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September 12, 2006

Mark B. McClellan, M.D., PhD
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore MD 21244-1850

Dear Dr. McClellan:

I am writing to express my concern about the dismal rate of annual influenza immunizations among U.S. healthcare workers. Vulnerable patients in hospitals and other healthcare settings face serious risks from influenza and its potentially life threatening complications due to exposure to unvaccinated personnel. The current healthcare worker influenza immunization rate, which hovers slightly below 40%, is unacceptable.

I urge you to take action to address the serious public health threat posed by low healthcare worker immunization rates. Specifically, CMS should require that healthcare facilities establish comprehensive healthcare worker influenza vaccination programs as a condition of participation in Medicare, and should include healthcare worker vaccination rates as a performance measure by which to measure patient safety quality. These vaccination programs should include a strong educational component and provide the vaccine at no cost to the employee.

Background

In the United States each year, influenza causes 36,000 deaths and approximately 200,000 hospitalizations.[1] When influenza affects people who are already sick, the resulting illnesses can be severe. Influenza-related mortality results not only from respiratory diseases like pneumonia, but also from exacerbation of pre-existing conditions such as heart, lung, and kidney diseases.[2]

The most efficient method of preventing influenza outbreaks and resulting illnesses and death is pre-exposure immunization. Because the people who are most vulnerable to the

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[1] Centers for Disease Control and Prevention, *Key Facts About Influenza and the Influenza and the Influenza Vaccine*(online at: www.cdc.gov/flu/keyfacts).

[2] *Prevention and Control oflinfluenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP),* Morbidity and Mortality Weekly Report. (Apr. 2003).

complications of influenza – the very young, old, and sick – frequently come into contact with healthcare workers, immunizing healthcare workers is an important mechanism to reduce the exposure of these vulnerable populations to the influenza virus.[3]

The inactivated influenza vaccine can prevent influenza illness in approximately 70% to 90% of healthy adults under 65.[4] Such vaccination not only benefits healthcare workers by providing them direct immunity against the influenza virus, but it also has been proven to reduce influenza-related illness and mortality among patients with whom they come in contact.[5] There is a negative correlation between health care worker (HCW) influenza vaccination and influenza illness and mortality. In one hospital study, the increase in the staff vaccination rate from 4% to nearly 70% resulted in a decrease in the proportion of hospital-acquired influenza cases among hospital patients from 32% to zero.[6]

Healthcare worker immunization is particularly important in nursing homes and other health care settings populated by older, more vulnerable patients particularly since the influenza immunization has shown lower efficacy among older patients.. In one randomized trial set in a nursing home, staff influenza vaccination was associated with a 43% reduction in influenza-like illnesses and a 44% drop in mortality among patients.[7]

Troublingly, low influenza vaccination rates are a pervasive problem in the United States. The Centers for Disease Control and Prevention (CDC) estimates that 188 million Americans should be vaccinated against influenza annually, but only about 80-85 million actually are.[8] Among health care workers, the rates are lower still. The CDC-sponsored initiative Healthy People 2010 set a goal for healthcare worker influenza immunization at 60% by 2010. However, in 2004, only about 40% of healthcare personnel (under 65) had been vaccinated in the previous 12 months.[9]

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[3] Gregory Poland, Pritish Tosh, Robert M. Jacobsen, *Requiring Iinfluenza Vaccination For Healthcare Workers: Seven Truths We Must Accept*. Vaccine 23 (2005).

[4] *Influenza Vaccination of Health-Care Personnel: Recommendations of the Health Care Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP),* Morbidity and Mortality Weekly (Feb. 9, 2006).

[5] *Id.* at 3

[6] *Id.* at 3.

[7] *Id.* at 4.

[8] Partnership for Prevention, *Strengthening Adult Immunization: A Call to Action* (2005).

[9] *Id.*

As of January 2005, 13 states and the District of Columbia required healthcare workers in long-term care facilities to be vaccinated against the influenza.[10] In June 2006, the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) changed its accreditation standards to require that health care facilities offer influenza immunization programs to their employees. This standard, which requires facilities provide the vaccine on-site during work hour and also offer education about the vaccine, will go into effect January 1, 2007.

While the efforts discussed above are important first steps toward increasing healthcare worker immunization rates, they are not sufficient to ensure adequate patient safety standards across the country. For example, healthcare facilities are not required to have JCAHO accreditation. Even if they were, the JCAHO standard does not apply to home or ambulatory care. CMS should amend its regulations to provide the necessary assurances that healthcare workers at facilities that treat elderly patients – who may be most at risk for influenza related illnesses – have access to the vaccine.

Recommendations

(1) CMS should require influenza vaccination programs for healthcare workers as a condition of participation in Medicare.

CMS does not currently require healthcare workers in Medicare participating facilities to be immunized as a precondition for participating in the Medicare program. CMS should expand the conditions of participation to include a health care worker immunization program requirement. This requirement should apply broadly to not only hospitals and long term care facilities, but to other healthcare settings where vulnerable patients are at risk of infection.

For example, elderly home care patients may themselves be vaccinated, but because the vaccine is not as effective in older people, it is critical that individuals who have contact with elderly home care patients, such as home health care workers, be vaccinated as well. In addition, ambulatory care patients can actually be exposed to potentially infected individuals while sitting in doctor's office waiting rooms, filling out intake forms in hospital emergency departments, or having blood drawn. The best way to protect these patients is to vaccinate the professionals who treat them.

(2) CMS infection control standard pertaining to influenza vaccination should require a comprehensive healthcare worker education program.

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[10] The states that require flu vaccinations for healthcare workers in long-term care facilities include Alabama, Arkansas, Kentucky, Maine, Maryland, New Hampshire, New York, Oklahoma, Oregon, Pennsylvania, Rhode Island, Texas, and Utah.

As with other infection control interventions, achieving widespread compliance with influenza vaccination policies requires accurate information be provided to healthcare workers in a comprehensible and appropriate manner.

Fears of side effects and the vaccine's efficacy are barriers to health care worker immunization.[11] Several studies have demonstrated that correcting healthcare workers' misperceptions can sometimes increase vaccination rates.[12] Limited English proficiency among some healthcare workers can also restrict their ability to understand printed information about vaccines.

When combined with efforts to increase access to the influenza vaccine, education campaigns in one facility were successful in raising healthcare worker vaccination compliance to 75%.[13] CMS should require participating facilities to provide evidence-based education programs accessible to all employees. Curricula should include information on vaccine safety and effectiveness, patient safety considerations, and risks and benefits to healthcare workers. In addition, a knowledgeable speaker should be available on-site to provide information about the vaccine and answer questions that healthcare workers may have.[14]

(3) CMS standard should require healthcare facilities to provide influenza vaccination at no cost to employees.

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[11] *Influenza Vaccination of Health-Care Personnel: Recommendations of the Health Care Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP),* supra note 4 at 4-5..

[12] Gregory A. Poland, *Influenza Immunization of Healthcare Workers: A Patient Safety and Quality of Care Opportunity* (Unpublished manuscript submitted to CDC Advisory Committee on Immunization Practices).

[13] *Interventions to Increase Influenza Vaccination of Health-Care Workers—California and Minnesota,* MMWR (Mar. 4, 2005).

[14] This recommendation is based on the 1991 OSHA Bloodborne Pathogens Standard, which requires healthcare facilities to offer employees the hepatitis B vaccine. It requires "an opportunity for interactive questions and answers with the person conducting the training session" and specifies "the person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address." As a result of this regulation, the rate of hepatitis B infection in healthcare workers declined 95% between 1983 and 1995 and is now lower than the rate for the general U.S. population. Mahoney FJ, Stewart K, Hu H, Coleman P, Alter MJ, *Progress toward the Elimination of Hepatitis B Virus Transmission among Health Care Workers in the United States,* Arch Intern Med 1997;157:2601--5.

Another major obstacle to widespread influenza immunization among healthcare workers is cost. In fact, in one survey, 33% of healthcare workers said they would forgo vaccination if they were required to pay for the vaccine.[15] Removing this barrier – along with providing vaccine in locations and at times easily accessible to healthcare workers – can substantially improve vaccine acceptance.[16]

Studies have shown that providers have concerns regarding the costs of purchasing and administering influenza vaccine.[17] However, while such costs may seem burdensome, healthcare facilities will see benefits from the program. Expanding the accreditation requirement and providing the vaccine free of charge will benefit healthcare facilities by maintaining productivity and assuring consistency of services. Immunization has been associated with reduced work absenteeism and use of health-care resources like antibiotics and over-the-counter medications.[18] Lower rates of staff absenteeism translate into better staffed facilities, particularly during the winter months when inclement weather and seasonal illnesses can interfere with full provision of services.

In the past, healthcare administrators have been hesitant to order large supplies of vaccines because they must order and purchase vaccine months before it is administered. Manufacturers' "no return" policy for influenza vaccine have also made providers wary about potentially ordering excess vaccine and receiving no reimbursement for unused product.[19] In the case of healthcare workers, this should not be a concern, since employers know how many workers are in a facility and could easily estimate the number of doses needed.

(4) CMS should establish healthcare worker influenza vaccination as a patient safety performance measure.

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[15] *Influenza Vaccination of Health-Care Personnel: Recommendations of the Health Care Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP),* supra note 4 at 5.

[16] *Influenza Vaccination of Health-Care Personnel: Recommendations of the Health Care Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP),* supra note 4 at 5.

[17] National Vaccine Advisory Committee, *Strengthening the Nation's Influenza Vaccination System: An NVAC Assessment* (Dec. 2, 2004).

[18] *Influenza Vaccination of Health-Care Personnel: Recommendations of the Health Care Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP),* supra note 4 at 4.

[19] National Vaccine Advisory Committee, supra note 17.

Requiring facilities to develop vaccination programs is an important first step towards promoting patient safety. However, these programs alone will not guarantee a protective level of immunization among healthcare workers.

To ensure that facilities are fully implementing immunization programs, I urge CMS to include monitoring influenza vaccination coverage as a specification in performance measurement initiatives such as the Hospital, Home Health, and Nursing Home Quality Initiatives. There is evidence to suggest that measuring how well providers deliver immunizations actually increases vaccination rates.[20]

It is critical that healthcare worker vaccination rates must increase in order to insure the facilities are able to achieve a protective level of influenza immunity. Toward that end, I also request that, as part of the performance measurement initiative, CMS -- in collaboration with CDC, JCAHO, or other relevant bodies -- develop a target vaccination level to provide institutions with a benchmark for care.

Finally, once vaccination rates are measured and submitted, this information should be made available to the public in a simple and accessible manner. Providing this information regarding the level of infection control compliance in a facility will inform patients' and families' when making health care decisions.

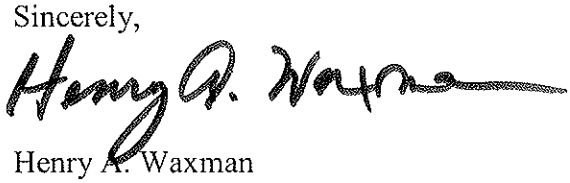
Conclusion

Increasing healthcare worker immunization rates is an important public health goal. As healthcare worker immunization rates increase, infection rates among healthcare workers themselves, their families and their patients will decrease. CMS has a critical role to play to achieve this goal.

I would very much appreciate the opportunity to discuss these recommendations with you. Please contact Sarah Despres on my staff to set up a meeting. She can be reached at (202) 225-5420.

Thank you for your attention to this matter.

Sincerely,



Henry A. Waxman

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[20] Partnership for Prevention, *Strengthening Adult Immunization: A Call to Action* (2005).