



July 2, 2008

RADM W. Craig Vanderwagen, MD
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

Re: Interim Guidance on the Use and Purchase of Facemasks and Respirators by Individuals and Families for Pandemic Preparedness, FR Doc. E8-12357

Dear Dr. Vanderwagen,

The Society for Healthcare Epidemiology of America (SHEA) and the Infectious Diseases Society of America (IDSA) appreciate this opportunity to comment on *Interim Guidance on the Use and Purchase of Facemasks and Respirators by Individuals and Families for Pandemic Preparedness*. SHEA is an organization representing over 1,400 physicians and other professionals who direct the infection prevention and control programs in our nation's healthcare facilities. IDSA represents over 8,000 infectious diseases physicians and scientists devoted to patient care, education, research, and public health. As such, we are vitally interested in evidence-based, effective means of reducing the transmission of infectious agents, including pandemic influenza, both in healthcare facilities and in the community. We are, therefore, concerned about the appropriate use and supply of personal protective equipment, such as facemasks and respirators.

We commend the Department of Health and Human Services (DHHS), and its component agencies, for continued responsiveness to public concern about the utility and use of respiratory protection and for the very clear explanation of the absence of scientific data supporting the use of masks by the general public; for the focus on the overriding need for community-based interventions, preventive measures and social distancing; and for clearly defining the difference between masks and respirators. The current guidance extends previous guidance, while addressing questions about household stockpiling of respiratory and barrier protection devices. We have several concerns and comments on the use of masks and respirators in the pandemic influenza circumstance.

The emphasis in this and the previous guidance documents on non-pharmacologic interventions in an influenza pandemic such as hand hygiene, source and environmental controls, and social distancing, is necessary and particularly important. Public over-reliance on respiratory protection in the situation in which the vast majority of the public is untrained and inexperienced in the use of masks and respirators and in the appropriate handling of contaminated personal protective equipment, particularly if masks and respirators are re-used, is an ongoing concern.

This concern persists despite the clearance of respirators for use by the general public by the Food and Drug Administration (FDA). These guidelines do address these issues and the fundamental difference between healthcare and community settings. However, they imply the minimum standard of respiratory protection for direct caregivers of a patient in the home is at the minimum level of an N95 respirator. We question the appropriateness and practicality of this suggestion. In the past, SHEA and IDSA have questioned the basis for this minimum standard for influenza infection control in the healthcare setting as being poorly supported by available scientific evidence and potentially counterproductive to patient care and to the protection of healthcare workers using evidence-based measures.

We feel that more focus and stress should be directed to the instruction in and the encouragement of use of surgical type masks and the general discouragement of the use of N95 respirators by the general public. Pandemic influenza, as a human-adapted viral infection, would be overwhelmingly transmitted directly or indirectly by wet respiratory droplets in a similar fashion as seasonal influenza. The evidence for transmission of influenza by airborne droplet nuclei is limited in contrast to the considerable evidence supporting transmission by large droplets. Although DHHS has stated this in prior guidance documents and continues to do so, this still has not been made generally clear to the public and contributes to confusion regarding consistency of information on respiratory and barrier protection. The focus of education should be on respiratory hygiene and cough etiquette in the context of droplet precautions. Focus on respirators diminishes from the emphasis on what we believe would be most useful for community containment of influenza.

An influenza pandemic would be characterized by widespread community infection and repeated exposures which would make prolonged use of respirators by large numbers of the public infeasible in terms of comfort, correct use, and adequate supply, even for care of family members in the home. There will be frequent opportunities for exposure to others who are infectious, in addition to exposure to a particular ill individual in the household to whom exposure is unavoidable. Such contacts with persons with pandemic influenza can and should be expected to occur frequently, and be the rule rather than the exception, i.e. exposure to infectious individuals will be unavoidable even without a sick household member. For this reason, respiratory hygiene and cough etiquette could be critically important in limiting or delaying the pandemic. Widespread use of N95 respirators for non-professional home care, or even overuse in healthcare settings, could potentially result in shortages of personal protective equipment for situations where such use would be critical and evidence-based. As pointed out in the guidance, there is no evidence that a respirator (including those cleared by FDA for use by the general public) not used correctly with fit-testing is more protective than a facemask. We would encourage language that is even less supportive of use of respirators in non-occupational community settings than the current language, and more focus on the proper use and supplies of facemasks.

We understand the constraints on recommendations regarding facemasks not cleared by the FDA, such as washable fabric masks; however, these guidelines are applicable to non-occupational use of masks as a community intervention, not as medical devices. Supplies of facemasks will almost certainly be limited. They will still be needed in healthcare settings where the intensity of influenza exposure will be higher as well as for other purposes such as surgical procedures. The public is appropriately counseled to discard facemasks after use, as there are

inherent risks of contamination with reusing masks. Therefore, rather than discourage the use of improvised fabric masks, it would be desirable to provide the public with guidance on how to create and safely use improvised fabric masks to supplement the supply of disposable facemasks. There will be people who cannot afford to purchase FDA approved facemasks or will not be able to gain access to them. If the science was available to support the efficacy of regulated facemasks for prevention of influenza, then use of alternatives could be regarded as less effective. But, in the absence of such evidence, it is hard to deny people advice about alternatives to specialized medical devices. Hence, we urge the inclusion of recommendations on alternatives for adequate barrier protection as part of droplet precautions beyond the use of FDA-cleared facemasks.

As DHHS and its component agencies have and continue to emphasize, there is a critical need for research on prevention of transmission of influenza by the use of respiratory and barrier protection. Resources need to be brought to bear to accomplish this research agenda as soon as possible. Seasonal influenza offers the opportunity to pursue this research goal each year and this research would offer an inherent incentive of potentially reducing the impact of these predictable epidemics and their resulting morbidity and mortality. This research should be a major priority.

These interim guidelines are a welcome refinement of earlier guidance and we recognize the difficulties of making recommendations in the absence of scientific evidence. However, we remain concerned about the impact recommendations have on how the public may be directed or not directed toward the most effective means of protecting themselves and their loved ones in the most realistic way. Preparedness and response capacity in healthcare facilities require the assurance of adequate supplies of equipment where they are of proven value.

Both SHEA and IDSA appreciate the opportunity to offer these comments in response to the proposed DHHS guidance on the use of respiratory protection by the public during an influenza pandemic, and look forward to continued collaboration with federal, state, and local government agencies on these important issues related to pandemic preparedness.

Should you have any questions, please feel free to contact Nancy Olins, MA, SHEA's Policy and Strategic Initiatives Manager, at nolins@shea-online.org or (703) 684-0761; or Julie Hantman, MPH, IDSA's Senior Program Officer for Public Health, at jhantman@idsociety.org or (703) 299-0015.

Very truly yours,



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