



October 26, 2005

National Vaccine Program Office
Office of the Assistant Secretary for Health
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave, SW – Room 725H
Washington, DC 20201-0004

The Society for Healthcare Epidemiology of America is most appreciative of the opportunity to comment on the draft Pandemic Influenza Preparedness and Response Plan. This impressive document provides a wealth of background information necessary to develop comprehensive plans aimed at national, state, local, and hospital levels. The document points out complex issues and challenges facing the public health agencies and hospitals. Embedded in the lengthy draft document is the core of a detailed preparedness plan but the document needs further refinement before it accomplishes its stated intent of defining the roles, responsibilities and actions of key stakeholders.

In addition to the core document, the response plan contains twelve annexes that focus on specific topics. Although the annexes draw upon one another, there is some redundancy in the background materials. This redundancy along with the size of the sections and fragmentation of response plans which are commingled with recommendations and “considerations” impairs the readability of the document. The impact of the response plan would be enhanced by making the document more concise and by formulating a discrete response plan. This plan should be detailed and should make specific recommendations for action. The summary of key actions by pandemic phase beginning on page 40 of the core document is an excellent framework for the response plan. One of the important lessons from the swine influenza program is the importance of having “go/no go” decision points as the situation unfolds. This document should clearly identify these points (for example, if there is no further spread after an initial outbreak as occurred in 1976) and should describe who or what group would make these decisions.

In many respects, this document is not a plan but, as stated in the executive summary, background information that guides and assists healthcare facilities and health departments in developing pandemic influenza preparedness and response plans. There will certainly be state-to-state variation and institution-specific approaches taken but it is essential that national guidance be as specific as possible so state and lower level plans can take national recommendations into account.

The introduction of Annex two makes reference to the approach of identifying common elements of emergency response to a variety of biologic and other threats that can be

included in an “all hazards” plan. We believe that this concept should be encouraged to simplify the response plans that are burdening healthcare facilities. Annex 12 points out that infectious diseases threats behave differently and that to some degree plans need to be tailored to each threat. That said, seeking out common features for a general response plan is a worthy cause.

The infection control section in Annex two provides guidance that is well founded. This guidance should be as specific as possible. These guidelines would be strengthened by having specific examples of plans that have been developed, even if these examples are not “ideal” models. In addition, we recommend exploring ways for healthcare institutions to share plans. This could greatly reduce the workload involved with these preparedness efforts. The annex closes with recommendations for providing healthcare in non-traditional facilities should acute care hospitals become overwhelmed. Providing care in such a setting will be a challenging and monitoring care in these non-traditional facilities during a pandemic will especially be challenging. The recommendation to monitor and investigate medical errors, nosocomial infections and unexpected deaths as soon as they are identified may not be realistic.

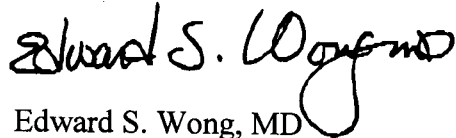
Annex 6 discusses vaccination strategies and has added relevance given the current vaccine shortage. We want to stress the importance of resolving outstanding issues related to vaccine production and distribution. Some of the policy decisions that need to be discussed and decided now include the role of the federal government in purchasing and distributing vaccine. Although priority groups for vaccine administration in the setting of vaccine shortage (non pandemic) have recently been published, this document should further clarify priority groups for vaccination, particularly during early phases of a pandemic when there will not be adequate supplies of vaccine. Annex 6 page 9 references the Canadian Pandemic Preparedness and Response plan which contains specific recommendations for vaccine use. We recommend that DHHS’s document contain similar specific recommendations rather than stating “State and local health departments should define priority groups for early vaccination in their pandemic influenza preparedness and response plans...”. There will certainly be state-to-state variation in specific approaches taken but it is essential that national guidance be enunciated now so state (and lower level) plans can take national recommendations into account. Similar issues with regard to antiviral drugs should be addressed.

Annex 8 gives strategies to limit transmission of influenza. Most are listed as “possible containment measures”. As stated above, recommendations should be as specific as possible. Although the terminology is mostly consistent with HICPAC guidelines, there are exceptions such as “hand washing” instead of “hand hygiene on page 4. The recommendation to use negative pressure rooms “if feasible” early in a pandemic is reasonable but should be clarified. There is mention in Annex 2 page 17 that N-95 respirators are not required for influenza. We agree. However, because the recommendation to use negative pressure in this manner is not consistent with airborne infection isolation in the draft HICPAC isolation guidelines, there should be clear guidance when this additional measure should be taken (eg. when there is documentation or concern of a pandemic influenza strain with enhanced virulence and before case load overwhelms the limited negative pressure rooms in most institutions). This annex discusses isolation strategies during Phase 0 levels 2 and 3. The proposed strategy requires isolation for seven days or until viral shedding is no longer detected or until the viral isolate is

confirmed not to be a novel influenza A. The need to wait until shedding has resolved will prolong isolation in many situations, especially if laboratory support is suboptimal.

Thank you again for the opportunity to comment on this draft document. This is an important document and with some refinement will be extremely valuable at many levels.

Sincerely,

A handwritten signature in black ink that reads "Edward S. Wong". The signature is written in a cursive style with a large, looping "W" at the end.

Edward S. Wong, MD