

Failure to Become Immunized When Caring for Patients: An Ethical and Professional Obligation

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In late September 2012, changes to the Rules and Regulations Pertaining to Immunization, Testing, and Health Screening for Health Care Workers (R23-17-HCW) were proposed to reflect the most current (2011) recommendations of the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP). One of the proposed changes drew many people to a public hearing: the requirement that all Health Care Workers (HCW) either receive seasonal influenza vaccine or wear a mask when providing face-to-face patient care during "period(s) in which flu is widespread." A brief review of the rationale for mandating seasonal influenza vaccination among HCWs follows, along with ethical implications. The risks and benefits of seasonal influenza vaccination are reviewed as well.

Who Must Be Vaccinated And Why?

HCWs make valuable contributions to our health care system and are essential in meeting patients' health care needs. HCWs, broadly defined, are those individuals who are employed or volunteer in a health care facility and have direct contact with patients, including, but not limited to, physicians, physician assistants, nurses, nursing assistants, pharmacists, clinicians and therapists from all disciplines (for a complete definition see RI Regulations: R23-17-HCW, 2012). When individuals become licensed HCWs, they accept the responsibility to uphold professional standards of care and practice, defined by a specific code of ethics. Regardless of professional discipline, all HCWs are obligated to adhere to the general ethical principles of *non-maleficence*, the duty "to do no harm," and *beneficence*, to behave in way that promotes patients' best interests. These principles imply an obligation not to expose patients to vaccine-preventable illnesses which HCWs may themselves contract and transmit to patients, in short, to make provisions (e.g., vaccination of HCWs) to avoid doing harm to patients and to enable HCWs to continue giving care to patients (by themselves avoiding illness).

The notion that HCWs may spread pathogens dates back to Ignaz Semmelweis' 19th-century data on the infection of patients whose providers had not washed their hands. Since that time, HCWs have been enjoined to minimize the risk of disease transmission to patients (and vice versa) by washing



hands before and after patient encounters, by allowing themselves to be screened for communicable diseases such as tuberculosis, and by allowing themselves to be vaccinated against vaccine-preventable communicable diseases such as rubella. (See, for example, relevant Rhode Island regulations: <http://www.health.ri.gov/immunization/for/healthcareworkers/index.php>).

Why Vaccinate?

Seasonal influenza is a significant public health issue. In the United States alone, it causes more than 200,000 hospitalizations and 36,000 deaths annually.¹

Fortunately, seasonal influenza vaccines have proven to be effective in preventing illness onset in a majority of exposed-but-vaccinated people, with the exception of those who are immune-compromised or immune-suppressed. Several random control trials have demonstrated significant reductions in influenza-related mortality – as high as 44% among nursing home residents and hospital inpatients – when HCWs are vaccinated.²⁻⁹ Similarly, mathematical models of seasonal influenza vaccination of HCWs in nursing homes suggest a 60% prevention of influenza virus infections among vulnerable patients.¹⁰

Reasons to vaccinate *both* patients *and* HCWs against influenza are well documented. HCW vaccination *indirectly* protects high-risk patient populations for which *direct* immunization does not suffice to reduce risk, e.g., infants, elders, and patients who are immune-compromised or immune-suppressed.⁶ As well, vaccination reduces the risk that HCWs will become infected, thus contributing to societal immunity ("herd immunity"), and reducing workforce attrition during influenza outbreaks.^{10,11}

In fact, many scientific and government organizations have recognized the importance of HCW seasonal influenza vaccination, and have supported efforts to increase the proportion of HCWs thus vaccinated. Since July 2007, for example, the Joint Commission has required some hospitals and long-term care centers to establish onsite influenza vaccination programs, including education and the evaluation of coverage. In this vein, the Centers for Medicaid and Medicare Services is likely to require hospitals (beginning in 2013) to report influenza vaccination coverage as part of inpatient quality reporting. Furthermore, many professional

societies have endorsed influenza vaccination requirements for HCWs: the Infectious Diseases Society of America, the National Foundation for Infectious Diseases, the Society for Healthcare Epidemiology of America, the Association for Professionals in Infection Control, and the American College of Physicians. (See: <http://www.immunize.org/honor-roll/>)

Table 1. Benefits and risks associated with administration of influenza vaccine

Costs	Benefits
Vaccine Side Effects: Soreness at the injection site, low-grade fever, aches, Guillian Barre Syndrome, allergic reaction	Patient Safety and Public Health: • Decreased morbidity and mortality • Increased safety and quality of care
Economics: Upfront costs for employers offering vaccines at no cost to employees	Economics: Savings in influenza related health care expenditures and time missed from work due to illness

The Historical and Scientific Aspects of Vaccine Controversy

The controversy surrounding mandatory vaccination, in general, dates back almost a century (Stern, 1927), and perhaps even further. The controversy incorporates issues of individual rights *as well as* ethical obligations to do no harm and to promote the best interests of patients, and the costs and benefits of seasonal influenza vaccination for various groups (Table 1).

Safety Issues

Safety concerns (vaccine side effects) likely represent the most commonly cited reason to not be vaccinated. Although seasonal influenza vaccine is both safe and effective *most* of the time, adverse reactions can and do occur. These events are closely monitored and researched by the CDC's Vaccine Adverse Events Reporting System (VAERS). In 1990, VAERS was established as a national passive reporting system, accepting reports from the public on adverse events associated with vaccines licensed in the United States. According to VAERS (<http://www.cdc.gov/flu/professionals/acip/adverse-tiv.htm>), serious adverse events are rare, often 1 or 2 per million, and in clinical trials, serious adverse events associated with the use of seasonal influenza vaccine were reported to occur in less than 1% of all vaccinations.^{12,13} Similarly, although it is true that an individual can be vaccinated and still contract the flu, being vaccinated significantly decreases the chance of disease transmission.²⁻⁹

Why Mandate?

Significant precedents for mandatory vaccination are well established in the United States.¹⁴ In the early 20th century, for example, the country was ravaged by communicable diseases that have been virtually eliminated since that time because of mandatory vaccination (Table 2).¹⁴

Specific to seasonal influenza vaccines, the CDC has *recommended* that health care workers get yearly influenza vaccine

since 1981, with a national goal of 90% of HCWs vaccinated (CDC, 2012). As noted, some health care organizations *offer* no cost vaccines to their workforce and others *assure* high vaccination rates by *mandating* vaccination. Nonetheless, during the 2009-2010 influenza season, an estimated 61.9% of HCWs were vaccinated, and during the 2010-2011 influenza season – the season *after* the 2009 H1N1 pandemic – an estimated 63.5% of HCWs were vaccinated. In comparison, 98.1% of HCWs whose employers *assured* vaccination were vaccinated in the 2010-2011 influenza season.¹⁵⁻¹⁷

Given the history of vaccine uptake percentages in HCWs whose employers offer optional influenza vaccination, it is unlikely that voluntary programs will achieve vaccination rates sufficient to protect the health and safety of patients. Therefore, in line with licensed health professionals' obligation "to do no harm" (non-maleficence), on the one hand, and to promote health (beneficence), on the other, mandating seasonal influenza vaccination is essential.

We should note that In the United States, HCWs are not the only group required to be vaccinated against communicable diseases. Children, for example, are required to be vaccinated prior to enrollment in school, camp or child care settings – a requirement that dates back to the 1850s in Massachusetts for smallpox vaccination.¹⁵⁻¹⁷

Why Regulate?

In the past, seasonal influenza vaccination has been left in the hands of individual health care organizations, under the aegis of quality and safety standards. Some *offered* vaccination; others *required* it. Some *offered vaccine at no cost* to HCWs, while others *passed on the cost* to HCWs. In a situation such as this, rules and regulations, under the aegis of strong laws, are a good way to achieve uniformity.

Newly promulgated (December 2012) regulations in Rhode Island do not require HCWs to obtain annual vaccinations for seasonal influenza, but rather, require HCWs to protect their patients against influenza transmission one way or another: *either* by being vaccinated, *or* by wearing a mask for direct patient contact during periods in which flu is widespread. This approach places responsibility on the individual HCW, who, not withstanding possible medical exemptions, is accountable for his/her choice to obtain, or not obtain, the influenza vaccine.

Ever since society began understanding the mechanisms of communicable disease transmission, HCWs have had an

Table 2. Early 20th Century Reports of Communicable Disease Cases and Deaths in the United States¹⁴

Year of Reporting	Communicable Disease	Number of Cases	Number of Deaths
1900	Smallpox	21,064	894
1920	Measles	469,924	7,575
1920	Diphtheria	147,991	13,170
1922	Pertussis	107,473	5,099

ethical obligation to protect themselves and their patients from exposure. Now, the obligation to protect patients from seasonal influenza has been enshrined in Rhode Island law and its accompanying rules and regulations. This development will work to protect patients, enhance the public's trust, and protect a much-needed healthcare workforce.

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