Influenza Immunization for All Health Care Personnel: Keep It Mandatory

Committee on Infectious Diseases

The purpose of this statement is to reaffirm the American Academy of Pediatrics’ support for a mandatory influenza immunization policy for all health care personnel. With an increasing number of organizations requiring influenza vaccination, coverage among health care personnel has risen to 75% in the 2013 to 2014 influenza season but still remains below the Healthy People 2020 objective of 90%. Mandatory influenza immunization for all health care personnel is ethical, just, and necessary to improve patient safety. It is a crucial step in efforts to reduce health care–associated influenza infections.
at a minimum to ensure high coverage rates and granted only on an individual basis. Rigorous standards, such as requiring counseling, detailing the benefits of influenza vaccination, and insisting on a signed affidavit stating an acceptable reason for opting out, will place a higher burden on nonadherent HCP and would make it more difficult for HCP to impose unnecessary risks on their patients.12 Granting specific medical exemptions is constitutionally required, but states do not have to grant philosophical or religious opt-outs.12 Consistent policies also must be developed for management of exempted HCP during influenza season. For example, although scientific evidence supporting the medical concept of unvaccinated employees wearing a mask is limited,13 some institutions have required such an approach throughout the influenza season.

BACKGROUND
Influenza Is a Significant Public Health Problem

Influenza is a major public health concern. Each year in the United States, more than 200,000 hospitalizations are associated with the influenza virus.14 The number of annual influenza-associated deaths has ranged from a low of about 3000 to a high of about 49,000 in recent decades.14 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 old, 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 people with underlying chronic cardiopulmonary, neuromuscular, and immunodeficient conditions. Hospital-acquired influenza has been shown to have a particularly high mortality rate, with a median of 16% among all patients and a range of 33% to 60% in high-risk groups such as transplant recipients and patients in the ICU.1 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 7 days; infants and immunocompromised people may shed virus even longer. Some infected people remain asymptomatic yet contagious.15 Immunization is the most effective way to prevent influenza, so the vaccine is universally recommended by the American Academy of Pediatrics (AAP), Centers for Disease Control and Prevention (CDC), and American Academy of Family Physicians for everyone 6 months old and older.16,17 A 2010 meta-analysis of randomized clinical trial results among healthy adults 16 through 65 years of age suggested that when vaccine and circulating influenza virus strains were well matched, efficacy against influenza symptoms was 73% (95% confidence interval, 54%–84%) whereas efficacy was 44% (95% confidence interval, 23%–59%) when they were not well matched.17 However, in the 2014 to 2015 season, early data estimated overall vaccine effectiveness to be much lower, at 19%.18 Vaccine effectiveness can vary based on the match of circulating virus with vaccine strains, vaccine product, previous influenza vaccination, and age and immune status of patients. The influenza vaccine still remains the best available preventive measure. Many people at high risk of influenza and its associated complications are in frequent, close contact with HCP because of their need to seek medical services. Therefore, immunization of HCP is a crucial step in efforts to protect those at risk for health care–associated influenza, similar to the concept of cocooning, in which immunization of parents, caregivers, and other close contacts of children is intended to reduce their risk of contagion. It is important not to rely solely on influenza immunization of HCP for prevention of nosocomial transmission. Other infection precaution controls are necessary, such as use of masks and hand hygiene and careful evaluation of sick employees, even if no fever is present.19

HCP Immunization May Prevent Patient Morbidity and Mortality

Influenza vaccination of HCP has the potential to reduce both morbidity and mortality among patients. Ahmed et al20 systematically reviewed the evidence surrounding this concept, using the Grading of Recommendations Assessment, Development, and Evaluation framework. With pooled results of 4 cluster randomized trials conducted in 116 long-term care facilities, they estimated a 29% reduction in all-cause death and a 42% reduction in influenza-like illness. In addition, pooled results of 4 observational studies conducted in 234 long-term care facilities and 1 hospital-based setting indicated significant protective associations for influenza-like illness and for laboratory-confirmed influenza. On the basis of these findings, the authors graded the quality of the evidence for the effect of HCP vaccination on mortality and influenza cases in patients as “moderate” and “low,” respectively. The authors concluded that the benefits of immunizing HCP outweigh possible harms and can increase patient safety.20 In contrast, a 2013 Cochrane review concluded that there were no accurate data supporting the vaccination of health care workers to prevent laboratory-confirmed influenza in residents 60 years and older in long-term care facilities.21 Specifically, the authors did not find a significant decrease in respiratory illness or in deaths related to respiratory illness.
Cost-Effectiveness of HCP Immunization

Annual influenza epidemics account for 610,660 life-years lost, 3.1 million days of hospitalization, and 31.4 million outpatient visits. Influenza in the United States generates a cost burden estimated to be $87 billion per year. The bulk of this cost is a result of medical care in outpatient and inpatient settings, work absenteeism, and mortality. A retrospective cohort study found that unvaccinated HCP had a larger increase in absenteeism attributable to all-cause illness during the influenza season than vaccinated HCP. The fiscal benefit of reduced absenteeism from vaccination was more than $1 million, whereas the cost of introducing a new policy requiring staff in clinical areas to be vaccinated or wear a mask was minimal by comparison. Impaired on-the-job productivity (known as presenteeism) also contributes significantly to the total economic burden caused by illness. Presenteeism accounted for 18% to 60% of costs for the top 10 health conditions affecting US employers and for approximately two-thirds of lost productivity costs related to the common cold. Similar to absenteeism, it is a major contributor to the economic burden associated with influenza and is a threat to patient safety. Although 86% of HCP report their intent to leave work if they have an influenza-like illness, 59% report having worked in the past with a fever or influenza-like symptoms. Furthermore, 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, highlighting the cost-effectiveness of immunization against influenza. A decision-analytic computational simulation model that determined the cost/benefit ratio of employer-sponsored workplace immunization from the employer’s perspective found cost savings across diverse occupational groups in all seasonal influenza scenarios.

HCP Immunization Rates Remain Suboptimal

The growing understanding of the effect of influenza on all age and risk groups prompted the Advisory Committee on Immunization Practices of the CDC to expand annual influenza immunization recommendations to include all people 6 months and older starting in 2010. This universal recommendation is especially important for HCP and people in training for health care professions, such as physicians, nurses, workers in hospital and outpatient care settings, medical emergency response workers, and employees of nursing homes and longer-term care facilities. HCP who are pregnant or breastfeeding also should receive the influenza vaccine. The Advisory Committee on Immunization Practices began recommending influenza immunization for HCP in the early 1980s. Despite this long-standing recommendation, overall immunization rates for HCP never exceeded 50% before the 2008 to 2009 influenza season. Coverage has gradually improved in recent years, reaching a high of 75% during the 2013 to 2014 season, but it still remains below the Healthy People 2020 objective of 90%. Influenza vaccination coverage among acute care hospital-based HCP in 2013 to 2014 reached a level of 81.8%, with the highest proportion among those directly employed by the health care facility (86.1%) and the lowest among licensed independent practitioners who are affiliated but not directly employed by it (61.9%). Just over one quarter of states reached the Healthy People 2020 objective of 90%. Voluntary Programs Are Not Sufficient to Increase HCP Immunization Rates

In the past, 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 increase participation. The Advisory Committee on Immunization Practices have demonstrated only a modest increase in influenza immunization. It is difficult to assess the overall effectiveness of declination statements, because the language and context can vary between programs, and multiple strategies to prevent influenza are often initiated simultaneously.

Although these efforts may lead to an immediate increase in immunization rates, it appears that sustainability of high immunization rates in health care settings can be achieved only through a mandated policy. Despite many organizations’ efforts to increase influenza immunization rates with the use of voluntary campaigns, influenza coverage within such organizations remains below the Healthy People 2020 objective of 90%, ranging from 65% to 77% since 2010. In contrast, coverage among HCP who have reported a mandatory influenza vaccination requirement has exceeded 94% each year. In 1 study, more than half of unvaccinated HCP stated that they would have been vaccinated had it been required by their employer. Voluntary programs have proved ineffective, in part because HCP have misconceptions about the risks and benefits of the influenza vaccine. In a cohort of HCP providing direct patient care, the most commonly reported barriers to vaccination were concerns about vaccine safety and effectiveness and low perceived susceptibility to influenza. Furthermore, 17% of unvaccinated participants falsely believed that the vaccine could cause influenza.
Joint Commission found that the 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. 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, transmission is unlikely to occur, and the duration of shedding is less in adults than in children (ie, 0–4 days vs 5–9.8 days, respectively). Serious illness has not been reported among unvaccinated, otherwise healthy people who have been infected inadvertently with virus from LAIV vaccine. HCP immunized with LAIV may continue to work in most units of a hospital, including the NICU and general oncology wards, if they use standard infection control techniques. 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, implementation of mandatory programs around the country is a crucial step in efforts to improve patient safety.

Health Risks to Patient Populations Cared for by Unimmunized HCP

Mandatory influenza immunization of HCP is a matter of patient safety. In a prospective surveillance study of laboratory-confirmed influenza among hospitalized adults in a network of Canadian hospitals from 2006 to 2012, 17.3% of influenza cases were health care associated. The risk of transmission is possible because HCP work when they are mildly symptomatic or ill, putting their co-workers and patients more at risk. 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 subclinical infection.

HCP can transmit influenza virus to patients and co-workers. Two landmark studies highlight the negative effect 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). Of respondents who had an influenza-like illness in the preceding 4 months, half occurred during the outbreak period, and only 14% reported taking time off work because of illness; these data suggest that symptomatic personnel had a role in transmission.

- 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. Five staff members developed influenza-like illness during the outbreak. Surveys revealed a vaccination rate of 12% among unit staff. The hospital took measures during the next influenza season to implement a multifaceted voluntary education program aimed at improving immunization rates. But even with these aggressive measures, 42% of the staff on the bone marrow transplant unit remained unimmunized the next year.

The Solution: Mandatory Immunization of All HCP

Mandatory immunization is not a novel concept. All states have laws requiring 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. However, 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 all of the following conditions are met. The intervention (ie, influenza vaccination) must

- Be a public health necessity
- Have been proven to be effective
- Not be "gratuitously onerous or unfair"
- Not pose a health risk to the subject

For example, school immunization laws are judicially sanctioned, emphasizing that mandatory immunization programs have long existed without infringing on constitutional rights.

Evidence That Mandatory Influenza Vaccine Policies Increase Rates of Immunization

Mandatory influenza vaccination policies are increasingly common in the United States. During the 2013 to 2014 influenza season, 36% of all HCP and 58% of HCP working in hospitals reported such a requirement at their institutions. Of those required, 98% received the vaccine; coverage rates were greater than 96% for all occupational settings, including hospitals, ambulatory care offices, and long-term care facilities. Nationally, more than 500 health care facilities...
A recent report estimated increases in influenza vaccine coverage after implementation of a mandatory vaccination program. More than 200 nationally representative US hospitals were surveyed. On average, coverage increased by 14.7% in a single season; in contrast, institutions with voluntary policies have rarely reported single-season increases of greater than 10%. Most hospitals that reported postrequirement coverage greater than 10% were those that terminated HCP who refused vaccination.40

The following examples each resulted in a substantial increase in employee immunization rates, demonstrating success with the implementation of a mandatory program.

- BJC Healthcare, 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 to greater than 80%.41 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. The result was an immunization rate of 98.4% for the organization. Only 8 employees refused to be vaccinated, and their employment was terminated.41

- Seattle’s Virginia Mason Medical Center implemented a mandatory influenza vaccination program in 2005. HCP who were granted an accommodation for medical or religious reasons were required to wear masks during the influenza season. The institution reported 97.6% coverage among its employees in the first year. For the remainder of a 5-year study period, vaccination rates of greater than 98% were sustained. In comparison, vaccination rates in the years before the study period ranged from 29.5% to 54.0%.42

- 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 (eg, concern about adverse effects or believing that the vaccine was ineffective). 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.43

- 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 74%. This mandatory policy offered influenza vaccine to 140,599 HCP; 96% of these employees complied.44

- University of California Irvine Healthcare instituted a mandatory vaccination program beginning in the 2009 to 2010 season, after a series of less successful vaccination campaigns that began in 2006. Voluntary programs, which used mobile carts, mandatory declination, and peer-to-peer vaccination efforts, increased rates from 44% to 63%. The mandatory vaccination campaign, which required unvaccinated HCP to wear a mask during the influenza season, increased coverage to greater than 90%.45

Support for Required Influenza Vaccination of HCP

It is certainly possible to implement a mandatory influenza vaccination policy that is supported by the majority of the affected staff. Among a sample of HCP in the United States, almost 60% agreed that HCP should be required to be vaccinated for seasonal influenza.46 Support was significantly higher among HCP who were already subject to employer-based influenza vaccination requirements; a mandate was supported by 77% and 95%, respectively, of HCP covered by vaccination requirements with and without penalties for noncompliance.46 Support was also much higher among those who perceived seasonal influenza as a serious threat to their own health and to the health of people around them, those who agreed that the vaccine is effective in protecting them and their contacts, and those who agreed that the vaccine is safe.46 Increased educational outreach regarding the safety and efficacy of the influenza vaccine and additional communication of HCP vaccination as a patient safety issue therefore should be expected to increase staff support for influenza vaccination requirements. Widespread support for influenza vaccination of HCP also exists among patient caregivers, according to a cross-sectional survey of parents and guardians of hospitalized children during the 2011 to 2012 season.47 Independent of their feelings about the safety and efficacy of the influenza vaccine, most (88%) believed that HCP should be vaccinated, and 76% thought that vaccination should be required.47 In addition, an increasing number of professional organizations have released their own statements in support of mandatory influenza vaccination for health care personnel, including the CDC, American
Academy of Family Physicians, American Hospital Association, Society for Healthcare Epidemiology of America, Infectious Diseases Society of America, Pediatric Infectious Diseases Society, Association for Professionals in Infection Control and Epidemiology, Inc and American Public Health Association.\textsuperscript{48–52}

**State-Based Influenza Vaccination Requirements for HCP**

Compared with employer-based requirements, state-based or even county-wide vaccination requirements are more reliable and efficient in increasing coverage of HCP. This approach creates a uniform policy and takes the burden off individual facilities to develop, implement, and defend management decisions related to mandatory programs.\textsuperscript{53} As of November 2014, fewer than half of all states have influenza vaccination requirements for HCP, and the scope of the requirements varies widely.\textsuperscript{53,54} For instance, some states require only that employers offer the vaccine to HCP, whereas others require HCP to be vaccinated or declare in writing that they have declined vaccination.\textsuperscript{54,55} Recently, some state-level requirements have incorporated stricter policies for unvaccinated HCP, such as requiring them to wear masks during patient care.\textsuperscript{54,55}

Beginning in the 2012 to 2013 influenza season, Rhode Island mandated statewide annual influenza vaccinations for HCP.\textsuperscript{56} All HCP in licensed health care facilities in the state are now required to either receive the vaccine or formally decline by December 15 each year. Unvaccinated HCP must wear a surgical face mask during patient contact when influenza is declared widespread; those who fail to comply face a $100 fine per violation.\textsuperscript{55} As a result of these regulations, the proportion of immunized HCP in Rhode Island increased dramatically, from 70% in the 2011 to 2012 season to 87% in the 2012 to 2013 season.\textsuperscript{56}

In a qualitative evaluation, the majority of facilities reported that HCP had mostly positive or compliant attitudes toward its revised policy.\textsuperscript{55} Successful implementation was facilitated by early and regular communication from the state health department and the facilities’ ability to adapt their existing influenza vaccination programs to incorporate provisions of the new regulations.\textsuperscript{55}

In contrast, an evaluation of California’s 2006 influenza vaccination law for HCP found that hospital employees were no more likely to be vaccinated than their counterparts in other states.\textsuperscript{57} This is not surprising, given that California’s law imposes a permissive state-level requirement. Although the statute requires hospital employees to be vaccinated or sign a declination statement, it does not require masking of unvaccinated HCP or include penalties for noncompliance. Therefore, permissive state-level requirements may not be sufficient to increase coverage of HCP.\textsuperscript{57}

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

The US Constitution supports a medical exemption requirement but not religious and philosophical opt-outs.\textsuperscript{12} 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.\textsuperscript{58} Although some argue that mandatory influenza vaccination violates an individual’s right to make decisions about his or her own health and well-being, employees of health care institutions are obligated to honor the requirement of causing no harm and to act in the best interests of the health of their patients.\textsuperscript{11}

Although some have suggested that medical and religious exemptions be granted on an individual basis,\textsuperscript{41,59} the US Constitution requires the granting of medical exemptions but not religious exemptions, so mandating influenza immunization for HCP can be ethically justified. Three criteria that a public health intervention must meet to justify mandatory status have been proposed.\textsuperscript{60}

- **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.

- **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 are obliged to take preventive measures to protect patients when they join the profession. The effects on the health of patients and on the loss of days worked by personnel have been sufficiently demonstrated.

- **A mandate must be considered the only option.** Current rates of influenza immunization remain suboptimal 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 through education, insurance coverage, public outreach and so on, then a mandate would not be needed and should not be used.”\textsuperscript{60}

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 in implementing a mandatory policy, relevant factors include the following:

- Having full support of health care leadership.

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• 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
  ◦ Creating a volunteer team of staff HCP to offer education (and vaccines, 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 the vaccine
  ◦ Increasing the number of locations where the vaccine is given
  ◦ Offering the vaccine at various venues and gathering places within the institution

• Using a universal form with defined acceptable medical and religious exemptions. This procedure is 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 considerable effect on clinical practice. Therefore, the AAP has developed implementation guidance on supply, payment, coding and liability issues; these documents can be found at http://redbook.solutions.aap.org/selfserve/ssPage.aspx?SelfServeContentId=vaccine-policy-guidance.

LIMITATIONS
This policy statement reaffirms the AAP’s support for a mandatory influenza immunization policy for all HCP. Vaccine effectiveness is unpredictable from year to year because of various factors such as the match of circulating virus with vaccine strains, vaccine product, previous influenza vaccination, and age and immune status of patients. Despite this variability, the influenza vaccine remains the best available preventive measure. Presenteeism should not be condoned, because vaccination is not expected to prevent all cases of influenza. However, even in years with suboptimal vaccine efficacy, millions of cases of influenza are prevented and influenza-related hospitalizations and complications are reduced. Because health care workers are exposed to the most vulnerable populations, prevention of even some fraction of influenza cases in health care workers is an advantage for patients.

Unfortunately, there only is modest published evidence for the effect of HCP influenza vaccination policies on patient outcomes20 because of a low number of randomized control trials with nonintervention groups.

CONCLUSIONS
Mandatory influenza immunization programs for HCP 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, highlighting the safety and effectiveness of annual immunization. HCP fail to lead by example if they recommend universal immunization, including influenza vaccine, to their patients but do not require it of themselves. Furthermore, unvaccinated HCP feed public distrust and fear of vaccines.11

Health care–associated influenza creates a financial burden on health care systems and contributes to patient morbidity and mortality. Voluntary programs have failed to increase immunization rates to acceptable levels. Large health care organizations have implemented highly successful mandatory annual influenza immunization programs without significant problems. Mandating influenza vaccine for all HCP nationwide is ethical, just, and necessary.7–9 For the prevention and control of influenza, we must continue to put the health and safety of the patient first.

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