

Commentary

National Strategy for Pandemic Influenza and the HHS Pandemic Influenza Plan: Thoughts and Comments

ON NOVEMBER 1 and 2, 2005, the Bush Administration released two documents that describe what the federal government—and everyone else—should do to prepare and respond to a flu pandemic. *National Strategy for Pandemic Influenza* is a clear, 12-page overview of the conceptual categories or “pillars” that frame the government’s approach: “preparedness and communication,” “surveillance and detection,” and “response and containment.” The content of this document largely mirrors the speech given by President Bush at the NIH on November 1.

The second document, the long-awaited, 200-plus-page *HHS Pandemic Influenza Plan* (the “Plan”) was released by Secretary Leavitt the next day. It was expected to describe the priorities, roles and responsibilities, and operational details of the actual implementation of the national strategy in states, cities, towns, and hospitals across the nation. Unfortunately, the Plan does not meet those expectations.

Without question, the Plan is a significant document. It presents some of the federal government’s assumptions and provides detailed lists describing what should happen on the state or local levels and what could be done in areas such as “community disease control and prevention.” In truth, though, the federal “plan” is more reference document than plan, with its comprehensive checklist of the considerations, actions, authorities, and problems that might confront states, localities, hospitals, businesses, and citizens as they prepare for or deal with a flu pandemic.

Puzzlingly, some of the priorities emphasized by the President, such as “a crash program” to create large supplies of pandemic flu vaccine using cell culture technology, are given scant attention in the HHS plan. And key elements of the U.S. strategy that were announced by the President are not supported adequately. For example, efforts “to control and monitor flu in Asia” are allotted only

\$251 million—about equal to the cost of building a single bridge in Alaska.

PANDEMIC VACCINE DEVELOPMENT AND SUPPLY UNCERTAIN

The HHS Plan is surprisingly vague about the critical issue of pandemic vaccine development. It does not make clear how soon the country will have a pandemic influenza vaccine, or in what quantities.

It does not indicate whether or not the U.S. will use adjuvants (vaccine additives that boost immune response) to increase the number of vaccine doses, nor does it describe how the U.S. government is organizing to make vaccine, in either the near term or once a pandemic has begun. It also leaves key questions unanswered: What are the elements of the “crash program” to produce vaccine and rebuild the domestic vaccine manufacturing base? Is there a coordinated effort underway to ensure that the world’s vaccine producers maximize the amount of pandemic vaccine they could produce in an emergency? The Plan is silent on these central issues.

The sections of the Plan that address vaccine distribution are both confusing and concerning. State and local health departments are advised to review and modify as necessary national recommendations regarding who should be on vaccine priority lists, even though assignment of such priorities is irrelevant if there will be no substantial vaccine supply for years.

Furthermore, the Plan advises state health departments and providers (hospitals? individual doctors’ offices?) to seek pandemic vaccine directly from vaccine manufacturers. This would create a situation in which state and county governments around the country would be required to compete with each other, and with hospitals and doctors, in a race to buy scarce vaccine in a pan-

demic. It is unlikely that such a process will be fair, efficient, or effective in the midst of a worldwide public health crisis.

UNANSWERED QUESTIONS ABOUT THE AVAILABILITY OF ANTIVIRAL MEDICINES

The Plan does not make clear that there will be no significant federal stockpile of antiviral medicines (such as Tamiflu) until at least 2007. Many other countries have already placed orders for Tamiflu ahead of the U.S., and the single Tamiflu manufacturer is backlogged for years.

States are being advised to identify sources of antiviral drugs, even though possible sources are not made clear, and they are being asked to consider the creation of local governmental and “institutional” stockpiles. This recommendation does not make sense, given that there is only one manufacturer of Tamiflu, the most widely studied drug for treating H5N1 influenza. What the plan should do, but does not, is outline a “crash program” to develop and rapidly manufacture more Tamiflu or to make a broader range of antiviral medicines available [see Andrew Pollack, “Is the Bird Flu Drug Really so Vexing?” *New York Times*, Nov. 5, 2005, B1, for review of Tamiflu manufacturing process].

The Plan also calls for states to assume more than \$500 million of the total cost of stockpiling antivirals. As with the vaccine, the plan does not identify any process for allocating or distributing scarce antiviral medicines during a pandemic. States are instructed to prepare distribution systems for needed vaccines and medicines, but the Plan offers no advice on how such systems—long recognized as a missing vital ingredient in state bioterrorism preparedness—are to be constructed.

NUTS AND BOLTS OF RESPONSE ARE LEFT TO STATE AND LOCAL GOVERNMENTS

The most striking aspect of the Plan is the clear, but not explicitly stated, assumption that state governments and the private sector, including healthcare facilities, will bear the lion’s share of the burdens of designing and executing most aspects of pandemic response. While this division of labor reflects the constitutional division of government responsibility for public health (which places the authority for protecting the public’s health with the states), most state and local public health agencies lack the people, money, and political clout to manage an epidemic. State and local leaders will quickly recognize that

they have just been assigned responsibility for a huge unfunded mandate.

HOSPITALS: MUCH TO DO BUT NO WAY TO PAY FOR PREPAREDNESS

The Plan includes a long list of flu preparedness activities that hospitals should pursue, including the establishment of new systems for communication between hospitals and the CDC, and the creation of mechanisms by which competitive hospitals can “share” their staff. But the Administration has proposed no money for hospital preparedness. It is highly unlikely that any hospital will act on the Plan’s recommendations until the federal government addresses ways to compensate hospitals for the investments being advocated.

The Plan provides no indication that the federal government intends to coordinate or intervene in the delivery of medical services during a pandemic. The fragmentation, inefficiencies, and problems with access to care that already beset American medicine will pose special challenges during a pandemic, when the demand for medical services will be crushing. However, it appears that HHS has assigned the solution of this problem to the private sector and to any governors or mayors brave enough to tackle these immense and entrenched problems. The Plan also fails to address how hospitals forced to cancel elective procedures to accommodate flu patients will be able to survive financially in the face of a pandemic.

FALSE HOPES OF “DISEASE CONTAINMENT”

In general, the Plan draws clear distinctions between what is known, what is assumed, and what is scientifically unknown or unknowable (e.g., how transmissible a pandemic flu strain would actually be). However, the Plan conveys a clear impression that a flu pandemic might be stopped in Asia if it is detected early enough, or that measures such as the cancellation of public gatherings or the imposition of travel restrictions might limit the spread of disease. These suggestions are scientifically unfounded, and presenting them in this context has the potential to create false expectations about what can be accomplished by government officials and their proposed containment measures.

No one knows—or can know—how the pandemic virus that emerges will behave. It is possible that it will be less deadly than the current H5N1, or less transmissible than typical flu, or more so on both counts. Those infected with influenza are contagious both before they be-

come symptomatic and after they feel well again, making it extremely difficult, if not impossible, to stop the spread of the virus. It is quite likely that the beginnings of a pandemic will be apparent in many places at once. It is extremely unlikely—as WHO’s Klaus Stöhr has remarked—that efforts to detect and isolate the first 30 people to suffer from a transmissible pandemic flu strain will snuff out the virus. There is no evidence that travel restrictions or other methods that were used to control SARS would be successful when applied to influenza, though they would certainly be disruptive and costly. Canceling schools and conventions and imposing travel restrictions may be necessary due to absenteeism, but there is little evidence that such measures would limit the spread of flu.

The Plan lists all manner of interventions intended to control the transmission of influenza but offers no judgments about the efficacy or downside of various actions or the resources needed to implement them. As a result, it appears that the Plan assigns the responsibility for making decisions to close airports or train stations or to prohibit public gatherings to governors, mayors, and others. It is not even clear that the federal government will be

in charge of determining who enters the country from abroad.

The HHS Plan’s long list of possible disease containment approaches for local authorities to consider contrasts with the United Kingdom’s influenza plan, which promises that “clear guidance will be issued” when the need arises. The UK guidance further states that because of the biological nature of the flu virus, it is “unlikely that similar interventions [to those used in SARS] will do more than delay or slow the transmission of pandemic influenza at best . . .” [accessed on November 7, 2005, at <http://www.dh.gov.uk/assetRoot/04/12/17/44/04121744.pdf>].

President Bush has made a personal commitment to pandemic flu preparation, and the HHS Plan is an important step forward in efforts to mitigate the potentially calamitous toll of an influenza pandemic. Many critical elements of the Administration’s strategy remain to be clarified, and there is much to do. Let us hope we are given the gift of time to sort it out and get it done.

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November 7, 2005*