



# Policy Statement—Recommendation for Mandatory Influenza Immunization of All Health Care Personnel

COMMITTEE ON INFECTIOUS DISEASES

## KEY WORDS

health care personnel, mandatory, influenza, immunization, vaccine, children, pediatrics

## ABBREVIATIONS

HCP—health care personnel

CDC—Centers for Disease Control and Prevention

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## abstract

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The purpose of this statement is to recommend implementation of a mandatory influenza immunization policy for all health care personnel. Immunization of health care personnel is a critically important step to substantially reduce health care–associated influenza infections. Despite the efforts of many organizations to improve influenza immunization rates with the use of voluntary campaigns, influenza coverage among health care personnel remains unacceptably low. Mandatory influenza immunization for all health care personnel is ethically justified, necessary, and long overdue to ensure patient safety. *Pediatrics* 2010;126:809–815

## INTRODUCTION

Health care–associated influenza outbreaks are a common and serious public health problem that contributes significantly to patient morbidity and mortality and creates a financial burden on health care systems. Annual immunization of health care personnel (HCP) is a matter of patient safety and necessary to significantly reduce health care–associated influenza infections. Immunization rates of 80% or higher are essential for providing the “herd immunity” needed to have a significant impact on transmission of influenza by HCP in medical settings, but overall immunization rates for HCP remain near 40%.<sup>1</sup>

Mandatory immunization is not a novel concept. Many health care facilities currently require specific vaccines and a tuberculin skin test as conditions for working in specific areas of the institution or for employment. Despite the sustained efforts of many organizations to improve influenza immunization rates with the use of voluntary campaigns, influenza coverage among HCP in the United States remains unacceptably low.

Mandatory programs for all HCP should be implemented nationwide. Mandating influenza vaccine for all HCP is ethically justified, necessary, and long overdue. Employees of health care institutions have both ethical and professional obligations to act in the best interests of the health of their patients. Medical and religious exemptions to required influenza immunization can be granted on an individual basis. Individual organizations and practices must decide at a local level the additional objections to vaccination, which may be required by state law (eg, philosophical), that are reasonable and the ones they are willing to accept for an individual to be granted an exception and be allowed to continue to work. Policies should be developed for management of exempted HCP during influenza season, including efforts to ensure patient and staff safety and to identify ill HCP.

## BACKGROUND

### Influenza Is a Significant Public Health Problem

Each year in the United States there are, on average, more than 36 000 deaths and 200 000 hospitalizations associated with the influenza virus, which makes influenza outbreaks a major public health concern.<sup>2</sup> Serious morbidity and mortality can result from influenza infection in any person of any age. Rates of serious influenza-related illness and death are highest among children younger than 2 years, seniors 65 years and older, and people of any age with medical conditions that place them at increased risk of having complications from influenza, such as pregnant women and those with underlying chronic cardiopulmonary, neuromuscular, and immunodeficient conditions. Transmission from an infected, previously healthy child or adult begins as early as 1 day before the onset of symptoms and persists for up to 5 to 7 days; infants and immunocompromised persons may shed virus even longer. Some infected individuals remain asymptomatic yet contagious.<sup>3</sup>

Immunization is the most effective way to prevent influenza outbreaks, so it is recommended for everyone 6 months of age and older.<sup>2</sup> Among healthy adults, including HCP, annual immunization with a vaccine antigenically well matched to circulating strains reduces laboratory-confirmed influenza cases by 70% to 90%.<sup>1</sup> In contrast, the vaccine has been shown to be less effective for some high-risk groups.<sup>1</sup> Many individuals at high risk of influenza and its associated complications are in frequent, close contact with HCP because of their need to seek inpatient and outpatient medical services.<sup>1</sup> Therefore, immunization of HCP is a critically important step for protect-

ing those at risk from health care-associated influenza.

### HCP Immunization Rates Remain Low

The growing understanding of the impact of influenza on all age and risk groups has prompted the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention (CDC) to expand annual influenza immunization recommendations to include all people aged 6 months and older.<sup>4</sup> This universal recommendation includes HCP and persons in training for health care professions, such as physicians, nurses, workers in hospital and outpatient care settings, medical emergency response workers, employees of nursing home and longer-term care facilities, and students in these professions.<sup>1</sup> There also is no contraindication to receiving influenza vaccine for HCP who are pregnant or breastfeeding.

The Advisory Committee on Immunization Practices began recommending influenza immunization for HCP in the early 1980s.<sup>5</sup> Despite this longstanding recommendation, overall immunization rates for HCP remain near 40%.<sup>1</sup> It is surprising that many HCP and the organizations that employ them have been inexcusably silent in addressing this patient safety issue. The low seasonal immunization rate among HCP prompted the US Department of Health and Human Services to make increasing HCP immunization rates to 60% a part of their *Healthy People 2010* objectives. However, even this modest objective has not been achieved in many institutions.<sup>6</sup> The gap is magnified when one considers that The Joint Commission estimates that influenza immunization rates of 80% or higher are essential for providing the herd immunity necessary to substantially reduce health care-associated influenza infections.<sup>7</sup>

During the 2009–2010 influenza season, it was recommended that HCP protect themselves against both the expected seasonal influenza strains and the 2009 pandemic H1N1 influenza A virus. The Advisory Committee on Immunization Practices recommended that HCP be a priority group to receive the 2009 H1N1 monovalent vaccine when it was first released, a time when its availability for the general public was limited.<sup>8</sup> In January 2010, the CDC estimated that the percentage of HCP receiving influenza vaccine<sup>8</sup> was as follows:

- 61.9% for seasonal influenza vaccine;
- 37.1% for 2009 H1N1 monovalent vaccine; and
- 34.7% for both vaccines.

### Voluntary Programs Are Not Sufficient to Increase HCP Immunization Rates

Efforts to increase immunization rates among HCP have focused primarily on voluntary programs, which attempt to increase rates by ensuring that the vaccine is conveniently available and free of charge and providing influenza-prevention education and incentives or rewards to improve participation. A more comprehensive approach involves the use of signed declination statements coupled with education about risks and benefits of being immunized. However, use of declination statements in 22 hospitals resulted in only a modest increase in influenza immunization.<sup>9</sup> It is difficult to assess the overall effectiveness of declination statements, because the language and context can vary among programs, and multiple strategies for preventing influenza are often initiated simultaneously.<sup>10</sup>

These efforts may lead to an immediate increase in immunization rates, although a lasting effect has yet to be shown. The CDC has reported that an

employer recommendation was associated with two- and fourfold higher coverage rates for seasonal and 2009 H1N1 influenza vaccination, respectively, when compared with employers who made no recommendation. Coverage rates for both influenza vaccines improved by three- to eightfold when employers required influenza immunization of HCP.<sup>8</sup>

It seems that sustainability of herd immunity in health care settings can be achieved only through a mandated policy. Despite many organizations' efforts to improve influenza immunization rates with the use of voluntary campaigns, influenza coverage among US HCP remains unacceptably low at a rate of 44.4% between 2006 and 2007,<sup>1</sup> and even fewer receiving both seasonal and H1N1 vaccines during the 2009–2010 season. Voluntary programs have proven to be ineffective, in part because HCP have misconceptions regarding the risks and benefits of the vaccines. HCP were more likely to believe that seasonal influenza vaccine was safe when compared with the 2009 H1N1 vaccine (80.9% vs 66.6%), although the 2009 H1N1 vaccine was manufactured by using the same processes as seasonal vaccine and had undergone more extensive human safety testing. HCP also were more likely to report that seasonal influenza vaccine was worth the time and expense when compared with the 2009 H1N1 vaccine (74.2% vs 62.8%). Immunization coverage was higher among HCP in hospitals than in outpatient clinics and among HCP working in intensive care, burn, and obstetric units or around seriously ill patients. A survey conducted at 2 obstetric outpatient facilities revealed that 34% to 39% of the obstetric HCP surveyed did not receive yearly influenza immunizations.<sup>11</sup> HCP with a bachelor's degree or higher were more

likely to be immunized against the 2009 H1N1 virus.<sup>8</sup>

The Joint Commission found that reasons HCP decline immunization include fear of getting influenza-like illness from the vaccine, fear of adverse effects, perceived low or no likelihood of developing influenza disease, and concern about exposure to thimerosal, among others.<sup>7</sup> With the use of live-attenuated influenza virus (LAIV) vaccine, some HCP expressed concern that the vaccine virus could be shed to vulnerable patients, infecting them with the influenza virus. Although LAIV recipients shed vaccine virus, much lower amounts are shed than during natural infection, and transmission is unlikely to occur. Serious illness has not been reported among unvaccinated, otherwise healthy persons who have been infected inadvertently with virus from LAIV vaccine.<sup>1</sup> These findings highlight the importance of educating HCP of the risks, benefits, and basic principles of influenza vaccination. Given the ineffectiveness of voluntary programs in increasing rates of HCP influenza immunization and the effectiveness of influenza immunization in decreasing infection among those most vulnerable to severe complications from influenza, mandatory programs must be implemented around the country.

### Health Risks to Patient Populations Cared for by Unimmunized HCP

Mandatory influenza immunization of HCP is a matter of patient safety. The risk of transmission is augmented, because many HCP work when they are mildly symptomatic or ill, which puts their co-workers and patients at risk.<sup>12</sup> A serosurvey conducted in 4 acute care hospitals in the United Kingdom revealed that 23% of HCP had serologic evidence of influenza virus infection during a single influenza season; the majority reported mild illness or sub-

clinical infection. One limitation of this study is that comprehensive culture or polymerase chain reaction–based surveillance was not also performed.<sup>1</sup>

It is well known that HCP can transmit influenza virus to patients and co-workers before the onset of symptoms or during symptomatic illness.<sup>2</sup> The results of 2 published studies highlight the negative effect that HCP infected with influenza can have on their patients.

- In a NICU, 19 of 54 (35%) infants were infected with influenza A as a result of health care–associated transmission; 6 became ill, and 1 died. Only 15% of staff survey respondents in this NICU had received influenza vaccine—67% of physicians and 9% of nurses. Fourteen percent of the employees reported taking time off from work because of illness, which suggests that these symptomatic personnel had a role in transmission.<sup>13</sup>
- During an outbreak of influenza in a bone marrow transplant unit, there were 7 cases of health care–associated influenza; 6 patients developed pneumonia, and 2 patients died.<sup>14</sup> Five staff members developed influenza-like illness during the outbreak. Surveys revealed a vaccination rate of 12% among unit staff. The hospital took measures the following influenza season to implement a multifaceted voluntary education program aimed at improving immunization rates. However, even with these aggressive measures, 42% of the staff on the bone marrow transplant unit remained unimmunized the following year.<sup>14</sup>

### THE SOLUTION: MANDATORY IMMUNIZATION OF ALL HCP

Annual influenza epidemics account for 610 660 life-years lost, 3.1 million days of hospitalization, and 31.4 million outpatient visits.<sup>15</sup> Influenza in the

United States generates a cost burden estimated to be \$87 billion per year.<sup>15</sup> The bulk of this cost is a result of work absenteeism and premature mortality. “Presenteeism,” or working while symptomatic, also contributes a significant amount to the cost burden and decline in productivity associated with influenza infection. Influenza B virus infection in healthy adults impairs the ability to perform certain tasks to a level similar to that seen with sleep deprivation or alcohol consumption.<sup>16</sup> Presenteeism is a threat to patient safety. In addition, healthy adults who receive the influenza immunization have 25% fewer upper respiratory infections, 44% fewer physician visits, and 43% fewer sick days off, saving an average of \$47 per person annually and highlighting the cost-effectiveness of immunization against influenza.<sup>17</sup> A decision-analytic computational simulation model that determined the cost/benefit of employer-sponsored workplace immunization from the employer’s perspective found cost savings across diverse occupational groups in all seasonal influenza scenarios.<sup>18</sup>

Mandatory immunization is not a novel concept. All states have laws that require certain vaccines for school entry or attendance. Many health care facilities currently require specific vaccines and a tuberculin skin test as conditions for working in certain areas of the institution or for employment.<sup>2,12</sup> Despite this reality, implementation of mandatory influenza immunization programs for HCP continues to be controversial to some who argue that a mandatory program violates civil liberties. The US Supreme Court ruled in 1905 in *Jacobson v Massachusetts* that states have the power to require immunization if it is necessary for public health or safety of the people. The power of states to enforce immunization requirements or other public

health initiatives is constitutionally permissible when the intervention:

- is a public health necessity;
- has proven to be effective;
- is not “gratuitously onerous or unfair”; and
- does not pose a health risk to the subject.

For example, school immunization laws are judicially sanctioned, which emphasizes the fact that mandatory immunization programs have long existed without infringing on constitutional rights.<sup>19</sup>

### **Evidence That Mandatory Influenza Vaccine Policy Increases Rates of Immunization**

Each of the following examples resulted in a substantial increase in employee immunization rates, which demonstrates success with the implementation of a mandatory program.

- BJC Health care, a large nonprofit health care organization with approximately 26 000 employees, implemented a mandatory influenza immunization program in 2008 after voluntary models failed to increase rates above 80%.<sup>20</sup> BJC made influenza immunization a condition of employment as a patient safety initiative. Employees could be granted medical or religious exemptions on review by an occupational medicine professional. Medical exemptions were granted to 321 employees (1.2%), of which 107 were for an egg allergy, 83 for previous allergic reaction or allergy to an influenza vaccine component, and 15 for a history of Guillain-Barré syndrome. Exemptions were granted to 116 other employees, of whom 14 cited pregnancy,<sup>20</sup> although it is highly recommended that pregnant women receive influenza vaccine because of the documented increase in risk of serious complications, including

death.<sup>12</sup> Religious exemptions were granted to 90 employees. The result was an immunization rate of 98.4% for the organization of 25 980 employees. Only 8 employees refused to be vaccinated, and their employment was terminated.<sup>20</sup>

- Seattle’s Virginia Mason Medical Center implemented a mandatory influenza immunization program in 2005. The medical center reported a 99% immunization compliance rate among its employees.<sup>7</sup>
- The National Institutes of Health Clinical Center passed a mandatory influenza immunization policy in 2008. The policy required that employees who had patient contact be immunized or complete an online declination statement specifying the reason for refusal. The policy achieved 100% participation in that all 2754 employees who were identified to have direct patient contact were either immunized or formally declined vaccination. Compared with vaccination rates of 40% to 60% from previous years, the organization achieved an immunization rate of 88% (2424) among employees with patient contact. Of employees who formally declined, 36 reported medical contraindications to influenza vaccine, and 294 declined for other reasons such as concerns about adverse effects, belief that they were not at risk of influenza, or perceptions that the vaccine was ineffective or harmful. Philosophical reasons were cited 5 times as frequently as religious reasons for declining vaccination.<sup>21</sup>
- Hospital Corporation of America, which includes 163 hospitals, 112 outpatient centers, and 368 physician practices in 20 states, put a mandatory policy into effect in late 2009. The policy required all employees in contact with patients to either receive the annual influenza



vaccine or wear a surgical mask in patient areas. Before the policy, vaccination rates in Hospital Corporation of America facilities varied from 20% to 70%. This mandatory policy offered influenza vaccine to 140 599 HCP; 96% of these employees complied.<sup>22</sup>

### **A Mandatory Recommendation as a Public Health Intervention Is Justified**

Medical and religious exemptions can be granted on an individual basis,<sup>20,23</sup> so mandating influenza immunization for HCP is ethically justified. The regulations of New York State's mandatory program highlight the details that compel individuals to be vaccinated to protect the public from seasonal and pandemic influenza.<sup>24</sup> Employees of health care institutions have an ethical and professional obligation to act in the best interest of the health of their patients. Three criteria that a public health intervention must meet to justify mandatory status have been proposed.<sup>25</sup>

- 1. There should be clear medical value from the intervention to the individual.** The positive effects of the influenza vaccine on the health of the person immunized are well known.
- 2. The public health benefit of the mandatory intervention must be clear to justify the infringement on personal liberties.** Populations staying at or frequenting hospitals are especially vulnerable to increased health risks from influenza. HCP were obliged to take preventive measures to protect patients when they joined the profession. The effects on the health of patients and on the loss of days worked by personnel have been sufficiently demonstrated.
- 3. A mandate must be considered the only option.** Current rates of

influenza immunization are unacceptably low among HCP, despite decades-long recommendations using myriad other strategies. When other approaches have failed, a mandate is a reliable way to achieve improvement. "If it is possible to obtain herd immunity, for example, without a mandate but through education, insurance coverage, public outreach and so on, then a mandate would not be needed and should not be used."<sup>25</sup> To satisfy a mandate, each health care facility should design, implement, and evaluate a program tailored to fit its particular needs.

### **Key Points to Consider in Implementing a Mandatory Influenza Immunization Policy**

To maximize success when implementing a mandatory policy, relevant factors include:

- Having full support of health care leadership.
- Customizing the plan for each institution; the policy must be tailored to the geographic setting, educational resources, financial assets, local culture, and potential language barriers.
- Making vaccine free to all HCP.
- Publicizing the program to HCP at all levels by:
  - communicating program details regularly;
  - making presentations about influenza prevention and the program;
  - holding "question-and-answer" sessions; and
  - creating a volunteer team of staff HCP to offer education (and vaccine, if possible) to fellow HCP with concerns.
- Offering convenient times and locations for education and immunization administration, preferably

within the institution; vaccinators should adapt to accommodate HCP schedules, including:

- expanding available hours to receive vaccine;
- increasing the number of locations at which vaccine is given; and
- offering vaccine at various venues and gathering places within the institution.
- Using a universal form with defined acceptable medical and religious exemptions, which will be more effective, concrete, and uniform than requiring a physician's note.
- Creating a clear institutional policy for management of employees who are exempted from immunization.

These recommendations for the prevention and control of influenza in HCP will have a considerable impact on practice. Therefore, the American Academy of Pediatrics has developed implementation guidance on supply, payment, coding, and liability issues; these documents can be found at [www.aapredbook.org/implementation](http://www.aapredbook.org/implementation).

### **CONCLUSIONS**

Mandatory influenza immunization programs for HCP will benefit the health of employees, their patients, and members of the community. The influenza vaccine is safe, effective, and cost-effective. Health care organizations must work to assuage common fears and misconceptions about the influenza virus and the vaccine. Immunizing all HCP will serve as an example to patients and highlight the safety and effectiveness of annual immunization. HCP fail to lead by example if they recommend universal immunization, including influenza, to their patients but do not require it of themselves.

Data clearly show that an influenza vaccine mandate is necessary and

long overdue. Health care–associated influenza outbreaks are becoming more common, creating a financial burden on health care systems, and contributing to patient morbidity and mortality. Voluntary programs have failed to increase immunization rates to acceptable levels. Results from a recent CDC survey indicate that HCP who were subject to employer requirements for vaccination were more likely to be vaccinated, compared with those not subject to such requirements.<sup>8</sup> Large health care organizations have implemented highly successful mandatory annual influenza immunization programs without significant problems. The implementation of mandatory annual influenza immunization programs for HCP nationwide is long overdue. For the prevention and control of influenza, now is the time to put the health and safety of the patient first.

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