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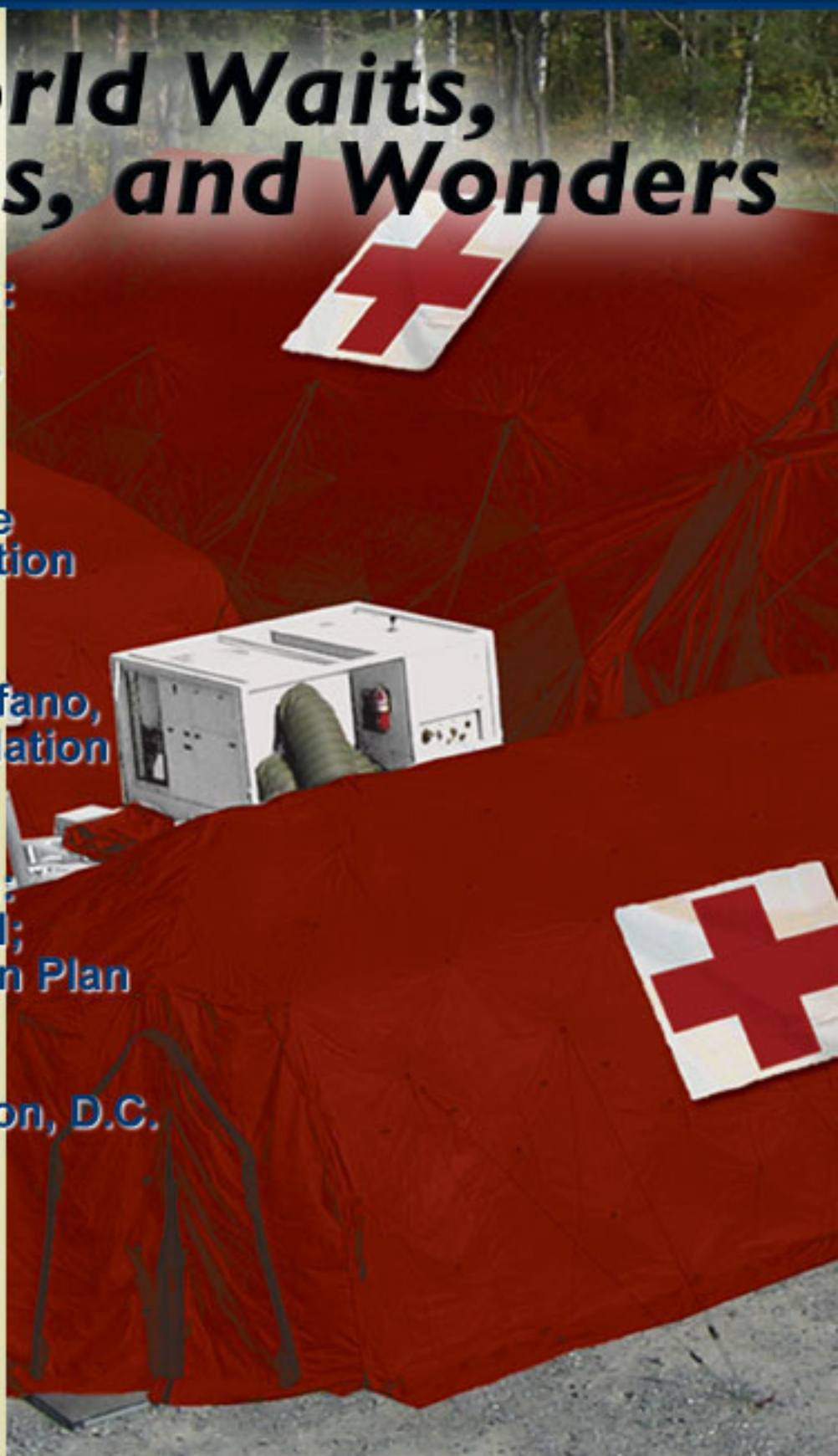
The World Waits, Watches, and Wonders



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Editor's Notes

By James D. Hessman, Editor in Chief

The invisible cloud of avian influenza now gathering just over the horizon may eventually dissipate and be remembered five years hence as only the latest in a long series of hyperventilated news events predicting a global doomsday that never quite arrives. Or it may be the precursor to a true apocalypse, of biblical proportions, that kills more humans than all of the wars, tsunamis, hurricanes, earthquakes, and other disasters, both natural and manmade, of the past 20 years or more combined.

Regrettably, the latter possibility seems more likely than the first. The misnamed "Spanish Flu" of 1918 and 1919 (which medical researchers say may well have started somewhere in Asia) killed anywhere from 25 million to 50 million people worldwide. Despite notable improvements in scientific detection and research technology, medicines and vaccines, and the treatment of mass casualties, the outbreak of a similar pandemic today could be even more lethal.

Of course, no one knows for sure what the final death toll might be. The only thing really known for sure, in fact, is that time is on the side of the suspect avian flu virus officially designated as H5N1. The several interrelated articles in this special Pandemic Influenza issue of DomPrep Journal discuss how and where the virus probably started, the ways it might mutate and evolve into a medical threat, of terrifying magnitude, to the citizens of all nations of the world, and the need for a massive cooperative international effort to stop--insofar as possible--the spread of the disease and, if that effort is too late (or not enough), to mitigate the short- and long-term consequences. Again, insofar as possible.

Included in this issue's lead article, by Dr. Jerry Mothershead, is a long and reasonably comprehensive list of *some* of the most important preventive and/or remedial steps that contingency planners, public-health officials, and the medical community recommend be taken both on the international level and by individual nations to protect their citizens.

The financial cost of following through on these recommendations will be extremely high--whether that cost is paid in dollars, dinars, or drachmas. The cost--in human lives and in the massive social, economic, and political disruption that would result--of *not* following through would be much higher.

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It also should be kept in mind, though, that excessively rigorous implementation of seemingly sensible (albeit painful) measures might cause other problems that are even more disruptive. Dr. Mothershead points out, for example, that millions of domestic fowl "already have been destroyed in Southeast Asia." If that example is repeated in too many other countries the result might be not only a significant reduction of the world's food supply but also, perhaps, a precarious shift in the delicate balance of nature.

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Pandemic Influenza - A Catastrophe in Waiting?

Guest Commentary
By Jerry Mothershead

"Bird Flu" has recently become a household word. Experts warn that the world is unprepared for an avian influenza pandemic. President Bush met recently with leaders of pharmaceutical companies to discuss vaccine-production issues. Officials from international organizations have been meeting to determine ways to fight a pandemic that at least some experts already believe is inevitable.

Although many people still consider influenza, also called "the grippe," more a nuisance than a serious illness, it can be deadly. More than 30,000 Americans die annually from this disease. The three great influenza pandemics of the 20th century (Spanish Influenza in 1918, Asian Influenza in 1957, and Hong Kong Influenza in 1968) affected up to one third of the world's population and produced staggering numbers of deaths. It is impossible to predict if the current strain of avian influenza will make the jump to the human population – and, if it does, how severe the consequences would be.

Current U.S. government worst-case mortality figures are 1.9 million fatalities, with 200,000 dead a "best case" scenario. In any case, it is reasonable to assume that at some time not too far into the future another influenza pandemic will occur, and the results could very well be as catastrophic as any other disaster, natural or manmade, in modern history. Prudence dictates an organized approach to preparedness and response on the part of government at all levels, emergency managers, public health officials and medical professionals, and the general public as well.

Epidemics occur all the time. An epidemic is a sudden increase, within a defined geographic area, in the incidence of a particular disease above the normal levels. Pandemics have three characteristics that distinguish them from epidemics. First, they are global in nature, affecting people over the entire world. Second, they spread rapidly in progressive "waves" – typically over a year or so, sometimes longer, sometimes less. Finally, they are caused by particularly virulent organisms that affect large segments of the population. Pandemics are rare events that result in widespread illness, death, and both social and economic disruption.

Virology 101 And the Early Years of H5N1

Of the three types of influenza viruses – A. B, and C – Influenza A viruses

are of the greatest concern because they are capable of mutating at an alarming rate and they can infect many species of animals. Influenza A subtypes are identified and designated by protein markers on their coats – e.g., H1N1, H4N7, etc. All Influenza A viruses exist in aquatic migratory birds.

Influenza A viruses mutate in two different ways. "Antigenic drift," which is caused by small changes in their DNA structure during replication, occurs frequently and gives birth to a "new" virus. Prior immunity may not totally protect a human against infection from this changed virus. It is largely for that reason that annual influenza vaccinations are recommended – but effective vaccines can be developed only after the prevalent types of modified viruses have been identified, and this usually is not possible until at least a few months after an outbreak begins.

"Antigenic shift," a more worrisome type of mutation, occurs when a host is infected concurrently by different subtypes of the Influenza A virus. When that happens, whole segments of DNA may be exchanged. If the "new" virus contains significant genetic material to which the "host" to the virus has never been exposed, the host species will have no immunity to the disease. If the new virus is particularly virulent, the disease may be fatal. Moreover, if the new virus retains characteristics that facilitate transmission, the disease will spread easily and rapidly. When all of these "if" factors occur, the result will be a pandemic.

The Highly Pathogenic Avian Influenza or H5N1 virus, first identified in 1997 but not widespread throughout Southeast Asia until recently, is of significant concern to the medical community – and to governments all over the world – for several reasons. Highly Pathogenic Avian Influenza viruses produce a rapidly fatal disease in birds – but certain migratory waterfowl, such as geese and ducks, may harbor H5N1 infections without significant impairment, thus serving as relatively asymptomatic spreaders of the disease.

Although once considered an exclusively avian virus, H5N1 has caused disease in other species, including humans (but not yet, so far as is known, through human-to-human transmission). For antigenic drift to occur, pigs usually have been the species that have been co-infected with human and avian influenza viruses. That does not seem to be the transmission chain for the H5N1 virus. The human disease caused by this virus is particularly lethal, and tends to more severely affect different segments of the population – e.g., children and young adults – than are affected by typical seasonal influenza. Moreover, unlike other "typical" cases of influenza, H5N1 viruses cause a primary viral pneumonia, and also seem to have developed a resistance to many antiviral drugs. Finally, so far as can be determined, the human population has never before been exposed to H5N1 influenza viruses, so it seems likely that the

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human vulnerability to infection following exposure to H5N1 will be almost universal.

Needed: An All-Options Preparedness/Response Plan

It is clear that the necessary ingredients for an influenza pandemic already exist. The primary wild cards in the equation are the timing and resultant magnitude of the catastrophe. Moreover, there is an important piece of the puzzle missing – namely, that public health officials are uncertain why H5N1 has not yet undergone antigenic shift. If a shift occurs in the future, there probably will be no way to quickly predict the resultant transmissibility or virulence of the hybrid virus, compared to what is now known or likely to be known about either of the original viruses. This lack of certainty is the principal cause of the wide variability in predictive models – on rate of spread, for example, and overall lethality – of any pandemic that might occur.

Several facts already seem obvious: First, not planning for a pandemic cannot be an option – the potential consequences are too great. Second, the likelihood of a pandemic affecting all the peoples of the world is a truly international issue of the highest magnitude that requires international – as well as, within the United States itself, federal, state, and local – cooperation and, it is hoped, solutions or at least partial solutions. Third, whatever preparedness and response requirements are developed to protect humans from this potential catastrophe are likely to be adaptable to other disasters or public-health emergencies, and thus provide an incentive for dual-benefits solutions. Fourth, there is no "magic bullet" that will with absolute certainty prevent a pandemic. Finally, all medical and other options must be considered, because it probably will take combinations of varying options to mitigate and respond if a pandemic does evolve.

A major question of terrifying magnitude, and an uncertain list of partial answers

The logical question that now arises is a simple one: What can be done? In fact, a lot *is* being done, at all levels of government – international, federal, state, and local. Still, many public health experts warn that many of the actions taken thus far are too little, and may be too late as well. Following is a composite list – not necessarily in order of importance – of what most if not all of these same experts consider to be among the most effective initiatives, within the parameters indicated, that might be undertaken to improve national and international preparedness and response capabilities.

1. Public information and education. The public must be much better educated about the manifestations and risks of influenza epidemics and pandemics as well as the measures that can and should be taken to reduce risk. The information provided should include advice on basic hygienic behavior, personal protective actions recommended, and forewarnings of the government actions likely should an outbreak be detected.

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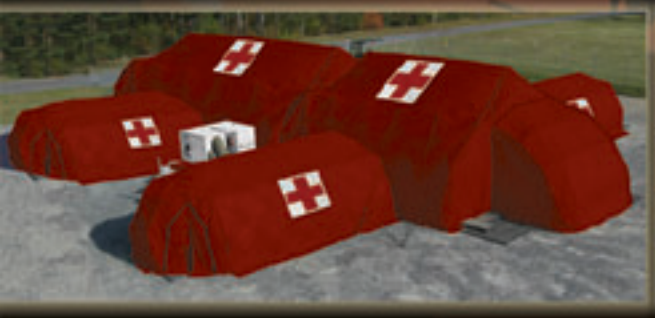

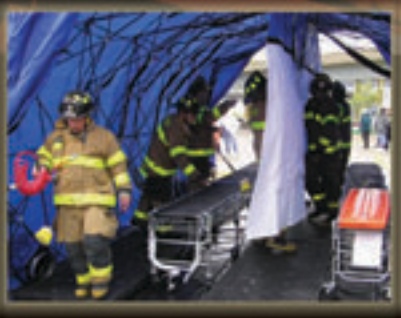

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Interview: Dr. James Jay Carafano, Senior Fellow for National Security and Homeland Security, The Kathryn and Shelby Cullom Davis Institute for International Studies, The Heritage Foundation

Dr. Carafano discusses in depth his take on the key lesson learned from the Hurricane Katrina response: the need for a 0-to-96-hour federal national-response capability in a catastrophic disaster to support decentralized execution of the consequence management actions needed.

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2. The prevention of disease in domestic bird populations. Various truly heroic measures that already have been taken in Southeast Asia to prevent H5N1 disease in domestic birds have had only limited success thus far, and it may be impossible to eliminate disease in the wild bird population. There are, though, a number of "holding" strategies – e.g., the wholesale vaccination of domestic chickens that is being instituted in Vietnam – to delay subsequent waves of outbreaks. A similar strategy may not be needed globally at this time, but should be included in the armamentarium of those responsible for disease control within the poultry industry. Farms and other sites – poultry manufacturing and processing chokepoints are perhaps the most important example – where there are significant numbers of domestic fowl must be required to create and be ready to implement a graded response plan geared to current national and global H5N1 conditions.

3. Animal disease surveillance. A close review of previous pandemics indicates that even the most draconian containment measures will at best only slow the progression of a pandemic. Migratory fowl infected with avian influenza have already been found in Russia, Turkey, and other countries outside Southeast Asia. It is unlikely in any case that any containment measures that might be implemented would prevent the spread of H5N1 to North America. Because H5N1 can infect, and already has infected, many animal species, the surveillance and immediate investigation of unusual disease patterns in domestic or wild animals may offer some limited or temporal protection against further spread. That surveillance must be conducted at all international ports of entry as well as within a country's own borders.

4. The rapid containment of animal outbreaks. An outbreak of H5N1 in a domestic flock would be devastating economically and in a number of other ways. Millions of domestic fowl already have been destroyed in Southeast Asia in an attempt to control the spread to unaffected flocks. Similar slaughters would be a likely mainstay of containment in other countries. In the United States, the poultry industries have developed a number of graduated plans that include the culling of vulnerable flocks. Inadequately addressed, however, are the large numbers of farms and households that maintain small flocks for personal consumption and are not part of the national poultry industry per se. Government oversight agencies must develop programs to prospectively identify these farms and households – prior to an outbreak, of course – and include them in the educational, surveillance, and potential culling operations that are or might be required. In addition, because H5N1 may affect other animals, those devising and refining the containment programs would be well advised to ensure that the actions recommended (or possibly mandated) are adaptable to other domestic species of animals as well. Finally, even those communities that are not considered part of the nation's major agrarian industries should have their own parallel programs in place.

5. Medical surveillance. All states as well as the federal Centers for Disease Control and Prevention (CDC) already have medical surveillance systems in place. However, the historic record shows, unfortunately, that accurate and timely disease reporting has been less than ideal. Many communities are now evaluating the value of so-called "syndromic surveillance" systems, in which data is provided not by final diagnosis but by the symptoms of patients cared for in doctors' offices and/or emergency departments. A few communities are evaluating the possibility of instituting more sophisticated systems that might include, for example, the accumulation of data from such diverse sources as pharmacies, workplaces, and schools. These newer systems probably would not detect initial human cases, but may have value by helping to rapidly identify the leading edge of an outbreak, thereby facilitating the earlier institution of response measures. For these and other systems to work, providers and healthcare systems must use interoperable systems that possess many and diverse data-collection points. To be as effective as possible, however, the data accumulated must be reviewed, collated, and analyzed on a real-time basis.

6. The continuation of vaccine and antiviral medication research and development, the streamlining of approval processes, and the improvement of production and distribution. The cornerstone of disease prevention, and of pandemic eradication as well, will most likely be widespread

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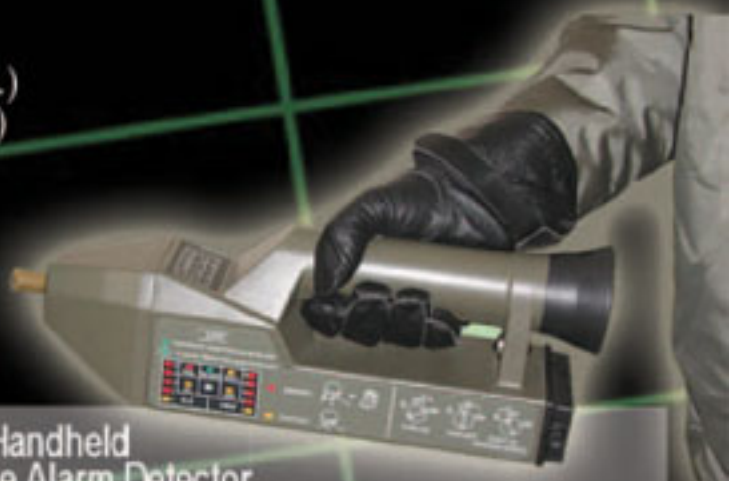

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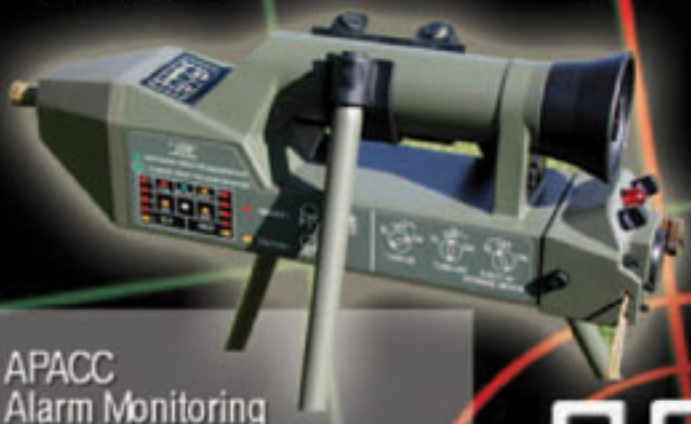

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vaccination – assuming that a vaccine can and will be developed, approved, mass produced, distributed, and administered in time to a sufficiently large segment of the population, a long but necessary series of actions that could not be carried out during previous pandemics. The development of a vaccine against human-variant H5N1 will have to await the detection of initial cases, of course. However, the machinery and processes most likely to be required can be in place well ahead of time, enabling governments to rapidly ramp up production once the vaccines needed are developed. Currently, European countries are the source of about 70 percent of the world's vaccine production. If all of the U.S. vaccine manufacturing resources were devoted to a single pandemic vaccine, only enough vaccine for about five percent of the American people could be produced. The enactment of federal laws providing reasonable liability protection to vaccination manufacturers is one potential way to alleviate this unsatisfactory situation. In addition, more widespread acceptance by the American people of annual vaccinations would justify the cost of building larger production facilities.

The required approval by the Food and Drug Administration (FDA) of new vaccines can and frequently does take considerable time. There already has been some streamlining of FDA processes, though, and the president can use an Executive Order to bypass various safeguards in a declared public health emergency. Here it should be noted that the government's well publicized smallpox-vaccination initiative met with only limited success, so it is far from certain that the general public would quickly accept an investigational new drug, even in the face of a pandemic. In any event, there must be a continuing effort to ensure safety while expediting the development, production, and distribution of effective new antiviral medications. In addition, researchers must continue to look for novel vaccines that work against multiple strains of influenza and/or target different viral processes at the cellular level.

Antiviral medication research must receive much greater emphasis for years to come. Viruses are remarkably adaptive, and the possibility that the hybrid H5N1 will develop resistance to all existing antivirals is real. The two primary antiviral medications showing promise against H5N1 are zanamivir and oseltamivir. Most attention has been focused on the latter, both because it is taken orally (zanamivir is inhaled), and because it already has been widely used against seasonal influenza outbreaks. Here, a footnote on two important developments: (a) the welcome decision by the Swiss-based manufacturer of oseltamivir that it may soon release its patent rights; and (b) a recent announcement in Hong Kong that, although animal studies indicate that oseltamivir is effective against H5N1, the strain that produced human disease in Vietnam earlier this year is apparently resistant to that drug. (In any event, the United States currently has only enough oseltamivir to treat approximately two percent of the population if that drug is needed on short or no notice.)

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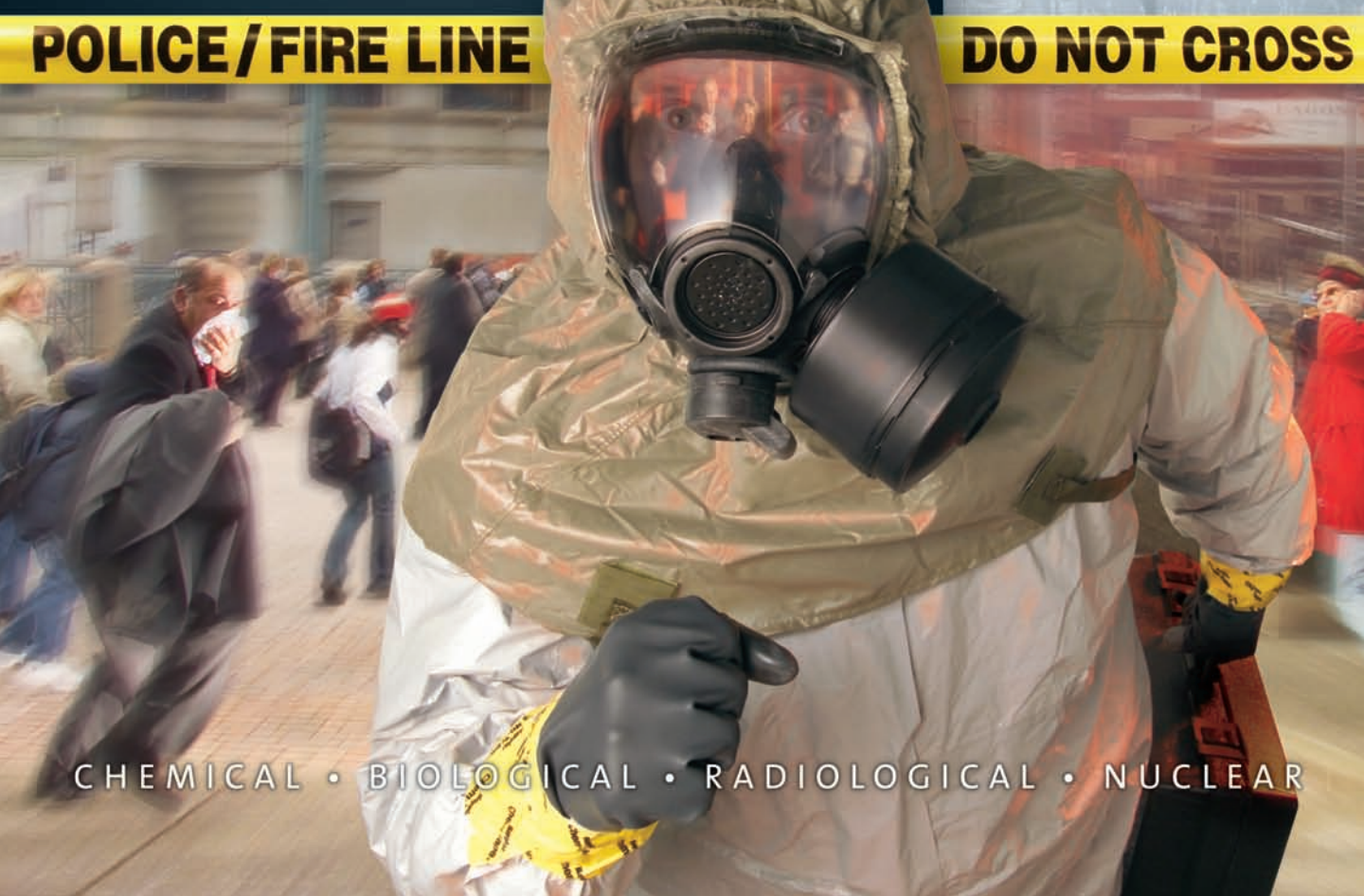

7. Implementing a prioritized vaccination campaign against anticipated annual influenza virus subtypes and the development of stratified protective measures for high-risk populations. Humans co-infected with typical influenza viruses and avian H5N1 may serve as the mixing bowl for antigenic drift. People protected (by vaccination) from developing the more usual seasonal influenzas will of course reduce the likelihood that such mixing will occur. In addition to those segments of the population – the elderly, for example – at risk for developing severe disease and those who live and/or work in exposure-prone locales (college campuses, schools, healthcare facilities, and military installations), individuals who work around domestic birds, or who may be exposed, even episodically, to wild waterfowl should seriously consider being vaccinated against the identified seasonal influenza variants.

There are other segments of the population that may require additional physical protection. The atypical animal-to-human transmission pattern that has occurred in Southeast Asia probably does not represent the pattern that would be most likely in the United States. People who are immunocompromised, are very old or very young, are afflicted by concurrent chronic diseases, and/or work in certain occupational sectors all will be at an increased risk for contracting H5N1 or of developing the most severe cases of the disease. Should a pandemic emerge, programs that go beyond prioritized vaccinations against H5N1 and the provision of personal protective equipment (e.g., masks and gloves) must be in place well ahead of time to provide enhanced protective measures to these segments of the population.

8. The establishment and maintenance of regional countermeasure caches. The federal Strategic National Stockpile Program has proven itself, at the national level, to be highly effective. However, many states and cities are still struggling with a number of difficult issues – involving storage and security, for example, and the distribution and dispensing of medicines and medical supplies to the local citizenry and to healthcare sites – that must be resolved before the start of a pandemic. Recently, an adjunctive program, referred to as Chempak, has been instituted to regionally pre-position certain chemical-agent antidotes. All states should consider the purchase and storing of limited caches of antiviral medications, personal protective equipment, and other critical supplies. Even if such caches could not meet all needs of the general public, rapid access to these supplies for personnel involved in critical-infrastructure operations – as well as firemen, policemen, and other emergency-services professionals – might ensure the availability of more of these individuals during the outbreak.

9. The rapid containment of human disease outbreaks. Viral pandemics almost always progress in waves, with later waves affecting larger segments of the population with usually less (although sometimes more) virulent forms of the virus. Examination of the three twentieth-century pandemics previously mentioned indicates that even the most severe imposition of isolation (sequestration of the ill from the healthy) and quarantine (separation of people who are well but might possibly have been exposed – as opposed to those known positively not to have been exposed) has been unable to prevent progression of the outbreak. What isolation and quarantine have been able to do – most successfully in Australia during the 1968 pandemic – was to slow the progression of the later waves, creating the time needed to institute other defensive measures, including the dissemination of more and/or later and more effective vaccines. The Model State Emergency Health Powers Act, prepared for the CDC by the Center for Law and the Public's Health at Georgetown University, has been used by many states to revise their own public health laws, including some requiring the imposition of mandatory quarantines. Here, another footnote: A panel of public health and legal experts that reviewed the success of quarantines in previous outbreaks concluded that a mandatory enforced quarantine is probably not only impossible to implement, but also creates a number of administrative, legal, and logistical problems. Nonetheless, quarantine probably should be included in the toolkits of emergency planners as at least a potential line of defense against further spread of the disease. A well educated public will most likely take certain "shielding" actions on its own initiative. Among a number of other containment measures recommended are voluntary home confinement, the mass distribution of protective masks and gloves, business "holidays," the issuance of advisories on travel restrictions, and the temporary cancellation of mass-gathering situations – including but not limited to school functions and sports events of various types.

10. The creation of prospectively developed plans and policies on medical surge capacities and decremental standards of care. The cornerstone of federal medical response to disasters is the National Disaster Medical System, consisting of nearly 100 general and specialty medical-response teams, a patient medical evacuation system, and cooperative agreements with approximately 2,000 hospitals that have pledged access to 100,000 acute-care beds. Unfortunately, this system was designed primarily to provide an overflow capability to augment military healthcare systems during wartime – or to provide services for large-scale regional disasters – and might be totally ineffective in a pandemic. The contractual requirements of the Metropolitan Medical Response System Program, operated by the Department of Homeland Security, would be totally inadequate in the face of a pandemic that authorities say could affect half the population and necessitate acute care, in an inpatient setting, for up to 80 percent of those afflicted with the disease. Moreover, containment measures may slow but would probably not prevent a pandemic.

A related Medical Reserve Corps initiative

has thus far received limited funding and has had only limited success. The nation's overall healthcare surge capabilities must be greatly enhanced in any case. To do this, though, would require, among other things: the enactment of legal liability protection for volunteers; interstate medical personnel licensing and certification reciprocity; and the creation of prospectively developed registers of physicians, nurses, emergency medical technicians, and other healthcare professionals (including those who have either retired, left the active workforce, or are in training). Methods to use non-professional volunteers, after providing them just-in-time training, also must be sought. Job-action sheets and standardized protocols must be prepared in advance. Even if all these steps are taken, the surge capability available is still likely to be inadequate and the extremely difficult problems of medical triage and the stratification and provision of decremental healthcare by "routine" standards would have to be addressed well beforehand so that policymakers and providers would not have to face the same issues during a pandemic.

To many experts, the threat of an influenza pandemic is as great as, if not greater than, the threat of a terrorist attack involving nuclear or even biological weapons. As recent hurricanes and earthquakes have demonstrated, the history of mankind is replete with natural disasters and public health emergencies of various types that dwarf the effects of manmade catastrophes, accidental or intentional. Modern science and the nature of the current H5N1 Avian Influenza have given the world the opportunity of being better prepared than was possible before or during any previous pandemic. Some positive strides forward have been and are being taken. Whether they are sufficient remains to be seen.

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The Art and Science Of Biological Detection

By Rob Schnepp, Fire/HAZMAT

It is no secret to anyone in the hazardous-materials response field that the detection of biological agents is a complicated process. The detectors themselves are complicated, at least in terms of the sciences and operating principles involved. The biological agents that may or may not be present also are complicated, as is the determination that a suspicious white powder or other substance poses a credible health threat. Finally, the processes of sampling a biological agent and running a reliable and trustworthy test, or series of tests, add a completely different set of complications. Practically speaking, therefore, everything must go exactly right in order to run a dependable test and feel confident about the results. Moreover, even when everything is done right, a negative reading does not always mean that a biological agent is completely absent; on the other hand, a positive reading does not absolutely guarantee that the suspected agent is present.

From a broad perspective, responders should look at effective biological detection as a multi-faceted operation, not reliant on a single test or detection technology. Monitoring for radiation hazards, flammability, corrosivity, and the presence of volatile organic compounds should be automatic, of course. In addition, any suspected biological agent should initially be tested against a protein screen and/or other "rule out" systems or devices. Determining whether or not a sample contains a protein (which may indicate the presence of a microbe) is a good first step. Basically, if a sample turns up negative for proteins, and the overall situation does not appear to be a credible threat, there usually is a low probability that the substance poses a significant health hazard.

The next step should include an attempt to identify the substance. This is where the selection of current biological-detection systems comes into play. There are a number of detectors on the market, each employing a slightly different testing methodology. Regardless of what technology – PCR or immunoassay, for example – is selected, a few basic features of the machine should be understood.

Polymerase chain reaction (PCR) technology involves genetic-based detection, which identifies the specific DNA or RNA of a suspected biological agent.

Immunoassay tests are based on an antigen-antibody response. Antigens are molecules present on the surface of foreign microbes; antibodies of various types form strong and specific interactions with antigens. The use of known antibodies to determine the presence of specific antigens is one of the most effective detection tools available to the scientific community.

The user of the machine should understand two things from the beginning: First, that each monitor is unique in terms of *sensitivity,* a characteristic related to the detector's ability to determine the presence of even a small amount of biological agent in a sample.

Second, the monitor should not only be sensitive enough to pick up a biological agent below what is considered an "infective dose," but also specific enough to rule out so-called neighbor organisms (thereby reducing the instances of false positive readings). If an assay is not sensitive enough, or if there are not enough microorganisms in the sample, a false

negative reading may occur. If a detector is not specific enough to identify a particular agent, a false positive reading is likely.

Prerequisites to Understanding

The sampling aspect of the operation can be thought of as the Achilles' heel of biological detection. In many situations, if the responder does not completely understand the particular parameters the machine requires to run a test, the test may not be valid. There may be too much powder put into a buffered solution, for example, thereby making the machine incapable of processing the sample. On the other hand, if the sample is too diluted – i.e., there are not enough organisms present – the test may come up negative, leading the responder to believe there is no agent present. Either way, the results may be questionable, causing additional stress at the incident scene. It is important, therefore, to ensure that all samples are taken in strict accordance with the guidelines established by the manufacturer of the biological detector.

If a suspected substance comes up positive for the presence of protein and is specifically identified by a reliable detector, the testing process should move toward confirmation by a public health laboratory, the commonly accepted "gold standard" of biological detection. Anthrax, to cite but one example of several biological agents now in the news, is not considered to have been truly identified as anthrax until a high-level public health lab has confirmed it by culturing. The process of culturing includes: (a) growing a colony of spores on a nutrient surface such as blood agar; and (b) visually observing the results through a microscope. In this instance, identifying a biological agent is considered by many to be as much of an art form – based on the observations and experience of the microbiologist running the test – as it is a science.

Most biological agents, even those at or above lethal concentrations, would be invisible to the naked eye and therefore

To eliminate the troubling doubts about tests results, most experts in the field of biological detection recommend using several different technologies and/or techniques to help confirm the presence or absence of a biological agent.

might require a responder to sample numerous areas of potential presence – e.g., any and all surfaces, liquids, and/or airborne environments – to obtain a sufficient quantity of the agent to run a test. This requirement adds a few additional complications. A slight breeze or air current created by a ventilation system, for example, may push or pull an aerosolized biological agent throughout a building, forcing responders to sample air-handling systems and secondary locations far removed from the original release location.

A Simple Enough Challenge

Essentially, the accuracy of a biological-detection operation depends first on taking a sample in the right place with the right tools, and then on using a machine with a proven track record of reliability – i.e., sensitive enough to detect the suspected agent, but not prone to false positives. "To run a reliable test for a bio agent," said Rick Thomas, Vice President of Government Programs for Sceptor Industries Inc., "you need to collect enough material to run a test. That may seem simple enough, but in reality, especially with an aerosolized release, collecting enough agent is a challenge."

Thomas, who has over 25 years of experience in the chemical and biological instrumentation field, recommends that responders adopt a "collect to detect" philosophy when it comes to positively identifying a biological agent. In situations where responders suspect an airborne release of a biological agent, or where powders may have become airborne, Thomas recommends the use of a concentrator and collector as an adjunct to a biological detector. "Our machine helps to concentrate air samples," Thomas said. "We manufacture high-volume air samplers, intended to draw in and collect larger quantities of a suspected material and concentrate those substances in a solution. A responder can then remove that vial of solution, withdraw whatever amount the detector requires, and run a test."

Sceptor Industries, the manufacturer of the Omni 3000, a rugged and portable air sampler, has supplied aerosol sampling equipment for such major public venues as the Super Bowl and World Series, various Mardi Gras festivities, and other high-profile events. It is important to understand, Thomas said, that a sampler such as the Omni "is not a biological detector; it is designed to expand the ability of a responder to detect an aerosolized biological release by providing a highly concentrated sample of the ambient air. At events like the Super Bowl, for example, these air samplers can be strategically placed throughout the venue, and run for specific periods of time. The sample vials can be removed at certain intervals, and responders can use whatever amount of the solution they need to run a test with their own bio detector. It provides a unique opportunity to do biological detection at a large venue."

When it comes to sampling a suspect powder, Thomas said he believes that responders often neglect to consider the potential for an airborne hazard. "Responders should keep in mind that powders like anthrax are very easily blown around. If an agent happens to be dispersed into the ventilation system of a building, or otherwise released or blown into the air, the only way to retrieve those particles is by using an air sampler like the Omni. The way I see it, if you don't sample the aerosol component, you may be missing something critical."

Differences and Distinctions In the Detection Process

To a large degree, biological detection is a unique science – considerably different

from the standard principles and practices of gas detection that most hazardous-materials responders are accustomed to. The primary difference is that biological detectors do not, as the typical gas detector does, sample the suspected environment and provide the user with real-time results. Similarly, in the field of chemical detection, if the proper detector is used and the released substance is within the detectable range of the machine, the user will receive an immediate reading that does not require validation by a laboratory or a public health agency.

Another critical distinction lies in the fact that chemical substances (gases and vapors) do not need to be prepared or handled in any way in order to detect them. If a gas is present, and the detector is capable of "seeing" it, a reading will be obtained. In contrast, biological detection, because of the nature of the agents themselves and the limitations as well as capabilities of current detection technologies, will be effective only when all facets of the sampling and detection processes are performed correctly. To that end, it is incumbent on all responders both to understand the operational principles of their particular machines and to be fully trained to sample all potential environments with a wide array of tools and equipment.

It is in that context that Thomas again cautions responders to consider the entire environment when sampling for a biological agent: "If you swab a desk, for example, and get a negative test result, you may not really have a 'clean' room," he noted. For that reason alone it is "imperative," he added, "to look not only at the surfaces, but also at the air. If you don't know what's in the air you may not be truly safe."

Pandemic Influenza: The Issues Involved, and the Need For an Armageddon Plan

By Joseph Cahill, Emergency Medicine

Pandemic influenza, or "Pan Flu," differs from the "regular" flu in a number of substantial ways. To understand them it is important first to understand what the flu is – namely, an infectious disease that is caused by a virus.

In the simplest terms, viruses are strands of deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), the blueprints that cells use to reproduce. When the virus infects healthy living cells it plugs its own DNA into the cellular machinery of reproduction and tricks the invaded cells into creating more viruses.

For the person infected with influenza the results can range from mild "flu-like" symptoms such as body ache, fever, headache, tiredness, sore throat, runny nose, and cough – lasting a week to ten days or so – through a fatal pneumonia. Hundreds of thousands of people die each year from the flu – including, according to the U.S. Centers for Disease Control and Prevention (CDC), an estimated 36,000 in the United States.

Control Measures And the Drift-and-Shift Effects

The main method for protecting oneself from influenza is to be vaccinated every year. There are both an injection version and a spray version of the vaccine in use in the United States. Every virus has proteins on its outer surface that are unique to that viral strain. When a person encounters these proteins it "takes an image" of them and stores it within his or her immune system.

Later, when the person encounters other proteins, that person's immune system checks them against the stored images. If a match is found, the immune system can deal fairly quickly with the virus. A vaccine works by introducing just enough material into the body to trick the immune system into forming images that will help identify the complete virus.

The influenza virus is not a static creature. Central to understanding why annual vaccinations are needed is a factor called genetic drift and shift. Each time a virus reproduces itself there is the possibility of a mistake. When enough small mistakes accumulate, these errors result in a virus that no longer matches the old image, so the immune system sees it as something novel. This process, which is called drift, may take six months or more to become different enough to evade even vaccinated immune systems.

Vaccine stored away this year will probably be no longer effective next year.

When two viruses encounter one another they sometimes exchange pieces of their genetic material, and each comes away as something distinctly different from the original. This process, called shift, allows for rapid major changes in the virus in a single event. The exchange is often significant enough to transfer characteristics from one virus to the other.

Of major concern is that a flu virus such as H5N1 (the designation given to the avian flu) that is lethal to

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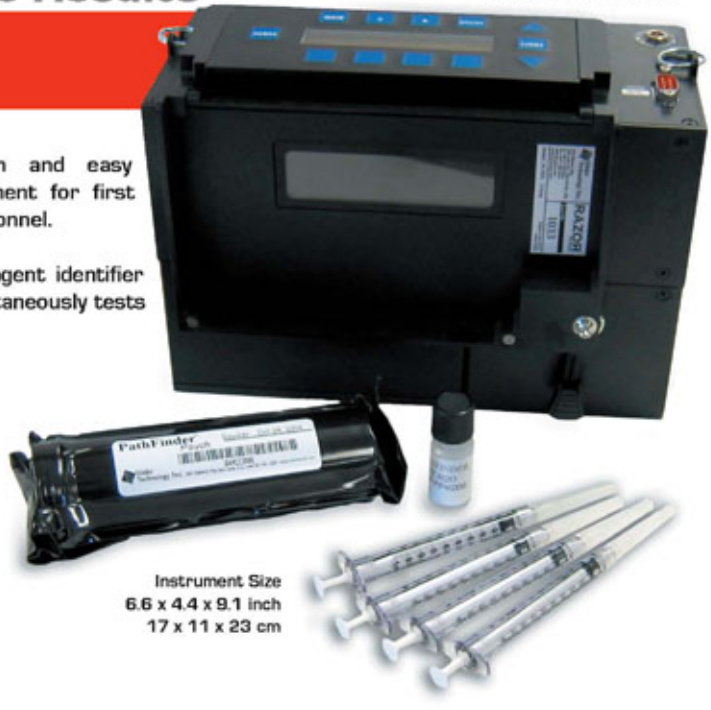

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humans but hard to pass from person to person will exchange material with a virus that is relatively easy to pass from person to person. If this shift occurs, the resulting virus not only may cause a high mortality rate but also be person-to-person transmissible – and thus would be a likely candidate for causing the next pandemic influenza.

Regardless of the process, shift or drift, that creates a new virus, current immunity to the original might not be effective against the new virus. In other words, last year's flu shot probably would not be effective against this year's flu.

There are other defenses against influenza. Anti-viral medications can be administered. From the patient's perspective these are somewhat similar to antibiotics: One pill one or more times a day helps the body fight off the infection. Unfortunately, there are not enough of these medications available to treat all probable cases of the flu in the United States (and the shortages are worse in almost all other countries). Moreover, viruses repeatedly exposed to these medications may become resistant to them, rendering the antiviral less effective.

Good basic hygiene and good manners both play a large role in controlling the spread of influenza. Washing one's hands and covering one's mouth when coughing will significantly slow the spread of the flu. Alcohol-based waterless hand-washing liquids also can help, particularly in situations that do not allow for frequent hand washing.

Emergency Planning And the Issues Involved

Pandemic influenza presents some specific, and major, problems for medical professionals involved in emergency planning and/or with vaccine production and delivery. There is no way to stockpile the vaccine, because the vaccine stored away this year will probably be no longer effective next year. However, the stockpiling of anti-viral medications is possible.

Last year's vaccine shortage in the United States provides a good model to use in estimating the possible effects on the vaccine supply at the start of a pandemic. The British manufacturer of vaccine, Chiron Corporation, was unable to bring its product to market. It was more than just a lost batch of vaccine; Chiron's operation was shut down for the season. The company's production capacity was thus removed from the total worldwide capacity. But there is very little excess worldwide capacity available at any time; as a result, even with a full-capacity effort by other manufacturers, shortages ensued.

Vaccine production during an influenza pandemic can be expected to exhibit a similar gap – of much greater magnitude, though – between capacity and demand. During the initial phase of pandemic influenza there probably will be little or no effective vaccine available. Because the normal time lag between vaccine development and production is about six months, this means that there will undoubtedly be major shortages – resulting more from the increase in demand than the decrease in supply – during the first year of a new pandemic. An even worse problem, perhaps, is that, because of shift and drift, the vaccine developed during year one may be ineffective during year two and so on.

Question: Who Will Be Saved?

One of the major issues facing state and local public health officials is determining

who or what categories of citizens must or should receive the first doses of the vaccine. There are two schools of thought on this issue. The first places highest priority on the *risk imperative*, as presented by the CDC recommendations for annual flu vaccinations, which holds that those persons considered to be at an increased risk should be vaccinated on a priority basis. The second school adheres to what is called the *functional imperative*, as outlined in the World Health Organization (WHO) Guidelines on the Use of Vaccines and Antivirals During Influenza Pandemic, which holds that those who are essential to the safety and basic functioning of the community should be the first persons vaccinated.

A good example for discussion are those in the medical community who would care for the ill. These people should be protected not only because of the increased risk they face from their continuous work exposure but also because of the essential role they play in saving the lives of others.

During a supply crisis one of the most important tasks facing decision makers will be to prioritize groups needing vaccination on a priority basis. Doctors and nurses working at hospitals are an obvious first choice. Less obvious are all other hospital workers: the technicians who provide respiratory care, for example; the doctors who are now administrators, primarily, and no longer see patients; the housekeepers without whom patients' rooms never get cleaned and therefore become unusable (because proper hygiene is a mainstay of flu prevention). The litany of groups with varying claims to priority status is, in short, a very long one.

Even if high priority is given to the entire hospital staff, difficult triage-type decisions must still be faced. Many medical people do not work in hospitals, for example. Nor do the first responders in the community – firemen and policemen as well as EMS (emergency medical services) workers who play an essential role in times of crisis. Truck drivers, railroad engineers, and the officers and crews of ships who transport the food, energy supplies, and other necessities of life – and keep the nation's economy on an even keel – all could justifiably lay claim to the title of "essential worker."

Unfortunately, there simply will not be enough vaccine and/or other medications to protect all of these groups. In fact, a decision that priority be given to the entire staff of hospitals may require more vaccine than is likely to be initially available.

During a supply crisis one of the most important tasks facing decision makers will be to prioritize groups.

According to a Government Accountability Office (GAO) report, 15-37 percent of the population is likely to be affected at any given time during the pandemic. The CDC estimates that 5-20 percent of the population would be ill at any time. The difference between these seemingly conflicting estimates is that the CDC estimate includes those who are actually ill, whereas the GAO estimate also includes both those who, because they are concerned about being infected, choose not to come to work, as well as those who are staying at home to take care of a sick relative. For practical purposes, it seems reasonable to use a 15-percent average to represent the number of people staying home for all of these and perhaps other reasons.

By canceling elective procedures and taking other short-term steps a hospital may be able to operate without 15 percent (or perhaps slightly more) of its staff. The history of previous influenza pandemics suggests, though, that a future pandemic may well continue for at least several years - beyond the effectiveness of these short-term solutions. Moreover, hospitals and other medical facilities will have an extra burden to carry if 15 percent of their own service populations are seeking medical care for the flu (more, if there are large numbers of what are described as the "worried well").

Also contentious is the issue of how to prioritize under the imperative of risk. The priority could be assigned by age, giving babies from six months to two years or so the highest priority because their immune systems are not up to the challenge of fighting off the virus; another option is to give the old and infirm high priority because their immune systems have become weak.

The Right Answers Are Not Always Fair

Coming up with the "right answers" – however that term is defined – will not be easy. During the first days of a pandemic there simply will not be enough vaccine to cover all of those in the priority groups, much less all others who, fairly or unfairly, are in lower-priority categories.

If and when an effective vaccine is available in sufficient quantity, moreover, it will be a daunting challenge to inoculate the entire population. Annual flu vaccination clinics cannot be looked at as the solution for dispensing the pan flu vaccine. "Routine" clinics conducted by public health officials and the medical communities differ significantly, in two critical ways – the first is volume; the second is security – from those needed to respond to a pan-flu outbreak.

Annual flu clinics inoculate about half of the population; numerically, therefore, the complete inoculation of the population required in a pan-flu crisis would require the capacity of twice as many clinics. But with the estimated non-availability

of 15 percent of those needed to operate existing clinics this may not be possible.

A better model to consider, perhaps, may be the local POD (points of distribution) plans developed for use under the Strategic National Stockpile (SNS) program. In the event of a pandemic flu that is killing people in large numbers it can be anticipated that when there is not enough vaccine available there well may be violent encounters when and where the vaccine is believed to be. One result is that, to maintain order, even those clinics *without* vaccine probably will need a law-enforcement presence, a requirement that would undoubtedly put another strain on the community.

It seems obvious that decision makers at all levels of government – federal, state, and local – must develop the mindset that *Pandemic Influenza represents as significant a public-health emergency as a smallpox attack by a terrorist*, and then let that mindset guide their planning. The only substantive difference between these two extremely different crisis scenarios is that even the most rigorous actions and investigations by law-enforcement personnel cannot stop pandemic influenza.

Too Much To Do, And Not Enough Time

In short, time is on the side of the virus. It normally takes about six months to bring a vaccine to market. That time may be shortened somewhat by hard work and the cutting of bureaucratic red tape, but it is almost certain that major improvements in speed would be impossible.

Pandemic influenza can start at any time, independent of what is believed to be the flu "season," and it runs its course over the span of years, not just one year. Once a pandemic strain of influenza starts to roll, moreover, it will affect a certain percentage of the population constantly for a number of years. This means that at any time during a pandemic the same estimated 15 percent of the population will not be going to work. The net effect will be that every government agency, every component of the public and private infrastructure, and every other business and non-government organization will have to operate with only 63 to 85 percent of their current work forces available – management and technical experts included – and few if any replacement workers on call as substitutes.

Dealing with a pan-flu outbreak will require exploration of the extremes of continuity both of operations and of government planning. Every agency, organization, and business should for that reason develop what might be described as an "Armageddon" plan – i.e., one that deals with the total loss of all resources. Systematically, planners should go through the normal operations of the organization and ask at least three questions: (a) "What resources are needed for each task?" (b) "What would be the impact of losing this or that specific resource or function?" (c) "What contingency plan can and should be activated to deal with the loss of each such resource or function?"

It should not be assumed, of course, that *all* provisions of an Armageddon plan would have to be put into operation at one and the same time. Such a scenario would mean that there had been a total loss of all resources, but at that point *no* contingency would work because there would be nothing to work with. The purpose in developing an Armageddon plan is that it would be a resource unto itself. Because the response to the loss of each specific resource and/or function would be spelled out in considerable detail, the plan could be activated whenever there is the loss of just one resource or function.

Government also must plan well ahead of the pan-flu time curve, not only for how essential services will continue to be provided, but also for how the legitimate leadership of government will continue. At the federal level there are provisions in place for the orderly transfer of power if the president dies or can no longer function in office (the vice president would be next in succession, then the speaker of the House, and then the president pro tempore of the Senate, and so on). Individual government agencies also should consider either setting up their own orders of succession (under the direction of the president, of course) or face the possibility of being unable to provide their services during future times of crisis. Done properly, these and other forward-looking steps would be equally applicable during any future event that might stress the system.

To summarize: Pandemic influenza represents a major threat not only to the United States but to all other countries of the world, friends and foes alike. It is for that reason that a projection of the effects of pandemic influenza is one of the national-crisis scenarios that is of continuing concern to contingency planners. Moreover, unlike the various scenarios projecting terrorist attacks of one type or another, there is no law-enforcement solution available that might lower the risk from a pandemic. Continued surveillance, by the U.S. CDC and the World Health Organization, of the H5N1 strain of the flu is likely to be the only consistent source of valid intelligence information available to contingency planners and public officals for the foreseeable future.

But that should not stop the governments of all nations – all businesses and other private-sector entities, individual citizens as well – from making their own plans and preparations *now* while there is still time. Even with the best, most detailed, and most comprehensive planning, though, and the most energetic follow-on effort required, there still may not be enough time to prevent the death of not just millions, but tens of millions of people throughout the world.

Ohio and Washington, D.C.

By Adam McLaughlin, State Homeland News

Ohio Installs New Anthrax Detection System In Toledo

The post offices in Toledo are using new technology to prevent the possibility of an anthrax attack by mail on its citizens. Raymond Jacobs of the U.S. Postal Service (USPS) commented as follows on the installation of biological-detection systems: "We never envisioned that a postal service would have to become experts in bio-terror detection systems." However, since 2001 – when anthrax-tainted letters claimed the lives of five people in the Washington, D.C., metropolitan area – the USPS has spent countless hours on research, installation, and the training of its work force on the use of such systems.

Once installed, the Biohazard Detection System (BDS), which was designed specifically for the postal service, continually collects air samples from mail-canceling equipment, and uses sophisticated DNA matching to test for the presence of anthrax in the mail.

The cancellation machine can process 35,000 letters an hour, which is about the same time it takes for the system to detect anthrax. Postal officials say the new detection system does not slow the mail process or affect how employees do their jobs. The BDS equipment has been set up at 240 USPS mail-processing sites to date, and the USPS plans to install many more on a high-priority basis.

Washington, D.C. Detects Traces of Tularemia On the National Mall

Small amounts of bacteria that cause Rabbit Fever were found on Washington's National Mall in late September when thousands of protesters marched against the Iraq War. Officials representing the U.S. Centers for Disease Control and Prevention (CDC) said that environmental air monitors positioned throughout the National Mall detected low levels of Francisella tularensis bacteria over the weekend of 24-25 September.

> ***"We never envisioned that the postal service would have to become experts in bio-terror detection systems."***

The Francisella tularensis bacteria is what causes Tularemia, commonly known as Rabbit Fever. The most obvious symptoms of the disease are sudden fever, chills, headaches, conjunctivitis, diarrhea, muscle aches, joint pain, a dry cough, and progressive weakness. Symptoms usually appear three to five days after exposure, but in rare cases can take up to two weeks. Rabbit Fever, which cannot be passed from person to person, can be effectively treated with readily available medicines.

Although public health agencies had received no reports of any related human or animal illnesses caused by the bacteria detected on the National Mall, CDC officials issued a precautionary alert on 30 September so that medical personnel would be aware of the situation and could report any suspected cases. The CDC waited a week to notify Washington, D.C., officials of the detected bacteria because it took that long to test the samples at labs and confirm its presence.

According to the CDC, people can be infected by Tularemia in any of several ways: being bitten by an infected tick, deerfly, or other insect, for example; by handling infected animal carcasses; by eating or drinking contaminated food or water; or by inhaling the bacteria. The fact that the bacteria could be used as a weapon if made into an aerosol that could be inhaled has become a major concern to public health and law-enforcement officials, and to the Departments of Defense and Homeland Security, since the start of the global war on terrorism.

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