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Increasing Annual Influenza Vaccination Rates through Primary Prevention Strategies Among Health Care Workers in a Psychiatric Long-term Care Facility: An Evidence-based Approach

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Abstract

Background: Influenza is a highly infectious, serious respiratory virus that causes almost 226,000 hospitalizations and averages 36,000 deaths annually in the United States (U.S.). Those at the highest risk for influenza-related complications and death include the elderly, the very young, those with chronic disease, and people with weakened immune systems. Since 1981, the Centers for Disease Control and Prevention's (CDC) Advisory Committee for Immunization Practices (ACIP) have recommended that all medically eligible healthcare workers (HCWs) receive an influenza vaccination annually. Despite recommendations, many HCWs decline the seasonal influenza vaccination putting themselves and their patients at risk. The CDC reports that U.S. vaccination rates for HCWs in long-term care settings averaged just 69.2% for the 2015-2016 flu season. Healthy People 2020 has set a goal of 90% compliance among eligible HCWs by 2020.

Methods: This research translation project examined the effects of evidence-based primary prevention strategies of personalized education and mentoring on increasing vaccine compliance among 105 HCWs in a long-term forensic psychiatric facility. A synthesis of evidence-based practice interventions and associated factors to improve flu vaccine uptake is included, discussing barriers and facilitators to implementation in this special population and unique setting.

Results: Although individualized education and mentoring are recommended evidence-based practice interventions to increase vaccine rates in HCWs they resulted in only a 3% increase in uptake, well below the 10% goal.

Conclusions: Mitigating factors, including personal belief systems, cultural factors, and health literacy continue to impact vaccination rates negatively and are contributing factors to low influenza vaccine rates especially among unlicensed, assistive HCWs.

Keywords: influenza, health care workers, vaccination, compliance, primary prevention

Increasing Annual Influenza Vaccination Rates in Health Care Workers through Primary Prevention Strategies in a Long-term Psychiatric Facility: An Evidence-based Approach

Introduction

Influenza (flu) is an acute, preventable, viral respiratory infection that results in nearly a quarter of a million hospitalizations and as many as 49,000 deaths annually in the United States (Marshall, Tetu-Mouradjian & Fulton, 2010; Public Health Reports, 2013). Influenza is the sixth leading cause of death among American adults and is a causative factor in one in 20 deaths in persons older than 65 years (Ottenburg, 2011). Influenza continues to be a significant national public health concern, and immunization has been found to be the most effective way to prevent the disease (Garattini & Koleva, 2011; Public Health Reports, 2013). Most complications associated with influenza occur in medically vulnerable populations including infants and children, the elderly, pregnant women, the chronically ill, and the immunocompromised (Garrattini & Koleva, 2011).

Patients in psychiatric facilities are also at increased risk for complications of influenza. DeHert, Correll, Bobes, Cetkovich-Bakmas, Cohen et al. (2011) assert that patients with severe mental illness, as “compared to individuals in the general population”, are at higher risk for “viral diseases and respiratory tract disease” and have shorter lifespans “mainly due to physical illness” (p.52). DeHert et al. also state that disparities in “access to and quality of health care” exist for this population and are a contributing factor to morbidity and mortality (2011, p. 52).

The flu vaccine is highly efficacious in preventing illness when the vaccine is closely matched to circulating viral strains and remains partially effective at preventing infection, minimizing symptoms, and shortening the duration of illness even if a discrepancy between the vaccine and prevalent strains exists (Talbot, Babcock, Caplan, Cotton, Maragakis, et al., 2010).

Meanwhile, current vaccine rates in long-term care employees average less than 70% annually in the U.S. (Black et al., 2016), Healthy People 2020 has set a goal of 90% annual vaccine uptake in health care workers (HCWs) by 2020 (Office of Disease Prevention and Health Promotion [ODPHP], 2016). The CDC's Advisory Committee for Immunization Practices (ACIP) has recommended that 100% of medically eligible HCWs receive the annual influenza vaccine (CDC, 2008).

Background

Despite the efficacy and demonstrated safety of the influenza vaccine, many eligible HCWs exhibit vaccine hesitancy, and subsequently, decline the annual immunization. HCWs who decline the vaccine put themselves, their families, their patients, and their community at increased risk for influenza infection, sometimes with devastating results.

The National Business Group on Health has reported that the cost to businesses, including health care facilities, in the United States from medical expenses directly related to influenza infections average over 10 billion dollars annually (Public Health Reports, 2013). Lost earnings to businesses due to decreased productivity from the flu added an average of 16 billion dollars per year to costs, which constitutes a significant burden to the economy (Public Health Reports, 2013). Absenteeism from influenza infections in HCWs exacerbates staffing shortages in health care institutions already struggling with a nationwide nursing shortage. HCWs who come to work with the flu virus infection may inadvertently expose their colleagues and their patients to the disease as the virus is shed prior to the onset of symptoms (Talbot et al., 2010).

The Joint Commission's (TJC) National Patient Safety Goals (#7) includes "prevention of health care associated infections" as an important safety goal and tracks compliance rates of HCWs influenza vaccines as part of the accreditation process for member organizations to

address this gap in practice (TJC, 2016, p.14). TJC's Standard IC 02.04.01 addresses the need for long-term care and hospital settings to establish influenza vaccination programs for staff and licensed independent practitioners with a goal of measuring and improving vaccine rates (TJC, 2011). The Institute of Medicine (IOM) also recognizes lapses in patient safety (e.g. preventable nosocomial infection, including influenza) as a gap in healthcare quality in its seminal works "To Err is Human" and "Crossing the Quality Chasm" (IOM 1999; IOM, 2001).

The National Vaccine Advisory Committee (NVAC) has recommended that all health care facilities implement a comprehensive and multifaceted influenza prevention program (Public Health Reports, 2013). Multiple studies have examined the relationship between vaccine behaviors in HCWs, factors related to HCWs refusals, and the use of evidence-based practice (EBP) interventions to increase rates. Programs including free, flexible, vaccine access; promotions; prizes; contests; measurement and feedback; education; e-mails; mandates, and mentoring have been reported in the literature with varying degrees of success. The CDC recommends educational influenza campaigns, role modeling, improved access, measurement and feedback, as the interventions most likely to positively impact flu vaccine uptake in HCWs (Public Health Reports, 2013).

Problem Statement

The risk of spreading the influenza virus infection to medically vulnerable others, including psychiatric patients, is evidenced by the declination of influenza vaccine by HCWs. This lack of compliance with recommended public health guidelines results from low health literacy, health concerns, misinformation, misconceptions, inconvenience, needle phobia, and personal or religious belief systems.

The implementation of EBP primary prevention modalities as part of this quality improvement initiative were utilized to address these concerns and provided or facilitated by this doctoral student. Individual, personalized education and mentoring sessions were conducted and tailored to meet the specific needs of each HCW. Free, flexible on-site access to the vaccine was provided by the institution, as well as mentoring and endorsement of primary prevention behaviors by this author as part of the project. These EBP interventions have been demonstrated in the literature to improve influenza vaccine acceptance among HCWs (Abramson et al., 2010; Durando et al., 2016; Hollmeyer et al., 2012; Lam et al., 2010; Marshall et al., 2010, Public Health Reports, 2013; Talbot et al., 2010).

Organizational Gap Analysis of Project Site

The site chosen for this scholarly project has averaged an influenza vaccine rate of 66% among eligible healthcare workers over the past three flu seasons. As of May 4th, 2017, the end of the most recent flu season, 77% of employees received the annual vaccine. Particularly concerning, is the rate of only about 50% vaccine uptake among those in the Therapist Assistant (TA) role, a direct care position akin to an orderly or care attendant in an acute care medical facility. Many of the TAs have only a high school education and little to no medical education or training. This is in sharp contrast to those with advanced medical education such as physicians, nurse practitioners, pharmacists, and physical therapists who exhibit over 93% vaccine compliance at the facility.

As a State facility, the policy for influenza vaccines at the project site is dictated by State mental health laws based upon the State Department of Health (DOH) regulations. The regulations require that any health care facility that is licensed under Public Health Law, must abide by the regulations of the State Sanitary Code. The code states that all HCWs, as defined

by the regulation, who are unvaccinated against influenza during the current flu season must wear a surgical or procedure mask while in areas where patients or residents are usually present, and when influenza infection has been deemed prevalent or widespread in the State by the Commissioner of the DOH.

Educational interventions about influenza are limited at project site facility. The Infection Control Department consists of two infection control nurses who are charged with educating the approximately 900 inpatient and outpatient employees as well as 400 patients about influenza infection and the influenza vaccine. These tasks are in addition to the myriad of other infection control duties at the facility that include both employee health and patient care responsibilities.

Currently, the educational program for the facility consists of a one-page State Office of Mental Health generated consent (or declination) hand out and the Vaccine Information Statement from the CDC (2017c); (Appendix A). These forms are distributed to employees as they attend annual flu vaccine clinics to receive or decline the vaccine. Many HCWs do not choose to read the information provided before signing the form. Those who decline the vaccine receive no further formal information or training about the flu. Additionally, there is no training for proper mask procedure and many HCWs have been seen throughout the facility wearing the mask inappropriately or incorrectly.

Review of the Literature

A thorough review of the literature was performed using the online databases of the Cumulative Index of Allied Health Literature (CINAHL), PubMed, WorldCat, and the Cochrane libraries. Search criteria included full text, peer reviewed articles, published in English from 2008 to the present, as well as some older historical sources. The decision to include articles and guidelines greater than five years of age was made as more recent research has not resulted in

any significant changes to recommendations regarding influenza vaccines in HCWs and the inclusion of additional research would result in a more robust literature review. Manual and Boolean searches of Medical Search Headings (MeSH) terms included influenza/flu, health care workers/personnel, primary prevention, immunization/vaccination, vaccine hesitancy, attitudes/beliefs, health literacy, and long-term care, using various combinations.

Approximately 30 articles were reviewed from the online databases and 24 were deemed appropriate for the project. Searches resulting in "abstract only" and articles suggesting EBP interventions applicable solely to acute care facilities and unable to be generalized to long-term care settings were excluded. Duplicate studies encountered via searching multiple search engines were counted only once.

Randomized control trials, systematic reviews, and meta-analyses were preferred for the literature review; however, cross sectional, retrospective review, and prospective studies were included if appropriate to the setting and overall objectives of the project. All articles retrieved were evaluated using the Johns Hopkins Nursing Evidence-based Practice Rating Scale (Newhouse, Dearholt, Poe, Pugh & White, 2005). Preference was assigned to articles graded at Levels I-III (of V) for strength of evidence (I= strongest; V= weakest), and quality ratings of A or B (high or good), however some clinical practice guidelines formulated by nationally known expert panels and based on research evidence that were rated level IV, were also included. Studies identified as having possible major flaws or rated of low quality—i.e. C rating (as interpreted by this writer using the Johns Hopkins Scale) were excluded from consideration and were not included in the final literature review (Newhouse et al., 2005). Additionally, guidelines from the CDC, ACIP, NVAC, TJC, The Healthcare Infection Control Practices Advisory Committee (HICPAC), The Society of Healthcare Epidemiology (SHEA), The Agency for

Healthcare Research and Quality (AHRQ), the World Health Organization (WHO), and Healthy People 2020 (HP2020) were reviewed to increase this writer's understanding of the standards of care and the recommendations for influenza vaccination in HCWs for this scholarly project.

Ultimately, two randomized control trials (evidence/quality levels IA), four systematic reviews (evidence/quality levels II A/B), one meta-analysis (evidence/quality level IA), four cross sectional studies (evidence/quality levels II A/B), three retrospective reviews (evidence/quality levels IIB), nine national and international guidelines (evidence/quality levels IVA), and one editorial perspective/commentary (evidence level IV B) from the aforementioned online databases were used in the development and execution of this project.

The literature review revealed several modalities for the implementation of EBP interventions to increase influenza vaccine rates among HCWs in long-term care settings (Abramson et al., 2010; Durando et al., 2016; Hollmeyer et al., 2012; Lam et al., 2010; Marshall et al., 2010, Public Health Reports, 2013; Talbot et al., 2010). Although the literature described some EBP as being more beneficial than others, all the articles reviewed endorsed the opinion that any EBP approach to increasing influenza vaccine uptake in HCWs is better than none (Abramson et al., 2010; Durando et al., 2016; Hollmeyer et al., 2012; Lam et al., 2010; Marshall at al., 2010; Public Health Reports, 2013; Talbot et al., 2010).

Generalized Versus Individualized Educational Programs

Some studies sanctioned comprehensive, general, multifaceted influenza programs as being the most beneficial approach to improving vaccine uptake (Hollmeyer et al., 2012; Lam et al., 2010; Public Health Reports, 2013). In contrast, others suggested a more individualized approach that addressed the specific needs, situations, and concerns of unimmunized HCW who exhibit vaccine hesitancy (Abramson et al., 2010; Durando et al., 2016; Kim & Real, 2016; Marshall et

al., 2010). All the studies reviewed above recommended the primary prevention strategy of education as a part of any comprehensive influenza vaccine program.

Free and Flexible Vaccine Access

All the articles that examined access to care barriers promoted interventions to increase vaccine uptake that included free, easy, flexible vaccine access through on-site vaccination clinics, and/or the use of mobile vaccine carts and the availability of the vaccine on all work shifts (Abramson, et al., 2010; Durando et al., 2016; Hollmeyer et al., 2012; Lam et al., 2010; Marshall et al., 2010; Public Health Reports, 2013). Immunization has long been a mainstay of primary prevention practices and the identified strategies have proven conducive in decreasing employee opposition related to cost or accessibility issues in obtaining the influenza vaccine.

Mandatory Versus Voluntary Vaccination Policies

Mandatory vaccination, including vaccination as a condition of employment or continued professional privileging, is cited as the EBP intervention most helpful in improving vaccine rates in HCWs (Hollmeyer et al., 2012; Lam et al., 2010; Marshall et al., 2010; Talbot et al., 2010). "Soft" mandating, achieved through required mask wearing as an alternative to the vaccine is noted to be less effective than strict mandating as a strategy to increase flu vaccine uptake in HCWs (Marshall et al., 2010; Talbot et al., 2010). The CDC (2017d) reports that in the early 2014-15 influenza season vaccine coverage was almost doubled to 85.8% in HCWs whose organizations required that they be vaccinated, compared to those whose workplace did not have any mandated plan or endorsement for flu vaccination (43.4%). Surprisingly, the State Nurses Association's Influenza Immunization Position Statement released in 2012 endorsed voluntary vaccination only, citing the uncertainty of a good match between the vaccine and circulating influenza strains, and the "inappropriate and ineffective" use of face masks.

Administrative Support, Mentoring, and Role Modeling

Behavioral interventions, through high visibility and role modeling by the administration and health care professionals, one on one mentoring, assignment of a "champion" and endorsement or recommendation for the influenza vaccine by a health care provider have been reported to be moderately or somewhat effective in improving HCWs immunization uptake (Abramson, 2010; Lam et al., 2010; Marshall et al., 2010). NVAC (2012) reported that "vaccination of senior medical staff or opinion leaders has been associated with higher vaccination acceptance among staff (p. 8).

Management Mentors website defines mentoring as "a professional relationship in which an experienced person (the mentor) assists another (the 'mentee') in developing specific skills and knowledge that will enhance the less-experienced person's professional and personal growth" (2017, para. 1). Some of the functions of a mentor, as described by Management Mentors, are providing a safe milieu for learning with a goal of personal or professional growth that allows for risk taking, sharing resources, and educating about specific topics (2017, para. 2).

Promotional Campaigns, Competitions, and Related Interventions

Hollmeyer et al. (2012) reported that promotional programs that included education modules, competitions between facility units with feedback and prizes, and incentives for vaccination were shown to be "complementary" (p. 616) in enhancing immunization in HCWs and are also recommended by the CDC (Public Health Reports, 2013), but these interventions remained less likely to have increased vaccine uptake than mandatory vaccination and mentoring (Hollmeyer, 2012; Kim & Real, 2016, Lam et al., 2010). Reminders (via emails, postcards, signage, and banners), have also been shown to be somewhat helpful in increasing vaccine uptake among HCWs but were minimally effective unless combined with other EBP

recommendations (Hollmeyer, 2012; Kim & Real, 2016, Lam et al., 2010; Public Health Reports, 2013).

Education, Without Other Intervention

Generalized mass education activities and distribution of educational materials, not delivered in conjunction with other EBP interventions, have been identified as the strategies least likely to impact an individual HCW's decision to accept influenza vaccine (Lam et al., 2010; Marshall et al., 2010). While education is recommended as a mainstay of all influenza campaigns, comprehensive, multifaceted programs that include multiple intervention modalities are preferred over education alone (Abramson et al., 2010; Durando et al., 2016; Hollmeyer et al., 2012; Lam et al., 2010; Marshall at al., 2010; Public Health Reports, 2013; Talbot et al., 2010).

Evidence-Based Practice: Verification of Chosen Option

Interventional components gleaned from the literature review research were stratified by the strength of evidence, applicability, and feasibility to the practice site and population. Identified EBP modalities were compared to current and past practices at the project site, as well as their past successes in increasing vaccine uptake.

As all the interventions resulted in some positive effect of improving vaccine compliance--including those already implemented at the facility (free, flexible access, administrative support, educational materials and "soft" mandating), preference was assigned to interventions not previously attempted. The identified interventions were then reviewed for facilitators and barriers to implementation, such as cost, the number of personnel required, time, and acceptability to the facility to determine the most appropriate course of action to improve vaccine uptake among vaccine hesitant HCWs.

The intervention shown to the most helpful in the literature-- strict mandating-- as a condition of employment, reappointment, or continued credentialing was unable to be implemented due to prior labor union challenges in 2009 (Ottenburg et al., 2011). At the project site the lowest vaccine compliance rates over the past few years (~50%) were noted to be among TAs who have limited formal education (high school diploma) and little medical education and training. This student determined that efforts to increase uptake in this population would be the most helpful in moving facility-wide compliance with vaccination towards the HP 2020 goal of 90%. Thus, the interventions of individualized mentoring, private, personalized education sessions, and endorsement of primary prevention measures-- without direct, specific recommendation for the vaccine (due to facility constraints regarding protected health information of employees and organizational liability concerns) were selected for this scholarly project as these interventions could be adapted to address the specific concerns and needs not only for the TA's, but for all employees.

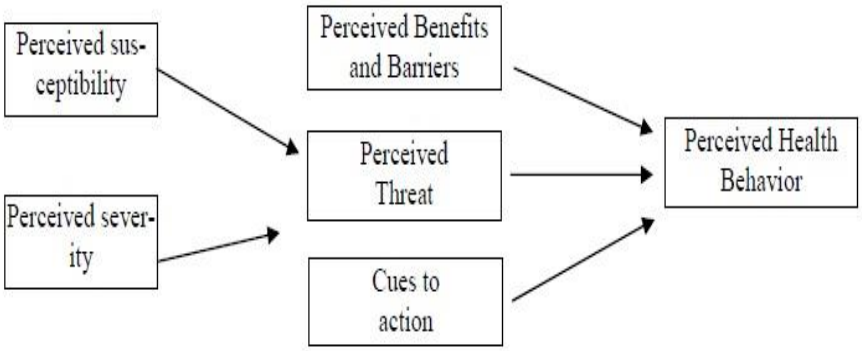
These interventions were chosen as they were found to be at least moderately helpful in improving vaccine rates in all HCWs, according to the evidence. The interventions were also acceptable to the administration and could be easily and inexpensively implemented at the facility (Abramson, 2010; Lam et al., 2010; Marshall et al, 2010).

Theoretical Framework

The Health Belief Model (HBM) has been chosen as the theoretical framework for this doctoral project. The HBM helps to explain and predict health behaviors based on an individual's attitudes and health beliefs. It was developed in the 1950's by three social psychologists to explain why people did not engage in preventive care or screening for infectious diseases including influenza (Rosenstock, 1974). The theory contains five key constructs:

perceived susceptibility, perceived benefits, perceived barriers, perceived severity, and internal or external cues to action. A sixth construct, self-efficacy i.e., an individual's confidence in their own capability to make changes in their behaviors, was later added by Rosenstock in 1988. The schematic below illustrates the HBM conceptual framework.

Figure 1. The Health Belief Model Flow Chart



Rosenstock (1974) and his partners theorized that for an individual to act to change negative health behaviors, one would need to perceive that one was personally susceptible, that there would be at least a moderately serious impact on one's life, and that by changing one's behaviors there would be a benefit to oneself. The individual then contrasts these three beliefs against perceived barriers to changing the negative health behavior as well as their own ability to make the necessary changes. The "cues to action", or the impetus to change the behavior can be multifactorial and may be triggered by either an individual's internal motivations, or occur due to an external stimulus, such as health care provider recommendation or media promotion (Rosenstock, 1974; Tsutsui, Bension, & Shahrabani, 2012).

Many HCWs reportedly do not view the flu as a serious illness, therefore, they perceive little benefit from receiving the influenza vaccine (Durando et al., 2016). Recently, vaccines have been portrayed negatively in the media as being harmful and possibly increasing risk for certain conditions such as Guillain-Barre´ syndrome and autism, and as a cause of early miscarriage (National Broadcasting Company [NBC], 2017). The current environment of herd immunity in America has decreased the risk for certain infectious diseases that were once commonplace. This has allowed many citizens to become complacent about immunization and has decreased their perceived risk of susceptibility to infection, resulting in increased incidences of vaccine hesitancy and declination.

A study by Durando et al. (2016) that examined HCWs beliefs and attitudes about the influenza vaccine revealed that concerns about vaccine efficacy, adverse events, and the belief that flu is not a serious illness were identified most frequently as being the reasons HCWs decline the immunization. Durando et al. (2016) also reported that self-protection and protection of family members were the top motivators for vaccine uptake among HCWs in the study, while patient protection and organizational and governmental endorsement were shown to be less effective.

Goals, Objectives & Outcomes

The overreaching goal of this proposed project was to improve HCWs compliance with the annual influenza vaccine in a long-term forensic psychiatric facility via the use of EBP primary prevention interventions of personalized education, mentoring, and endorsement of modalities such as immunization. Ideally, the goal was to move the facility towards meeting the HP2020 goal of at least 90% influenza vaccine compliance among HCWs in all health care settings by the year 2020 (ODPHP, 2016). Additionally, lessons learned, and information gleaned from the

project would also be used help to guide future influenza vaccine campaigns. Initial anticipated outcomes for this project included:

- A 10% increase, minimally, in HCWs vaccine rates, facility-wide, as compared to the previous three year's campaigns; prior to the implementation of the EBP practice interventions for the same period (October 1, 2016- February 28, 2017).
- An associated reduction in costs to the facility for overtime wage expenses for flu absenteeism, as well as those costs related to the purchase of personal protective equipment (PPE), e.g. procedure masks required for vaccine decliners, and droplet precaution equipment used in the care of flu-infected patients. It was hoped that these savings would be measured by comparing past costs from the 2016-17 influenza season as compared to the actual 2017-18 costs for these items. Unfortunately, these anticipated saving were unable to be quantified as the fiscal year budget runs from April 1st through March 31st, while the influenza season begins in September and runs through May, causing overlap in the budget which resulted in equivocal figures as expenses are not broken down by month.

In addition to the benefits of increased influenza immunization as noted above, another goal of this project was to initiate process changes to the existing influenza program that could be continued in subsequent influenza campaigns to maintain high rates of vaccine compliance. These included a plan to implement the following EBP interventions:

- This DNP student identified employees who were interested in and volunteered to receive additional information/education about influenza and the influenza vaccine by mass emails, TV banners, signage, and by offering an education 0recruitment table at various neutral locations within the facility during late

October and early November 2017. Signage about the project and the CDC Influenza Vaccine Information sheets were available at the table as handouts.

- The DNP student supplied participants with paper copies of informed consent prior to implementation of the education and mentoring sessions. As the project did not constitute research as defined by the Centers for Medicare and Medicaid Services (CMS), signatures were not required per the facility Institutional Review Board nor the University of Massachusetts, Amherst Institutional Review Board.
- This DNP student then met individually, at a mutually agreed upon time and private place, with HCWs who have self-identified as desiring additional information about influenza and the influenza vaccine between the period of October 26th, 2017 and February 28th, 2018.
- The DNP student conducted brief educational sessions, lasting 15-20 minutes, tailored to the specific questions and needs of the employee, offered endorsement of (but not specific recommendation for) primary prevention modalities which may include the influenza vaccination, and acted as a mentor and facilitator for timely vaccination, if desired and requested by the employee. Immunizations were administered by the facility's Infection Control Department for willing HCWs during the period October 2017 - May 2018.

Project Design

This scholarly project was conducted as a quality improvement (QI) initiative**.** The AHRQ (2013) describes quality improvement as a scaffold that can be employed methodically to improve the provision of health care. Although various processes for QI exist, they all share the same qualities. Processes must improve, be measurable, and be able to be analyzed and

controlled, to be effective. Quality improvement must be systems based and include the individuals actually invested in the issue. Quality improvement never stops. If the attempt at QI is not successful, no blame is placed. Failure is treated as an opportunity for learning and continuing the QI process.

The project site recently adopted the Lean Six Sigma model for quality improvement programs. Prior to utilizing Lean, the Plan, Do, Check, Act (PDCA) formula for quality improvement was used. The State Office of Mental Health rules related to student projects and requests for research or projects originating from, or to be reported to external agencies precluded this project from official quality improvement initiative status at the facility. For the purposes of the organization and the State Office of Mental Health therefore, this project is deemed "student research". Despite the project consisting solely of research translation activities including the implementation of EBP interventions, measurement of their efficacy via data already collected by the facility, and comparison to previously reported data from past years, this project could not be sanctioned as QI for the facility. Neither was this project constructed as a traditional research project nor was the intent to generate new information or data.

This student and her mentor worked in conjunction with the facility's Quality Management Steering Committee (QMSC), the Lean Team, the Cabinet, and the Infection Control Department to implement the project. This project also did not qualify as an official Lean project as outlined by the State Office of Mental Health or the facility's Lean Team. Their concept of Lean requires an existing project or process which needs revision in order to streamline the process or address existing process or systems issues. Since this was considered a new venture, it was deemed by the facility that it did not meet the criteria for a Lean project, per their benchmarks. After many discussions with the QMSC, the Lean Team, and this student's mentor, a hybrid that correlated

the PDCA format to the State Office of Mental Health approved Lean design was adopted to meet the needs of the scholarly project as well as providing potential benefit to the institution (Table 1).

"Lean" is based on the Lean principle and is widely used in many types of service industry including health care. The movement towards reducing patient errors while improving health care efficiency stemmed from recommendations put forth by the Institute of Medicine in 2000 and resulted in health care organizations adopting practices developed for industry. The "Lean" philosophy was originally utilized by the automotive industry to eliminate waste and streamline production processes (Ha, McCoy, Taylor, Kirk, Fry & Modi, 2016).

The Lean principle for quality improvement follows five steps. They are: define, measure, analyze, improve, and control, also known by the acronym DMAIC. Another well-known QI methodology, the Plan-Do-Check Act (PDCA) process for QI follows similar steps (the Deming cycle) with minor variations. In PDCA, the planning stage correlates with the defining, measuring and analysis stages of Lean. The "doing" stage of PDCA is labeled the improvement stage in Lean, while the checking and acting phases of PDCA correlate with the 'controlling" phase of Lean.

The following chart demonstrates how the PDCA design correlates with the process steps of Lean's DMAIC, which formed the basis of this QI undertaking.

Table 1.

Correlation Between Plan-Do-Check-Act and the Lean Methods for Quality Improvement

PDCA	Lean
Plan	Define
	Measure
	Analyze
Do	Improve
Check	Control
Act	

Figliolino, V. (2015). Lean Six Sigma University. Retrieved from: https://leansixsigma.community/file/view/486/pdca-vs-dmaic

The Agency for Healthcare Research and Quality (AHRQ) describes PDCA as a four-step QI cycle that allows one to "implement changes, solve problems, and continuously improve processes" (AHRQ, 2018, para 1). Because PDCA is a cyclic design, continuous QI is possible. PDCA was conceptualized by W. Edwards Deming in the mid-20th century. Deming (1986) was a firm believer that management was mainly responsible for quality issues and that management-controlled systems problems, accounted for up to 85% of quality concerns. Variations in processes by employees account for the other 15% of quality issues. Deming posited that through the use of statistical measures, managers could determine the root cause of quality concerns and thereby address them.

During the planning phase, the process to be changed or improved is reviewed to ascertain strengths and weaknesses of the current plan. Possible solutions, interventions, or adaptations to existing processes are proposed. Resources needed to implement the change are also identified and readied for the next stage of the project. A plan for change is then proposed, examined, solidified, and readied for implementation during the next phase of the cycle (AHRQ, 2018).

For this endeavor the planning phase encompassed exploration and research into the causes for influenza vaccine declination among HCWs, including defining the problem. This phase also included a thorough review of the literature, in order to understand the reasons for vaccine hesitancy, the underlying science of vaccines, the immune system response, interventions for promoting vaccine compliance in HCWs, and guidelines for health care facilities pertaining to vaccine administration. During this phase a plan was envisioned for implementation of the identified interventions, and IRB approval was sought and granted to approve continuation into the next phase of the scholarly project process.

AHRQ describes the “do” phase as the time for executing the new plan changes. The identified interventions, enhancements, and improvements from the planning phase are applied to the process or project. During this phase the interventions or changes are tried out, often on a smaller scale, and assessed for fit (AHRQ, 2018).

During the “do” phase for this project, 120 employee volunteers were enrolled to participate in the teaching and mentoring sessions through multiple recruitment activities. Volunteers were then contacted by this doctoral student and a mutually agreed upon time and place was arranged for the intervention. One hundred five personalized education and mentoring sessions were conducted with the HCW volunteers by this doctoral student.

The 15-20-minute private sessions included reviewing the IRB approved informed consent with participants, followed by a review of the CDC Influenza VIS. In addition, some interesting flu facts were shared with the volunteers (Appendix B). The sessions ended with a brief discussion and question and answer (Q&A) period where the participant could safely and privately voice concerns and receive answers to their questions without fear of reprisal.

The "check" phase is a time for review and analysis of the "do" phase. It is a time to identify what worked, as well as, what did not. During this period, revisions may be made to the original plan. New information may also be revealed which may impact the plan going forward. Once the data has been collated and reviewed, and the plan revised as appropriate, it will be put into action (AHRQ, 2018).

Data analysis and evaluation of results for this scholarly endeavor took place in the "check" phase. Findings were measured, and recurrent themes collated. These are elaborated upon in the results and discussion areas of this paper. Please refer to these sections for further elaboration. Data collection was done by the project site's Infection Control Department. The de-identified numerical data was supplied to this doctoral student. This student then reviewed and recalculated the data to ensure accuracy and inter-rater reliability.

The last phase of the PDCA cycle is "act". This is the time when the original or revised plan is put into actual practice on a larger scale. Data continues to be collected and reviewed to determine if the processes are meeting QI goals. Because PDCA allows for continuous QI, the cycle continues to progress, allowing for refinement of the plan, new interventions if needed, and revision of existing processes (AHRQ, 2018).

As this was a scholarly project and not an official facility QI initiative, during the "act" phase results were shared, and recommendations made to the institution's Infection Control

Department, the Quality Management Steering Committee, the Lean Team, and Facility Administration for further consideration for inclusion in future influenza vaccine campaigns

Methods

Methods included identifying employees who desired additional education about influenza, and other primary prevention measures for the flu including the flu vaccine. Participants were offered free, confidential, personalized education sessions at a mutually agreed upon place and time. Interested participants were recruited by mass email, signage, television banners, and at manned informational tables at neutral locations during peak traffic times at the facility during late October and early November 2017. Participants were asked to provide their names and a contact phone extension in order to set up a meeting time. The participants were then contacted to set up a meeting. Prior to the start of the intervention, the volunteers were also asked to review a facility IRB approved informed consent. The consent explained that the purpose of the meeting was to provide information and also clarified that while the student is also a Nurse Practitioner at the project site, she is conducting the education and mentoring sessions as a student of the University of Massachusetts-- and not as a representative of, or health care provider for the facility.

These forms were collected, collated, and maintained in a locked cabinet in a locked office. The writer had sole access to the forms and the ability to produce said forms if required by the organization's administration.

The employee participants were met at the agreed upon time and location for a short education session. The sessions required no more than 15-20 minutes and consisted of information from the CDC's VIS form, some interesting facts about influenza, and reiterated the institution's infection control policies, such as the mask requirement for vaccine decliners. The

teaching focused on identified concerns or questions posed by the participant and was driven by the participant's needs. Teaching was provided in a fair, balanced, and factual manner to avoid coercion or paternalism, and allowed autonomy and justice for the employee participant.

Personal health history or opinion questions regarding influenza or the influenza vaccine were not sought by the student mentor. The influenza vaccine was not recommended the specifically for any employee participant and although the student endorsed primary prevention modalities for influenza prevention, participant inquiries regarding recommendation for his/herself were directed to the Infection Control Department and/or their personal health care provider for follow-up.

Informational handouts including the CDC Influenza Vaccine Information Statement (Appendix A) were provided to the employee. If the HCW desired immunization at the conclusion of the teaching/mentoring session, the doctoral student facilitated administration of same with the Infection Control nurse, or on off shifts, the Nurse Administrator on duty was contacted to provide vaccination.

Project Site and Population

The setting for this scholarly project was a 400 bed, forensic psychiatric facility in the rural northeast. The institution is a State-run, court mandated, long-term care institution that serves approximately 300 civilly confined sex offenders and 100 incarcerated prisoners diagnosed with persistent personality disorders or active, severe mental illness. Employees number approximately 900 and include medical professionals, security personnel, and ancillary staff.

The population of interest is HCWs employed in the forensic long-term care psychiatric facility. The National Quality Forum (NQF, 2017) describes HCWs as anyone providing direct care, indirect care (such as ancillary staff), students, volunteers, and contractors. The facility has

approximately 900 employees employed in professional and ancillary roles. The HCWs consist of both males and females, approximate ages range from 20-75, and are racially and ethnically diverse. They have varying levels of education ranging from high school or GED diplomas to doctorates in health or psychological disciplines. For the purposes of this project, all staff was included in the study including direct and indirect (ancillary) care providers, students, contractors, and volunteers.

Key stakeholders were involved in all phases of the project and included facility administration, Cabinet members, the Infection Control Department, the Quality Management Steering Committee, and the state level OMH Infection Control Director who maintains oversight of individual facility infection control departments and to whom outcomes are reported. Engagement of key stakeholders was essential to ensuring the success of the project.

Setting facilitators and barriers. Institutional resources that facilitated this project included a supportive and concerned administration and Cabinet, determined and dedicated Infection Control department nurses, and a motivated and progressive Quality Management Steering Committee. All the recommended EBP interventions in the literature to improve rates are reasonable and realistic to implement and entailed little cost to the facility. Costs related to vaccine procurement, staffing, and photocopying of educational materials are already provided for in the budget. Additionally, the Cabinet granted this doctoral student access to de-identified data and information regarding current and past vaccine uptake rates in HCWs at the facility, after receiving the organization's Institutional Review Board (IRB) written approval.

Barriers to project success included employee resistance to vaccination, for a multitude of reasons, including low health literacy, personal health concerns, misinformation, misconceptions, needle phobia, and personal or religious beliefs. The previously identified interventions were

customized to address any specific needs or concerns of the HCWs revealed through discourse during the educational session.

Another barrier to project success included an inability on the part of the doctoral student to gain access to a list of vaccine decliners due to Health Insurance Portability and Accountability Act (HIPAA) concerns. Concentrating efforts on decliners versus a group of both acceptors and decliners would have been a more efficient and effective use of time and resources and likely would have moved the project closer to meeting the anticipated objectives.

All employees at the institution are unionized and union backing has interfered in the past with the ability of the State to implement laws requiring mandatory influenza vaccination. This was attempted in 2009, by the Governor, for existing employees as well as, a condition of continuing employment or credentialing of privileges but was quickly challenged by labor unions resulting in the mandate being subsequently redacted (Ottenburg et al., 2011). Thus, influenza vaccination remains voluntary for State-employed HCWs, with mask-wearing during flu season the only mandatory intervention allowed.

This student also engaged in a dialogue with local union stewards within the facility to factually explain both the benefits and risks associated with influenza immunization for HCWs. Although it was unlikely that this discussion would result in labor unions reversing statewide legal barriers to mandatory immunization, through open communication with local leaders it was hoped that labor union resistance would be minimized at the local level within the facility. The union already allows for mandatory annual state tuberculin skin testing for their members.

Staffing concerns within the Infection Control Department presented another barrier for implementation of the project as there was little time for influenza education by the department. This was addressed through the voluntary services of this doctoral student during non-working

hours. This student was responsible for the educational programming and mentoring of all employee participants. To facilitate this plan, this writer asked for and was granted an alternative work schedule to free up time during the work day, and on other shifts to meet with project participants. This project required the student to come in on all shifts and the weekends to meet with employee participants in order to implement the EBP interventions of personalized, individual education, mentoring, and facilitation of primary prevention modalities.

All the interventions were facilitated by an open, interactive dialogue style by this writer. Attempts were made to place the HCWs at ease, by ensuring confidentiality, and encouraging candid discussion driven by the concerns of the volunteer. The employee volunteer was asked about their knowledge of influenza, its transmission, and preventative measures available. The participants were also asked if they had any questions or concerns related to influenza or related factors. The education was then individualized to meet the needs of the participant. A balanced approach discussing both the risks and benefits of the influenza prevention modalities was utilized to allow the HCWs to decide which, if any, preventative measures were appropriate for them and what was in their best interests. Allowing the HCWs to verbalize their concerns about preventative measures such as the influenza vaccine and to receive validation, along with individualized mentoring and encouragement, helped to facilitate further dialogue about the perceived benefits and risks of influenza immunization and may result in increased vaccine uptake among this population, if not during the current season, possibly in future seasons.

Other facilitators to this project included the support of the facility administration, including that of the Executive Director, and the Medical Director. The Infection Control Department nurses were also engaged in the project and supportive of the endeavor. Members of the Lean Team were ready and willing to consult and assist, not only in implementing the project as soon

as IRB approval was obtained, but also aided this doctoral student in learning more about the Lean methodology. The QMSC and Risk Management Department were extremely helpful in facilitating the approval for the project at the organizational level and have been a strong source of support and encouragement. The Lean Team was also instrumental in assisting this doctoral student with the institution's IRB application and process, as was the onsite project mentor.

Implementation Plan/Procedures

Measurement Instruments

The State Office of Mental Health has specific requirements for analyzing and reporting data that is based on the formula of the National Quality Forum (NQF). NQF, a non-profit group, dictates the formula for analyzing and reporting data for Centers for Medicare and Medicaid Services (CMS) regarding the flu vaccine compliance rates through measure #0431. The formula compares the denominator of all employees, students, contractors, and volunteers in the facility against the numerator of vaccine acceptors, vaccine decliners, and those medically ineligible. The value is then expressed as a percentage of vaccine acceptors (NQF, 2017). Information related to vaccine acceptance rates for this scholarly project was obtained from de-identified data collected by the Infection Control Department.

The monthly employee influenza vaccination rates were compared, by percentages, utilizing the accepted State Office of Mental Health formula for the months of October, November, and December 2017 as well as January and February 2018 against the same periods over the past three influenza seasons (going back to October of 2014) at the institution. Facility statistics for influenza vaccine rates prior to 2014 were not available for this project. Due to multiple personnel changes in the Infection Control Department over the past five years, the data has been lost. The available data was tracked using run charts and graphs. This allowed for comparison of

pre- and post-intervention statistics to measure project effectiveness and to determine if this project was a viable addition for future influenza campaigns at the facility.

Data Collection Procedures

Data related to the number of employee volunteer participants and their contact information for this project was collected and collated. Additional data related to facility influenza immunization rates was also collected from statistics supplied by the Infection Control Department. This information was reported monthly to the parties of interest including the Administration, the Cabinet, the Infection Control Department, the Lean Team and Quality Management Steering Committee for the period of October 2017 through February 2018. A comparison of influenza vaccine rates between the current and past three influenza seasons, going back to October 2014, obtained through the Infection Control Department was included, as well as visual aids such as run charts and graphs. Influenza vaccine rates for the facility were not available prior to 2014. A summary report was issued at the end of February 2018, and a full report of the effectiveness of the endeavor to the parties of interest is planned for May 2018.

Data regarding vaccination acceptance and declination was recorded on handwritten forms, which are kept in a locked file cabinet in a locked office in the Infection Control Department. The infection control nurse then transfers data by hand into an Excel spreadsheet. HCWs individual records were not able to be accessed for this project per agreement with the facility, as they contain protected health information. Only de-identified numerical data was supplied by the Infection Control Department.

Data regarding employee vaccine rates were collected and collated monthly by the infection control nurses, and reported monthly, to the parties of interest including facility administration, the State Office of Mental Health, and the State Department of Health. State level data is

reported online via the Health Commerce System (HCS) using the Health Emergency Reporting Data System (HERDS).

Aggregate data for the facility was also recorded and maintained for organizational accrediting body review by The Joint Commission (TJC). Data results for this undertaking are disseminated as figures in the form of numbers and percentages and include run charts and graphs comparing data from past influenza seasons from 2014 onward. Statistics prior to the evidence-based intervention are compared to those of the current influenza season when the evidence-based intervention was implemented (Table 2).

Data Analysis and Results

This scholarly project implemented and evaluated the EBP primary prevention modalities of individual, personalized education and mentoring on improving influenza vaccine compliance on 105 long-term HCWs in a forensic psychiatric center in a rural setting in the northeast. The interventions took place, and data was collected and collated from October 2017 through February 2018.

Numerical, de-identified data for this endeavor was calculated separately and compared to data obtained from the facility's Infection Control Department staff for the same period (October 2017 through February 2018). These figures were then compared to ensure inter-rater reliability and accurate reporting to the key stakeholders and for inclusion in this academic paper. Data from the last three influenza seasons dating back to October 2014 were also included in this work and compared to that of the current flu season (Figure 2).

As previously noted, the NQF formula compares the denominator of all HCW employees, students, contractors, and volunteers against the numerator of HCW vaccine acceptors, vaccine decliners, and those medically ineligible at the organization. This allows the data to be reported

as percentages of vaccine acceptance. All categories were reported separately using the HERDS program by the Infection Control Department. Raw, aggregate data related to the outcomes of the proposed interventions for the project were tracked and reported monthly during the period October 1st through February 28th, 2018 to key stakeholders for this project by this author. It should be noted, however, that the "influenza season" continues into early May of each year (ending on May 4th in 2017) when the disease is no longer declared prevalent or widespread by the Commissioner of the State Department of Health. Data related to vaccine rates collected from March 1st to May 2018, will continue to be collated and reported to stakeholders by the Infection Control Department, but will not be included in this scholarly endeavor. Data required solely for this project will be analyzed through February 28th, 2018.

During the period of October 2017 through February 2018, 105 individual, personalized education and mentoring sessions with HCW employee volunteers were conducted. Of the 120 volunteers who initially agreed to participate, 15 were lost through attrition due to retirement (3), termination of employment at the organization (8), inability to contact (2), or through changing their minds (2).

It was also unknown how many of the volunteers had accepted or declined the influenza vaccine as this was considered to be protected health information and was restricted by the facility and therefore unavailable to this writer. Specifics regarding HCW demographic information, including age, gender, ethnicity, and job title were also considered restricted data and were not to be included in this project per the organization's administration.

During the same period, from October 2017 through February 28th, 2018, 681 employees were vaccinated by the institution's Infection Control Department. The HCW employee population numbers 899, equating to a percentage of 76%. At the same time last year, only about

73% of HCWs were vaccinated for influenza. This constitutes a small, but positive increase, in vaccine acceptance.

Comparatively speaking, in the 2014-2015 and the 2015-2016 flu seasons the HCW vaccine uptake rates at the end of February were 61% and 59% respectively. Total number of HCW's vaccinated in the 2014-2015 season was 66% in May with 565 out of 856 employees receiving the immunization. The numbers were similar in 2015-2016 with 592 out of 940 HCW employees being vaccinated for a rate of 63% vaccine compliance by the end of the season in May. In the last flu season ending May 4th, 2017, a total of 77% of facility employees were immunized for influenza with 704 of 919 HCWs participating. A comparison of numbers of HCWs immunized by month during the project period for the current and the prior three flu seasons are illustrated in Table 2.

The 2016-2017 cumulative season rate for February was of 73%. The current season's cumulative rate at the end of February is 76%. This demonstrates a 3% increase in HCW influenza vaccine rate as compared to the same period last year. This increase occurred after the implementation of the EBP primary prevention strategies by this doctoral student.

With at least two months remaining in the 2017-2018 influenza season further increases in HCW s vaccine rates may still be realized. It appears likely that organizational rates will surpass last years' record of 77% influenza vaccine compliance, however, it is unlikely that vaccine uptake this season will meet the hoped-for project goal of a 10% increase to 87% immunized, or the upcoming HP2020 objective of 90% HCW vaccine compliance for the institution. Regardless of the final totals, it is probable that the primary prevention modalities implemented as part of this scholarly endeavor demonstrated a positive effect on overall HCW vaccine rates.

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Table 2.

Comparisons of Numbers of HCWs Vaccinated by Month During the Project Period with Those of the Previous Three Influenza Seasons

	Month				
Influenza Season	October	November	December	January	February
2014-2015	300	385	471	488	514
2015-2016	329	423	517	536	555
2016-2017	322	414	505	597	671
2017-2018	459	519	604	656	681

The actual individualized teaching and mentoring session occurred from late October 2017 into February 2018. Monthly data was collated and trended (Figure 2). Examination and comparison, of each Novembers' vaccine rates against those of the prior past three seasons reveals a 16% increase with 61% vaccinated in the current influenza season as compared to 45% in the 2016-2017, 2015-2016 and the 2014-2015 seasons. The most teaching and mentoring sessions were held in November with 70 sessions completed. This may help explain the significant upswing in figures during that period.

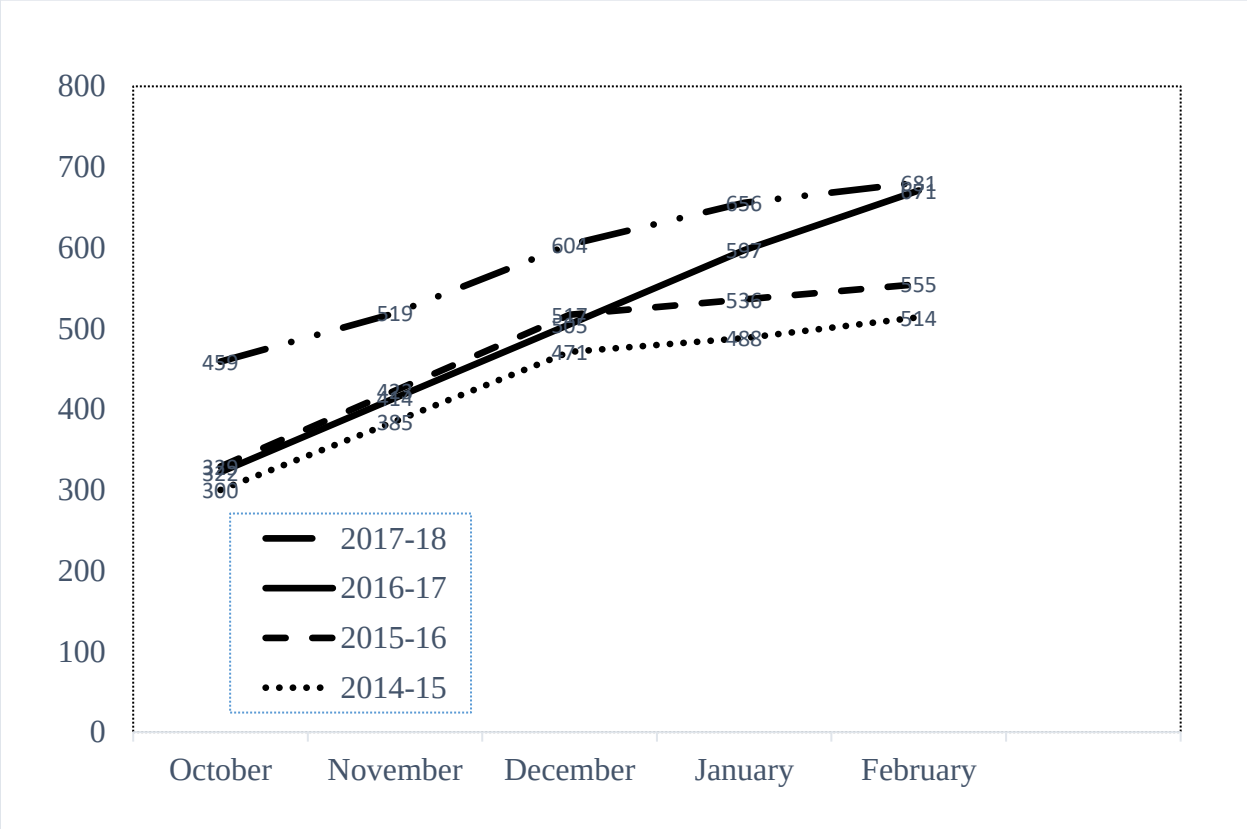
Analysis of the December rates were similar with 10% increase to 71% in the current season as compared to the three previous seasons which also had 10% increases. This may be attributed to fewer teaching and mentoring sessions conducted in December (20) due to the holidays.

The January statistics for the current 2017-2018 season showed a 4% increase, while the 2014-2015 and the 2015-2016 seasons demonstrated only 2% increases. The 2016-2017 season reported a 10% increase. Again, fewer educational and mentoring interventions were conducted

in January, partially due to holidays, and fewer remaining volunteers to be educated/mentored. Eleven volunteers received the EBP intervention for this project in January.

Evaluation of the February rates showed a sharp increase in HCW vaccine uptake in the 2016-2017 with 73% of employees vaccinated during that period. Comparatively, the 2014-2015 and the 2015-2016 February data for that period shows an increase to 60% and 59% respectively, for those years, while the 2017-2018 current season is currently ahead of all the previous three seasons at 76%. Only four interventional meetings occurred in February 2018. The following graph illustrates monthly trends for the currently and past three influenza seasons during the project period of October through February.

Figure 2. Monthly Comparison of Influenza Vaccine Rate Trends for Current Season and the Prior Three Influenza Seasons



Although the influenza season continues annually into May, totals compare only the data gathered until the end of February. The current season is slightly ahead of last season with 681 HCWs immunized which is 10 more than the same period last season. The 681 employees represent 76% of the total number of employees at the institution. Last year the 671 HCWs immunized represented 73% of the total population of 919. This demonstrates a 3% increase over the past years' results for the same period. It should be noted that this year, the facility's workforce numbered 899, 20 less than last year at that time.

In February 2015, 856 HCWs were employed at the project site and 514, or 60% had received the influenza vaccine by the end of the month. In 2016, of the 940 employees, 555, or 59% were vaccinated by February 28th. The current seasons' rate of 76% exceeds the 2014-2015 and 2015-2016 by 16% and 17% respectively for the total numbers of HCWs immunized by the end of February.

Interpretation/Discussion

Discussion

Several factors help to explain the reasons that the EBP interventions did not meet the anticipated objectives/goals. Firstly, the influenza season extends into May. Data for this project was collated through the end of February. Thus, the possibility for additional increases in HCW vaccination as a result of this project remains a possibility in March, April, and May.

Oftentimes a person needs time to process and reflect on health information before making a change. This correlates with the HBM model that explains that perceived severity, perceived susceptibility, and perceived benefits need to be reviewed and weighed against perceived barriers and one's ability to reconcile and make the changes in behavior. In this case the cue to action for changing the behavior would be the education/mentoring sessions conducted by this student.

Another factor to be considered is that the majority of vaccine decliners occur in the TAs population of HCWs. Historically over the past three influenza seasons total TAs vaccine compliance has hovered around 50%. In the current flu season, as of February 28th, TA vaccine uptake is at 49%. It should be noted that this population is dominated by young adults, some of whom may still be in the adolescent phase of development. The period of adolescence continues into the mid-twenties for some people (Sawyer, Azzopardi, Wickremaranthe & Patton, 2018).

Adolescents have historically been associated with the "theory of invulnerability" (Wickman, Greenberg & Anderson, 2009). Bernheim, Halfon and Boutrel suggest that "recent observations suggest that a relative immaturity in frontal cortical neural systems may underlie the adolescent propensity for uninhibited risk taking and hazardous behaviors" (2013, p.1). This may help to explain why TAs are less likely than some other employee groups to accept the influenza vaccine. Additionally, the TA workforce is predominantly male. The CDC (2017f) reports that in the 2015-2016 influenza season adult men were less likely to take the flu vaccine then women of the same age group until the age of 65.

Cultural factors may also have contributed to lower than hoped-for vaccine rates. The HCW population at the project site is culturally diverse. This writer was not allowed access to HCW demographic information; however, employees represent many ethnic groups. Some cultural groups have been associated with decreased vaccine uptake. The CDC (2017e) reported that for the 2015-2016 influenza season among all Black Americans over 18, the vaccine rate was only 36.6%, and it was even lower for Hispanic Americans at 34.4%. White Americans reported 44.5% vaccine compliance. Asians reported 44.0% for the 2015-2016 influenza season while Native Americans vaccine uptake was at 42.9%.

Gender may also account for some of the failure to achieve the anticipated objectives. The number of HCWs at the facility are skewed positively towards males. This is necessary because psychiatric patients are sometimes difficult to handle and may require physical restraint and "show of force" to prevent self-harm or harm to others. Fit young men are attractive to the facility for this reason. The facility also houses approximately 100 inmate-patients for psychiatric treatment who are currently serving sentences at statewide correctional facilities. Many have histories of violent behavior, so maintaining control is necessary to ensure the safety of HCWs and other patients.

The CDC (2017f) report concludes that among American adults over 18, women were more likely to accept the influenza vaccine than men at all age groups until the age of 65, when men surge ahead slightly. As there are more male employees than females, this may also help to explain the lower vaccine rates.

Thematic Findings

Several recurrent themes arose during the educational and mentoring sessions. Among them, concern about why the CDC could not formulate a more closely matched vaccine to the circulating virus. This student explained that vaccines are formulated based upon prevalent strains in the southern hemisphere which experiences winter, and hence the influenza season, before the northern hemisphere. Additionally, it was also clarified that influenza strains often mutate over time, so an exact match is not possible, and a close match is the best scientists can hope for when formulating the vaccine.

Another concern voiced by volunteers was why vaccine formulation was not altered to meet the prevalent strains in the U.S. It was explained that it takes several months to grow cultures and manufacture vaccines, resulting in a less than close match between the vaccine and circulating

virus during the current influenza season. Volunteers were also reminded that the U.S. has become a global society with people arriving from other parts of the world continually. It is not possible for scientists to develop a different influenza vaccine for each geographic area.

The flu vaccine causing influenza was another myth that required frequent dispelling. The vaccine may cause mild symptoms, most notably a sore arm, and mild systemic effects including malaise. These complaints are the result of the recipient's immune system reacting to the vaccine and creating antibodies that will protect against, or minimize symptoms, and shorten the duration of illness should the person come into contact with the influenza virus, and not a mild case of the flu (Talbot et al., 2010).

The belief that the flu is not a serious illness was also a recurrent theme. Although many of the volunteers were young, seemingly healthy, adults and able to survive the flu without further issue, there exist many populations for whom this is not true. Infants, children, pregnant women, psychiatric patients, the immunocompromised, and the elderly are all at increased risk for morbidity or mortality from influenza. The HCWs that posed this belief were reminded that although the flu may not pose a significant threat of disability or death for themselves, many have children, pregnant relatives, patients, and parents and grandparents that could be adversely affected by the HCWs decision to decline the vaccine.

A few of the HCWs that volunteered were engrained in the belief that vaccines are a nefarious plot by the government or the pharmaceutical industry to somehow "infect" or conduct research upon unsuspecting citizens or make money for "Big Pharma". These anti-vaxxers were often quite vocal and firm in their beliefs of conspiracies. An article in Health Psychology (2018) reveals that people who believe in conspiracy theories in general are 15% more likely to decline vaccines and an additional 39% are distrustful of vaccines.

Another argument against the influenza vaccine that was voiced by some HCWs was that they were hesitant to put anything "artificial" into their bodies. This doctoral student countered that humans are constantly coming into contact with artificial chemicals in the environment or ingesting foods fortified with preservatives and other chemical substances.

Study Limitations

The inability of this doctoral student to know which HCWs declined the influenza vaccine was a major limitation to this study. Concentrating efforts on HCWs who declined the vaccine would have been a more efficient use of the student's time and may have proven more effective in increasing vaccine rates in the target population.

In recruiting HCW volunteers for the project, the group that might have benefitted most from additional education and mentoring, such as the TAs, appeared to be less likely to enroll. This may be due in part that the person might have been uncomfortable with the subject matter or was concerned that this writer might have attempted to persuade or "hard-sell" them into taking the vaccine. Conversely, many who signed up for the interventional meeting disclosed freely and without prompting that they had already taken the vaccine. Therefore, the interventions did not reach the target audience of HCW vaccine decliners.

The project site is a unionized workplace. This affords employees protection from unfair labor practices. Several years ago, the unions brought suit when the governor tried to institute mandatory influenza vaccine for all HCWs and the law was subsequently repealed. As mandatory immunization was the measure most likely to improve vaccine rates, this limited the choice of possible interventions for this project and resulted in sub-optimal increases in vaccine uptake.

Cost-Benefit Analysis

It is widely accepted that primary prevention activities are more cost effective than secondary and tertiary prevention (Fiore et al., 2008; Murray & Frenk, 2010). The CDC (2017a) posits that "when people receive preventive care, such as immunizations and cancer screenings, they have better health and lower health care costs" (p.1). Thus, the cost of vaccines and education to prevent influenza are more cost effective than absenteeism related to HCW flu infection or costs associated with the spread of influenza to others.

As this doctoral student's contributions for the project were gratis and occurred on off shifts, additional staffing costs for the project were not needed. The institution already pays for vaccine procurement and costs related to administration. As this is factored into the budget, no additional costs related to this area were anticipated. Costs related to copying of informed consent forms and educational materials and other incidentals are also already provided for in the existing budget (Appendix C).

The facility historically provides educational materials; however, the educational materials are not reviewed with HCWs regardless of whether they accept or decline the immunization. This writer met with as many willing, employee volunteers as available, to educate, explore, and discuss primary prevention options with endorsement of same. There was no cost to the facility for this student's participation and additional cost savings were identified including the value of this nurse practitioner's voluntary service to the facility (Appendix D).

The CDC (2017a) reported the 2017-18 cost per dose of the Fluzone influenza vaccine in the private sector is $166.22 for a multi-dose vial to vaccinate 10 HCWs. This does not include staffing and related costs, such as syringes, alcohol prep pads, and gloves. Healthwarehouse.com (2017) put the price of 100 intramuscular syringes with attached needles at $24.95. The same

supplier quoted a price of $3.95 for 100 alcohol prep pads and nitrile gloves at $11.95 for 50 pairs.

The costs associated with this project were offset by savings recouped from employee overtime wage expenses due to influenza-related absence and costs for procedural masks. Overtime wages are usually paid at "time and a half". Uline.com (2017) reported the price for procedural masks at $7.00 per box of 50. Additional details on the financial breakdown for this project are provided (Appendix C and D).

Timeline

This scholarly project took place between the months of October 2017 and February 2018. Identification of eligible vaccine decliners and interventions took place from late October 2017, through February 2018. Data analysis of the impact of interventions (outcomes) were conducted through February 28th, 2018 while monthly reports to parties of interest began in October 2017 and will continue into May 2018.

Ethical Considerations and Protection of Human Subjects

As the proposed interventions consisted primarily of providing education about influenza, preventative options, and mentoring, with facilitation of the vaccine if desired (by a third party within the facility), there is little if any risk of harm to subjects other than possible psychic discomfort related to the discussion topic. Participants reviewed informed consent forms that openly denoted their participation as voluntary and revocable. It also clearly stated that this doctoral student was conducting this scholarly project as part of her education at The University of Massachusetts, Amherst, in the Doctor of Nursing Practice Program, and was not working in her usual facility role as a Nurse Practitioner during the educational and mentoring sessions. The consent form explained that the teaching sessions were confidential, and no confidential

demographic or medical information was to be asked or collected by the student. Any personal demographic or health information disclosed by the participant during the session is protected under HIPAA, and any data reported, or reports issued to stake holders, (including the University of Massachusetts, Amherst) as a result of this endeavor will be de-identified.

Additionally, the volunteer participant was allowed to direct the flow of the conversation during the teaching session. All influenza and influenza vaccine information provided for the intervention came from the CDC's VIS (Appendix A). Discussion also included some interesting influenza facts, and, on some occasions, discussion of facility policy related to influenza. No personal demographic or medical information, including whether the participant has received, planned to receive, or declined the vaccination was asked or reported. No personal medical advice to participants (including individual recommendations for the vaccine) were provided as part of this undertaking. Participants that requested information about whether he/she was a candidate for the vaccine were referred to the Infection Control Department (who handle employee health) or their personal health care provider for further discussion.

Although there was little anticipated risk to participants, the project proposal was submitted to the Institutional Review Boards (IRB) of both the institution and the University of Massachusetts, Amherst for approval. As previously noted, the facility utilizes the State's Institutional Review Board. Approval by both IRBs was requested and received prior to the commencement of the project. Any employee identifying or personal data that was disclosed during the educational and mentoring sessions remained confidential in accordance with HIPAA regulations. Any information provided in reports by this scholar was de-identified or consisted only of statistics. Any employee specific contact information was kept by this writer in a secure

location to ensure participants confidentiality and to protect their identities and were shredded after the education session had been completed.

The actual administration of vaccines was performed by facility personnel under the auspices of the organization's influenza vaccination program. None of the immunizations were given or prescribed by this nurse practitioner/doctoral student as part of this undertaking. All participants who accepted the vaccine after the education and mentoring session signed a State Office of Mental Health generated and approved vaccine permission form which outlines the risk and benefits of the vaccine.

As protecting the rights of the individual are the ethical onus of all health care providers, every effort was made to conduct this project in an ethical manner. This included protecting each HCW's autonomy, i.e., one's right to choose what one perceives as being in one's best interest through the facilitation "of autonomous decision making" (Grace, 2009, p.21). All information was provided in a fair and balanced manner that includes a discussion of both the risks and benefits of the intervention. All mentoring provided was delivered in a collegial, equitable manner without patronization or condescension. Every attempt was made to ensure that all information was provided in a manner that prevented paternalism, avoided coercion, and ensured justice for the volunteer HCWs.

Conclusion

The Health Belief Model weighs the concepts of one's perceived susceptibility and seriousness against the obstacles to changing one's health behaviors related to a health threat, including the amount of effort needed to make the behavior change, the ability of the individual to change the behavior, and barriers such as cost, personal beliefs, and available support systems (Rosenstock, 1974). The purpose of this scholarly project was to positively change the health

behavior of influenza vaccine declination to one of acceptance among HCWs in a long-term forensic psychiatric facility. The EBP identified modalities including individual, personalized education and mentoring. One hundred five HCWs volunteers participated in the educational intervention resulting in a 3% increase in HCWs vaccine acceptance. Although the initial goal of 10% improvement in compliance was not met, the project was successful in making progress towards meeting the objective of 90% vaccine uptake in HCWs set by HP2020 and the current CDC goal of 100% compliance among medically eligible HCWs.

The National Vaccine Advisory Committee suggests that both health care institutions and HCWs bear a responsibility to protect the patients they care for by complying with immunization practice recommendations (Public Health Reports, 2013). HCWs caring for higher-risk patients, such as psychiatric patients, assume even a greater burden. In 1863, Florence Nightingale wrote "…the very first requirement in a hospital is that it should do the sick no harm" (p. iii), 150 years later, this statement still resonates. Hospitals are intended to be places of healing. HCWs, as agents of health care institutions should also be invested in this principle and held to this standard.

Influenza vaccine compliance is a professional responsibility of HCWs, incorporating the ethical concepts of beneficence, non-maleficence, and justice. Vaccine declination for other than bona fide medical or religious concerns constitutes a lapse of medical ethics. Ottenburg et al., (2011) support this assertion by stating "health care workers assume special obligations and responsibilities. Health care professionals have obligations to do no harm, to do good, to respect patient autonomy, and to treat all patients fairly" (p. 213). This belief is echoed by Kim and Real's study that posits "HCWs are trained to protect patients from harm" (2016, p.235). Lee (2014) asserts that "in addition to the HCWs fiduciary duty to do what is best for the patient and the

public health duty to protect the community with effective and minimally intrusive interventions, HCWs are members of a just society in which all members have an obligation to participate equitably in order to partake in the benefits of membership" (p. 682).

The influenza vaccine is safe and effective (World Health Organization, 2014, para. 6). Efforts to increase influenza vaccine uptake among HCWs are needed to protect all citizens. Evidence-based practice interventions have been shown to be effective in promoting compliance with vaccine among the HCWs population in multiple studies. Through the use of research translation modalities to improve influenza vaccine compliance and enhance facility influenza campaigns utilizing evidence-based practices such as those proposed in this project, the Doctor of Nursing Practice can positively impact this gap in practice as well as reduce health care costs, prevent additional morbidity and mortality, and reduce the pain and suffering associated with influenza and related complications.

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Appendix A
CDC Influenza Vaccine Information Statement

Vaccine Information Statement

Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Influenza ("flu") is a contagious disease that spreads around the United States every year, usually between October and May.

Flu is caused by influenza viruses, and is spread mainly by coughing, sneezing, and close contact.

Anyone can get flu. Flu strikes suddenly and can last several days. Symptoms vary by age, but can include:
- fever/chills
- sore throat
- muscle aches
- fatigue
- cough
- headache
- runny or stuffy nose

Flu can also lead to pneumonia and blood infections, and cause diarrhea and seizures in children. If you have a medical condition, such as heart or lung disease, flu can make it worse.

Flu is more dangerous for some people. Infants and young children, people 65 years of age and older, pregnant women, and people with certain health conditions or a weakened immune system are at greatest risk.

Each year **thousands of people in the United States die from flu**, and many more are hospitalized.

Flu vaccine can:
- keep you from getting flu,
- make flu less severe if you do get it, and
- keep you from spreading flu to your family and other people.

2. Inactivated and recombinant flu vaccines

A dose of flu vaccine is recommended every flu season. Children 6 months through 8 years of age may need two doses during the same flu season. Everyone else needs only one dose each flu season.

Some inactivated flu vaccines contain a very small amount of a mercury-based preservative called thimerosal. Studies have not shown thimerosal in vaccines to be harmful, but flu vaccines that do not contain thimerosal are available.

There is no live flu virus in flu shots. **They cannot cause the flu.**

There are many flu viruses, and they are always changing. Each year a new flu vaccine is made to protect against three or four viruses that are likely to cause disease in the upcoming flu season. But even when the vaccine doesn't exactly match these viruses, it may still provide some protection

Flu vaccine cannot prevent:
- flu that is caused by a virus not covered by the vaccine, or
- illnesses that look like flu but are not.

It takes about 2 weeks for protection to develop after vaccination, and protection lasts through the flu season.

3. Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**
  If you ever had a life-threatening allergic reaction after a dose of flu vaccine or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Most, but not all, types of flu vaccine contain a small amount of egg protein.

- **If you ever had Guillain-Barré Syndrome (also called GBS).**
  Some people with a history of GBS should not get this vaccine. This should be discussed with your doctor.

- **If you are not feeling well.**
  It is usually okay to get flu vaccine when you have a mild illness, but you might be asked to come back when you feel better.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of reactions. These are usually mild and go away on their own, but serious reactions are also possible.

Most people who get a flu shot do not have any problems with it.
Minor problems following a flu shot include:

- soreness, redness, or swelling where the shot was given
- hoarseness
- sore, red or itchy eyes
- cough
- fever
- aches
- headache
- itching
- fatigue

If these problems occur, they usually begin soon after the shot and last 1 or 2 days.

More serious problems following a flu shot can include the following:

- There may be a small increased risk of Guillain-Barré Syndrome (GBS) after inactivated flu vaccine. This risk has been estimated at 1 or 2 additional cases per million people vaccinated. This is much lower than the risk of severe complications from flu, which can be prevented by flu vaccine.

- Young children who get the flu shot along with pneumococcal vaccine (PCV13) and/or DTaP vaccine at the same time might be slightly more likely to have a seizure caused by fever. Ask your doctor for more information. Tell your doctor if a child who is getting flu vaccine has ever had a seizure.

Problems that could happen after any injected vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy or have vision changes or ringing in the ears.

- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

5. What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness – usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get the person to the nearest hospital. Otherwise, call your doctor.

- Reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. There is a time limit to file a claim for compensation.

7. How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.

- Contact the Centers for Disease Control and Prevention (CDC):

  - Call **1-800-232-4636** (**1-800-CDC-INFO**) or

  - Visit CDC's website at **www.cdc.gov/flu**

Vaccine Information Statement

Inactivated Influenza Vaccine

8/7/2015 42 U.S.C. § 300aa-26

Appendix B

Influenza Facts

1. One in five Americans will get the flu this winter. Young children, the elderly, chronically ill, and immunocompromised are at the highest risk for complications of the flu.
2. About 200,000 people will be hospitalized with complications of the flu this year in the US.
3. The flu kills. About 36,000 people die annually in the United States from flu.
4. There have been four major global flu pandemics since 1900.
5. In the 1918 flu pandemic 50-100 million people died. Many were young healthy adults and pregnant women.
6. More people died in 24 weeks during the 1918 epidemic than died from AIDS in 24 years.
7. The 1918 flu pandemic was the deadliest plague in the 20th century. That pandemic killed more Americans in 1 year than WWI, WWII, the Korean War and Vietnam combined.
8. The flu virus can live up to 48 hours on hard surfaces. One does not have to be in close proximity to a sick person to get the flu.
9. One can transmit the flu to others even if they don't feel ill. The flu virus can be "shed" prior to the onset to symptoms.
10. Even if the flu vaccine is not a "perfect match" for the virus that is circulating it still helps to minimize symptoms should one contract the virus.

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Appendix C

Project Implementation Costs

		Cost	Amount	Total
Personnel	Infection Control Nurse	$38.46/per hour	80 hours	$3,076.80*
	Nurse Practitioner (This Student)	$52.88/per hour	200 hours	(10,576.00)**
Materials	Vaccine	$16.62/per dose	900 employees	$14,958.00*
	Syringes/Gloves/Alcohol	$.53/per employee	900 employees	$477.00*
	Flu Vaccine Stickers	$.25/per sticker	900 employees	$225.00*
	Educational Material Copying (estimated)	$.02/per page	5000 pages	$100.00*
Total cost for 2017-18 flu season				**$18,836.80**

*These costs already factored into the existing budget.

** Nurse Practitioner/doctoral student participation is gratis.

Appendix D

Project Cost Savings

Overtime staffing costs	Average Wage Per Hour	Average Wage Per Shift	*Overtime cost for four lost shifts (Avg. lost work per employee w/flu illness)	*Overtime cost for ten employees with flu (with four lost shifts per employee)
Registered Nurse per hour $28.85 x 1.5	$43.27	$346.15	$1384.60	$13846.00
Licensed Practical Nurse per hour $16.83 x 1.5	$25.24	$201.92	$807.68	$8076.80
Therapist Assistant per hour $14.42 x 1.5	$21.63	$173.08	$692.32	6923.20
Ancillary Staff $12.50 x 1.5	$18.75	$150.00	$600.00	$6000.00
Mask savings @ $.07 per	One employee vaccinated saves $12.12 in mask costs per season			Twenty employees vaccinated (~10% of decliners) $242.48

Total Savings				**$35,088.48**

*Staff overtime salaries are included to illustrate potential savings in overtime costs that will be recouped/avoided due to decreased incidence of influenza and lost productivity through increased influenza vaccination compliance.