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TITLE OF RESEARCH ***: A comparison of policies to limit the transmission of influenza virus from health care workers (HCWs) to patients.***

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This Project examines policies that attempt to limit the transmission of the influenza virus from Health Care Workers (HCWs) to patients. Apart from legal, ethical, and scientific viewpoints, the impact of a mandatory immunization program on adverse effects, absenteeism, rates of immunization and attitudes of the HCWs were explored to gain information on the utility of mandatory vaccination by reviewing articles from the published literature.

OBJECTIVE:

The focus of this project is to compare the influenza immunization rates of HCW's in hospitals that mandate influenza vaccine to those that do not. Attitudes, adverse events and absenteeism in these two groups were also addressed.

BACKGROUND:

Among adults in the US, influenza is the sixth leading cause of death, having the same mortality rate as breast cancer but three times that of HIV/AIDS [1]. Annually, influenza epidemics cause approximately 36,000 deaths and 200,000 hospitalizations [2, 3]. For 2009-2010 the estimated is up to 90,000 deaths and 1.8 million hospitalizations in US (US Presidential report). [4] During outbreaks in acute care or long term–care facilities (LTCF), HCWs act as an important reservoir of infection, being implicated in the transmission of influenza to other HCWs and to patients.

The single-most effective measure for prevention of transmission of influenza within health care facilities is to immunize HCWs against influenza [5]. Regardless of long-standing (since 1981) recommendations from the Centers for Disease Control and Prevention (CDC) to vaccinate all HCWs, annually only ~40% of HCWs in US are vaccinated [5]. World Health Organization recommends that HCWs should be vaccinated against influenza. However, the policy in Europe is variable and the vaccination rate is low (less than 25%), [6]. Recently Healthcare Infection Control Practices Advisory Committee (HICPAC) and the Advisory Committee on Immunization Practices (ACIP) of CDC issued evidence-based recommendations to administrators responsible for influenza vaccination programs to deal the steady low influenza vaccination rates among HCWs [5]. According to 1997 and 2001 CDC's National Health Interview Survey (NHIS) reports, only 34% and 36% of HCWs received immunization. [5] HCWs that received flu vaccination have been associated with reduced work absenteeism and fewer deaths among nursing home patients. [5]

Declination form is the consent to, waiver of, or declination of influenza vaccination by the HCWs for reasons other than religious and medical contraindications. The declination statement is intended to make sure that HCWs are properly informed of the rationale for influenza vaccination, to promote the message of patient safety, and to eliminate the commonly held misconceptions regarding influenza and influenza vaccination.

Many health authorities feel that the current recommendation by CDC for the use of a declination form and education is not working. Everyone cannot be vaccinated because of serious adverse events, allergies, or religious beliefs in 10 % of HCWs.

METHODOLOGY:

This research project utilizes the published articles through 2009 from Medline/Pubmed database which have been relevantly identified using the keywords (Mandatory, Influenza, Immunization, Health care Workers, Attitudes, Nosocomial and Absenteeism) related to influenza immunization, the perception and coverage among HCWs.

DISCUSSION:

Steckel [1] states that vaccination among HCWs should be used as a measure of hospital quality and patient safety [1]. Often HCWs fail to recognize the importance of vaccination for the safety of patients and themselves. [5] The CDC recommendations strive to balance patient's rights with the rights of HCWs while attempting to decrease influenza transmission in the health care settings. The Significant morbidity and mortality affect the public on an annual basis due to the serious illness of influenza infection among HCWs, who transmit this deadly virus to their vulnerable patients.

Vaccinating HCWs against influenza would save money for employees and employers and prevents workplace disruption. Poland et al [7] specifies that there are 25% fewer upper respiratory infections, 44% fewer doctor visits, and 43% fewer sick days off, saving an average of $47 per person annually in the healthy working adults who receive influenza vaccination.[7]

Before the outbreak of 2009 H1N1, a small number of hospitals and facilities required mandatory influenza vaccine among HCWs:

> *Within the US, only two groups of hospitals - Virginia Mason in Seattle and BJC HealthCare in St. Louis are making their employees to get vaccination against flu, if not the HCWs may face dismissal* [8]

The Virginia Mason Medical Center's (Seattle) new policy evolved from a 2004 workshop that aimed at improving influenza immunization rates of HCWs. To improve influenza vaccination among HCWs, VMMC's made vaccination a condition of employment. [9, 10] For the year 2005–06, this center launched a mandatory influenza vaccination program for all the HCWs. Those workers who refused to take the flu vaccination due to medical or religious reasons must follow stringent infection-control measures, including wearing a mask while on duty. According to the hospital, 98% of those targeted received their influenza vaccination during the year 2006 and 99% for the year 2007 [11]. Before this went into effect, coverage rates at VMMC were about 30–50% [12]

Though VMMC mandated influenza vaccination, the facility initially met with resistance from the nurses. The nurses at VMMC with the help of the Washington Nurses Association were successful in having the individual mandate for vaccination repealed but one cannot argue the effectiveness of the program at boosting HCW influenza vaccination rates. [10, 13]

Barnes-Jewish Hospital, in St. Louis, requires all employees to get flu shots or face dismissal. Nearly 26 000 employees are vaccinated each year; last year 8 workers were let go because

they refused to be vaccinated. [14] In 2008, vaccination was made a condition of employment for all employees at BJC HealthCare - large Midwestern health care organization as the influenza vaccination rates within the organization remained below expected. Medical or religious exemptions could be requested. Predetermined medical contraindications include hypersensitivity to eggs, prior hypersensitivity reaction to influenza vaccine and history of Guillan-Barré syndrome. Medical exemption requests were reviewed by occupational health nurses and their medical directors. Employees who were neither vaccinated nor exempted by 15 December 2008 were not scheduled for work. Employees still not vaccinated or exempt by 15 January 2009 were terminated. 98% of active employees were vaccinated and 2% were not vaccinated due to various reasons which also lead to the termination from the job. [15]

Other health care facilities, and hospitals in the US, are standing by to take a proactive step for those who fail to get vaccinated. Examples: The New York State Health Department is requiring all hospital health care workers who come in direct contact with the patient to get vaccinated for seasonal influenza as well as H1N1 and those HCWs who decline will take duties that do not involve patient contact and could face termination. [14]

In another scenario, MedStar, the - largest private health care system in Washington, DC, mandated vaccination to all of its workers whether or not the HCWs come in direct contact with the patient. In some cases, work termination occurred for those who refused to take the vaccination. [14]

Previous studies reveal that institutional influenza outbreaks can lead to serious implications such as infection of otherwise healthy patients who are at risk of contracting influenza; staff shortages can result and increased costs may be incurred. [16]

Case Studies on institutional influenza outbreaks:

a) Oklahoma City Veterans' Hospital (1957) - Asian influenza pandemic infected 39 % of patients on the neurology ward; all but one of the physicians on the ward was bedridden.

b) Winnipeg hospital, the strain caused a 70 % increase in absenteeism during a two-week period and cost approximately $24,500 in excess sick leave.

c) New York Hospital - New York City, 62 % of unvaccinated staff contracted influenza[16]

Studies in five large health care facilities revealed that total patient mortality was significantly lower in those sites where HCWs were routinely vaccinated when compared to sites where routine vaccination was not offered to HCWs. [17, 18, 19]

Mandating Healthcare Worker Influenza Vaccination:

When mandating individual vaccination among HCWs, there are other issues such as legal disputes between employees and institutions. [10] Within US, 15 states already regulate HCW vaccination in Long Term Care Facilities (LTCF) and 4 require that HCWs be vaccinated, unless religious, philosophical or medical contraindications exist. [11].

Vaccination rates and Absenteeism among HCWs who get influenza vaccination or not:

HCWs in 20 long-term elderly-care hospitals were randomly offered or not offered influenza vaccine. 50% of the HCW's were vaccinated and then compared with the unvaccinated HCWs. This study identified laboratory-confirmed influenza in 20% of unvaccinated HCWs in long-term care facilities (LTCF) during one flu season [27]

An important mathematical model by Van den et al [26] uses a stochastic transmission model where all individuals in the model, whether patient, HCW, or visitor are equally infectious or susceptible. In addition, all individuals from the same group are assumed to have similar contact probabilities. This model demonstrated a strong linear relationship between increased uptake of influenza vaccine among HCW and decreased influenza attack rates among nursing home patients. This model also predicts that if all HCWs in a facility were vaccinated, approximately 60% of influenza infections among patients would be prevented. [26]

3 studies LaVela et al, Potter et al and Talbot et al [2, 17, 18] revealed that the vaccination rates among the HCWs within the Health care Facilities would prevent the death rate among patients. In two separate studies in geriatric long-term care facilities, total patient mortality was significantly lower in those sites where HCWs were routinely vaccinated when compared to sites where routine vaccination was not offered to HCWs (10% vs. 17% and 14% vs. 22%). [18]

Wilde et al [19] predicted that influenza vaccine is effective in preventing infection and may help to reduce cumulative days absent from work during the influenza epidemic. Carman et al [11] conducted the trial on residents by splitting into two groups: vaccine and no vaccine, which also predicted that vaccination would prevent the mortality in the patients. During nosocomial influenza outbreaks in acute care and geriatric facilities the median Patient mortality rates have been reported to be 16%, and as high as 33-60% in transplant or intensive care units. [11]

Each episode of nosocomial influenza in1993 was estimated to cost over US $7500 which are 10 times higher than estimated costs of vaccinating its HCWs. [11]

HCW attitudes:

HCW are insufficiently vaccinated even though CDC recommends annual influenza vaccination, due to misperception of influenza vaccination, its risks, the role HCW play in its transmission, and a lack (or perceived lack) of accessible free vaccine[20]. Studies by LaVela, et al [2] reveal that 69% of HCWs felt that taking influenza vaccine would decrease transmission to patients, 27% believed that there would be some reduction of transmission and 4% reported that it was irrelevant.

Allocation and rationing of limited health resources are conflicting ethical issues related to mandatory vaccination during an influenza pandemic. HCWs professional versus family responsibilities, staff absenteeism and workforce issues, risk to HCWs personal safety, restrictions of personal liberties during quarantine, are others [21]

HCWs avoid vaccination assuming that they may fall sick or consider the vaccine to be ineffective. [22] Older age, previous vaccination against influenza, and contact with hospitalized patients are the most common factors often associated with better compliance. Perception that the vaccine is ineffective, fear of adverse effects including prior experience of post-vaccination adverse effects, inconvenience due to insufficient time for vaccination and dislike of injections or medication are the most common reasons associated with noncompliance.

The ethical obligation to cause no harm to others—in this context, not to transmit influenza—outweighs the relatively minor risk of adverse effects from the influenza vaccination. [9]

Adverse Events:

Serious adverse events as defined by Food and Drug Administration are "those resulting in death, life-threatening illness, hospitalization, prolongation of hospitalization, persistent or significant disability, or congenital anomaly" [21 CFR Part 600.80].

The published literature suggests that up to 45% of HCWs are afraid that they will get influenza from the vaccine. There is no scientific evidence to support this fear since the influenza vaccine contains inactivated virus that is not infectious. Up to 37% of HCWs worry about developing severe side effects or Guillain-Barre syndrome (GBS). A double-blind, placebo-controlled study suggested that the side effects of the split-virus vaccine and placebo were identical except that the vaccine was more likely to produce soreness at the injection site [23].

Normally, about 1 in 100,000 people per year will develop GBS, a rare disorder characterized by fever, nerve damage, body's immune system attacks part of the peripheral nervous system resulting in muscle weakness and sometimes paralysis. It is thought that GBS may be triggered by an infection. The infection that most commonly precedes GBS is caused by a bacterium called *Campylobacter jejuni*. Other respiratory or intestinal illnesses and other triggers may also precede an episode of GBS. [24]

In cases where the patient is totally paralyzed to the extent muscles cannot be used at all, the disorder is considered to be life-threatening and indicates medical emergency. However, most patients even recover from the most severe cases of GBS. Some continue to have a certain degree of weakness. In 1976, vaccination with the swine flu vaccine was associated with an attack of GBS. Several studies have been done to evaluate if other flu vaccines since 1976 were associated with GBS. Only one of those studies showed an association. [24]

Mandating influenza vaccination would raise liability issues such as should an HCW experience a serious, albeit rare, side effect, such as GBS or an anaphylactic reaction to the egg component of the vaccine.[22]

Vaccine Shortage:

Some health care facilities that mandated the influenza vaccination could not provide proper vaccination to the HCWs for varying reasons:

- New York State mandated flu vaccination for HCWs but rescinded the requirement, citing shortages of H1N1 vaccine. [25]

- The University of Iowa Hospitals and Clinics, with 6300 workers, also discontinued their mandate for vaccination when Service Employees International Union (SEIU) won an arbitration hearing. [25]

- Cook County Health and Hospitals System - Chicago mandated seasonal and pandemic flu vaccination for 11,000 employees to be effective October 13, but delayed the H1N1 vaccine requirement to December 1. [25]

- Health Corporation of America mandated vaccination for 120,000 employees, but delayed the October 1 deadline because of supply delays. [25]

Strategies to improve Vaccination rates:

Understanding the barriers would help in developing strategies to improve vaccination. The fear of adverse reactions is the prime barrier. Awareness about the incidence of possible reactions can result in better vaccination rates. [20]

Current recommendation of CDC includes:

1. Publicity and educating HCW's about the benefits of influenza vaccination [5].
2. Making the vaccine free and easy to obtain for all HCWs [5].
3. Providing feedback of vaccination rates [5].
4. Obtaining a signed declination forms from the HCWs who refuse the vaccination [5].
5. Using the level of vaccination coverage as a measure of patient safety and quality of care [5].
6. Use of standing orders programs [5].

The CDC developed universal precaution guidelines to address concerns regarding Influenza transmission in health care settings. Universal precautions include the use of barrier techniques (gloves, gowns, and masks), appropriate use of disinfection and sterilization procedures.

Alternatives to mandating vaccination:

A multifaceted approach that mandates education regarding the potential health consequences for patients and the diagnosis, treatment, and mode of transmission of influenza are the key measures recommended by the CDC and the Society for Healthcare Epidemiology of America [1].Vaccinations for HCWs should be made convenient by offering them once a year, at no cost, and at the worksite during all shifts [1].

The CDC recommendations strive to balance patient's rights with the rights of HCWs while attempting to decrease influenza transmission in health care settings. Any increase in vaccination of HCWs will be beneficial to patients in nursing homes as there is a direct relationship between HCWs vaccination, patient protection and the lack of any herd immunity. However, 100% vaccination in HCWs cannot guarantee the influenza outbreaks which occur occasionally in nursing homes. [26]

Poland et al. [7] opined that it is the ethical and moral duty of HCWs and health care facilities to protect vulnerable patients from cross-transmission and contagious diseases. [7] Benefits to HCW's include decreased illness leading to reduced absenteeism, reduced medical visits and reduced antibiotic use. Benefits to patients are greater when compared to that of vaccinated HCWs. [16]

CONCLUSION:

Carmen et al [27] clearly explains the need to mandate influenza vaccination among HCWs. The implications of low HCW vaccination rates on patient care may determine the need for, and the type of strategies that may lead to enhanced vaccine acceptance in this population.

After reviewing the literature articles, these are few steps the Health care facilities have to consider in order to limit the transmission of influenza virus from HCWs to patients, make the vaccination mandate and improve the vaccination rates among HCWs.

1. The educational component of the campaign is the most important and should be designed to timely address and respond to HCWs fears, misperceptions, misunderstandings, opinions and beliefs about the flu and vaccination.

2. The educational campaign includes information on the role of HCW in transmission of flu, the benefits of vaccination – to protect the worker and patient, the side effects and risks of vaccination, and the HCWs professional and ethical obligations to the patient.

3. An effective education program may be accomplished through staff in-services, conferences, written pamphlets, and educational films, with targeted audiences at both group and individual levels.

4. Any worker not willing to make the commitment, other than for religious or medical reasons, should be asked to give a written reason why he or she is not willing to participate in the form of a declination statement.

5. The education program should then be geared to target those non-committed employees to facilitate their understanding of the importance of the shot and provide the necessary education to address and reconcile their fears, misperceptions, and doubts, as feasible.

6. Making the vaccine free and easy to obtain for all HCWs in the sense that actual vaccination program should be administered free of charge at convenient and readily

accessible locations, utilizing mobile carts and "walk-in" clinics, as feasible, and at reasonable times of the day.

7. A program planning has to be done in order to improve delivery of influenza vaccine to patients and staff by reviewing the literature and conducting the workshops.

8. Promotional ads must be placed whenever necessary in order to make the flu vaccine awareness.

9. Adequate notice, effectively communicating information about the vaccination program through various media outlets, such as individual invitations to participate via enclosure with pay slip, e-mail messages, intranet postings, memoranda, and posters in well-traveled areas. The notice should be timely and provide a schedule of convenient times (all shifts) and locations so HCWs can make their plans accordingly.

The responsibility of the HCWs is to decrease risk to patients in the health care environment, but they are not obliged to forfeit personal rights. HCWs should consider the patient risk and get vaccinated as they are on the front lines of fighting the seasonal flu and H1N1 flu. By doing so, they not only protect themselves from exposure to flu, but also prevent the spread of flu to the patients they are treating for. By integrating a survey of HCW beliefs and attitudes as a routine and integral part of a campaign, the answers collected can be used to refine the upcoming season's campaign [20].

To assess whether an influenza-infected HCW poses significant risk, the four factor analysis proposed by American Medical Association (AMA) which includes "*nature, duration, severity and probability of transmission"* can be used.

All HCWs are bound to their patients by the ethical principle of "*nonmaleficence"* & "*beneficence"*. *Nonmaleficence* requires HCWs know that they do no harm to the patients, their influenza status and should maintain and monitor their own fitness for medical practice. *Beneficence* requires HCWs to help, do good, or otherwise improve the health status of the patient.

In circumstances where there is a possibility of transmission of influenza, the infected HCWs must weigh potential risks and benefits to the patient as well as available alternatives. Though the scientific evidence and ethical principals have clearly shown the right thing to do to ensure patient's safety, it is the duty of the legislative leaders to take appropriate decision.

The importance of designing an effective, free flu vaccination program for its HCWs that provides timely notice, pertinent and responsive education about the flu and flu vaccine is necessary.

After a thorough review of the literature I infer that:

- Immunizing HCWs can result in a safer environment for HCWs as well as patients and decreased absenteeism

- By carefully designing effective campaigns which may bring in the change in attitudes of HCWs.

- Till to date there is no study designed to answer the question "*what the best way to get HCW immunized*".

- The results of small clinical trials on the effects of HCW vaccination may be inaccurate because of large variation in attack rates. In order to overcome this, the future studies should be designed on a very large population if they are to provide consistent estimates of the amount of protection that HCW vaccination provides to patients at risk.

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