and organizations.