A Systematic Review of Mandatory Influenza Vaccination in Healthcare Personnel

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Context: Influenza is a major cause of patient morbidity. Mandatory influenza vaccination of healthcare personnel (HCP) is increasingly common yet has uncertain clinical impact. This study systematically examines published evidence of the benefits and harm of influenza vaccine mandates.

Evidence acquisition: MEDLINE, Embase, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, Science Citation Index Expanded, and Conference Proceedings Citations Index were searched and analyzed in 2013. Studies must have assessed the effect of a requirement of influenza vaccination among HCP for continued employment or clinical practice. Studies were not limited by comparison group, outcome, language, or study design. Two reviewers independently abstracted data and assessed bias risk.

Evidence synthesis: Twelve observational studies were included in the study from 778 citations. Following implementation of a vaccine mandate, vaccination rates increased in all eight studies reporting this outcome, exceeding 94%. Three studies documented increased vaccination rates in hospitals with mandates compared to those without ($p<0.001$ for all comparisons). Two single-institution studies reported limited, inconclusive results on absenteeism among HCP. No studies reported on clinical outcomes among patients. Medical and religious exemptions and terminations or voluntary resignations were rare.

Conclusions: Evidence from observational studies suggests that a vaccine mandate increases vaccination rates, but evidence on clinical outcomes is lacking. Although challenging, large healthcare employers planning to implement a mandate should develop a strategy to evaluate HCP and patient outcomes. Further studies documenting the impact of HCP influenza vaccination on clinical outcomes would inform decisions on the use of mandatory vaccine policies in HCP.

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Introduction

Influenza contributes to 3,000–49,000 deaths annually in the U.S.[1] Although influenza vaccination effectiveness varies,[2] vaccination remains the primary strategy to prevent infection. The Advisory Committee on Immunization Practices (ACIP) recommends influenza vaccination for all healthcare personnel (HCP) to reduce transmission to vulnerable patients,[3] and *Healthy People 2020* calls for influenza vaccination of 90% of HCP in the U.S. by 2020.[4] In 2012, the National Vaccine Advisory Committee recommended that healthcare employers that fail to achieve Healthy People 2020 influenza vaccination goals "strongly consider" an employer requirement for influenza vaccination but stopped short of recommending a mandate.[5] However, many professional societies recommend mandatory influenza vaccination policies for HCP.[6–9]

Beginning in 2013, federal regulations require acute care facilities to report influenza vaccination rates among HCP,[10] which are increasingly viewed as a measure of patient safety and quality, endorsed by the National Quality Forum.[11] However, prior systematic reviews of non-mandatory influenza vaccination of HCP have drawn differing conclusions on the benefit to patients.[12–15] Furthermore, given the seasonal variability in vaccine effectiveness, the impact of vaccination policies on healthcare-associated influenza would also be expected to vary by influenza season.

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Because of the rise in employer mandates for HCP influenza vaccination,[16] the potential compromise of HCP autonomy, and the unclear evidence of benefit, a systematic review of the effect of these mandates on vaccination rates, clinical outcomes among HCP and patients, attitudes of HCP, and adverse events was conducted.

Evidence Acquisition

A study protocol was developed based on Agency for Healthcare Research and Quality methods,[17] which is available through PROSPERO, the National Institute for Health Research International Prospective Register of Systematic Reviews (ID number CRD42012002913).[18]

Data Sources and Searches

MEDLINE, Embase, the Cochrane Library, Cumulative Index to Nursing and Allied Health Literature, Science Citation Index Expanded, and Conference Proceedings Citations Index–Science were searched from database inception to August 9, 2013, using controlled vocabulary and key word searches. A research librarian assisted in the development of the MEDLINE search strategy.

The search encompassed three concepts, searched by Medical Subject Headings (MESH), including influenza (*influenza, human/prevention, and control* [MESH] or *influenza vaccines* [MESH]); HCP (*health personnel* [MESH:NoExp]); and mandatory programs (*mandatory programs* [MESH]). These MESH terms were combined with text word searches (Appendix A). The MEDLINE search was adapted for use in the remaining databases. The references of all included articles, as well as pertinent reviews and opinion pieces, were hand-searched for additional citations.

Study Eligibility Criteria, Participants, and Interventions

Studies must have assessed the effect of a mandate for influenza vaccination among HCP. A mandate was defined as the requirement of vaccination for continued employment or clinical practice, with limited exemptions for medical or religious reasons. HCP were defined broadly as clinical and support staff of a healthcare employer, in any healthcare setting, including outpatient, acute care, or chronic care facilities. Studies were not limited by comparison group, outcome, language, or study design but were restricted to published literature.

Studies without explicit use of the term *mandate* (e.g., "requirement") were excluded unless >75% of participants were subject to a mandate that met the study definition. When this was unclear from review of the manuscript, authors were contacted for verification. Studies were excluded if influenza vaccination was "mandatory," but there were no consequences or the mandate was not enforced.

Data Extraction

Two reviewers independently screened all articles by title and abstract with subsequent full-text review based on the specified eligibility criteria. Two reviewers abstracted data from each article, using a standardized form. The first reviewer abstracted the data, and the second reviewer verified the data. Disagreements were resolved by discussion and consensus, with consultation with a third investigator, if necessary.

Characteristics of the employer, communications (e.g., educational campaigns), vaccine availability, and tracking strategies used prior to and with the mandate, employees covered, mandate exemptions, and possible consequences of noncompliance were extracted. Information on prespecified outcomes was extracted, including vaccination rates, HCP absenteeism, influenza outcomes among HCP and patients, employee attitudes, and adverse events, including penalties and legal challenges. Adverse effects of vaccination were subsequently identified as a relevant outcome and extracted.

Risk of Bias and Strength of the Evidence

The risk of bias was assessed based on common limitations in observational studies (Appendix B).[19] Specifically, case reports and pre–post studies were assessed on the following three elements: (1) unclear definition of population subject to mandate or different populations in pre- and post-mandate assessment; (2) differential surveillance for outcome in pre- and post-mandate assessments; and (3) co-interventions or changes in vaccination procedures (e.g., availability of vaccine, educational, or media campaigns) in conjunction with the mandate or evidence of a possible secular trend related to the H1N1 pandemic.

Cross-sectional and cohort studies were assessed on the following three domains: (1) unclear definition of exposure (mandate); (2) inadequate control of confounding (influenza season, co-interventions); and (3) incomplete survey response or follow-up. The risk of bias was used to qualitatively assess the strength of the overall body of evidence.

Data Synthesis

A qualitative synthesis was conducted in 2013. Differences in study designs and strategies precluded quantitative pooling. Strategies to increase vaccination were classified into categories based on those used by the Healthcare Infection Control Practices Advisory Committee and ACIP.[20] Strategies that were clearly implemented prior to the mandate were not included. Publication bias and subgroup analyses were not performed owing to the small number of included studies.

Evidence Synthesis

Search Results

The search strategy yielded 778 unique records. Of these, 12 published studies were eligible for inclusion (Figure 1).

Of the 12 studies, eight examined single hospitals or health systems,[21–28] including five pre- and post-mandate studies,[21–25] one with pre- and post-mandate and cross-sectional components,[26] and two case reports.[27–28] Four studies[29–32] assessed mandates implemented at multiple institutions, including one performance improvement initiative[29] (Table 1). All studies for which exemptions were known allowed for medical and religious

exemptions. One additional exemption was for veganism.[28] Four studies[22,23,25,28] reported the presence of a labor union.

Eight studies[21–28] reported that HCP were covered by the mandate. All eight studies required vaccination of employed HCP; medical staff[22–24,26,28] and contractors[21–25] were each required in five studies, volunteers[22–25] and students[22–25] were each required in four, and vendors in three.[22–24] Of note, the specific subset of HCP covered by the mandate varied by study (e.g., by amount of clinical contact).

Study Quality

The majority of studies had at least one indication of elevated risk of bias (Table 2). Among the case report and pre–post studies, six of eight (75%) had a co-intervention or may have been affected by a secular trend because of implementation during the H1N1 pandemic[21–24,26,28] (Appendix C), and three of eight (38%) appeared to have had changes in surveillance methods.[21,26,28] Among the cross-sectional studies, three of four (75%) reported suboptimal response rates.[26,31,32]

Impact of Mandates on Vaccination among HCP

All 12 studies examined the impact on HCP vaccination: eight reported vaccination rates, two reported differences in vaccination without reporting rates, and two reported rates of vaccination policy compliance (i.e., HCP who were vaccinated or obtained an exemption). Among the eight[21–26,29,30] reporting vaccination rates, six[21–26] were single-institution pre–post studies.

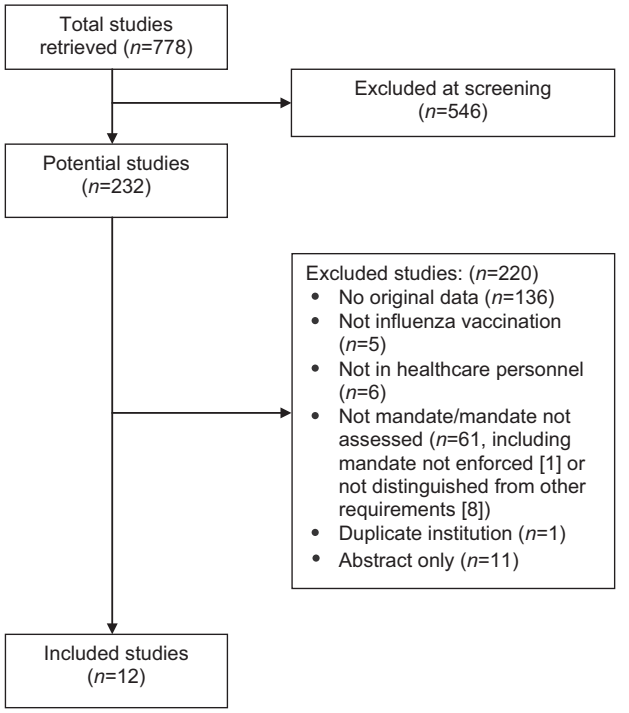

Figure 1. Summary of search and study selection

At the institutions in these six studies, vaccination rates before the mandate ranged from 30% to 92% (Figure 2). The employer with a 30% vaccination rate before the mandate reported that this was a decrease from the prior year (54%), possibly because of a vaccine shortage.[22] The employer with a 92% vaccination rate before the mandate had recently implemented a comprehensive influenza vaccination strategy and subsequently broadened the population for whom vaccination rates were reported following the mandate.[26] The remaining two studies[29,30] reporting vaccination rates assessed the impact of a mandate across multiple employers.

Following implementation of the mandate, overall HCP vaccination rates exceeded 94% in all eight studies. Seven of the studies[21–26,30] provided rates before and after the mandate, including one[30] that also compared institutions with mandates to other facilities. This study reported that hospitals with a mandate had a 24% adjusted absolute increase in vaccination compared with an 18% increase for hospitals with requirements with other consequences and a 9% average increase for institutions with no consequences ($p<0.001$). The remaining study[29] reporting vaccination rates, a performance improvement project, reported that at the end of 4 years, hospitals with a mandate had achieved a 96% vaccination rate compared with 87% in hospitals without a mandate ($p<0.001$).

Two studies reported vaccination rate differences. One study[31] used cross-sectional data for multi-level modeling to assess the impact of state laws and hospital policies, including mandates. This study found that hospitals with a mandate and hospitals with a vaccination requirement with other consequences (e.g., masking, reassignment) had 12.8% and 11.5% higher HCP vaccination rates, respectively, compared to those with no consequences ($p<0.001$ for both comparisons). State laws had no impact in this study.

A cross-sectional study[32] of pharmacists reported a significant increase in vaccination in pharmacists reporting mandatory vaccination without reporting quantitative rate differences. The two remaining studies[27,28] reported on rates of vaccination policy compliance (i.e., HCP were vaccinated or obtained an exemption) and found 100% compliance with vaccination policy.

One study[22] conceded that enforcement of a mandate in unionized nurses was disallowed by arbitration. Eighty-six percent of unionized nurses were vaccinated during the first season of the mandate compared with 98% of all HCP. The number of unvaccinated unionized

Table 1. Characteristics of included studies

		Population				Mandate	
Author (year)	Study design	Participants	Academic affiliation (Y/N)	Not-for -profit status	Union (Y/N)	Season	Number and type of personnel covered
Karanfil (2011)[23]	Pre–post	Medstar Health, a regional healthcare organization including: 9 hospitals (8 participated) 1 nursing home Visiting nurses association Research institute Employed physicians group	Yes	Not-for-profit	Yes	2009–2010	29,258 healthcare personnel All healthcare providers, including house staff all medical staff, including: Affiliated physicians Volunteers Contractors Vendors Students
Huynh (2012)[24]	Pre–post	Poudre Valley Health System, a community healthcare organization including: 2 hospitals totaling 417 beds Behavioral center Several clinics	No	Not-for-profit	Unknown	2010–2011	5,342 healthcare personnel Employees Affiliated licensed providers Volunteers Vendors Students Policy exempted contracted staff not providing direct care
Miller (2011)[30]	Cross-sectional	A sample of hospitals from the 2008 American Hospital Association annual survey database 998 hospitals surveyed 808 (81.1%) responded Of those that responded: 440 (54.5%) reported an institutional requirement Of these, 228 (51.2%) were included in analyses	Unknown	Unknown	Unknown	Varied	Unknown
Kidd (2012)[12]	Case report	University Hospital, a large teaching hospital	Yes	Unknown	Yes	2009–2010	Approximately 4,500 healthcare personnel All employees Medical staff

(continued on next page)

Table 1. Characteristics of included studies *(continued)*

		Population				Mandate	
Author (year)	**Study design**	**Participants**	**Academic affiliation (Y/N)**	**Not-for -profit status**	**Union (Y/N)**	**Season**	**Number and type of personnel covered**
Feemster (2011)[26]	Cross-sectional survey and pre–post	Children's Hospital of Philadelphia: 460-bed tertiary care hospital 29 primary care practices 13 subspecialty care centers 4 ambulatory surgical centers	Yes	Unknown	Unknown	2009–2010	9,300 HCP All staff who work in a building where patient care is delivered
Rakita (2010)[22]	Pre–post	Virginia Mason Medical Center, a tertiary care, multispecialty medical center: 336-bed hospital outpatient clinics 7 regional clinics research center	Yes	Not-for-profit	Yes, inpatient nurses	2005–2006	4,703 HCP All employees of the medical center Students Vendors Volunteers Contractors Outside physicians
Babcock (2010)[21]	Pre–post	BJC HealthCare 11 acute care hospitals 3 extended care facilities Daycare centers Employed physician groups Occupational medicine Home care Behavioral health services	Yes, 1 acute care and 1 pediatric care hospital are teaching hospitals	Not-for-profit[a]	Unknown	2008–2009	26,887 healthcare personnel Clinical and nonclinical staff Contracted clinical personnel Volunteers Hospital-employed physicians, including house staff (note: most attending physicians were not included)
Knapp (2006)[27]	Case report (quality improvement)	Bronson Methodist Hospital, the flagship of Bronson Healthcare Group, a tertiary healthcare system	Unknown	Not-for-profit	Unknown	2005–2006	3,201 healthcare personnel Direct patient care employees Hospital-employed physicians
Helms (2011)[29]	Retrospective cohort within a performance	Acute care hospitals in Iowa participating in a performance	Unknown	Unknown	Unknown	2009–2010, *n*=17; 2007–2008,	Unknown

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Table 1. Characteristics of included studies *(continued)*

		Population				Mandate	
Author (year)	Study design	Participants	Academic affiliation (Y/N)	Not-for -profit status	Union (Y/N)	Season	Number and type of personnel covered
	improvement project	improvement project: 119 acute care hospitals overall in the study 83 hospitals that responded to a questionnaire about mandatory vaccination and submitted data for all 4 years of the study were analyzed				*n*=1; 2006–2007 or prior, *n*=1	
Smith (2012)[25]	Pre–post	Aurora Health Care, a large regional healthcare system	Unknown	Unknown	Yes, nurses	2011–2012	30,048 healthcare personnel Employees with and without direct patient contact Contracted providers Students Volunteers
Ruiz (2010)[32]	Cross-sectional	Pharmacists targeted through the National Community Pharmacists Association 2008 annual meeting and e-link: Initial distribution to 24,000–26,000 e-mail addresses 1,028 individuals completed the survey	Yes (6%)	Unknown	Unknown	Unknown	Unknown
Zimmerman (2013)[31]	Cross-sectional with multi-level modeling	A random sample of hospital members of the American Hospital Association database matched with Association for Professionals in Infection Control and Epidemiology members 421 of 1,256 respondents to the survey	Unknown	Unknown	Unknown	Unknown	Unknown

[a]www.bjc.org.
N, no; Y, yes

Table 2. Risk of bias of included studies

Case study and pre–post outcomes			
Study	**Change in population under surveillance**	**Change in surveillance methods**	**Co-interventions or secular trend due to H1N1**
Karanfil (2011)[23]	No	Unknown	Yes
Huynh (2012)[24]	No	Unknown	Yes
Kidd (2012)[28]	Unknown	Yes	Yes
Feemster (2011)[26] vaccination outcomes	Yes	Yes	Yes
Rakita (2010)[22]	No	Unknown	Yes
Babcock (2010)[21]	No	Yes	Yes
Knapp (2006)[27]	Unknown	Unknown	Unknown
Smith (2012)[25]	No	No	Unknown
Cross-sectional outcomes			
Study	**Unclear exposure definition**	**Incomplete control of confounding**	**Incomplete response rate**
Miller (2011)[30]	No	No	No
Feemster (2011)[26] attitude outcomes	No	Not applicable	Yes
Ruiz (2010)[32]	No	Unknown	Yes
Zimmerman (2013)[31]	No	No	Yes
Cohort study outcomes			
Study	**Unclear exposure definition**	**Incomplete control of confounding**	**Incomplete exposure or outcome assessment**
Helms (2011)[29]	No	Unknown	No

nurses decreased over time, and by the fifth season following the mandate, 96% of all unionized nurses were vaccinated compared with 98% of all HCP. Unvaccinated union employees were required to wear a mask.

Eight studies[21–28] reported on exemptions to vaccination; six[21–26] reported the percentage of HCP receiving each exemption, which ranged from 0.3%–2.6% for medical exemptions and 0.02%–2.3% for religious exemptions, depending on the study and the population examined. Of the remaining two studies, one[27] reported that 2.5% met a criterion for deferral, and the other[28] reported 71 exemptions among approximately 4,500 HCP, consistent with the estimates from the six studies reporting medical and religious exemptions separately.

Clinical Impact of Mandates in HCP

Two single-institution studies reported on absenteeism among HCP, a case study and a pre–post study.[22,28] The case study noted that sick leave hours were reduced by approximately 8,000 hours from the previous year, but did not report the total number of hours of either year or statistical testing.[28] Based on an estimated workforce of 4,500 HCP, this is approximately 1.7 hours per HCP. The pre–post study did not find a significant change in sick leave in the years after the mandate, compared to prior years (6.6 hours per HCP during 2006–2009 vs 7.1 hours per HCP during 2001–2005, p=0.43).[22]

Clinical Impact of Mandates in Patients

No studies reported on clinical outcomes among patients in institutions where an HCP vaccination mandate was in place.

Adverse Effects of Mandates

Two studies[21,25] reported on adverse clinical events among HCP. One study[25] reported 15 workers' compensation claims, one hospitalization that was not associated with vaccination based on an independent review, and stated that "an informal assessment suggest[ed] a modest increase in the number of minor adverse events," without further details. The second study[21] reported 0.08% adverse events among those vaccinated, including one case of chronic inflammatory demyelinating polyneuropathy that was "not objectively linked to the influenza vaccine."

Six of the 12 studies reported on terminations and "voluntary resignations."[21–26] These studies reported 0.02%–0.15% combined terminations or voluntary resignations. A seventh study[28] reported "a few" resignations. One study[27] noted that 3% of employees left the organization but did not specify if this was related to the mandate. One study[23] reported suspensions of affiliated physicians (4%). Two studies[22,28] reported legal challenges; both had employee unions.

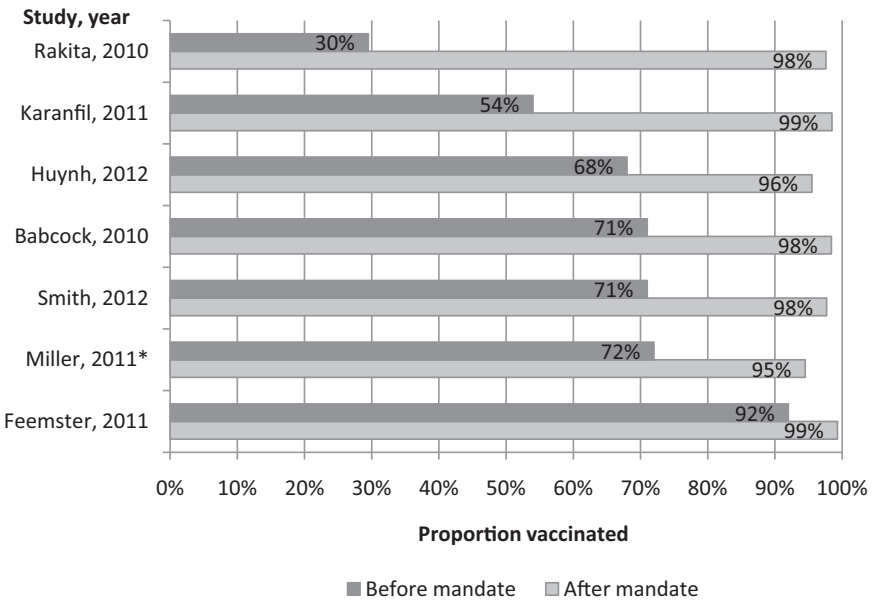

Figure 2. Overall proportion (%) of healthcare personnel with influenza vaccination before and after a mandate
Note: *Mean vaccination rate prior to a mandate, 72.1% (95% CI=66.6, 77.7); mean vaccination rate following a mandate, 94.5% (95% CI=93.5, 95.5).

HCP Attitudinal Response to Mandates

A single study reported on attitudes toward influenza vaccination among HCP subject to a mandate. In a cross-sectional survey (overall response rate, 58.2%) at an institution that had implemented a mandate the prior year,[26] a substantial majority (74.4%) of HCP reported that they strongly or somewhat agreed with a vaccine mandate. Almost all respondents thought that an influenza vaccine mandate was important for protecting patients (96.7%) and employees (96.4%), and 89.6% said that a mandate was an important professional ethical responsibility. Despite this, 72.0% thought an influenza vaccine mandate was coercive, and 17.7% thought it violated their contract. Additional outcomes are available in Appendix D.

Discussion

Evidence from observational studies suggests that a mandate for HCP influenza vaccination increases vaccination rates. Although changes in surveillance methods and co-interventions were identified in the risk of bias assessment, these changes are unlikely to explain the vaccination rate increases seen but could have led to overestimation of the effect of a mandate alone. There is insufficient evidence related to the impact of these mandates on clinical outcomes among HCP and patients. Only two studies reported on absenteeism in HCP, and no study included in the review examined patient outcomes. Among included studies, employee terminations and "voluntary resignations" as a result of mandatory policies were uncommon. Reporting on adverse clinical events was limited and heterogeneous, precluding conclusions.

Of interest, unionized nurses who were exempt from the mandatory vaccination policy in one study[22] still achieved high vaccination rates that increased over time. Nurses who refused vaccination were subject to mandatory masking. Policies requiring mandatory mask use among unvaccinated HCPs increased HCP vaccination rates above 90% in some studies.[33,34] However, such policies mandating mask use may present challenges in monitoring compliance and enforcement.

In the three multi-institutional studies,[29–31] hospitals with an influenza vaccine mandate had only modest increases in vaccination rates compared to hospitals with other vaccination policies, depending on the study and comparison group, with smaller differences when compared to hospital policies with other consequences (e.g., masking, reassignment).

The vaccination rate results are similar to those seen in a prior systematic review[35] and in a prior narrative review.[36] The systematic review,[35] an analysis of strategies to increase influenza vaccination rates in HCP in hospitals, restricted its search to PubMed through 2011. The narrative review[36] addressed a wider definition of mandate. This study used broad inclusion criteria to capture all relevant studies meeting the specific definition of a mandate and any evaluated outcomes. Through the study search and inclusion criteria, eight additional studies[24,25,27–32] were identified that were not included in

either prior review, including all multi-institutional studies. In addition, the risk of bias of included studies was formally assessed.

Given the paucity of direct evidence, understanding the potential impact of a mandate on critical patient outcomes requires an examination of the evidence of non-mandatory HCP vaccination. Although influenza has long been known to cause serious outbreaks in healthcare facilities,[37] there is a growing body of literature on the burden of healthcare associated influenza from studies of surveillance in the U.S. (2010–2011),[38] Canada (2006–2012),[39] the United Kingdom (2009–2010),[40] and Australia (2010–2011).[41]

Although case definitions in these studies varied, 2.0%–6.8% of hospitalized patients with laboratory-confirmed influenza infection had hospital-acquired or hospital-onset influenza, including 2.8% in the U.S. study. In the Canadian study, an additional 9.9% of patients had influenza onset in a long-term care facility. One prospective study[42] of hospital-acquired influenza-like illness (ILI) found a relative risk (RR) of 5.5 for exposure to an HCP with ILI, with even higher risks for exposure to a patient with ILI (RR=18.0) or both a patient and HCP (RR=34.7); however, only 13 (20%) cases had laboratory-confirmed influenza.

Although not within the scope of this review, the effect of influenza vaccination in HCP on patient outcomes in the absence of a vaccination mandate has been the subject of three recent systematic reviews,[13–15] all of which identified the same four cluster RCTs conducted in long-term care facilities, but varied in their inclusion of observational studies and outcomes assessed. One review[13] concluded that there was moderate quality evidence for a reduction in all-cause mortality in patients, but low-quality evidence for the specific outcome of influenza infection. This study identified a fifth cluster RCT conducted in acute care facilities in a postscript, which the authors did not believe changed the conclusions of the review.

A second review[14] reported limited evidence of a benefit of HCP influenza vaccination on multiple patient outcomes, and the third,[12] an update of a prior Cochrane review, excluded outcomes of influenza-like illness and all-cause mortality, and found no effect reporting on three of the four identified RCTs.[15] Overall, the evidence linking HCP vaccination to patient outcomes in the absence of a mandate is limited, with a small number of randomized trials predominantly conducted in long-term care facilities and varying strength of evidence depending on the outcome measured.

There are numerous studies on the overall effectiveness of influenza vaccination. In the general population (including HCP), the efficacy and effectiveness of influenza vaccines vary by age and immune status of the recipient, the degree of match between the vaccine strain and the predominant circulating influenza virus, and the outcome measured, with higher results for more specific influenza outcomes.[43]

A recent systematic review[2] demonstrated efficacy against laboratory-confirmed influenza in eight of 12 seasons, with a pooled efficacy of 59% in adults aged 18–65 years, but reduced or no protection in some seasons in some patient populations. Although influenza vaccine has been criticized for this variable efficacy, it remains the primary method for prevention of morbidity and mortality associated with influenza infection. Based on the existing literature, the impact of mandatory HCP influenza vaccination on patient outcomes still needs clarification.

The lack of evidence of an effect of an HCP influenza vaccine mandate on patient outcomes does not confirm a lack of effectiveness. However, increasing HCP personnel influenza vaccination by either voluntary interventions or mandatory policies requires a significant use of resources. No studies in this review quantified the costs of implementing mandatory influenza policies. Although HCP remain bound by ethical principles of non-maleficence and beneficence as previously described,[44] further studies documenting the impact of HCP influenza vaccination on critical patient outcomes would inform decisions on the use of resources and the need for compulsory policies.

Prospective studies across multiple facilities would likely be needed to obtain sufficient power to evaluate HCP and patient clinical outcomes following HCP influenza vaccination in acute care facilities. The diagnosis of influenza in acute care facilities is challenging, as the clinical presentation may be non-specific and the incubation period of influenza may exceed the length of stay. However, with the use of electronic health records or medical claims data, surveillance for clinical outcomes prompting medical care or treatment is increasingly feasible.

Although few institutions are likely to routinely track HCP clinical outcomes, healthcare employers who insure their employees would be able to evaluate these outcomes. Additional challenges of these studies include the need to account for other infection control practices (e.g., visitor exclusion policies); practice variation (e.g., number of staff contacts per patient, sick leave policy); regional influenza activity; and patient characteristics, including vaccination. These multi-institutional studies would benefit from standardization of the measurement of all outcomes.

Limitations

There were important limitations in this review. Only 12 studies met inclusion criteria; all studies were observational, often pre–post in design, and the definition of HCP varied by study. Many studies had limited descriptions of

vaccination delivery and surveillance prior to the mandate, and in the majority of studies, employers implemented additional strategies to increase vaccination with the mandate. Changes in surveillance methods for vaccination in HCP and co-interventions with the mandate could have led to overestimation of the effect of a mandate on vaccination rates. In addition, neither of the two studies that assessed HCP absenteeism described in detail how these outcomes were measured.

This review was restricted to the published literature. Based on reporting through the Immunization Action Coalition,[16] there may be unpublished descriptions of experience with an institutional mandate. However, studies described in abstract only[45–49] and in the gray literature[50] appeared to be consistent with the results of published literature.

Conclusions

Evidence from observational studies suggests that employer-mandated influenza vaccination among HCP increases vaccination rates, but evidence on HCP and patient outcomes is currently lacking. Assessing clinical outcomes will be challenging, but large healthcare employers that plan to implement a mandate should develop a strategy to evaluate these HCP and patient outcomes. Further studies documenting the impact of HCP influenza vaccination on clinical outcomes would inform decisions on the use of mandatory policies.

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Appendix

Supplementary data

Supplementary data associated with this article can be found at http://dx.doi.org/10.1016/j.amepre.2014.05.035.