

The variable efficacy of current influenza vaccines result in mandatory flu vaccination policies for health care workers being difficult to justify

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Public concern with influenza has increased in recent years, spurred on by the H1N1 influenza outbreak in 2009 and the fact that the United States is currently facing what is potentially the worst influenza season in a decade. As a result, increased attention has been placed on what more can be done to reduce the spread of influenza.¹ One approach that states² as well as long-term care facilities and health care institutions are taking to manage the risk of influenza transmission is to mandate influenza vaccination for all health care workers.

The influenza vaccine is routinely cited as the best protection against contracting and transmitting influenza, however, recent studies have indicated that the efficacy and effectiveness of the influenza vaccine is much lower than originally thought.³ The influenza vaccine is generally comprised of three influenza strains, which are chosen to best match strains predicted to circulate in the population in the coming year.⁴ Yearly vaccination is required because the influenza strains circulating in the population change frequently and the effectiveness of the influenza vaccine is

¹ Timothy W. Martin & John Kell, *Flu Is Tonic for Drugstore Sales*, WALL STREET JOURNAL, Feb. 6, 2013: *available at*: <http://online.wsj.com/article/SB10001424127887324906004578288401974926608.html> (Pharmacies have reported a significant increase in vaccinations sold this season relative to last year, CVS reported having administered 4.8 million flu shots as of Feb 6, 2013 more than all of last season, Walgreen reported giving 6.9 flu shots through January, compared to around 5.5 million last year).

² The state of New York mandated influenza vaccinations for health care workers in August 2009, and withdrew the regulation 2 months later, Rhode Island is currently the only state with a mandatory vaccination policy for all health care employees. See fn 13, 14.

³ Centers for Disease Control and Prevention, *Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 60 MMWR 1, 9 (2011); Center for Infectious Disease Research and Policy, *The Compelling Need for Game-Changing Influenza Vaccines*, 120 (Michael T Osterholm, et al. eds. 2012) *available at*: <http://www.cidrap.umn.edu/cidrap/files/80/ccivi%20report.pdf> (70-90% efficacy of flu vaccine commonly cited however the preponderance of efficacy and effectiveness data is from studies with suboptimal methodology, studies using optimal methodology have not shown this level of protection and show pooled protection of 59%).

⁴ Centers for Disease Control, *Vaccine Virus Selection for the 2012-2013 Influenza Season*: *available at*: <http://www.cdc.gov/flu/about/season/vaccine-selection.htm> (last visited March 11, 2013); The strains for the 2012/2013 influenza season were recommended and approved in February 2012, see: World Health Organization, *Recommended composition of influenza virus vaccines for use in the 2012-2013 northern hemisphere influenza season*, (2012): *available at*: http://www.who.int/influenza/vaccines/virus/recommendations/201202_recommendation.pdf; Vaccine and Related Biological Products Advisory Committee, February 20, 2012 Transcript, 190 *available at*: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/VaccinesandRelatedBiologicalProductsAdvisoryCommittee/UCM296458.pdf>.

largely dependent on the similarity between the virus strains in the vaccine and the viruses in circulation.⁵ The most recent report on the effectiveness of the 2012/2013 influenza vaccine reported a vaccine effectiveness of 56%,⁶ the CDC noted that this estimate is within the range of expected outcomes when “most circulating flu viruses characterized by the CDC are like the viruses included in the vaccine, which is what we are seeing this season.”⁷

Furthermore, even though employers of health care professionals are encouraged to obtain at least a 90% vaccination rate of their employees, there are very few studies investigating the effect of vaccination of health care workers on the rate of nosocomial influenza transmission.⁸ Moreover, a recent review of five studies looking at the effect of the vaccination of health care workers in long term care facilities found that there was no evidence that the vaccination of health care workers against influenza protected the elderly patients in their care and therefore there was no evidence on which to base a need for mandatory vaccination of such workers.⁹ The lack of evidence that vaccination of health care workers protects their patients, as well as the low effectiveness of the vaccine weighs against the need for mandatory influenza vaccination of such workers.

Discussions of the legal issues surrounding mandatory influenza vaccination for health care workers have largely omitted consideration of the effectiveness and efficacy of the influenza vaccine in their analysis. Vaccine effectiveness is a measure of the ability of a vaccine to prevent real world outcomes, in the case of influenza the vaccine effectiveness measures ability of the vaccine to prevent influenza infection as confirmed by laboratory tests.¹⁰ Vaccine efficacy looks at whether the vaccine works and measures the decrease in risk of infection for those vaccinated relative to people who were not vaccinated.¹¹ The influenza vaccine has been reported to have both a low

⁵ Centers for Disease Control and Prevention, *Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 60 MMWR 1, 9 (2011).

⁶ Centers for Disease Control and Prevention, *Interim Adjusted Estimates of Seasonal Influenza Vaccine Effectiveness – United States, February 2013*, 62 MMWR 119, 119 (2013).

⁷ Centers for Disease Control, *What You Should Know for the 2012-2013 Influenza Season*, available at: <http://www.cdc.gov/flu/about/season/flu-season-2012-2013.htm> (last visited March 11, 2013).

⁸ US Department of Health and Human Services, *Healthy People 2020 Objective IID-12.9* (2012): <http://www.healthypeople.gov/2020/topicsobjectives2020/objectiveslist.aspx?topicId=23> (Sets a target of 90 percent of health care personnel to receive the influenza vaccine).

⁹ RE Thomas et al., *Influenza vaccination for healthcare workers who work with the elderly (Review)*, 9 *The Cochrane Library* 1, 13 (2010) (Vaccination of health care workers was not shown to prevent laboratory-proven influenza, pneumonia or death from pneumonia).

¹⁰ Michael T Osterholm, *Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis*, 12 *Lancet Infect. Dis.* 36, 37 (2012) (defining influenza vaccine effectiveness and efficacy).

¹¹ *Id.*

vaccine effectiveness¹² and efficacy¹³. Not only do vaccinations for influenza differ from other vaccines that are mandated for health care workers, such as measles, mumps, rubella and varicella on the basis that the influenza vaccine requires yearly immunization, but also on the basis that the influenza vaccine has a varying and often low effectiveness relative to other mandatory vaccines. As noted above, this season's influenza vaccine has been reported to have an overall effectiveness of 56%.¹⁴ In comparison, other vaccines that are commonly mandated for health care employees have much higher effectiveness rates including: the measles vaccine has an effectiveness of 99%; the mumps vaccine has an effectiveness ranging from 79% to 95%; the rubella vaccine has an effectiveness ranging from 95% to 99%; and the varicella (chicken pox) vaccine has an effectiveness ranging from 80% to 85%.¹⁵

The relatively low effectiveness of the influenza vaccine, in conjunction with its requirement for yearly vaccination, must be considered in conjunction with employees' rights in an analysis to determine whether mandatory vaccination policies for health care workers are justifiable. The specific rights of employees that may potentially be infringed by mandatory vaccination policies depend on the source of the mandatory policy (state legislation or hospital policy), whether the hospital is a private or public institution and whether the employees are subject to a collective bargaining agreement.

In general, policies that are put in place by the state, (such as the short-lived New York mandate¹⁶, and the recent mandate in Rhode Island¹⁷) or that apply to state or federal employees will engage liberty and due process interests guaranteed under the U.S. and state constitutions in addition to

¹² Centers for Disease Control and Prevention, *Interim Adjusted Estimates of Seasonal Influenza Vaccine Effectiveness – Untied States, February 2013*, 62 MMWR 119, 119 (2013) (the effectiveness of the 2012-2013 vaccine was reported to be 56% as measured between December 3, 2012 and January 19, 2013).

¹³ Michael T Osterholm, *Efficacy and effectiveness of influenza vaccines: a systematic review and meta-analysis*, 12 *Lancet Infect. Dis.* 36, 39-40 (2012) (Median efficacy of eight studies looking at vaccine efficacy over 9 seasons in adults 18-64 was 62%);

¹⁴ Centers for Disease Control and Prevention, *Interim Adjusted Estimates of Seasonal Influenza Vaccine Effectiveness – Untied States, February 2013*, 62 MMWR 119, 119 (2013) (the effectiveness of the 2012-2013 vaccine was reported to be 56% as measured between December 3, 2012 and January 19, 2013).

¹⁵ Centers for Disease Control and Prevention, *Immunization of Health-Care Personnel: Recommendations of the Advisory Committee on Immunization Practices (ACIP)*, 60 MMWR 1, 9, 12, 15, 18, 25 (2011).

¹⁶ Maureen Minehan, *Flu Vaccines: Should you use a Carrot or a Stick?*, 27 *Emp. Alert 2* (“Westlaw”) (In August 2009 the state of NY adopted a regulation making annual influenza vaccinations mandatory for health care workers, lawsuits were filed requesting a temporary injunction and permanent revocation of the regulation and the regulation was subsequently revoked on October 22, 2009 with the reason for revocation being inability to obtain adequate vaccine supplies.).

¹⁷ R.I. Admin. Code 31-1-22: 3.54. (Rules and Regulations Pertaining to Immunization, Testing and Health Screening for Health Care Workers. Mandates seasonal influenza vaccination for all health care workers.).

private interests. A person is generally at liberty to refuse unwanted medical treatment, and this liberty interest will be impinged by a mandatory vaccination policy. The effectiveness of the vaccine impacts the ability of the state to justify such an impingement as the effectiveness of the vaccine decreases so to does the likelihood of protection from harm (influenza transmission). A mandatory vaccination policy first withheld constitutional scrutiny by the Supreme Court in *Jacobsen v. Massachusetts*, wherein the Court held that four elements should be considered in determining whether a mandatory immunization was justified in the name of public health namely: necessity, reasonable means, proportionality, harm avoidance.¹⁸ The effectiveness of a vaccination impacts all four of these elements making it more difficult to justify a mandatory vaccination policy where the vaccine being used is less effective.

All employees potentially have rights that may be infringed by mandatory vaccination policies under the Americans With Disabilities Act (“ADA”);¹⁹ or the Civil Rights Act of 1964 title VII.²⁰ Although most mandatory vaccination policies contain exemptions where there is a valid medical reason, even if the absence of an express exemption, an exemption would likely be required under the ADA with the need for such an exemption increasing as the vaccine effectiveness decreases. The Equal Opportunity Employment commission stated that “[a]n employee may be entitled to an exemption from a mandatory vaccination requirement based on an ADA disability that prevents him from taking the influenza vaccine. This would be a reasonable accommodation barring undue hardship (significant difficulty or expense)”.²¹ As the effectiveness of a vaccine decreases, it will become increasingly difficult for an employer to demonstrate a case of undue hardship as in the case of a vaccine that is 60% effective, it will be difficult to justify not granting exceptions where 40% of people who have received the vaccine may be in the same position to contract and transmit influenza as the person seeking the exemption. Furthermore, there is a lack of evidence that other measures such as hand washing, face masks, and liberal sick leave or policies encouraging employees not to attend work while ill would not be as effective as the low level of protection provided by influenza vaccination at reducing influenza transmission within a hospital, making it difficult to demonstrate undue hardship.

¹⁸ 197 U.S. 11 (1905).

¹⁹ 42 U.S.C.A. § 12101 (2008).

²⁰ Pub.L. 88-352 §701, as amended, 42 U.S.C.A. § 2000e-2.

²¹ US Equal Opportunity Employment Commission in technical assistance document “Pandemic in the Workplace and the American’s with Disabilities Act” available at: http://www.eeoc.gov/facts/pandemic_flu.html.

Although it will be very difficult, if not impossible, for an individual to bring constitutional claim on the basis that a mandatory vaccination policy violates their 1st Amendment right to free exercise of religion, a religiously based claim for an exemption from such a mandatory vaccination policy may nonetheless be based on the Title VII of the Civil Rights Act which prohibits discrimination in employment on the basis of religion.²² Similar to the provisions in the ADA, under the Civil Rights Act of 1964 once an employer becomes aware that an employee's religious belief or practice prevents her from taking the influenza vaccine the employer must provide a reasonable accommodation unless it would pose an undue hardship.²³ As described above, there is a heightened need for exemptions where the effectiveness of the vaccination is low, as in such circumstances it becomes increasingly difficult to demonstrate undue hardship.

Given the strong protections of the ADA and the Civil Rights Act of 1964, when employees are faced with mandatory influenza vaccination policies the major hurdle to getting an exemption may be proving that the employee falls within the definition of an ADA disability, or that they have a religious belief requiring accommodation, as once such a category is met the requirement of and exemption as accommodation seems forthcoming given the current low influenza vaccination effectiveness.

It is imperative that discussions on the legality of vaccination mandates for health care workers consider the effectiveness of the vaccine. In the case of the influenza vaccine, there has been a call for a reworking of the entire vaccination program to improve the efficacy and effectiveness.²⁴ Movements towards vaccine development continuously occur and recently include the approval of a four strain influenza vaccine to increase the effectiveness of the vaccine, as well as the approval of the first influenza vaccine grown in cultured mammalian cells instead of fertilized chicken eggs, potentially allowing vaccine to tackle shifts in flu strains faster.²⁵ However, until a consistently improved vaccine effectiveness in the range of other mandated vaccines (over 80%) can be

²² Mandatory vaccination laws are likely neutral towards religion and therefore do not violate the free exercise clause, see: *Emp't Div., Dept. of Human Res.'s of Oregon v. Smith*, 494 U.S. 872 (1990) (Where a state law has a neutral intent the law does not violate the 1st amendment free exercise clause).

²³ US Equal Opportunity Employment Commission in technical assistance document "Pandemic in the Workplace and the American's with Disabilities Act" available at: http://www.eeoc.gov/facts/pandemic_flu.html.

²⁴ Center for Infectious Disease Research and Policy, *The Compelling Need for Game-Changing Influenza Vaccines*, 120 (Michael T Osterholm, et al. eds. 2012) available at: <http://www.cidrap.umn.edu/cidrap/files/80/ccivi%20report.pdf>.

²⁵ Jeffrey L Fox, *Egg-free flu vaccines*, 31 *Nature Biotechnology* 93 (2013); Centers for Disease Control, *Vaccine Virus Selection for the 2012-2013 Influenza Season*: available at: <http://www.cdc.gov/flu/about/season/vaccine-selection.htm> (last visited March 11, 2013).

demonstrated the effectiveness of the influenza vaccine will continue to impact the ability of states and health care organizations to justify mandatory vaccination.

Furthermore, state legislation mandating influenza vaccination, and mandatory vaccination policies that are imposed on state and federal employees are Constitutionally difficult to justify due to the low effectiveness of the influenza vaccination. Furthermore, the low effectiveness of the influenza vaccine affects the analysis of undue hardship under both the ADA and Civil Rights Act resulting in the absence of exemptions for religion and disabilities being problematic. States and employers should reconsider mandatory vaccination policies in light of low vaccine effectiveness, and ensure that such policies are justifiable and that exemptions for religion and disability are available.

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