

Distribution of Medical Countermeasures FAQs

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- Why should hospitals prepare and exercise plans for pandemic influenza?
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Why should hospitals prepare and exercise plans for pandemic influenza?

Some will say this discussion of the Avian Flu is an overreaction. Some may say, "Did we cry wolf?" The reality is if the H5N1 virus does not trigger pandemic flu, there will be another virus that will.

HHS Secretary Michael Leavitt, November 2005

- Another influenza pandemic is inevitable
- All will be susceptible
- The impact on health and society will be great
- Asymptomatic or minimally-symptomatic individuals may spread infection
- We do not know to what viral strain will ultimately cause the pandemic; therefore, medical science is not yet able to fashion strain-specific targeted therapy (e.g., vaccine), nor do we know the efficacy of the antivirals currently available
- We cannot depend on a lengthy lead-time between determination of advent of pandemic and determination of the first case in Mississippi
- A wave of severe disease may last up to 4 months
- The pandemic may last up to 18 months, occurring in waves, with waxing and waning mortality and morbidity
- Seasonal flu infectivity is approximately 20%; pandemic influenza infectivity is predicted to range from 20-40%
- Predictions of deaths from PI in Mississippi are approximately 16,000 individuals; MS seasonal influenza death toll is approx 1,000
- Aggregate absenteeism may exceed 50%, with absenteeism based on illness, caring for those ill, or those who are the "worried well"
- Overplanning will be better tolerated than underplanning, given the consequences of underplanning
- Planning for pandemic influenza will facilitate, encourage, and generalize to more effective planning for other possible medical, natural, or man-made disasters

What types of medical countermeasures will be distributed to states by the Federal Division of the Strategic National Stockpile?

1. Antiviral medications— Two drugs (in the neuraminidase inhibitors class), oseltamivir (commercially known as Tamiflu ®) and zanamivir (commercially known as Relenza ®)
2. Facemasks-- Facemasks are loose-fitting, disposable masks that cover the nose and mouth. These include products labeled as surgical, dental, medical procedure, isolation, and laser masks. Facemasks help stop droplets from being spread by the person wearing them. They also keep splashes or sprays from reaching the mouth and nose of the person wearing the facemask. They are not designed to protect you against breathing in very small particles. Facemasks should be used once and then thrown away in the trash.
3. Respirators—There are multiple types of N-95 respirators on hand in the SNS. A respirator (for example, an N95 or higher filtering facepiece respirator) is designed to protect you from breathing in very small particles, which might contain viruses. These types of respirators fit tightly to the face so that most air is inhaled through the filter material. To work most effectively, N95 respirators must be specially fitted for each person who wears one (this is called “fit-testing” and is usually done in a workplace where respirators are used). **The Federal Strategic National Stockpile currently has N95 respirators from Kimberly Clark, 3M, Moldex and Gerson. N95’s from other vendors could be obtained with future procurements.**
4. Additional items in SNS inventory—Personal protective equipment (protective face shields, gowns, gloves), intravenous antibiotics, and other medical supplies.
5. Ventilators—Currently, the SNS includes two models of ventilators, the Puritan Bennett LP10 and the Impact Uni-Vent Eagle 754.

Figure 1. Surgical Mask



Figure 2. N95 Filtering Facepiece Respirators (A-E)

A. Cup style N95 respirator:



Photo courtesy of Moldex

B. Duckbill N95 respirator



Photo courtesy of Kimberly-Clark

C. C. Fan fold N95 respirator



Photo courtesy of Alpha Pro Tech

D. Flat fold N95 respirator



Photo courtesy of 3M



Photo courtesy of NIOSH

E. Pleated N95 respirator



Photos courtesy of Aearo



Photos courtesy of AO Safety

How can hospitals expect to receive medical countermeasures to support efforts during an influenza pandemic?

The Department of Health and Human Services (DHHS)/Centers for Disease Control and Prevention (CDC) plan for allocation and distribution of medical countermeasures includes a proactive push to States. The Director of the CDC in consultation with the Secretary of HHS will determine when to activate the SNS to begin the distribution of the medical materiel based on the WHO Phase characterization and the severity of disease. The "triggers" for deployment of these assets continue to be discussed within HHS and CDC, but confirmation of sustained human to human (domestically or internationally) will play very heavily on outcomes. Currently, States expect that receipt of medical countermeasures will be distributed using a "metered" methodology: Mississippi would receive 25% of the above-described medical materiel in 4 separate aliquots. The timeframe for receipt of each of the aliquots will also be determined by the CDC. Once medical materiel is received by the Mississippi State Department of Health (MSDH), it will in turn be distributed to locals without delay. The proactive distribution of medical materiel by Federal and State public health entities ensures supplies are received by locals before the need for assets becomes critical. Recommendations for appropriate use and timing for use will be communicated by the MSDH at that time as well. For Mississippi's plan for distribution to local medical entities, please see last question on this handout.

What are the medical recommendations for use of antivirals, facemasks, and respirators?

1. Antivirals

In speaking to the medical recommendations for the use of antivirals, the distinction must first be made regarding the logistical source of the antivirals. **Antivirals received through the Federally subsidized contract to states and antivirals received through distribution from the Federal SNS program are labeled and intended for treatment purposes only.**

Medical recommendations for use of antivirals are consistent at the time of this statement with guidance contained in the U.S. Department of Health and Human Services Pandemic Influenza Plan posted at www.pandemicflu.gov. Recommendations will be updated as additional federal guidance is received.

Use of antiviral drugs during an influenza pandemic will fall into three categories: pre-exposure prophylaxis, post-exposure prophylaxis, and treatment of influenza illness. Part 2, Supplement 7, of the HHS plan, addresses these uses of antiviral drugs. Because of the limited global capacity to manufacture antiviral drugs, federal guidance currently emphasizes their use for treatment of influenza illness. In addition, the use of antivirals for prophylaxis will be constrained by increasing risk of side effects with prolonged use and the potential emergence of drug-resistant variants of the pandemic strain, particularly with long-term use of M2 inhibitors (amantadine and rimantadine). Fortunately, the need for antiviral prophylaxis may decrease once an effective PI vaccine becomes available for use among healthcare workers and other groups receiving prophylactic antivirals.

According to current federal planning guidance, **pre-exposure prophylaxis** would be used primarily in the following three groups:

- Health care workers in emergency departments, intensive care units, dialysis centers, and EMS providers since these groups are most critical to an effective healthcare response and have limited surge capacity;
- Outpatients who are in the highest risk groups for hospitalization and death;
- Other health care workers with direct patient contact to decrease absenteeism and preserve optimal function of the health care system.

Post-exposure prophylaxis might be useful in the following settings:

- Attempts to control small, well-defined disease clusters, for example, outbreaks in long-term care facilities;

- For the protection of individuals with a known recent exposure to a pandemic virus, for example, household contacts of PI patients.

Additional consideration regarding the use of antivirals for prophylaxis:

- If a pandemic virus is susceptible to M2 ion channel inhibitors, amantadine and rimantadine should be reserved for prophylaxis, although drug resistance may emerge quickly;
- The number of persons who receive prophylaxis with oseltamivir should be minimized, primarily to extend supplies available to treat persons at highest risk of serious morbidity and mortality. If sufficient antiviral supplies are available, prophylaxis should be used only during peak periods of virus circulation to protect small groups of front-line healthcare workers and other providers of essential community services prior to availability of vaccine;
- Strategies for antiviral prophylaxis may be revised as the pandemic progresses, depending on supplies, on what is learned about the pandemic strain and on when a vaccine becomes available.

Considerations regarding the use of antivirals in the treatment of influenza illness:

- The effectiveness of the drugs, among other things, depends on their early administration (within 48 hours after symptom onset).
- Antivirals may help prevent infection in people at risk and lessen the impact of symptoms in those infected with influenza.
- It is unlikely that they would substantially modify the course or effectively contain the spread of an influenza pandemic.
- A number of antiviral medications (antivirals) are approved by the U.S. Food and Drug Administration (FDA) to treat and sometimes prevent flu. At this time, Tamiflu® and Relenza® are the most likely antivirals to be used in a pandemic.

2. *Facemasks and respirators*

Recommendations for use of facemasks are consistent at the time of this statement with guidance contained in the U.S. Department of Health and Human Services

Interim Guidance on Planning for the Use of Surgical Masks and Respirators in Health Care Settings during an Influenza Pandemic posted at www.pandemicflu.gov. Recommendations will be updated as additional federal guidance is received.

Use of Surgical Masks and Respirators in Health Care Settings

Surgical mask and respirator use is one component of a system of infection control practices to prevent the spread of infection between infected and non-infected persons where pandemic influenza patients might receive health care services (e.g., hospitals, emergency departments, out-patient facilities, residential care facilities, emergency medical services, home health care delivery). During an influenza pandemic, surgical masks and respirators—along with other forms of personal protective equipment (e.g., gloves, gowns, and goggles)—should be used by health care personnel in health care settings in conjunction with Standard and Droplet Precautions, respiratory hygiene, cough etiquette, vaccination, and early diagnosis and treatment.

Recommendations

1. National Institute for Occupational Safety and Health (NIOSH)-certified respirators (N95 or higher) are recommended for use during activities that have a high likelihood of generating infectious respiratory aerosols,^[c] including the following high-risk situations:^[d]

- Aerosol-generating procedures (e.g., endotracheal intubation, nebulizer treatment, and bronchoscopy) performed on patients with confirmed or suspected pandemic influenza
- Resuscitation of a patient with confirmed or suspected pandemic influenza (i.e., emergency intubation or cardiac pulmonary resuscitation)
- Providing direct care for patients with confirmed or suspected pandemic influenza-associated pneumonia (as determined on the basis of clinical diagnosis or chest x-ray), who might produce larger-than-normal amounts of respirable infectious particles when they cough

In the event of actual or anticipated shortages of N95 respirators:

- Other NIOSH-certified N-, R-, or P-class respirators should be considered in lieu of the N95 respirator.
 - If re-useable elastomeric respirators are used, these respirators must be decontaminated according to the manufacturer's instructions after each use.
 - Powered air purifying respirators (PAPRs) may be considered for certain workers and tasks (e.g., high-risk activities). Loose-fitting PAPRs have the advantages of providing eye protection, being comfortable to wear, and not requiring fit-testing; however, hearing (e.g., for auscultation) is impaired, limiting their utility for clinical care. Training is required to ensure proper use and care of PAPRs.
2. Use of N95 respirators for other direct care activities involving patients with confirmed or suspected pandemic influenza is also prudent. Hospital planners should take this into consideration during planning and preparation in their facilities when ordering supplies. In addition, several measures can be employed to minimize the number of personnel required to come in contact with suspected or confirmed pandemic influenza patients, thereby reducing worker exposure and minimizing the demand for respirators. Such measures include the following:
- Establishing specific wards for patients with pandemic influenza
 - Assigning dedicated staff (e.g., health care, housekeeping, janitorial) to provide care for pandemic influenza patients and restricting those staff from working with non-influenza patients
 - Dedicating entrances and passageways for influenza patients

Planning assumptions and projections suggest that shortages of respirators are likely in a sustained pandemic ([22](#)). Therefore, in the event of an actual or anticipated shortage, hospital planners must ensure that sufficient numbers of respirators are prioritized for use during the high-risk procedures described in [Recommendation 1](#). This will require careful planning as well as real-time supply monitoring to ensure that excess respirators are not held in reserve while health care personnel are conducting activities for which they would otherwise be provided respiratory protection. Conversely, excessive use of respirators could result in their unavailability for high-risk procedures. Decision guidance for determining respirator wear should consider factors such as duration, frequency, proximity, and degree of contact with the patient. Occupational health and safety professionals can assist with making these site- and activity-specific decisions. For example, a nurse entering a room with a suspected or confirmed pandemic influenza patient to obtain vital signs should wear an N95 respirator. A housekeeper entering multiple rooms of confirmed or suspected influenza patients to mop floors or clean patient equipment should be similarly protected. Work activities such as those performed by a receptionist at the entrance of a hospital should be designed to prevent exposure of the worker to large numbers of potentially infected patients. In such situations, the use of transparent barriers or enclosures is preferable to the use of respirators.

If supplies of N95 (or higher) respirators are not available, surgical masks can provide benefits against large droplet exposure, and should be worn for all health care activities for patients with confirmed or suspected pandemic-influenza.

3. Negative pressure isolation is not required for routine patient care of individuals with pandemic influenza. If possible, airborne infection isolation rooms should be used when performing high-risk

aerosol-generating procedures. If work flow, timing, resources, availability, or other factors prevent the use of airborne infection isolation rooms, it is prudent to conduct these activities in a private room (with the door closed) or other enclosed area, if possible, and to limit personnel in the room to the minimum number necessary to perform the procedure properly.

Guidance for Correct Use

Respirator use should be in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) regulations. Detailed information on respiratory protection programs, including fit test procedures, can be accessed at OSHA's Respiratory Protection eTool (www.osha.gov/SLTC/etools/respiratory). Staff with responsibility for direct patient care should be medically cleared, trained, and fit-tested for respirator use. Training topics should include the following:

- Proper fit-testing, wearing, and use of respirators
- Safe removal of respirators
- Safe disposal of respirators
- Medical contraindications to respirator use

If a respirator that provides protection from splashes of blood or body fluids is needed, NIOSH-certified, FDA-cleared surgical N95 (or higher) respirators should be selected. Additional information on N95 respirators and other types of respirators may be found in [Appendix B](#), at: NIOSH's Respirator Fact Sheet (<http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respfact.html>), and at FDA's Masks and N95 Respirators (www.fda.gov/cdrh/ppe/masksrespirators.html) fact sheet.

Persons who wear surgical masks or respirators should be advised that:

- Surgical mask or respirator use should not take the place of preventive interventions, such as respiratory etiquette and hand hygiene.
- To offer protection, surgical masks and respirators must be worn correctly and consistently throughout the time they are used.
- Wearing a surgical mask or respirator incorrectly, or removing or disposing of it improperly, could allow contamination of the hands or mucous membranes of the wearer or others, possibly resulting in disease transmission.
- Proper surgical mask or respirator use and removal includes the following:
- Prior to putting on a respirator or surgical mask, wash hands thoroughly with soap and water or use an alcohol-based hand sanitizer to reduce the possibility of inadvertent contact between contaminated hands and mucous membranes.
- If worn in the presence of infectious persons, a respirator or surgical mask may become contaminated with infectious material; therefore, avoid touching the outside of the device to help prevent contamination of hands.
- Once worn in the presence of a patient with patient with pandemic influenza, the surgical mask or disposable N95 respirator should be removed and appropriately discarded.
- After the surgical mask or respirator has been removed and discarded, wash hands thoroughly with soap and water, or use an alcohol-based hand sanitizer.
- Further information can be found at <http://www.cdc.gov/ncidod/sars/respirators.htm> and <http://www.cdc.gov/niosh/npptl/topics/respirators/factsheets/respsars.html#E>.

Will hospitals receive any ventilators?

Ventilators received through the SNS will be distributed to alternate care sites to support care for patients with pandemic influenza. Hospitals should take inventory of all ventilators, including those that may currently be out-of-service (may be an older model) but function properly. It is possible that these out-of-service models could augment supplies of ventilators at hospitals.

Will hospitals receive pandemic strain vaccine for immunization of hospital staff?

Yes, hospitals can expect to receive pandemic strain vaccine, **when available**, for immunization of hospital staff. The overarching objectives guiding vaccine allocation and use during a pandemic are to reduce the impact of the pandemic on health and minimize disruption to society and the economy. Important program objectives are to:

- Protect those who are essential to the pandemic response and provide care for persons who are ill;
- Protect those who maintain essential community services;
- Protect children; and
- Protect workers who are at greater risk of infection due to their job.

Furthermore, as characteristics of the influenza strain responsible for the pandemic emerges, risk groups will be more clearly identified and efforts will be streamlined to target these risk groups.

When could hospitals expect to receive pandemic strain vaccine?

To date, 1.8 billion dollars have been expended on research that enhances the methodology for vaccine production. This research is on-going. Planning assumptions have remained the same, with vaccine production requiring 4 – 6 months from the time the strain causing the outbreak is identified and the vaccine strain is selected.

Will vaccination require one or two doses?

Neither the amount of antigen included in each dose nor the requirement of one or two doses has been determined. A NIH trial of a Sanofi-Pasteur H5N1 vaccine found that high amounts of antigen (up to two 90-mcg doses) were required to generate an immune response inferred to be protective in most healthy adults (Trenor et al. NEJM 2006, 354:1343-51). Therefore, planning assumptions currently include the need for two doses given at a 28-day interval.

Will hospitals receive antivirals to provide prophylaxis to direct patient care workers?

Antivirals received through the Federally subsidized contract to states and antivirals received through distribution from the Federal SNS program are labeled and intended for treatment purposes only. MSDH encourages hospitals to be proactive in planning, addressing provision of prophylaxis for their staff.

Who will receive antivirals?

Due to the short time frame for initiation of antivirals, within 48 hours of symptom onset, most antivirals from the SNS will be distributed for use in the outpatient setting. Smaller proportions will be distributed to hospitals for treatment of hospitalized patients with pandemic influenza disease.

What is Mississippi's plan for distribution of medical countermeasures?

To aid in allocation and distribution of medical countermeasures, the MSDH Office of Emergency Preparedness and Response is currently collecting community data. Data includes information on local resources (e.g., number of first responders, number of hospitals, clinics, alternate care sites, home health agencies and nursing homes, etc) and evaluation of potential local impact from an influenza pandemic utilizing the CDC programs FluAid 2.0 and FluSurge 2.0 (located at www.pandemicflu.gov). These data will be collated as a needs assessment. Allocation will be *pro rata* by county with allocation to each receiving entity within the county based on the needs assessment. Allocations will be bundled by the State for each receiving medical entity prior to distribution to the counties. The MSDH will coordinate with each county to identify drop site(s). MSDH encourages local emergency planning agencies to coordinate in these planning and logistical issues associated with distribution of medical countermeasures.