



Medical Countermeasures

Vaccine Manufacturing, Distribution, Tracking and Administration

Vaccine development, research and purchase should be priority activities in planning for pandemic influenza on the federal level, as pandemic viruses might be resistant to antivirals or develop drug resistance due to widespread use.^{17,18} The goal of developing and utilizing a vaccine for pandemic flu will differ from the seasonal flu vaccine because of the expected severity of the illness. Ultimately, vaccine use should prevent mortality and severe morbidity associated with pandemic influenza.³⁴ Vaccine administration may also be different if two doses of vaccine are required to achieve a protective level of immunity. If two doses of vaccine are required, then the education of the public will be a key component, as they are accustomed to the one-dose seasonal influenza vaccine.⁹

The HHS plan did not clearly outline whether federal purchase of influenza vaccine and centralized distribution will continue beyond the onset of a pandemic. Our current system of private purchase, reliant on supply and demand, will not give vaccine manufacturers ample incentive to produce all the necessary pandemic influenza vaccine, as there is no guarantee that they will have leftover vaccine due to insufficient purchasing levels. Also of concern is that the distribution of pandemic vaccine to health departments and providers may occur through private-sector vaccine distributors or directly from the manufacturer(s), without adequate federal oversight, and state and local public health input. Thus, the vaccine may not be available to those at highest risk.

Therefore, APHA recommends that:

1. A substantial, if not complete, federal purchase of pandemic influenza vaccine, with some buyback provision included, be guaranteed by the federal government. This will ensure that there are a number of vaccine manufacturers committed to produce adequate amounts of the vaccine most effective against the pandemic influenza strain.
2. Congress appropriate additional resources to research activities targeted at manufacturing and utilizing cell-culture influenza vaccines.
3. Additional research be carried out targeted at pandemic vaccine development, including reducing the amount of HA antigen required to reach a protective level of immunity, alternative means to administer the vaccine and use of known and novel adjuvants to enhance immunogenicity.
4. Additional funds be made available to the CDC for developing and testing vaccine distribution and tracking systems.

Antiviral Drug Distribution, Tracking and Use

Antiviral medications such as oseltamivir and zanamivir have been shown to reduce the severity and duration of seasonal influenza, typically reducing the duration of illness by one or two days.^{19,20} However, their efficacy in effectively treating many individuals during an influenza pandemic is uncertain at best.²³ The problem is that influenza strains can become resistant to antivirals, the medication needs to be administered within the first two days of the onset of symptoms to be effective, and the supply will likely be dramatically less than the projected need.²⁴

The HHS plan, considering that an effective pandemic vaccine will not be in general circulation during the first months of an influenza pandemic, calls for the purchase of

enough antivirals — oseltamivir and zanamivir — to treat 25 percent of the population. Efforts center on the federal purchase of 44 million courses of antiviral drugs for treatment, with another 6 million courses for containment. However, the federal plan contains a strategy to leverage state tax dollars to purchase the remaining 31 million courses of antiviral drugs with a 25 percent federal subsidy. Public health officials must have the flexibility to provide the medication where outbreaks are most severe, as certain states and communities will likely be affected more than others. Also, the plan does not account for the fact that with current antiviral production capacity, there will likely be a shortage of antivirals at the advent of a flu pandemic as well.

Therefore, APHA recommends that:

1. Congress require the federal government protect Americans by purchasing all of antiviral treatment courses deemed necessary, as the level of protection Americans receive should not be determined by where they live and the current fiscal position of their states.
2. The U.S. government examine the effects of and consider increasing incentives for pharmaceutical companies to invest in the research concerning new drug development, efficacy assessments, and production capacity of antivirals to determine the most effective drugs, doses, timing for administration, the best methods of administration, and its integration into plans for vaccination.
3. Congress appropriate additional resources to bolster U.S. production capacity of antivirals to ensure that the supply of antivirals in the event of a flu pandemic is sufficient to meet national demand.
4. Congress appropriate additional funds to CDC to develop and test antiviral drug distribution and tracking systems.
5. HHS formulate guidelines that outline strategies and priority groups for both treatment and prophylaxis.

Medical and Lab Supply Stockpiling and Use

The Strategic National Stockpile plays a key role in amassing medical material. However, there are still inadequate funds for critical medicines and supplies, such as ventilators, syringes, gloves and intravenous antibiotics that will be in high demand during a pandemic. Equal priority should be given to assuring such material is available to permit a comprehensive response to a pandemic. Without it, manufacturers of key medical and lab supplies will not have the incentive necessary, or be able to invest in increasing their capacity, to produce such a high quantity of goods. Lessons learned from the Hurricane

Katrina response include the need to stockpile response-related equipment and medication as well.³ Stockpiling efforts must include durable medical equipment and assistive devices and medications for children with special health needs, immunizations, and equipment and medication needed to maintain the health status of those with chronic illness, HIV/AIDS and other health problems.

Therefore, APHA recommends that:

1. Congress appropriate new, additional and sufficient resources towards the stockpiling of critical medicines and supplies, such as ventilators, syringes, gloves, intravenous antibiotics, reagents and N95 respirators.
2. Funds be dedicated towards the stockpiling of equipment and medication needed to maintain the health status of those with chronic illness, HIV/AIDS and other health problems during a pandemic, including insulin, dialysis machines and oxygen.
3. HHS work in cooperation and coordination with state and local health departments to create guidelines for the public use of certain stockpiled supplies, such as surgical masks, which may be necessary to transport patients from one location to another.
4. The Food and Drug Administration review its guidelines that limit the supply of prescription medication to be dispensed per prescription, so that individuals with serious health problems can access the prescriptions they need in the event of isolation or quarantine orders during a pandemic.

Liability/Compensation Issues

Countermeasures administered in advance of or in response to an influenza pandemic may pose health risks to individuals receiving prophylaxis or treatment. Vaccines, antiviral medications and other medical countermeasures are necessary tools to slow or halt the spread of the pandemic and to treat affected, or infected, individuals. However, all medical countermeasures carry some risk of adverse effects. Individuals who experience illness, disability or death as a result of the administration of a medical countermeasure to combat pandemic influenza should have some method to receive compensation for their losses.

Immunity from tort liability for industry and fair compensation for patients offers a sound dual approach to vaccine policy. The national Vaccine Injury Compensation Program (VICP) has created a no-fault system that pays for injuries caused by specific immunizations.²¹ To recover compensation from the VICP, claimants must show that a listed vaccine caused their

injury. Compensation comes from a Compensation Trust Fund financed by a tax on each administered dose.²⁵ Congress added influenza to VICP in 2004.²⁵ However, the VICP only covers trivalent (annual) influenza vaccine.

Health care workers and patients would be less likely to volunteer without a fair compensation system, as the failed smallpox vaccination campaign demonstrated.²² A no-fault system, like VICP, would provide relief for injured patients and greater certainty for industry. A reformed VICP system would have to take account of important issues: an overwhelmed program, resulting in delays; assuring there is sufficient money in the compensation trust fund; and injustices caused by excessive burdens placed on patients injured by a new vaccine. In return, the industry should be spared lawsuits based on strict liability, but should answer to claims of recklessness or gross negligence.

Therefore, APHA recommends that:

1. Recommends that a federally funded compensation program be established for those who become ill or are injured, disabled or die as a result of receiving the pandemic or experimental influenza vaccine.