

Vaccinating Health Care Workers Against Influenza: The Ethical and Legal Rationale for a Mandate

Despite improvements in clinician education, symptom awareness, and respiratory precautions, influenza vaccination rates for health care workers have remained unacceptably low for more than three decades, adversely affecting patient safety.

When public health is jeopardized, and a safe, low-cost, and effective method to achieve patient safety exists, health care organizations and public health authorities have a responsibility to take action and change the status quo. Mandatory influenza vaccination for health care workers is supported not only by scientific data but also by ethical principles and legal precedent.

The recent influenza pandemic provides an opportunity for policymakers to reconsider the benefits of mandating influenza vaccination for health care workers, including building public trust, enhancing patient safety, and strengthening the health care workforce. (*Am J Public Health*. 2011;101:212–216. doi:10.2105/AJPH.2009.190751)

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state of New York issued a seasonal and pandemic influenza vaccination mandate for health care workers.¹ The mandate required health care organizations to vaccinate personnel who had direct contact with patients.² The instructions were clear: influenza vaccination must be established annually as a precondition of employment (personnel with medical contraindications were considered exempt).² In response, several groups filed suit against New York State, claiming that the mandate deprived them of liberty without due process and violated their right to free exercise of religion, rights guaranteed by the Fourteenth and First Amendments.^{3,4} In the end, unanticipated vaccine shortages in October 2009 caused Governor David Paterson to halt the mandate, temporarily relieving health care workers of the influenza vaccination requirement.⁵ New York State plans to reinstate the mandate for the 2010 to 2011 influenza season. Notwithstanding these legal challenges, overwhelming scientific, ethical, and legal justifications support mandating health care worker vaccination.

SCIENTIFIC EVIDENCE SUPPORTING VACCINE EFFICACY

The annual morbidity and mortality caused by influenza is a serious public health issue. Each year in the United States, seasonal influenza causes on average more

than 200 000 hospitalizations and 36 000 deaths.⁶ Influenza is the sixth leading cause of death among US adults and is related to 1 in 20 deaths in persons older than 65 years.^{7,8}

On June 11, 2009, the World Health Organization officially recognized the influenza A (H1N1) virus pandemic, and on October 24, 2009, President Obama declared a national public health emergency.^{9,10} Recent Centers for Disease Control and Prevention (CDC) estimates indicate that H1N1 has resulted in an estimated 42 to 86 million cases and 8520 to 17 620 deaths.¹¹ Note that the CDC has recommended vaccination of health care workers against influenza since 1981.

Health care organizations have enacted a variety of vaccination policies and interventions to guard against the known hazards of nosocomial influenza transmission, including longer patient stays, absenteeism, interruptions in health care delivery, and inpatient death.^{12–20} Two randomized controlled studies evaluating the effect of health care worker vaccination on nursing home residents found that health care worker influenza vaccination was associated with a 44% decrease in resident mortality.¹⁷ Furthermore, an algorithm evaluating the effect of health care worker influenza vaccination on patient outcomes predicted that if all health care workers in a facility were vaccinated, then approximately 60% of patient influenza infections could be prevented.¹⁶

In the United States, professional infectious disease societies (Infectious Diseases Society of America and National Foundation for Infectious Diseases), professional infection control associations (Society for Healthcare Epidemiology of America and Association for Professionals in Infection Control), and professional clinician societies (American College of Physicians and American Academy of Pediatrics) have all independently called for requiring influenza vaccination of health care workers.^{21,22} Recently, the National Patient Safety Foundation issued a press release expressing strong support for mandatory influenza vaccination, calling the issue “a matter of patient safety.”²³ In recent weeks, the American Medical Association’s (AMA’s) Council on Ethical and Judicial Affairs in conjunction with its Council on Science and Public Health reaffirmed its commitment to this issue. In its report the AMA concluded, “physicians have an obligation to: (a) Accept immunization absent a recognized medical, religious, or philosophical reason to not be immunized,” and (b) “Accept a decision of the medical staff leadership of health care institution, or other appropriate authority to adjust practice activities if not immunized.”²⁴

The best available evidence suggests that even when health care organizations implement aggressive, labor-intensive voluntary influenza vaccination programs for their employees, they are rarely able to achieve vaccination

rates higher than 70%.²⁵ By contrast, mandatory health care worker vaccination programs result in exceptionally high vaccination rates, as has been seen in mandates for measles-mumps-rubella, varicella, and hepatitis B vaccines.^{7,26} We believe that similar results can be achieved by mandatory health care worker influenza vaccination programs. In fact, a recent mandatory health care worker influenza vaccination program implemented at the National Institutes of Health Clinical Center achieved 100% participation (either successful vaccination or justified refusal).²⁷ Existing mandatory influenza vaccination programs that include exemption provisions sustain very high rates of vaccination—on average, 95% to 99%.^{28,29} One survey conducted with inpatient nurses found that vaccination (and if necessary, mandatory vaccination) was the most popular strategy. Of nurses surveyed, 83% (513) cited vaccination as the preferred method of prevention against influenza, and 59% (512) indicated they would support a policy requiring annual influenza vaccination of health care workers with declination.³⁰ Furthermore, emerging data, available scientific evidence from observational research, and basic principles of infectious disease support the concept that vaccinating health care workers against influenza protects patients and promotes public health.^{31–33}

Various approaches to mandatory vaccination of health care workers have been successfully used throughout the United States. Currently, 15 states mandate health care worker vaccination for at least one disease, and of those, eight allow for an exemption.^{34,35} Multiple health care organizations have mandated health care worker vaccination against influenza,

including Barnes-Jewish Hospital, Virginia Mason Medical Center, Johns Hopkins HealthCare, University of Iowa Hospitals, and Nashville-based Hospital Corporation of America.^{23,36,37} A comprehensive list of organizations that have employed mandates in health care settings is available at <http://www.immunize.org>. These organizations' experiences with the benefits of mandatory vaccination of health care workers against influenza complement ethical and legal principles that also justify such policies.

ETHICAL RATIONALE FOR HEALTH CARE WORKER VACCINATION

We have elaborated elsewhere the ethical arguments underlying mandatory vaccination.³⁸ Health care institutions should enforce vaccination for two primary reasons: (1) in support of the professional obligations of health care workers to benefit individual patients and to do no harm and (2) to meet the shared obligations of health care institutions and professionals to protect the public health in the face of preventable infectious disease. The important questions are as follows: "What are the responsibilities of health care workers to their patients?" and "Is it fair for patients and the public to expect health care workers to be vaccinated against influenza?"

As professionals in occupations that are freely chosen, clinicians are granted special privileges and powers by society; as a result, health care workers assume special obligations and responsibilities. Health care professionals have obligations to do no harm, to do good, to respect patient autonomy, and to treat all patients fairly.^{39,40} Health care workers should be vaccinated because

doing so prevents harm by reducing the transmission of preventable diseases in the context of clinical care.^{26,33} Health care worker vaccination against influenza is also consistent with a collective professional obligation to treat all patients fairly and to take basic precautions against preventable harms. Similar justifications have been offered by other bioethics analysts. Wynia concluded, "Given . . . our professional obligation to do no harm, flu vaccination should be mandatory for health care workers."⁴¹ Caplan agreed, "It's time to . . . make getting a flu shot a part of the responsibility of being a healer."⁴² The obligations of health care workers to be vaccinated are greater than those of the general population, and mandatory vaccination helps them meet those obligations.

Public health ethics focuses on interests of the community and the maintenance of an environment that supports and promotes good health.⁴³ From this perspective, health care workers should be vaccinated because doing so significantly promotes conditions necessary for maintaining a healthy community. Higher health care worker immunization rates reduce the spread of influenza and help maintain a sustainable and effective health care workforce.

Laws and regulations that restrict individual liberties are frequently needed to ensure community health and safety. Even staunch libertarians acknowledge this need. In his classic 1859 treatise, *On Liberty*, John Stuart Mill writes, "the only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others."⁴⁴ Communities, therefore, routinely and justifiably promulgate laws to create a safe place to

live (e.g., traffic laws and sanitation policies). In our view, laws or regulations mandating influenza vaccination of health care workers are similarly legitimate and necessary exercises of state power.

LEGAL FOUNDATIONS FOR HEALTH CARE WORKER VACCINE MANDATE

Mandatory influenza vaccination of health care workers fits within the framework of constitutional powers that the government possesses to promote the public's welfare. Government has both the responsibility and the power to restrict individual activities that threaten liberties of others and the common good. Under the US Constitution, the power to restrict individual liberties for public health purposes is primarily reserved for individual states through police power. The police power of the state is "the inherent authority of the state to enact laws and promulgate regulations to protect, preserve and promote the health, safety, morals, and general welfare of the people."⁴⁵ For the purposes of public health, the federal government's authority is generally limited to regulating interstate commerce, taxing, and spending.

STATE POWER JUSTIFICATION

Laws and regulations that restrict individual liberties are routinely enacted to protect and promote public health and welfare. These laws and regulations pervade our society, including sanitation laws, traffic laws, occupational health and safety laws, and environmental regulation. Historically, the judiciary has affirmed mandatory vaccination as a proper exercise of state police power. In *Jacobson v Massachusetts* (197 US

11, 25 SCt 358, 49 L. Ed. 643 [1905]), the US Supreme Court articulated a series of standards in affirming a Massachusetts law requiring smallpox vaccination: public health necessity, reasonable means, proportionality, and harm avoidance.⁴⁵ In *Wong Wai v Williamson, et al.* (103 F 1, 3 [CCD 1900]), the US Supreme Court had previously established a fairness standard in response to racially discriminatory vaccination practices in California.⁴⁵

Although the principles articulated in the cases of *Jacobson* and *Wong Wai* continue to inform analysis of public health actions, the standards for the constitutionality of state action have evolved significantly since 1905. Today, the US Supreme Court evaluates the constitutionality of laws burdening individual liberties by applying a hierarchy of rights and corresponding standards of review. Public health regulation usually involves liberties that trigger rational basis review, the lowest standard. The rational basis standard requires that state action must be justified by a legitimate state interest and that the action be rationally related to the state's interest.

Therefore, to be constitutional, mandatory health care worker immunization laws first must show a legitimate state interest. The state's interest is clear: reducing morbidity and mortality resulting from nosocomial spread of influenza and maintenance of a viable health care workforce. Second, states must show that mandating influenza vaccination is rationally related to reducing the influenza burden. Courts do not require large-scale, randomized trials to support constitutionality of state action; rather, to meet the rational basis standard, a state must establish only a plausible scientific relation between the proposed

action and the state's interest. Considerable scientific evidence supports the conclusion that vaccination reduces both the transmission and the incidence of influenza.^{17,18,46,47} As such, we believe that courts will very likely find that state laws and regulations mandating vaccination of health care workers, like the New York State statute, are constitutional exercises of state power.⁴

FEDERAL POWER JUSTIFICATION

Article I of the US Constitution gives Congress the power to tax, spend, and regulate interstate commerce. These powers have been interpreted expansively by courts, resulting in far-reaching power to regulate and promote public health and safety. Thus, the federal government also holds broad influence to encourage or potentially mandate health care worker influenza vaccination.

The commerce clause enables the federal government to regulate virtually any activity that affects interstate commerce, including elements of the health care industry that relate to infectious disease management and containment. For example, the Public Health Service Act⁴⁸ gives authority to the federal government to make and enforce rules to prevent the spread of infectious disease from other countries into the United States or from one state to another, including the power to establish vaccine clinics and to isolate and quarantine infectious individuals.^{33,49} Under the Public Health Service Act,⁴⁸ the US Department of Health and Human Services has created a National Vaccine Plan, the National Vaccine Advisory Committee, and the National Vaccine Injury Compensation Program. Through these

mechanisms, the commerce clause grants significant power to the federal government to regulate, encourage, or potentially mandate the vaccination of health care workers against influenza and ensure fair processes to adjudicate complaints related to vaccination.

The federal government also may regulate public health through the power to spend. The federal government may require states to meet federal standards in public health as a prerequisite to receiving federal funds. The federal government exerts influence on state and local authorities to comply with federally established standards through the use of conditional appropriations. Most states and local authorities comply because they can rarely afford to lose federal funding. For example, extensive federal standards are attached to receipt of payments through Medicare and Medicaid. Although the federal government may not have clear authority to mandate directly, the federal government has a broad range of powers to indirectly induce state, local, and institutional authorities to mandate vaccination.

CONCLUSIONS: TIME FOR CHANGE

The example of the 2009 H1N1 public health emergency compels health care organizations and policymakers to rethink current practices, asking whether minimally effective, expensive, voluntary health care worker influenza vaccination programs are adequate to protect patient safety for both seasonal and pandemic influenza. The available evidence suggests that voluntary vaccination programs enacted in various forms over three decades have failed to achieve acceptable rates of health care worker influenza

vaccination. Despite decades of influenza vaccine safety and efficacy data and the known risks to vulnerable patients, influenza vaccination coverage among US health care workers remains near 50%.⁵⁰ Therefore, vaccination of health care workers against influenza should be mandated and enforced not only by health care organizations but also by states and, if necessary, by federal agencies.

In mandating health care worker vaccination, health care organizations must ensure that vaccination is an informed process—health care workers should be clearly told the benefits and risks associated with influenza vaccination—and that vaccines are offered conveniently and free of charge. Special consideration may need to be in place for medical, religious, and perhaps philosophical exemptions, although no data are available on how exemptions affect rates of health care worker vaccination.

The implementation of mandatory vaccination also must address the unfounded fears and misconceptions about vaccine safety. Rates of serious adverse events following vaccination, such as Guillain-Barré syndrome, are vanishingly low (no higher than 1 in 1 000 000).⁵¹ These facts must be clearly conveyed. The National Vaccine Injury Compensation Program added influenza to its list of covered vaccines in 2004 to address rare instances of adverse events that can be reasonably linked to the influenza vaccine.⁴⁵ In the end, rumors and fears must not be a barrier to promoting patient safety and public health; it is time to move on. Over time, successful control of seasonal and pandemic influenza with repeated safe vaccine administration to health care workers will

allay fears and promote public trust.

Mandatory health care worker vaccination programs help health care workers carry out their professional duty to provide care to all patients without the threat of undue harm caused by nosocomial influenza transmission and ensure that the public's trust in health care organizations is well placed. The public has a right to expect that health care workers and the institutions in which they work will take all necessary and reasonable precautions to keep them safe and minimize harm. This lays the burden on health care organizations and the government to ensure that health care workers fulfill their obligations. Low voluntary vaccination rates leave only one viable option to protect the public: legally mandated health care worker vaccination against influenza. ■

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Contributors

A. L. Ottenberg drafted and revised the article. J. T. Wu assisted with the drafting of the article and provided legal analysis. G. A. Poland and R. M. Jacobson provided scientific expertise, clinical input,

and article review. B. A. Koenig provided ethical analysis. J. C. Tilburt assisted with the drafting of the article, provided ethical analysis, and performed a detailed critique. All authors approved the final article.

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