June 3, 2010

Statement of the National Association of State EMS Officials (NASEMSO) to the Institute of Medicine Workshop on Current Research Issues—Personal Protective Equipment for Healthcare Workers to Prevent Transmission of Pandemic Influenza and Other Viral Respiratory Infections

Conflicting information promulgated by national organizations, the scientific community, and the news media about the use of masks, respirators, and the utility of fit-testing diminishes the ability of the health care community, including Emergency Medical Services (EMS) to promote consistent practice among its practitioners. For example:

1.) One recent study conducted by an international team led by Dr. Raina MacIntyre of the University of New South Wales in Australia, reported that N-95s were superior to surgical masks but that fit-testing provided no added value. This outcome, reported during scientific meeting, remains unpublished.

2.) The Society for Healthcare Epidemiology of America (SHEA), the Infectious Diseases Society of America (IDSA) and the Association for Professionals in Infection Control and Epidemiology (APIC) recently urged the Obama administration to modify the guidance and issue an immediate moratorium on Occupational Safety and Health Administration’s (OSHA) enforcement of the current requirements (which includes minimum of N-95 respirators and fit-testing for healthcare workers at risk for exposure.) Regarding efficacy of fit testing, NIOSH continues to support the need for initial and periodic fit testing for employees who wear respirators and believes that there is sufficient scientific evidence to support the importance of fit testing as a measure to achieve better respirator fit. NIOSH has communicated to NASEMSO that it believes the evidence supporting fit testing as an essential element of a complete respiratory protection program is “scientifically substantial.”

3.) “Surgical Mask vs N95 Respirator for Preventing Influenza Among Health Care Workers A Randomized Trial” appeared in the Journal of the American Medical Association (JAMA) in October 2009. This study concluded that “Among nurses in Ontario tertiary care hospitals, use of a surgical mask compared with an N95 respirator resulted in noninferior rates of laboratory-confirmed influenza.” However, it appears that other variables that can prevent infection among health care workers were not evaluated. The CDC refuted the findings and opined that “this intense discussion over respiratory protection has distracted attention from the critical importance of implementing other strategies known to prevent the transmission of influenza in health care settings. Indeed, the use of personal protective equipment such as masks and respirators should be considered the “last line of defense” in a hierarchy of infection control measures.” The CDC continues to advocate the use of fit-tested N95s for healthcare workers in the most recent infection control guidance.

OSHA’s revised Respiratory Protection Standard (29 CFR 1910.134 and 29 CFR 1926.103) went into effect April 8, 1998. (The final standard replaces the respiratory protection standards adopted by OSHA in 1971.) Establishments whose respirator protection programs for tuberculosis formerly covered under 29 CFR 1910.139 were required to adapt their programs to comply with the requirements of 29 CFR 1910.134, effective July 2, 2004. Section 5(a)(1) of the OSH Act, often referred to as the General Duty Clause, requires employers to “furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees”. Section 5(a)(2) requires employers to “comply with occupational safety and health standards promulgated under this Act”. Twenty-four states, Puerto Rico and the Virgin Islands have OSHA-approved State Plans and have adopted their own standards.
and enforcement policies. For the most part, these States adopt standards that are identical to Federal OSHA. However, some States have adopted different standards applicable to this topic or may have different enforcement policies.

In a memo issued by OSHA earlier this year, the agency announced plans to conduct H1N1 compliance visits in upcoming months. In response to complaints, OSHA inspectors will ensure that healthcare employers implement a “hierarchy of controls” including source control, engineering, and administrative measures, encourage vaccination and other work practices recommended by the CDC.

OSHA has published “Enforcement Procedures for High to Very High Occupational Exposure Risk to 2009 H1N1 Influenza” to coincide with anticipated OSHA Compliance visits. This directive “establishes agency enforcement policies and provides instructions to ensure uniform procedures when conducting inspections to minimize high to very high occupational exposure risk to the virus identified as 2009 H1N1 influenza of workers whose occupational activities involve contact with patients or contaminated material in a healthcare or clinical laboratory setting.” In addition to documentation of worker training and fit-testing of N-95 respirators and optimizing ventilation of vehicles transporting suspected or confirmed 2009 H1N1 influenza patients, EMS agencies will be expected to implement a system that encourages employees at high to very high occupational exposure risk to get the 2009 H1N1 influenza vaccination and provide it at no cost.

On April 26, 2009, the Department of Health and Human Services Secretary declared a public health emergency related to the H1N1 Influenza A outbreak and the following day, declared an emergency justifying the authorization of the emergency use of certain personal respiratory protection devices accompanied by emergency use information, a first step in clearing the way for the distribution of specific N-95 respirators from the Strategic National Stockpile (SNS), should it become necessary, to the “general public.” On May 1, 2009, the Food and Drug Administration (FDA) issued an “emergency use authorization” (EUA) that permits the emergency use of certain types/models of disposable N95 respirators by the general public during this declared emergency. The agency clarified that the term “general public” was broad and included individuals performing work-related duties (such as EMS.) However, many state EMS offices were informed that N-95 respirators would not be available to paramedics and other medical first responders without evidence of compliance with the fit-testing requirement even though the civilian public could access the supply without such documentation.

Virtually every patient encounter contains the risk of exposure to infectious materials for EMS personnel. While advances have been made to protect workers from inhaled pathogens, risks associated with patient contact are not always known. The prehospital environment is frequently chaotic and inadvertent exposure can easily occur. This unpredictable environment suggests that a range of preventative measures must be implemented to minimize the risk of transmission to communicable diseases. Because personnel may not know if and when they are being exposed to an infectious person(s), EMS agencies have been encouraged to use a hierarchy of controls approach to minimize exposure of medical first responders and to prevent transmission of disease within EMS settings.

The national EMS workforce is comprised of individuals and agencies who are both career-paid and community volunteers. National estimates of the number of employed EMTs/paramedics are available, but are based on data with significant limitations. The cost burdens and expectations of EMS agencies to maintain “readiness” within a fragile health infrastructure is already quite high.

The Massachusetts Workplace Safety and Health Program reports that cost may be a significant factor in making the decision on which type of fit test to do. A qualitative fit test kit typically ranges in price from less than $100 up to several hundred dollars. There is a wide range in the number of persons that can be fit tested with a particular kit. Some kits can only test 25 persons, while others can test several hundred individuals with a single kit. This puts the cost range from as little as $0.30/person up to $5.00/person or more. The cost of the quantitative fit test machine ranges from about $6000 to $7000. This includes the cost of software which can be used in conjunction with a computer to store the data. Neither of these estimates includes personnel costs associated with baseline testing or the ongoing annual expense to ensure compliance with the requirement.
NASEMSO acknowledges that newer evidence suggests that a combination of strategies is most effective to mitigate the effects of respiratory borne illnesses, including the recent influenza pandemic.

NASEMSO appreciates the efforts of this Committee and strongly encourages greater collaboration among its many partners to provide a consistent message regarding the role(s) of fit-testing, surgical masks, and N-95 respirators in the transmission of disease. In spite of many differences, healthcare practitioners and employers are largely obligated to comply with OSHA standards with or without consensus. The ongoing public discord regarding efficacy is at best confusing to the healthcare community and seems counterproductive to overall compliance efforts.

NASEMSO is a national membership organization representing the lead agencies for emergency medical services for the fifty states, the District of Columbia, Puerto Rico, the territories of Guam, the Virgin Islands, American Samoa, and the Commonwealth of the Northern Marianas Islands. For more information, please visit our web site at www.nasemso.org.

Kathy Robinson, RN, EMT-P  
Program Advisor  
National Association of State EMS Officials  
201 Park Washington Court  
Falls Church, VA 22046  
Phone: 703.538.1799 extension 1708  
Email: robinson@nasemso.org