Data Behind Mandatory Flu Vaccinations for Health Care Workers in Tertiary Care Hospitals is Inconclusive

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Abstract

Background: Mandatory influenza vaccination of health care workers (HCWs) has generated significant controversy over the last several years. Many health care organizations have implemented mandatory policies in order to boost vaccination rates of health care workers due to failed attempts at voluntary strategies. The trivalent influenza vaccine has been proven to be a relatively safe and cost effective tool in mitigating influenza. However, it has also demonstrated a varied efficacy rate from season to season and person to person. There have been previous studies evaluating influenza vaccination for HCWs who work with the elderly, but little data is available on tertiary care hospitals. The object of this review is to determine if there is sufficient data behind the effectiveness of influenza vaccination of HCWs in preventing nosocomial infections in tertiary care hospitals to justify a mandate with negative associated consequences such as termination, relocation, or mask wearing for a non-compliant HCW.

Methods: An exhaustive search of available medical literature was conducted using Medline-OVID, CINAHL, Medline-PubMed, NIH clinical trials website, and the Center for Disease Control and Prevention website, using the keywords: health personnel, cross infection, nosocomial, influenza human, influenza vaccine, and tertiary care hospital. Relevant articles were assessed for quality using GRADE.

Results: Two studies met the inclusion criteria and were featured in this systematic review. A prospective observational study demonstrated an inverse association between HCW vaccination rates and nosocomial influenza rates among patients. A nested case-control investigation indicated a protective effect on hospital-acquired influenza (HAI) when more than 35% of healthcare workers were vaccinated.

Conclusion: The two studies included in this review demonstrate a protective effect in preventing nosocomial infections in tertiary care hospitals. However, these studies have multiple limitations and biases. Based on these studies, the data is inconclusive and does not support a strong recommendation for mandatory influenza vaccination of HCWs for prevention of nosocomial infections in tertiary care hospitals.

Keywords: Health care workers, influenza vaccine, nosocomial

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Data Behind Mandatory Flu Vaccinations for Health Care Workers in Tertiary Care Hospitals is Inconclusive

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A Clinical Graduate Project Submitted to the Faculty of the
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Biography

[Redacted for privacy]
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**Conclusion:** The two studies included in this review demonstrate a protective effect in preventing nosocomial infections in tertiary care hospitals. However, these studies have multiple limitations and biases. Based on these studies, the data is inconclusive and does not support a strong recommendation for mandatory influenza vaccination of HCWs for prevention of nosocomial infections in tertiary care hospitals.

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Table of Contents

Biography ............................................................................................................................ 2
Abstract ............................................................................................................................... 3
Acknowledgements ............................................................................................................. 4
Table of Contents ................................................................................................................ 5
List of Tables ....................................................................................................................... 6
List of Abbreviations .......................................................................................................... 6
Data Behind Mandatory Flu Vaccinations for Health Care Workers in Tertiary Care
Hospitals is Inconclusive .................................................................................................... 7
BACKGROUND ................................................................................................................ 7
METHODS ......................................................................................................................... 8
RESULTS ........................................................................................................................... 9
DISCUSSION ..................................................................................................................... 10
CONCLUSION ................................................................................................................... 16
References ......................................................................................................................... 17
Table I. Characteristics of Reviewed Studies and Summary of Findings ................. 20
List of Tables

Table I: Characteristics of Reviewed Studies and Summary of Finding

List of Abbreviations

CDC……………………………………… Center for Disease Control and Prevention
CI……………………………………………………………………. Confidence Intervals
GRADE .......... Grading of Recommendations, Assessment, Development and Evaluations
HCP ……………………………………………………………….. Health Care Personnel
HCW ……………………………………………………………….. Health Care Workers
HAI ........................................................................................... Hospital Acquired Influenza
ILI ........................................................................................... Influenza Like Illness
NIH ........................................................................................... National Institute of Health
VE ........................................................................................... Vaccine Effectiveness
Data Behind Mandatory Flu Vaccinations for Health Care Workers in Tertiary Care Hospitals is Inconclusive

BACKGROUND
Mandatory influenza vaccination of healthcare workers (HCWs) has generated significant controversy over the last several years. In 2004, two health care facilities, Virginia Mason Medical Center in Seattle, Washington and Bronson Methodist Hospital in Kalamazoo, Michigan, became the first in the nation to put into effect mandatory influenza vaccination programs for their staff. By 2009, at least 25 other institutions in 17 states had implemented similar requirements. In 2011, a survey sent out to 998 acute care hospitals in the US revealed 440 of these had mandatory requirements. Of those, 194 reported consequences that applied to HCWs who refused vaccination. Consequences of vaccination refusal included, but were not limited to, the requirement of HCWs to wear a mask, be restricted from patient care duties, appear before a committee, be required to be absent during influenza outbreaks, participate in additional education or training, and/or be terminated. Suboptimal influenza vaccination coverage of HCWs from previous seasons was most commonly cited as the reason leading to mandatory vaccine implementation.

Consequences have been met head-on with opposition and legal challenges. Lawsuits emerged defending the rights of individuals to refuse medical treatment and union collective bargaining over employment contract terms and conditions. In 2009 New York state issued a mandatory policy for influenza vaccination, but was temporarily restrained by the New York Supreme court until three individual lawsuits could be heard. Washington State Nurses Association (WSNA) opposed the mandate and filed a
labor grievance. The ruling in favor of the nurses was upheld all the way to the U.S. Court of Appeals for the 9th Circuit.\textsuperscript{3}

One of the most common reasons HCWs decline influenza vaccination is because they believe the vaccine is ineffective.\textsuperscript{6} The Center of Disease Control and Prevention states flu vaccine effectiveness (VE) can range widely from season to season and person to person depending upon its match to the actual virus and the characteristics of the person being vaccinated. Which in turn means one can “still get sick with influenza even if you have been vaccinated”.\textsuperscript{7} From December 3, 2012 to January 2, 2013 influenza VE was estimated at 62\% (95\% confidence intervals [CIs] = 51\%–71\%).\textsuperscript{8}

With suboptimal influenza vaccination coverage of HCWs being the driving force for the mandate and with only moderate efficacy of the vaccine,\textsuperscript{7} is there data to support mandatory influenza vaccination and therefore consequences for non-compliance?

The object of this review is to determine if there is sufficient data behind the effectiveness of influenza vaccination of HCWs in preventing nosocomial infections in tertiary care hospitals to justify \textit{mandatory} vaccination and therefore consequences such as termination, relocation, or mask wearing for a non-compliant HCW. Previous studies\textsuperscript{9} have investigated the efficacy of influenza vaccination of HCWs who work with the elderly, but little investigation has been done on tertiary care hospitals.

\textbf{METHODS}

An extensive search of available medical literature was conducted using Medline-OVID, CINAHL, Medline-PubMed, NIH clinical trials website, and Center for Disease Control and Prevention website, using the keywords: health personnel, cross infection,
nosocomial, influenza human, influenza vaccine and tertiary care hospital. The search was then narrowed to include only English language articles and human studies. The lists of references included in these articles were further searched for relevant sources. Articles with primary data evaluating hospital-acquired/nosocomial influenza were included. Relevant articles were assessed for quality using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE). A search on the National Institute of Health (NIH) clinical trials site revealed no currently registered trials, at any phase, relating to hospital-acquired influenza from healthcare workers.

RESULTS

The initial result of the search yielded 81 articles for review. After screening relevant articles for primary data and human studies, a total of two articles met the inclusion criteria. These articles include a prospective observational study and a nested case-control investigation. See Table I.

Salgado et al

This is a prospective observational study involving data collected from the University of Virginia Health System in Charlottesville, Virginia from 1987 to 2000. Hospital-wide surveillance was conducted to detect influenza like illness (ILI) by infection control practitioners. Rapid influenza antigen testing, nasal wash, or nose and throat swabs were used to diagnose influenza infection. Additional information was used to determine if the influenza was community-acquired or nosocomial. Laboratory-confirmed influenza in a patient developing symptoms after 72 hours of hospitalization
was defined as nosocomial influenza. The data was then further used to calculate the
relative frequencies of influenza among HCWs and patients and of vaccination among
HCWs. The relative frequency of nosocomial influenza cases was obtained by dividing
the number of nosocomial influenza cases by the total number of influenza cases among
hospitalized patients during each season. An influenza season was defined as the time
from the first to the last laboratory-confirmed case of influenza in that respective season.
A chi-square for trend and a logistic regression analysis were used to display the data.\textsuperscript{11}

The article states that nosocomial influenza occurred 49 times in 49 patients
during the 13 influenza seasons. The results demonstrated an inverse association between
HCW vaccination rates and nosocomial influenza rates among patients. HCW
vaccination coverage increased from 3\% in 1987 to 67\% in 2000 and the relative
frequency of nosocomial influenza decreased from 32\% in 1987 to 0\% in 2000.\textsuperscript{11}

The authors discussed additional hospital preventative measures that may have
influenced these numbers. These included a mobile cart for onsite vaccination of HCWs,
an increased effort placed on education regarding flu transmission and prevention,
motivation for vaccination, and regular feedback of HCW rates of vaccine compliance.
Additionally, HCWs with ILI were “furloughed” for 5 days, and employees with a
positive rapid influenza antigen test, were “furloughed” from work until their fever
resolved.\textsuperscript{11}

\textbf{Benet et al}

This nested case-control investigation\textsuperscript{12} was conducted in a prospective
surveillance study of HAI between October 15 and April 15, 2004-05, 2005-06, and
2006-07 in Edouard Herriot Hospital (Lyon, France). Thirty-six (84%) of the hospital’s 43 adult short-stay units participated on a voluntary basis: 12 with 224 beds in 2004-05, 29 with 493 beds in 2005-06, and 30 with 537 beds in 2006-07. Inclusion criteria consisted of all patients with ILI during hospital stay and all health care workers. HCW categories included: physicians, nursing staff, ancillary, and allied health staff.12

Once daily, research nurses searched for patients with ILI, defined as axillary or rectal temperature of ≥37.8°C, in the absence of antipyretics, with sore throat or cough. At the time of ILI diagnosis, nasal swab testing served to confirm influenza in cases and controls. Cases consisted of patients with virologically-confirmed influenza occurring ≥72 hours after admission in acute-stay units. Controls were patients with documented ILI during hospitalization who had negative influenza lab results. Among all eligible controls, four controls per case were randomly selected and matched per influenza season (2004-05, 2005-06, and 2006-07). The proportion of HCWs vaccinated against influenza cases in these units was calculated and reported.12

A total of 55 patients analyzed over the influenza seasons 2004-05, 2005-06, and 2006-07 met the case and control criteria. Of these patients, 11 (20%) had laboratory-confirmed HAI. Of the total hospital units, the median HCW vaccination rate was 36% (0% to 67%) with a mean of 34%. The results of this study indicated that the proportion of HCW vaccination rates greater than 35% provided a protective effect against HAI among patients (odds ratio = 0.07; 95% CI 0.005-0.98).12

The authors discuss the limitations of this study to include sample size, classification bias, and balance of confounders. The sample size is small in this study due to the case definition. The classification bias was presumed low due to the fact
controls were laboratory tested for the influenza virus. The confounders included gender, individual patient vaccination against influenza, type of ward, and underlying disease. The study also discussed the possibility that those units with a higher proportion of HCW vaccination rates also demonstrated higher standards of respiratory hygiene and infection control. Furthermore, visitors of hospitalized patients were not recorded and argued by the authors to constitute another non-assessed source of exposure to influenza.12

DISCUSSION

Mandating influenza vaccine for HCWs has generated vigorous debate and even litigation. There are multiple facets encompassed in this controversy that include, but are not limited to: administrative policy, moral and ethical responsibility on behalf of the HCW to do no harm, employee rights, the efficacy of influenza vaccines, and personal and religious views. However, the objective of this review was to determine if sufficient data supports making influenza vaccination of HCWs in tertiary care hospitals mandatory. To do so objectively, it is important to identify studies that directly affect this clinical question, additional studies influencing this mandate, and influenza vaccine statistics from the CDC.

The inclusion criteria of the studies in this review consisted of nosocomial influenza infection from HCW-to-patient via laboratory-confirmed influenza in tertiary care hospitals. Only two studies fit the inclusion criteria of this review.11,12 Although the data from each study demonstrated nosocomial infection from HCW-to-patient, there are multiple limitations to each study. The two studies show very low quality of
evidence, and therefore do not support a strong recommendation for mandatory influenza vaccination for HCWs.

In the study by Selgado et al,\textsuperscript{11} results demonstrated an inverse association between HCW vaccination rates and nosocomial influenza rates among patients. However, there are multiple limitations to this study. This was a prospective observational study and was at risk for bias. HCW and patient vaccination rates varied. In addition, flu precautions and prevention measures varied per department and HCW. Increased awareness and education may have influenced early intervention of suspected infection. Imbalance of confounders included age, gender, co-morbidities, and HCW and patient vaccination coverage. Also, it does not address exposure of hospitalized patients to visitors.\textsuperscript{11}

Benet et al\textsuperscript{12} reported a protective effect against laboratory-confirmed HAI among patients in which the proportion of vaccinated versus unvaccinated HCWs is greater than 35% (odds ratio= 0.07; 95% CI 0.005-0.98). Its strengths consist of four controls per case and virological lab testing for all controls. It also provides a prospective analysis of the effectiveness of the vaccination strategy. However, this article contained multiple limitations as well. This is a nested case control study with very small sample size. Of this 1000-bed hospital over the course of three flu seasons, only 55 cases and controls were identified and analyzed. Risk for bias was present in this study in similar ways as the other study in this review. Misclassification was possible, but likely low due to lab-confirmed influenza in cases and controls. Risk for bias was evident in the fact that vaccination rates for each unit of the hospital varied, and other preventative measures such as respiratory hygiene and infection control practices varied per unit. Balance of
confounders was also a significant limitation in this study. Due to the observational study design, there was no balance between case and control groups regarding age, gender, type of ward, co-morbidities, and individual vaccination status of patients. Also, patient’s exposure to visitors was not considered.12

Although not included in this review, it is important to note a Cochrane review9 published in 2010 investigated the influence of HCW influenza vaccination specifically on those who work with the elderly. All of the studies included in this review were geriatric long-stay hospitals and nursing homes. Many of the arguments supporting mandatory influenza vaccination quote studies included in this review. However, review author Tom Jefferson is quoted in the British Medical Journal as stating, “what’s incredible is [that] the people who keep pushing these vaccines, despite the evidence, keep quoting figures without understanding what they are saying.”13 Moreover, in a stated summary from the Cochrane review:

We conclude that there is no evidence that only vaccinating healthcare workers prevents laboratory-proven influenza, pneumonia, and death from pneumonia in elderly residents in long-term care facilities. Other interventions such as, hand washing, masks, early detection of influenza with nasal swabs, anti-virals, quarantine, restricting visitors, and asking healthcare workers with an influenza-like illness not to attend work, might protect individuals over 60 in long-term care facilities and high quality randomised controlled trials testing combinations of these interventions are needed.9
Additional variables affecting nosocomial influenza are also important to include in this discussion. These variables include overall VE and infection control precautions. According to the CDC, the influenza vaccine has been proven to be a relatively safe and cost effective tool to assist in flu prevention. However, the CDC also states that its efficacy varies significantly season to season and person to person. From December 3, 2012 to January 2, 2013, the influenza vaccine was estimated to have an overall VE of 62% (95% confidence intervals [CIs] = 51%–71%). The interim estimate indicated “moderate” effectiveness. The ability of the flu vaccine to prevent influenza depends on how well the vaccine matches the seasonal virus as well as the characteristics of the individual being vaccinated. Based on these variables, the CDC reports it is possible to become infected with influenza even if you have been vaccinated.

Influenza is a contagious respiratory illness spread commonly by airborne respiratory droplets and less commonly by touching an object with the virus on it and then touching mouth, eyes, or nose. Infection control precautions such as hand washing, masking those with a cough, isolation of infected patients, adequate sick leave for employees, and visitor regulations are all variables that influence the spread of influenza and can vary from institution to institution. Are tertiary care administrators focusing on these infection control variables as much as they are on influenza vaccination of HCWs?

Furthermore, scientific investigation is designed to find evidence (an attempt to know the truth) on whether or not an intervention can cause a desirable outcome. Once sufficient data is available, guidelines and policies can be made with less potential for litigation. Many would argue that the influenza vaccine is a valuable tool. However, others would argue that a policy which mandates vaccination of HCWs should be
underwritten by sufficient evidence and not driven by the desire to improve vaccination rates when volunteer methods fail.

CONCLUSION

The two studies included in this review demonstrate a protective effect in preventing nosocomial infections in tertiary care hospitals. However, the studies have multiple limitations and biases and combine for a very low quality rating under GRADE. Based on these studies, the data is inconclusive and does not support a strong recommendation for mandatory influenza vaccination of HCWs for prevention of nosocomial infections in tertiary care hospitals. In addition, although influenza vaccines are relatively safe and cost effective, its efficacy varies year to year and patient to patient. Continued research and development of a highly effective flu vaccine is needed not only to combat influenza, but to improve patient and HCW coverage rates. It is clear that further high quality studies to prove a protective effect of HCW vaccination on risk of nosocomial influenza are needed in order to clearly justify a mandate and to avoid further litigation.
References


10. Grade working group. Grade Working Group Web site.


13. Santry C. Health workers in british columbia must be vaccinated against flu or wear a mask, new policy says. BMJ. 2012;345:e7860.
### Table I. Characteristics of Reviewed Studies and Summary of Findings

<table>
<thead>
<tr>
<th>Quality Assessment</th>
<th>Summary of Findings</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Downgrade Criteria</strong></td>
<td><strong>Quality</strong></td>
</tr>
<tr>
<td>Design</td>
<td>Limitations</td>
</tr>
<tr>
<td>Salgado et al: Preventing Nosocomial Influenza by Improving the Vaccine Acceptance Rate of Clinicians&lt;sup&gt;1&lt;/sup&gt;</td>
<td>Observational</td>
</tr>
<tr>
<td>Benet et al: Influenza vaccination of healthcare workers in acute-care hospitals: a case control study of its effect on hospital acquired influenza among patients&lt;sup&gt;12&lt;/sup&gt;</td>
<td>Nested case-control</td>
</tr>
</tbody>
</table>


- a. Failure to account for confounders
- b. Small sample size