The National Vaccine Advisory Committee

Recommendations on Strategies to Achieve the Healthy People 2020 Annual Influenza Vaccine Coverage Goal for Health Care Personnel

08 February 2012

Final Report

EXECUTIVE SUMMARY

Influenza is a significant public health issue. Annual influenza-associated deaths range from 3,000 to 49,000 according to recent estimates, and more than 200,000 people are hospitalized each year for respiratory illnesses and heart conditions associated with seasonal influenza infections. Immunization is the most effective method for preventing infection from influenza and possible hospitalization or death. The Advisory Committee on Immunization Practices recommends that all persons ≥ 6 months of age receive annual influenza vaccination. In addition, vaccination of all health care personnel (HCP) is a particular focus of recommendations by the U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC), and other health care and public health agencies and professional organizations. However, in spite of these recommendations, influenza immunization rates for HCP in the United States remain below the Healthy People 2020 annual goal for influenza vaccine coverage.

To address this gap in immunization rates for HCP, the HHS Assistant Secretary for Health (ASH) directed the National Vaccine Advisory Committee (NVAC) to develop recommendations and strategies for the specific purpose of achieving the Healthy People 2020 coverage goal. The NVAC delegated this task to the Adult Immunization Working Group (AIWG), which in turn established the Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) to address the charge. These recommendations include a tiered set of strategies for achieving the Healthy People 2020 annual goal, from implementing and managing influenza prevention and vaccination programs to measuring and reporting vaccination coverage to issues surrounding the implementation of employer requirements for HCP vaccination. In approving these recommendations, the NVAC maintained that HCP who are committed to promoting the welfare of patients and the health of the public, and to safeguarding their own and their colleagues' well-being, have an ethical responsibility to take appropriate measures including vaccination, to prevent the spread of influenza infections in health care settings. The NVAC realizes that health care employers (HCE) range in their scope of practice, from traditional hospital settings to in-home health care settings, and no single strategy for improving immunization rates would be appropriate for all HCP. Thus, the NVAC presents a set of tiered options that can be applied to most health care settings to improve immunization rates of HCP to reach the Healthy People 2020 annual influenza vaccine coverage goal for HCP. The recommendations are:

Recommendation 1: NVAC recommends that health care employers (HCE) and facilities establish comprehensive influenza infection prevention programs that include education of HCP as a key component. Comprehensive influenza infection prevention plans are recommended by the CDC as an essential step for all HCE and facilities to achieve the Healthy People 2020

influenza vaccine coverage goal. NVAC recommends that the Assistant Secretary for Health (ASH) strongly urge all HCE and facilities to adopt these recommendations.

Recommendation 2: NVAC recommends that HCE and facilities integrate influenza vaccination programs into their existing infection prevention programs or occupational health programs. NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff and Federally Qualified Health Centers) and strongly urges all HCE and facilities to do the same.

Recommendation 3: NVAC recommends that the ASH encourage CDC and the Centers for Medicare and Medicaid Services (CMS) to continue efforts to standardize the methodology used to measure HCP influenza vaccination rates across settings. The ASH should also work with CMS to facilitate adoption of this recommendation.

Recommendation 4: For those HCE and facilities that have implemented Recommendations 1, 2 and 3 above and still have not consistently achieved the Healthy People 2020 goal for influenza vaccination coverage of HCP in an efficient and timely manner, NVAC recommends that HCE strongly consider an employer requirement for influenza immunization. In addition to medical exemptions, HCE may consider other exemptions in their requirement policies. NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff who are HCP and Federally Qualified Health Centers) and urge all other HCE and facilities to do the same.

Recommendation 5: NVAC recommends that the ASH encourage ongoing efforts to develop new and improved influenza vaccines and vaccine technologies including support for research, development, and licensure of influenza vaccines with improved effectiveness and duration of immunity, as well as steps that improve the immunogenicity and rapid production of existing influenza vaccines.

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INTRODUCTION

The National Vaccine Advisory Committee (NVAC) advises HHS on issues of vaccine policy. At the request of HHS and the ASH, NVAC formed the Adult Immunization Working Group (AIWG) with two charges: (1) review and make recommendations to improve federal adult immunization programs and (2) make recommendations to improve the overall adult immunization program in the United States.

In 2010, the ASH and the National Vaccine Program Office (NVPO) charged the NVAC to recommend strategies to achieve the Healthy People 2020 objective for annual influenza vaccination coverage among HCP[a]. The Healthy People 2020 objective is intended to reduce influenza infection in HCP and their patients, thereby decreasing the physical and financial burden on the overall health care system. This document reports the findings, conclusions, and recommendations deliberated on and adopted by the full NVAC on February 8th, 2012. A detailed account of the methodologies used to develop these recommendations can be found in Appendices A-C.

DEFINITIONS

Health Care Personnel (HCP), *Health Care Employers* (HCE), and *Employer Requirements* are referred to throughout this report. The following definitions of these terms serve as the basis for discussion in this document:

- HCP refers to all paid and unpaid persons working in health care settings who have the potential for exposure to patients and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. HCP might include (but are not limited to) physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff not employed by the health-care facility, and persons (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing, and volunteers) not directly involved in patient care but potentially exposed to infectious agents that can be transmitted to and from HCP and patients. Thus, HCP includes a range of those directly, indirectly, and not involved in patient care who have the potential for transmitting influenza to patients, other HCP, and others.[b]

[a] The Healthy People 2020 target goal is to increase the percentage of Health Care Personnel who are vaccinated annually against seasonal influenza to 90%. See the Healthy People 2020 website for more details: http://healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23 (Accessed 3 December 2011)

[b] From the *HHS Action Plan to Prevent Healthcare-Associated Infections: Influenza Vaccination of Healthcare Personnel* (http://www.hhs.gov/ash/initiatives/hai/tier2_flu.html#_ftn1). (Accessed 25 August 2011). Both definitions are adapted from the CDC/ACIP definition outlined in *Influenza vaccination of health-care personnel: recommendations of the Healthcare Infection*

- HCE refers to a person or entity that has control over the wages, hours, and working conditions of HCP in health care settings[c]. Health care settings include, but are not limited to, acute-care hospitals; adult day programs or facilities, ambulatory surgical facilities, long-term care facilities, such as nursing homes and skilled nursing facilities; outpatient clinics, physicians' offices; rehabilitation centers, residential health care facilities, home health care agencies, urgent-care centers, and outpatient clinics.
- Employer Requirements: For the purpose of this document, NVAC does not stipulate the scope and content of such requirements; it should be a decision made by the HCE based on the concerns and needs of their HCP, their patients, and the public.

RESULTS

OVERARCHING THEMES

In its review of available literature, the NVAC found three overarching themes that underlie all five recommendations:

1. Influenza is a significant public health issue.

In the United States, the Centers for Disease Control and Prevention (CDC) estimates that there are 3,000 to 49,000 influenza-associated deaths each year [1] and, on average, more than 200,000 people are hospitalized each year for respiratory illnesses and heart conditions associated with seasonal influenza virus infections [2]. Serious morbidity and mortality from influenza infection can occur in any person regardless of age but the following groups, who are often under the care of HCP in health care settings, are at higher risk for severe outcomes due to complications from influenza infection [3]:

- People older than 65 years of age – From 1979 to 2000, influenza hospitalization rates for elderly patients were two to fourteen times higher than in the general population. More than 90% of the patients who died from influenza infections were elderly [2, 4].
- Pregnant women – Pregnant women are at a higher risk of complications from influenza [5-7]. In addition, newborns born from vaccinated mothers are less likely to become infected with influenza during infancy and are less likely to be born premature than those from unvaccinated mothers [8].
- People with chronic medical conditions – During periods of high influenza incidence, hospitalizations of adults with diabetes, cardiovascular disease, or chronic lung, renal,

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Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) 2006. See reference #26.

[c] Adapted from CDC definitions http://www.cdc.gov/flu/professionals/infectioncontrol/healthcaresettings.htm.(Accessed 25 August 2011).

or liver conditions may increase two- to five-fold, depending on age group [9]. Influenza-related hospitalization rates in adults with cancer < 65 years of age are significantly higher than for the general population, making this population a particularly high-risk group [10]. In addition, all cancer patients, but especially those <65 years of age, are at higher risk of influenza-related deaths [10].

- Residents of long-term care facilities (LTCFs) – Residents in LTCFs have greater risk for infection because they live in close proximity within closed settings and have contact with numerous caregivers [11]. Many residents may have multiple underlying medical problems, and health care-associated influenza outbreaks in LTCF are often associated with significant morbidity and mortality [12-14].
- Newborns and infants, especially those in NICUs – Children younger than 6 months of age cannot be immunized for influenza and are at high risk of hospitalization for influenza [15, 16].

2. Immunization is the most effective way to protect patients and HCP from influenza infections.

The NVAC's recommendations are built on the principles that influenza is a significant public health threat, that the influenza vaccine is safe and effective, and that vaccination is currently the most effective mechanism for preventing influenza infection.

According to the Advisory Committee on Immunization Practices (ACIP), "the most effective strategy for preventing influenza is annual vaccination"[5]. Routine influenza vaccination is now recommended for all persons ≥ 6 months [14]. The ACIP and the Health Care Infection Control Practices Advisory Committee (HICPAC), in addition to many other medical organizations and leaders, recommend that all HCP in the United States be vaccinated annually against influenza, establishing influenza vaccination as a standard of care [17]. Immunizing HCP has two potential benefits: 1) directly protecting HCP from influenza for their own health, allowing them to continue to work thus minimizing disruption of health care settings [18]; and 2) indirectly protecting other HCP and patients with whom they come in contact who may be at high risk for complications of influenza [11, 19-21].

Vaccination is the best documented and most effective intervention to prevent influenza transmission [22]. Determining the overall effects of HCP vaccination on patient outcomes is methodologically challenging and the outcomes measured often vary between studies. Findings specific to the effectiveness of HCP influenza vaccination in protecting patients vary by setting, year, and population studied and may lead to differing interpretations of the available data [21, 23-27]. Collectively, the impact of HCP vaccination on patient morbidity and mortality in health care settings requires continued investigation. While the working group discussed several scientific studies that evaluated the impact of HCP influenza

vaccination on reducing health care-associated influenza infection among patients, evaluating the full merits of HCP vaccination was not included in the charge of the working group, and therefore is not directly addressed in this report.

3. In spite of long-standing recommendations for all HCP to receive vaccination against influenza, HCP immunization rates are well below the Healthy People 2020 goal.

HCP vaccination rates vary from year to year but are consistently well below the Healthy People 2020 goal. For the 2009–10 influenza season, 61.9% of HCP were vaccinated; for the 2010–11 season, 63.5% were vaccinated [28]. In a 2011 report from the CDC, vaccination coverage was reported to be higher among HCP working in hospitals (71.1%), compared with the coverage of HCP working in ambulatory or outpatient centers (61.5%), patient homes (53.6%), and "other" health care settings (46.7%).

Vaccination coverage among physicians and dentists (84.2%) was similar to coverage among nurse practitioners and physician assistants (82.6%), and was significantly higher than for those working in all other occupational groups. Coverage also was significantly higher among HCP aged ≥60 years (74.2%), compared with those aged 18–29 years (56.4%) and 30–44 years (57.8%) [28].

FINDINGS, CONCLUSIONS and RECOMMENDATIONS

1. Implementing a Comprehensive Influenza Prevention Program for Health Care Personnel in All Health Care Settings

Findings

HCP can acquire influenza infection and transmit it to patients.

Exposure to influenza infection in health care settings is an occupational hazard for HCP. Influenza infections range from asymptomatic/mild infections to severe infections and death. Asymptomatic HCP, along with those that come to work ill, can potentially transmit the virus to colleagues, their families, and patients. One study looking at serological testing of HCP in acute care hospitals, found that 120/ 518 (23.2%) of HCP tested positive for influenza infection [29]. Of these, 71/120 (59%) could not recall having an influenza infection, and 32/120 (28%) did not report experiencing any respiratory infection [29].

Patients that are at higher risk for influenza and its associated complications have frequent, close contact with HCP while seeking inpatient and outpatient medical services. Some of these patients may not always be easily identified as high risk. Unvaccinated HCP have been implicated as sources of influenza infections in outbreaks among adults and children in both

acute and long-term care settings [14, 21, 27], although attribution of the source of such infections is often difficult. Therefore, HCP immunization is a vital step to protect those at high risk from severe influenza infection. Patients have the right to be protected against influenza infection transmission by HCP that have the responsibility to care for them.

A study at the University of Virginia Health System, a tertiary care center, reported an association between increased influenza vaccination among HCP (defined as hospital employees) and decreased health care-associated influenza in hospitalized patients [30]. In this study, a rise in HCP vaccination rates from 4% to 67% was associated with a significant decrease in the proportion of laboratory-confirmed influenza cases in HCP from 42% to 9% and a decrease in the number of health care-associated influenza cases in hospitalized patients (32% to 0%) [30]. However, because influenza vaccination was part of a comprehensive multipronged intervention, these results cannot be attributed solely to the vaccination of HCP.

Comprehensive infection prevention plans that include immunization for influenza are the most effective method to protect HCP and their patients from infection.

Other infection prevention practices, when used in conjunction with influenza immunization, may enhance the protection of HCP and their patients from infection. A comprehensive influenza prevention plan should include, but not be limited to 1) offering free influenza vaccination to all HCP across varying work-shifts, locations, and days; 2) providing targeted, interactive education programs annually to all HCP on the impact of influenza, particularly among high-risk patients, and to address misconceptions and concerns about the safety of influenza vaccination; and 3) educating HCP about the importance of influenza vaccination in promoting patient and employee safety [26, 31].

A comprehensive influenza prevention plan should include implementation of hand and respiratory hygiene and cough etiquette; screening for and appropriate isolation of HCP and patients identified with acute respiratory tract infections; appropriate management of ill HCP; adherence to standard precautions for all patient care activities as well as implementation of transmission-based precautions as indicated; and the implementation of engineering and environmental infection prevention measures as outlined in CDC's *Prevention Strategies for Seasonal Influenza in Health Care Settings* [31].

Comprehensive infection prevention plans that include voluntary influenza vaccination have been shown to improve influenza vaccination rates in HCP in some health care facilities.

St. Jude Children's Research Hospital in Memphis, Tennessee specializes in the care of severely immunocompromised children, and essentially all patients are at a significant risk for complications from severe influenza infection [32]. The hospital achieved and sustained high voluntary compliance to influenza vaccination among HCP (defined in this analysis as any staff member with direct patient care duties) due to the implementation of a comprehensive program that included focused educational campaigns, increased availability of vaccine, and individual follow-up with an infection control officer [32]. Prior to the introduction of a comprehensive program, the hospital reported HCP vaccination rates of 44.7%. However, the introduction of a comprehensive program was successful in increasing and sustaining rates between 80-96%. The program's success was attributed to educating HCP on the importance of HCP vaccination in protecting vulnerable patients; an idea reflected in surveyed HCP's attitudes towards vaccination. On the other hand, it was also acknowledged that these results may be unique to St. Jude Children's Hospital due to its high-risk patient population and the impact of the hospital's medical director who championed a culture of individual accountability [32].

The Iowa Healthcare Collaborative (IHC), a provider-led organization, initiated a program to increase influenza vaccination rates among HCP (defined as paid employees) in acute care hospitals throughout the state [33]. This program included a number of evidence-based strategies for improving HCP vaccination rates including common educational materials and a data reporting system that enabled individual hospitals to track their performance compared to the target vaccination rate of 95% established by the IHC. Within two years, the median vaccination rate had increased from 73.1% to 82% (2006-2008) [33]. A follow-up report tracking the success of the program showed that median vaccination rates among acute care hospitals had reached 93% after four influenza seasons [34]. Several factors may have contributed to the program's overall success including strong leadership support, strong collaborations with the Iowa Infection Control and Epidemiology Education and Consultation program, a challenging and time-limited vaccination target goal, reporting of vaccination coverage rates among hospitals, and the use of several evidence-based strategies for increasing vaccinations among HCP. In addition, several hospitals reported implementing mandatory vaccination policies in the fourth influenza season, and this strategy likely contributed to a number of hospitals reaching their target goal. In this study, the median vaccination rate in hospitals that implemented mandatory policies was 96% versus 87% in hospitals without such policies [34].

Conclusion

Annual influenza vaccination has been determined by many health care organizations to be the most effective strategy for preventing influenza. Coupling vaccination with a comprehensive infection prevention plan may improve protection of HCP and their patients from influenza infection. Influenza vaccination programs that include a number of evidence-

based strategies can achieve increased rates if they are strongly supported by leadership and are backed by an aggressive focus on vaccination as a patient safety measure. However, these strategies may not be as effective in all health care settings, and HCE may need to employ additional strategies in order to reach target vaccination rates among all HCP.

The NVAC believes that HCE and HCP have a joint responsibility to protect patients by adopting all reasonable interventions to reduce the transmission of influenza, including vaccination.

Recommendation

NVAC recommends that Health Care Employers (HCE) and facilities establish comprehensive influenza infection prevention programs that include education of HCP as a key component. Comprehensive influenza infection prevention plans are recommended by the CDC as an essential step for all HCE and facilities to achieve the Healthy People 2020 influenza vaccine coverage goal. NVAC recommends that the Assistant Secretary for Health (ASH) strongly urge all HCE and facilities to adopt these recommendations.

2. Managing Influenza Vaccination Programs

Findings

Comprehensive influenza vaccination programs are multifaceted and have proven to be successful.

Vaccination of HCP should be part of a multifaceted, comprehensive influenza prevention program that emphasizes all aspects of an influenza prevention program, such as full, visible leadership support with the expectation for vaccination fully and clearly communicated to all HCP; provision of adequate resources and support for the HCP vaccination program; and inclusion of all practices necessary to reduce the spread of influenza in health care settings, including patient isolation, use of personal protective equipment, hand and respiratory hygiene and cough etiquette, and restriction of ill visitors and ill HCP [35]. These practices have been proven to reduce the spread of influenza. Additionally, leadership support and the provision of adequate resources have been shown to have a direct impact on HCP compliance with disease prevention strategies.

The CDC finds that successful HCP vaccination programs are multifaceted and that single-component interventions will likely be minimally effective in achieving desired vaccination coverage levels [26]. The CDC recommends the following [26]:

Education and Campaigns – Basic knowledge about influenza and influenza vaccination has been associated with vaccine receipt. Participation in structured in-service education or conferences has been associated with improved vaccination rates.

Role Models – Vaccination of senior medical staff or opinion leaders has been associated with higher vaccination acceptance among staff.

Improved Access – Removing administrative barriers and providing vaccine in locations and at times easily accessible by HCP can substantially improve vaccine acceptance.

Measurement and Feedback – Posting of vaccination coverage levels in different areas of the hospital is a component of successful vaccination programs.

Influenza vaccination programs are cost effective and cost saving approaches to influenza prevention.

Three entities have offered evidence to support that influenza vaccination programs are cost effective and cost saving approaches to influenza prevention

- The National Business Group on Health (NBGH), representing approximately 330 large employers who provide coverage to 55 million Americans, reports that direct medical costs of influenza average $10.4 billion annually and that lost earnings due to illness and loss of life associated with influenza epidemics average $16.3 billion each year [36].

- The National Foundation for Infectious Diseases (NFID) cites studies in which vaccination has been found to be highly cost effective and cost saving. One study reported those who received the influenza vaccine had 25% fewer episodes of respiratory illness, 43% fewer days of sick leave from work due to respiratory illness, and 44% fewer visits to physicians' offices for upper respiratory illness than those who received a placebo [37].

- The CDC finds that vaccination can reduce medical costs and indirect costs such as those from lost work productivity. The report states vaccination could result in 13%–44% fewer health-care provider visits, 18%–45% fewer lost workdays, 18%–28% fewer days working with reduced effectiveness, and a 25% decrease in antibiotic use for influenza-like illness ILI. In addition, vaccination may contribute to $60–$4,000 savings per illness in healthy adults under 65 years of age depending on the cost of vaccination, the influenza attack rate, and vaccine effectiveness against influenza-like illness [26].

Employers of HCP will encounter barriers to immunizing HCP.

An in-depth literature review describing universal influenza vaccination attitudes among hospital-based HCP identified a number of reasons commonly cited for not receiving the vaccine [38]. In twenty-one studies in nine countries, the authors reported that the five most frequently reported categories for vaccine refusal included: 1) fear of adverse reactions; 2) lack of concern (i.e., perception that influenza does not pose a serious public health risk); 3) inconvenient delivery; 4) lack of perception of own risk; and 5) doubts regarding vaccine efficacy [38]. These studies also found that HCP are more likely to be vaccinated to protect themselves against influenza than to be vaccinated for the protection of patients [38]. Similarly, a recent CDC report found that the prevalence of beliefs regarding influenza and influenza vaccination differ between vaccinated and unvaccinated HCP [28]. This study found that 92.7% of vaccinated HCP believed getting vaccinated could protect them from influenza infection, while only 54.2% of those who were unvaccinated shared that belief. Notably, the CDC study also indicated that 55.4% of unvaccinated HCP do not believe that vaccination better protects those around them from influenza infection [28]. The most important factor facilitating vaccine acceptance was a desire for self-protection, with previous receipt of influenza vaccine, perceived effectiveness of vaccine, and older age also contributing to vaccine acceptance [28]. Collectively, these studies highlight the importance of educating HCP on the seriousness of influenza as a public health threat and the importance of vaccination as a safe and important infection prevention measure.

The use of signed declination statements[d] for HCP who refuse vaccination has had mixed results in increasing vaccination rates.

The Society for Healthcare Epidemiology of America (SHEA) supported the use of signed declination statements in 2005, but as more data on the impact of these statements became available showing only modest increases in vaccination rates, SHEA has altered its position. SHEA now finds that declination statements work best as part of a comprehensive program [39]. The American Academy of Pediatrics (AAP) notes that the use of declination statements in 22 hospitals resulted in only a modest increase in influenza immunization [40]. The American College of Occupational and Environmental Medicine (ACOEM) finds mixed results from the use of declination statements to document vaccine refusal, from improved rates to no effect [41].

Education and training are vital components of a comprehensive influenza vaccination program.

Providing comprehensive education and training about the risks of influenza and the safety and efficacy of influenza vaccine are essential components of a comprehensive approach.

[d] A declination statement is a tool used by HCEs to improve HCP immunization rates. It is a written document that may state the rationale for influenza immunization, promote HCP and patient safety, and dispel misconceptions about influenza and the influenza vaccine. It provides the HCP an opportunity to opt out of immunization for a stated reason, and is signed by the HCP.

Comprehensive training required under the Occupational Safety and Health Administration (OSHA) Blood-borne Pathogens (BBP) standard has contributed to increasing hepatitis B vaccination rates and reducing hepatitis B cases among HCP from 17,000 a year to less than 400 based on a 1995 study [42]. A similar comprehensive educational approach may also contribute to improving influenza vaccination coverage.

It is important that educational materials are appropriate in content and vocabulary for the educational level, literacy, and language of targeted HCP. HCP should be educated regarding the benefits of influenza vaccination and the potential health consequences of influenza illness for themselves and their patients; the epidemiology and modes of transmission; diagnosis; treatment; and non-vaccine infection prevention strategies, in accordance with their level of responsibility in preventing health care-associated influenza [26, 38]. The completion of required education must be monitored and enforced by the health care facility staff and compliance with education should be tracked in conjunction with vaccination rates.

Conclusion

Annual influenza vaccination is the most effective strategy for preventing influenza, especially when provided as a component of a comprehensive influenza vaccination program and influenza prevention program. A comprehensive influenza vaccination program should be multifaceted, consider known barriers to immunization, and provide for substantial education and training on influenza regarding both the benefits and risks of receiving influenza vaccination. As with Recommendation 1, the implementation of a comprehensive influenza vaccination program can improve HCP vaccination rates.

The NVAC believes that the best practices for vaccinating HCP are for HCE and facilities to integrate influenza vaccination programs into their existing infection prevention or occupational health programs. To implement these best practices, HCE will need to prioritize building capacity for a comprehensive influenza vaccination program within the context of their overall infection prevention programs and assess which mechanisms, or combination of mechanisms, are appropriate for their particular institution and workforce.

A comprehensive influenza vaccination program should be only *one* component of a multi-component influenza prevention program. Each HCE should implement as many components as is applicable to protect both patients and HCP against influenza infection. HCE and facilities should involve HCP, managers, and professional staff in the planning, implementation, and evaluation of their programs in order to improve quality and increase the opportunity for program success. Factors to consider include the content and delivery of infection prevention education, HCP access to vaccination, involvement of senior leadership,

local community variables, and how other health care settings have met Healthy People 2020 goals.

Recommendation

NVAC recommends that HCE and facilities integrate influenza vaccination programs into their existing infection prevention programs or occupational health programs. NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff and Federally Qualified Health Centers) and strongly urges all HCE and facilities to do the same.

3. Measuring and Reporting HCP Influenza Vaccination Coverage

Findings

Measuring and reporting influenza vaccination rates helps to increase vaccination of HCP.

Reporting individual facility influenza vaccination rates as an indicator of an institution's commitment to the delivery of safe, quality care can help to increase influenza vaccination rates. In a study of influenza vaccination rates in acute care hospitals in Iowa, the authors observed a 10% increase in vaccination rates that they attributed to the anticipation of the public release of hospital vaccination rates [34]. Likewise, significant increases in voluntary vaccination rates among HCP within BJC HealthCare hospitals were attributed to the use of a "Best in Class" scorecard, a quality report provided to leadership at each hospital to reach target goals [43]. In addition, ACIP suggests that monitoring vaccination coverage by facility area (e.g., ward or unit) or occupational group could pinpoint areas where vaccination levels are low and interventions should be targeted [26].

Standardized methodologies are being developed to facilitate measuring and reporting of HCP influenza vaccination rates within specified health care facilities.

Work is currently underway to standardize methodologies used to measure and report HCP influenza vaccination rates within health care facilities. In 2008, the CDC proposed a standardized measure for assessing influenza vaccination of HCP to the National Quality Forum[e] (NQF). The measure was designed to ensure that reported HCP influenza

[e] The National Quality Forum (NQF) is a nonprofit organization that develops, evaluates, and endorses consensus standards for health care quality measures and reporting guidelines. Some measures that receive NQF endorsement are adopted for use in national health care quality reporting programs in both the public and private sector. The Centers for Medicare and Medicaid Services (CMS) gives preference to fully-endorsed NQF measures when considering measures for inclusion in its Hospital Inpatient Quality

vaccination rates were comprehensive within a single health care facility and comparable across facilities, and was pilot-tested in a number of health care facilities including acute care hospitals, ambulatory surgical centers, long-term care facilities, outpatient clinics, and renal dialysis centers.[f] A revised measure was approved by the NQF Population Health & Prevention Steering Committee in September, 2011.

CMS recently adopted a rule for reporting influenza vaccination rates among HCP. Starting in January 2013, CMS will require acute care hospitals to report HCP influenza vaccination rates through the CDC's National Health care Safety Network system using the NQF measure as part of the Hospital Inpatient Quality Reporting (IQR) Program. Data from the IQR program will be made publicly available on the HospitalCompare.gov website. In addition, starting in 2014, acute care hospitals that fail to report these quality measures will be subject to a 2% payment reduction. CMS also has proposed implementing this measure in outpatient and ambulatory care settings. However, this proposal is still under review.[g]

Conclusion

Measuring and reporting HCP influenza vaccination rates leads to improved vaccination levels among HCP. While HCE may differ in their HCP populations, it is important that all HCE develop strategies for measuring HCP vaccination coverage with the purpose of using this data to evaluate and inform existing influenza vaccination programs. Likewise, standardized methodologies to measure and report HCP vaccination rates within specified health care facilities will provide comparable data that can be used to help improve HCP vaccination rates. NVAC believes that measuring influenza vaccination coverage of HCP is a prerequisite for achieving and sustaining high coverage levels.

Recommendation

NVAC recommends that the ASH encourage CDC and the Centers for Medicare and Medicaid Services (CMS) to continue efforts to standardize the methodology used to measure HCP influenza vaccination rates across settings. The ASH should also work with CMS to facilitate adoption of this recommendation.

4. The Role of Employer Requirements for HCP Vaccination in Influenza Infection Prevention

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Reporting (IQR) Program, as well as programs for other health care venues, such as hospital outpatient departments, ambulatory surgical centers, and long-term care.

[f] National Quality Forum #0431, *Influenza Vaccination Coverage Among Healthcare Personnel*

[g] Details on this measure can be found at *The National Healthcare Safety Network (NHSN) Manual, Healthcare Personnel Safety Component Protocol*

Findings

Many health care facilities have difficulty achieving and maintaining high vaccination coverage rates of HCP despite efforts to implement comprehensive infection prevention programs and voluntary influenza vaccination programs.

Although ACIP has long recommended annual influenza vaccination for HCP, a national estimate of influenza vaccination coverage of HCP for the 2010–11 influenza season was 63.5% [28]. At the institutional level, the progressive incorporation of evidence-based strategies into voluntary influenza vaccination campaigns has often produced marginal increases in vaccine uptake over the course of several seasons [44].

For example, a study conducted at BJC HealthCare hospitals analyzed 10-years of aggregate data on vaccination coverage of HCP (defined as hospital employees) and found that progressive voluntary interventions implemented over several years were not sufficient to reach the hospital system's target vaccination rate of 80% [43]. More generally, voluntary "opt-in" programs have not been successful as an approach to achieve and sustain high influenza vaccination coverage worldwide among health care organizations [45]. The Healthy People 2020 objective for influenza vaccination coverage of HCP, and its inclusion in proposed Joint Commission hospital accreditation requirements, may result in additional efforts to increase uptake [44].

Employer requirements are effective in increasing HCP immunization rates.

In the 2010-11 influenza season, CDC found that approximately 13% of HCP reported that their employers required influenza vaccination as a condition of employment. Among this group, vaccination coverage was 98.1%, compared to 58.3% among those without an employer requirement [28]. A national survey of acute-care hospitals conducted by Miller *et al.* found that 55.6% of the hospitals surveyed had implemented an institutional requirement [46], but that vaccination coverage rates increased most significantly in hospitals that also enforced consequences for vaccine refusal [44]. Consequences ranged in severity from mandatory masking to employee termination for noncompliance. Examples of employer required influenza vaccination policies and their impact on HCP vaccination rates are described below:

- Septimus *et al.* evaluated an influenza vaccination requirement for HCP (defined as clinical employees and individuals with access to patient care areas) implemented throughout the Hospital Corporation of America (HCA), Inc. national health care system [47]. Vaccination among HCP was required, but this policy permitted medical, religious, and philosophical exemptions. Unvaccinated HCP were required to either wear a surgical mask for the duration of the influenza season, or revise their

workflow to eliminate patient contact. Prior to the requirement, the study reported mean vaccination rates of 58%; post-requirement coverage levels rose to 96% [47].

- The Virginia Mason Medical Center in Seattle, Washington was one of the first hospitals to report on its success using a mandatory vaccination program for HCP (defined in this study as employees of the medical center including students, vendors, contractors, outside physicians, and volunteers) as a condition of employment [48]. Medical and religious exemptions were considered, and exempt HCP were required to wear a surgical mask. Unionized nurses were also exempt from this policy. Within the first year of implementation, vaccination coverage rates increased from 54% (2003) to 97.6% (2005), and coverage levels were sustained at >98% for the following influenza seasons (2006-2009) [48].

- A mandatory influenza vaccination policy as a condition of employment was also implemented in hospitals within BJC HealthCare, following failed attempts by the organization to achieve target influenza vaccination rates through voluntary mechanisms [49]. This policy defined HCP as all employed hospital staff (both clinical and nonclinical, including volunteers and vendors). Medical and religious exemptions were considered, and HCP that qualified for an exemption were encouraged to wear masks for the remainder of the influenza season. Non-compliant HCP were terminated for not meeting the conditions of employment. The authors reported increases in HCP vaccination coverage from 71% (2007) to 98% (2008). Within the BJC HealthCare system, 0.03% were terminated for failing to comply with hospital policy, similar to reports from the Virginia Mason experience [49].

A comprehensive list of HCE and facilities that have implemented employer requirements for influenza vaccination can be found on the Immunization Action Coalition, Honor Roll for Patient Safety website.[h]

Requirements for vaccination are broadly used for HCP.

In general, HCP must accept a number of strategies as necessary occupational precautions for mitigating the spread of disease including hand hygiene, wearing personal protective equipment such as gloves, and vaccination against a number of communicable diseases. These policies are generally intended to improve workplace safety by reducing the risk of infectious disease transmission to HCP. Requirements for immunity to, or vaccination against, varicella, measles, mumps, and rubella are standard for most health care facilities. Hepatitis B vaccination or documented declination is required under OSHA's blood-borne pathogen standard. While influenza vaccination must be completed annually, there are other

[h] http://www.immunize.org/honor-roll/ (Accessed 29 November 2011).

comparable periodic requirements, such as tuberculin skin testing. However, tuberculin testing requirements are generally stratified according to occupational risk, and are variably implemented with respect to documentation requirements and consequences for non-compliance.

Every state in the U.S. requires certain vaccines as a prerequisite to school enrollment, although most states allow religious exemptions and many states allow philosophical exemptions. The U.S. Public Health Service (PHS) requires vaccination of its Commissioned Corps officers. The U.S. Department of Defense (DoD) requires vaccination for all civilian HCP who provide direct patient care in DoD treatment facilities [50]. Additionally, as noted above, HCE and facilities require specific vaccines and a tuberculin test with varying policies regarding individual exemptions.

A state's power to mandate vaccinations in the interest of the public health was established in 1905 with the smallpox vaccination. Some states simply require hospitals to have an influenza vaccination policy, some states require health care facilities to offer influenza vaccination to their employees, while still other states require that some HCP receive influenza vaccination or indicate a religious, medical, or philosophical reason for not being vaccinated [40].

Employer requirement programs need leadership buy-in, education, and resource allocation in order to be successful.

Visible and vigorous leadership and accountability for vaccination are essential for programs requiring influenza vaccination as a condition for employment [35]. The key points to consider in implementing an employer required influenza vaccination policy include 1) having full support of health care leadership; 2) tailoring the policy to the geographic setting, educational resources, financial assets, local culture, and potential language barriers; 3) providing free vaccinations to all HCP; 4) publicizing the program to HCP at all levels; 5) offering convenient times and locations for education and immunization administration; 6) clearly defining applicable exemption policies; and 7) developing policies for managing employees who are exempt from immunization or refuse immunization [40].

Taking all appropriate measures to prevent the spread of infectious disease in health care settings, including influenza vaccination, represents a duty of care among HCP [51].

Arthur Caplan, the Emmanuel and Robert Hart Professor of Bioethics and director of the Center for Bioethics at the University of Pennsylvania, elaborates on three ethical reasons for requiring vaccination of HCP [52]. First, Caplan points out that every code of ethics adopted by physicians, nurses, nurse aides, social workers, pharmacists, and other HCP states that the best interests of the patient must come first. Secondly, Caplan states that HCP are obligated to honor the core medical ethics requirement of "First Do No Harm," which includes taking

necessary precautions to prevent transmission of infectious diseases, including influenza vaccinations. Finally, Caplan argues that HCP have a special duty to protect vulnerable patients, especially those that cannot protect themselves such as newborn babies, infants, and the seriously immunocompromised [52]. Patient advocacy groups have echoed this sentiment [53].

Some have argued that vaccination programs should focus predominately on HCP with direct contact to high-risk patients [54]. This argument assumes that an individual patient's risk category can be promptly and easily determined so that appropriate staff assignments or patient placement can be arranged. The rights of all patients should include knowledge that they will be cared for by HCP who are using all available infection control methods including vaccination to decrease transmission [55]. This should be done for both high-risk and lower-risk patients. Therefore, receiving influenza vaccination may not only be an ethical obligation of HCP, but non-vaccination can be considered a failure to provide patients with an appropriate standard of care [54, 56]. Patients are justified in the expectation that they should be informed if they are not being provided with health care that meets the national standard of care and current recommendations. They should then be given the opportunity to request an alternative. Caplan emphasizes that "Few people pick their health care providers or even know to ask if they have been vaccinated" [52].

George Annas, professor of health law, bioethics, and human rights at Boston University School of Public Health, also states that HCP have an ethical obligation to take all reasonable steps to protect their patients. However, he argues against mandatory influenza vaccination for HCP [57]. Annas states that influenza vaccination should be based on an informed choice and that HCP should not be forced to become non-consenting patients.

Annas argues that mandatory influenza vaccination may have negative impacts including building opposition that could result in an unenforceable mandate if a significant number of HCP refuse vaccination. This, in turn, could confuse the public regarding the safety of the influenza vaccine. Annas concludes, "The most effective way to maximize the numbers of the public being vaccinated is to send the message that physicians and nurses believe this is the most reasonable approach to take to prevent wide-scale death and disease…"[57].

Hospitals that have implemented mandatory influenza vaccination programs have not reported the backlash by HCP predicted by Annas. The Children's Hospital of Philadelphia surveyed a number of paid HCP (both clinical and non-clinical staff) and found that 74.4% of respondents indicated they agreed with the hospital's vaccination policy even though a number of them (72%) described the influenza vaccine requirement as coercive [58]. Finally, in addition to the protective benefits to HCP and their patients against influenza

infection, requiring HCP to be vaccinated sets a good example to the public and could help to promote influenza vaccination in all populations [58, 59].

Ethical and Social Concerns Regarding Employer Requirements

HCP may oppose employer-required vaccination on the basis of worker autonomy, culture, or religion.

When considering employer required vaccination of HCP, HCE should consider the following arguments:

- Worker autonomy – The rights of HCP to make their own health care choices and have their autonomy respected are ethical considerations [60]. One of the many ways autonomy is protected under the law is through the right to refuse medical treatment. Mandatory approaches are coercive and it can be argued that these policies infringe on an individual's autonomy to make informed choices about their health. However, an individual's autonomy is not unlimited [61] and the duty of HCP to limit the transmission of influenza through vaccination to avoid causing significant harm to vulnerable patients may override personal autonomy [54].
- Culture – A Joint Commission report noted that cultural considerations may play an important role in HCP decisions to accept or decline vaccination. In studies comparing differences in HCP influenza vaccination declination, the authors found that HCP in North America cited fear of adverse reactions as the primary reason for refusing vaccination. In contrast, HCP in Switzerland cited the perception that they did not feel at risk for illness as the primary reason for refusing vaccination [60].
- Religion – Some HCP may oppose influenza vaccination based on religious convictions, and many mandatory vaccination policies have allowed religious exemptions for HCP who decline vaccination in good faith because of strongly held beliefs [61]. However, HCE should ensure that their exemption policies are in accordance with state-defined legislation.

Employer requirements for vaccination may be subject to the collective bargaining process for unionized workers.

Employees represented by labor unions have successfully challenged mandatory influenza vaccination policies. These cases do not directly address whether influenza vaccination is safe or effective, but rather whether the implementation of mandatory influenza vaccination policies that affect the job security and working conditions of HCP are subject to the collective bargaining process.

Several HCE have indicated that mandatory influenza vaccination policies are necessary to achieve the core purpose of their facilities, which is to promote patient health and safety. These HCE have argued that mandatory influenza vaccination policies are designed as patient protection measures, such that HCE should not be obligated to negotiate these policies and the implementing procedures with unions. However, union representatives have successfully argued that mandatory influenza vaccination policies are subject to the usual collective bargaining process because the requirements constitute a change in the terms and conditions of employment.

Relevant Decisions

- *SEIU 121RN and United Health care Workers West and California HCA Hospitals:* In arbitration between five hospitals owned by Hospital Corporation of America (HCA) and the Service Employees International Union (SEIU), HCA contested that the majority of patient care policies outlined in the hospitals' infection control manuals were not subject to the collective bargaining process and claimed that implementation of the mandatory influenza vaccination policy was a management right.

  The Union argued that this policy was subject to the collective bargaining process because it proposed new terms and conditions of employment and the mandatory masking requirement created a discriminatory working environment that stigmatized unvaccinated HCP.

  The arbitrator upheld the right of the Employer to implement the mandatory influenza vaccination policy as a patient safety measure, but ordered the Employer to bargain with the Union "to determine a mutually agreeable means of enforcing its policy without violating the provisions cited, and reducing the potential for discrimination and/or violation of the just cause provisions of the Contract."[i]

- *Board University of Iowa Hospitals and SEIU:*
  The hospital claimed that the implementation of a mandatory influenza vaccination policy was a management right directly related to patient safety and was contractually protected under the Employer's right "to change and modify programs and practices related to health and safety to address ongoing health and safety concerns as required or deemed necessary by regulatory agencies and changes in technology and information."

[i] http://seiu121rn.wtf.localsonline.org/admin/Assets/AssetContent/0293f717-13dc-4603-a412-31c56eaa16a2/546bfa9e-94e2-495f-9d30-54cc81f55e47/7669cf93-d86d-410b-a575-bab5e53a0470/1/Arbitrator_s_Opinion_and_Award-HCA_mand_flu_arb.pdf

The arbitrator disagreed and ruled that the hospital had violated the Collective Bargaining Agreement by implementing a mandatory influenza vaccination policy that instituted unpaid leave as a consequence for noncompliance. Instead of negotiating with the Union, the Employer chose to unilaterally rescind its policy for both unionized and non-unionized HCP[j].

- *Virginia Mason Hospital and Washington State Nurses Association:*
  The Washington State Nurses Association (WSNA) filed a successful grievance against the Virginia Mason Medical Center regarding its mandatory influenza vaccination program. As a result, the hospital modified its influenza prevention policy to require all unvaccinated nurses to initiate influenza antiviral drug prophylaxis or wear a mask as part of a comprehensive influenza infection prevention program.

  The Union then filed a second grievance, claiming that the hospital policy to require non-vaccinated HCP, who were not taking antiviral medication, to wear a facemask while at work constituted an unfair labor practice for failure to bargain and the implementation of unilateral change. The Administrative Law Judge (ALJ) sided with Virginia Mason, holding that the hospital was not required to bargain because the masking/ antiviral requirement relates to the "core purpose" of the hospital.

  The Union appealed to the National Labor Relations Board. In August 2011, the Board issued a split decision that reversed the ALJ's holding. The Board indicated that the unilateral implementation of a masking or medication policy is subject to the bargaining process and that the policy was outside the core purpose of the hospital. The case was remanded to permit the ALJ to prepare another decision. In November 2011, the ALJ found that the Employer policy was protected under the management's rights clause and that the policy did not constitute an unfair labor practice. The complaint was dismissed.[k]

Employer requirements raise vaccination rates, but the impact on patient safety needs continued evaluation.

The primary intent of all influenza vaccination programs for HCP is to reduce influenza infections in patients and in HCP. Surveillance for health care-associated influenza is not routine. Without ongoing measurement of health care-associated influenza or prospective

[j] http://www.seiu722.org/PDF/Flu0911/flu%20vaccine%20mandate%20arbritation%20victory%2011-2-09.pdf (Accessed 07 March 2012).
[k] ALJ decision JD(SF)-44-11found at https://www.nlrb.gov/cases-decisions/case-decisions/administrative-law-judge-decisions (Accessed 07 March 2012).

controlled studies, significant gaps in understanding the impact of increasing vaccination rates on patient safety will persist. Further studies are also needed to determine if patient risk assignment (i.e., high risk versus lower risk) is reasonable and effective in preventing health care-associated influenza infections.

Conclusion

The NVAC realizes that employer-required vaccination of HCP against influenza is the subject of fervent discussion, both for the concept and against it. Such requirements have been shown to be effective methods of achieving high coverage but may face ethical, cultural or collective bargaining issues. For those HCE who cannot achieve the Healthy People 2020 annual goals for influenza immunization of HCP through implementing a comprehensive influenza prevention program, managing influenza vaccination programs, or measuring and reporting HCP influenza vaccination coverage, employer-required vaccination then becomes the next option for increasing influenza immunization rates of their HCP. The NVAC considered a variety of factors when evaluating the merits of employer requirements, including target vaccination rates, vaccine efficacy, whether herd immunity might reasonably be expected to decrease disease rates, and vaccine policy options, such as exemptions and consequence for non-compliance. The NVAC does not stipulate the scope and content of employer requirement policies; these must be a decision made by the HCE based on the concerns and needs of HCP, patients, and the public.

NVAC believes that, at present, HCE or facility requirements for influenza vaccination are the most effective mechanism to rapidly reach and maintain the Healthy People 2020 goal. Factors to consider when implementing such a policy include the vulnerability of the patient population cared for, what will be considered acceptable reasons for exemption from influenza vaccination, applicable bargaining agreements, and consequences of non-compliance with the policy. It is critical that patients know that everything possible is being done to protect them from health care-associated influenza infection while in an inpatient, outpatient, or home situation.

NVAC recognizes that prior to the development of these recommendations, many HCE have already implemented employer requirements in conjunction with, or following the implementation of, Recommendations 1, 2 and 3. This approach is consistent with NVAC recommendations. NVAC recognizes that local resources, patient safety needs, available expertise, labor concerns, and target vaccination goals must be taken into consideration when developing such policies. HCE or facility requirement policies should define affected workers and the affected employer, outline affected worker and employer obligations, and incorporate an exemption policy. NVAC notes that employer requirements need strong leadership, messaging and partnership with all HCP, and a consistent focus on the goals of protecting patients and HCP consistent with the ethics of the health care profession.

Recommendation

For those HCE and facilities that have implemented Recommendations 1, 2 and 3 above and still have not consistently achieved the Healthy People 2020 goal for influenza vaccination coverage of HCP in an efficient and timely manner, NVAC recommends that HCE strongly consider an employer requirement for influenza immunization. In addition to medical exemptions, HCE may consider other exemptions in their requirement policies. NVAC also recommends that the ASH assure that this recommendation is implemented in HHS facilities and services (including the Public Health Service, HHS staff who are HCP and Federally Qualified Health Centers) and urge all other HCE and facilities to do the same.

5. Supporting Influenza Vaccine Development

Findings

Influenza vaccine effectiveness is highest when the vaccine strains are well-matched to circulating virus. In years when the circulating virus strains vary from the vaccine strains, vaccinated HCP and their patients may have an increased risk for contracting and spreading influenza infection compared to years when the vaccine is well-matched.

Vaccine efficacy can vary from year to year and from person to person, but usually some protection is provided against illness or severe illness. There is a great deal of debate regarding the effectiveness of the influenza vaccine. Previous studies found that annual immunization with a vaccine antigenically well matched to circulating strains reduced serologically-confirmed influenza cases by 70% to 90% among healthy adults under the age of 65 [23, 62-66]. However, recent studies estimate that vaccine effectiveness may be considerably lower. Osterholm *et al.* reported a pooled efficacy of only 59% in adults 18-65 years old [67]. Others have also reported reduced vaccine effectiveness in the range of 45 to 75% [24]. The lower estimates in more recent studies may reflect new information regarding diagnostic testing; vaccine effectiveness is overestimated when serology is used as an endpoint [73]. While current vaccines are a critical component of reducing influenza infection, an opportunity exists to provide next-generation vaccines with improved effectiveness, broader protection, and increased duration of immunity. Additionally, novel approaches to improving influenza vaccines could result in vaccines that offer multi-year protection against numerous influenza strains, which will reduce the frequency of immunization [68-70].

Despite significant progress in influenza vaccine technologies and manufacturing since 2009, vaccine shortages could remain a challenge to implementing vaccination as an employer requirement.

In response to the 2009-H1N1 influenza pandemic, New York State became the first state to issue a mandate requiring HCP to be vaccinated against influenza. However, this regulation was stayed in a lawsuit brought by SEIU local 4053, the NY State Public Employees Federation. A week after the regulation was stayed, the NYDOH rescinded the regulation due to a shortage of vaccine supplies. The Commissioner of Health noted that the requirement "…set up a dynamic where HCP covered under the regulation might compete for vaccine with persons with underlying risk factors for adverse outcome of influenza infection."[71] Since the 2009-H1N1 response, national strategies have included improvements to the vaccine supply chain. However, improved vaccine availability and stable supply chains will ensure that HCE and facilities can attain vaccination coverage rates that meet quality measures [72].

Conclusion

Improved efficacy and reduction in the need for annual vaccinations will make it easier to achieve and sustain high vaccination coverage rates among HCP. Ensuring that adequate vaccine supplies are available will also help HCE and facilities to provide vaccine free of charge to HCP and, ultimately, achieve the Healthy People 2020 annual goal of vaccination of HCP or even higher coverage rates.

An influenza vaccine that confers multi-year protection against influenza with increased efficacy and comparable safety relative to the current annual vaccines could facilitate achieving and maintaining high coverage rates for influenza immunization in HCP and other populations. An ideal influenza vaccine would not need to be updated each year depending on circulating influenza strains and could provide extended or life-time immunity [68-70]. A longer lasting vaccine may contribute to higher coverage, reducing the need for employer requirements.

Recommendation

NVAC recommends that the ASH encourage ongoing efforts to develop new and improved influenza vaccines and vaccine technologies including support for research, development, and licensure of influenza vaccines with improved effectiveness and duration of immunity, as well as steps that improve the immunogenicity and rapid production of existing influenza vaccines.

CONCLUSION

Influenza is a significant public health issue. Annual influenza-associated deaths range from 3,000 to 49,000 according to recent estimates, and more than 200,000 people are hospitalized each year for respiratory illnesses and heart conditions associated with seasonal influenza infection. Immunization is the most effective method for preventing infection from influenza and possible hospitalization or death. For this reason, HHS, CDC, and other health care and public health agencies and organizations recommend vaccination as a critical influenza prevention strategy. However, in spite of these recommendations, immunization rates for HCP in the United States remain low.

To address this gap in immunization rates for HCP, the NVAC, as directed by the ASH, developed the recommendations and strategies presented in this report for the specific purpose of achieving the Healthy People 2020 objective for annual influenza vaccine coverage of HCP. These recommendations were carefully reviewed, deliberated, debated, and then approved by a majority of NVAC members. These recommendations present a tiered set of strategies for achieving the Healthy People 2020 annual objective for influenza vaccination of HCP, including the implementation and management of influenza prevention and vaccination programs, and measuring and reporting vaccination coverage to employer requirements for HCP vaccination. The thought behind this approach was that NVAC realizes that HCE range in their scope of practice, from the traditional hospital setting to the in-home health care setting, and no single option for improving HCP immunization rates would work for all HCE. Thus, a set of recommended options is presented that can be applied to most health care settings to improve immunization rates of HCP.

In presenting these recommendations to the ASH, NVAC acknowledges that there are individuals or groups that may be opposed to each recommendation in whole or in part for varied reasons, such as concerns about the quality of evidence in the literature regarding the impact of HCP vaccination on patient risk of health care-associated influenza and the issue of workers' rights. The NVAC carefully considered all sides of the argument for each recommendation and believes that the recommendations made herein represent the most effective approach to achieving the stated goal of achieving the Healthy People 2020 annual influenza vaccine coverage objective for HCP. With this in mind, the NVAC submits these recommendations to the ASH for consideration.

APPENDICES

APPENDIX A. HEALTH CARE PERSONNEL INFLUENZA VACCINATION SUBGROUP MEMBERSHIP

In 2010, the ASH and the National Vaccine Program Office (NVPO) charged the NVAC to recommend strategies to achieve the Healthy People 2020 objective regarding annual influenza vaccination coverage for HCP. The NVAC delegated this task to the Adult Immunization Working Group, which in turn established the Health Care Personnel Influenza Vaccination Subgroup (HCPIVS) to address it. This document reports the findings, conclusions, and recommendations of the HCPIVS working group, which were deliberated on and adopted by the full NVAC on February 8th, 2012.

The HCPIVS consists of five NVAC members, 15 liaison representatives, nine ex-officio federal representatives, and five staff members/technical advisors. They were chosen by the NVAC and Subgroup chairs with recommendations and approval from NVPO. NVAC members are experts from various fields who are special government employees representing their own views. Two NVAC members (Drs. Julie Morita and Christine Nevin-Woods) co-chair the Subgroup. Liaison representatives bring stakeholder viewpoints from a wide variety of important medical and public health agencies and professional organizations. Ex-officio federal representatives provide information from relevant federal agencies and departments. The HCPIVS staff members and technical advisors include members of the NVPO (including the Designated Federal Official) and the HHS Office of the General Counsel. A detailed list of HCPIVS members is provided below:

Co-Chairs

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Liaison Representatives

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American Academy of Pediatrics (AAP)
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Liaison Representatives (continued)

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APPENDIX B. METHODOLOGY FOR ESTABLISHING THE RECOMMENDATIONS

To address its charge, the subgroup conducted an extensive literature review examining many recent articles, reports, and position statements on the issue of influenza vaccination of HCP. The HCPIVS also held a series of conference calls and in-person meetings during which presentations were made on a number of topics. Based on the literature review, conference calls, and meetings, the HCPIVS developed the recommendations presented in this report.

The HCPIVS has received 13 briefings to-date from experts in each topic area as summarized below:

- Epidemiology of influenza in health care settings – Dr. Hilary Babcock
- Ethics of strategies to improve HCP influenza vaccination – Dr. Nancy Berlinger
- Legal issues and a model law for HCP influenza vaccination – Professor Alexandra Stewart
- Reporting influenza vaccination coverage – Ms. Megan Lindley
- HCP influenza vaccination: the New York State experience – Dr. Guthrie Birkhead
- Management of Occupational vaccine programs – Dr. Melanie Swift
- HCP influenza vaccination – the St. Jude Children's Hospital experience – Dr. Jon McCullers
- Update on ACIP's In-Clearance HCP Immunization Report – Dr. Paul Cieslak
- HCP influenza vaccination: the VA experience – Dr. Richard Martinello
- Vaccine ethics and mandatory vaccination policies – Mr. Jason Schwartz
- Health care-associated influenza – Dr. Thomas Talbot
- New influenza vaccine technologies – Dr. Jackie Katz
- CDC-sponsored NQF measure of HCP influenza vaccination: final results – Ms. Megan Lindley

APPENDIX C. Executive Summary of Public Comments

This summary represents comments received by NVPO as of January 20, 2012

I. Solicitation of Public Comment

The draft report and draft recommendations were released for public comment through the Federal Register process in order to solicit additional input on strategies and/ or potential barriers to achieving the Healthy People 2020 annual goal of 90% influenza vaccine coverage among healthcare personnel that are not addressed in the current draft report. Public comment has been collated and summarized for consideration and deliberation by the NVAC committee. The NVAC committee may choose to use the public comments to revise or inform the final report.

II. Summary of Public Comment Submitted by Individuals

Public comment was submitted by 145 individuals including a number of health care personnel across the health care sector. These comments are almost exclusively in response to Recommendation 4 and represent general opinions and personal accounts. In general, the majority of individual comments can be categorized into themes (themes represent ≥5 common responses).

Recommendation 4: For those HCE and facilities that have implemented Recommendations 1, 2 and 3 above and cannot achieve and maintain the Healthy People 2020 goal of 90% influenza vaccination coverage of HCP in an efficient and timely manner, the HCPIVS recommends that HCE and facilities strongly consider an employer requirement for influenza immunization.

Individuals that oppose Recommendation 4:

- Personal Autonomy (94 responses)
- Concern over adverse events (specific to the influenza vaccine) (45)
- Concern over vaccine effectiveness (specific to the influenza vaccine) (43)
- Concern over vaccine safety (specific to the influenza vaccine) (26)
- Concern over exemption policies that did not include religious, philosophical, and personal exemptions (26)
- Concerns that there in an insufficient scientific basis for mandatory vaccine policies (23)
  Concerns over vaccine safety (general) (20)
- Concerns over adverse events (vaccinations in general) (19)
- Liability for adverse events under mandatory policies (8)

Individuals that support Recommendation 4:

- Support for draft recommendations (general) (10)
- Support for draft recommendation 4 (as a patient safety measure) (5)

III. Summary of Public Comment Submitted by Organizations/Associations

Public comment was also submitted on behalf of 37 organizations/ associations that represent:

- 15 Professional Associations
- 13 Labor Organizations

- 5 Non-Profit Organizations
- 2 Public Health Departments
- 1 Federal Agency
- 1 Other

Organization/Association comments on the report have also been grouped into themes that include general comments, recommendation specific comments, and comments that directly address Recommendation 4.

General Comments

Definitions of Health Care Personnel (HCP) and Health Care Employers (HCE)

- Definitions should be expanded (3)
- HCPIVS definitions of HCP and HCE do not match the definitions outlined in the NQF and CMS reporting measures.(2)

Additional resources are needed to implement the recommendations – *5 responses*

Education (General)

- Education is mentioned throughout the report but is not called out explicitly in the 5 recommendations (4)

Comments on Recommendations 1, 2, and 3

Recommendation 1 and 2

- Recommendation 1 and 2 should state that HCP and their representatives should be directly involved in the development and implementation of influenza prevention programs and influenza vaccination programs (3)
- Vaccination programs should include free vaccine available during multiple shifts, locations, and days (general) (5)

Recommendation 3

- HCPIVS should indicate the effects of vaccine shortages on CMS reporting (1)
- HCPIVS should recommend that NQF measures be applied to ambulatory and outpatient settings (1)
- Other key agencies such as OSHA should be included in defining incentives and requirements (1)

Comments on Recommendation 4

Similar to the public comment submitted by individuals, the majority of public comment from organizations/ associations focused on Recommendation 4.

15 Organizations/Associations Directly Stated Support for Recommendation 4

- 13 Professional Associations
- 2 Non-profit Organizations

16 Organizations/Associations Directly Opposed Recommendation 4

- 12 Labor Organizations
- 2 Non-profit Organizations
- 1 Professional Association
- 1 Federal Agency

6 Organizations/ Associations did not directly address Recommendation 4 in their comments

Comments specific to Recommendation 4:

Employer requirements (General)

- Language should be modified to more strongly support employer requirements (3)
- Recommendation should be changed to state that employer requirements include vaccination as a condition of employment and credentialing unless documented medical contraindications exist, or in states that allow personal exemptions (2)
- Recommendation 4 should be eliminated (6)
- Recommendation 4 should state that it does not support vaccination as a condition of employment (7)
- Requirements should be modeled after the OSHA Blood-borne Pathogen Standard for Hepatitis B which includes mandatory education/training, and mandatory offering of vaccine (9)

Exemptions/ Personal Autonomy

- Language in the report should state exemptions are a state specific decision should be in accordance with state legislation (1)
- Recommendation 4 should support flexible exemptions (religious, philosophical, and personal) and should not indicate any punitive measures or discrimination for employees that opt-out (10)

Concern that vaccine effectiveness does not support mandatory policies *(12)*

Concern that there is insufficient scientific evidence on the impact of HCP vaccination on patient safety to support policies that require influenza vaccination without exemptions (other than medical exemptions)

- General (8)
- Suggestion to include a 6th Recommendation that addresses surveillance and research evidence on vaccine impact and efficacy in HCP (2)
- Limited to no data outside of LTCF on the impact of HCP vaccination in patient safety (3)

Concern that an over-emphasis on vaccination as a preventive measure may lead to poor adherence to other infection control practices

- General (8)
- Over-reliance on vaccination as a public health measure during years of vaccine mismatch, unsuccessfully vaccinated HCP or during vaccine shortages (3)

Employer Requirements would be considered a unilateral change to the conditions and terms of employment and could be subject to Collective Bargaining Negotiations *(4)*

Other Comments General to Recommendation 4

Healthy People 2020

- Healthy People 2020 goals are voluntary objectives to strive for and are not public health mandates (2)
- Evidence that 90% vaccination coverage rates is the appropriate level (5)

Liability for adverse events under mandatory policies (not commented on in the draft report)

- Compensation for employees that suffer any adverse effects under mandatory policies (1)
- Need to cover vaccine injuries under the National Vaccine Injury Compensation program and not worker's compensation programs (1)

Masking (not commented on in the draft report)

- Request that recommendations state the infection prevention measures for unvaccinated HCP including the use of masks or to be precluded from working in certain areas (1)
- Request the LTCF be exempt from any masking policies because of difficulties communicating with hearing impaired patients and patients with dementia (1)
- Request that the report not endorse masking for unvaccinated HCP (3)
- Request that the report comment on the safety and appropriateness of this type of requirement for vaccine refusal (1)

APPENDIX D. ABBREVIATIONS AND ACRONYMS

AAP..... American Academy of Pediatrics
ACIP .....Advisory Committee on Immunization Practices
ACOEM .....American College of Occupational and Environmental Medicine
ACP.....American College of Physicians
AIWG.....Adult Immunization Working Group
ALJ.....Administrative Law Judge
AMA .....American Medical Association
ANA.....American Nurses Association
ANAC ..... Association of Nurses in AIDS Care
APHA.....American Public Health Association
ASH..... Assistant Secretary for Health
CDC .....Centers for Disease Control and Prevention
CEJA.....Council on Ethical and Judicial Affairs
CMS .....Centers for Medicare and Medicaid Services
DoD.....U.S. Department of Defense
FDA.....Food and Drug Administration
GAO.....General Accounting Office
HICPAC..... Health care Infection Control Practices Advisory Committee
HCP.....Health care personnel
HCPIVS .....Health Care Personnel Influenza Vaccination Subgroup
ILI .....Influenza-like illness
LTCF..... Long-term care facility
MMWR.....Morbidity and Mortality Weekly
NBGH .....National Business Group on Health
NFID .....National Foundation for Infectious Diseases
NIH .....National Institutes of Health
NLRB..... National Labor Relations Board
NQF.....National Quality Forum

NVAC ..... National Vaccine Advisory Committee

NVPO..... National Vaccine Program Office

OSHA..... Occupational Safety and Health Administration

PPE..... Personal protective equipment

SHEA ..... Society of Health care Epidemiology in America

WHO ..... World Health Organization

WSNA..... Washington State Nurses Association

APPENDIX E: REFERENCES

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