

RESEARCH ARTICLE

Effectiveness of a Pharmacist-Directed Tdap Immunization Program for a University Campus

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ABSTRACT

Background/Objectives: Despite a slight increase in Tdap immunization rates, the total numbers are still low among adults. The purpose of this study is to determine the impact of a pharmacist-directed immunization program. The primary objective was to assess the increase in vaccination rates among the subjects indicated to receive the Tdap vaccine. The secondary objective was to assess changes in pre and post vaccine knowledge scores.

Methods: Employees enrolled in the pharmacist-directed employee wellness clinic on a university campus in Ohio were screened for Tdap vaccination at the annual employee health fair during Fall of 2016. Results were cross-referenced with the state vaccination database. Subjects were recruited via email to an educational program. Indicated patients were asked to schedule an appointment with a pharmacist. Assessment data on the educational program was collected before the presentation and after the appointment when the vaccine was administered. The efficacy endpoint for the primary objective was a 20% increase in baseline vaccination rates.

Results: Of the 198 subjects recruited, a total of 54 received Tdap vaccination. The baseline vaccination rate of the study population was 37.4% and increased by 27.2% after the intervention to a total vaccination rate of 64.6% ($p < 0.001$). Six knowledge assessments were utilized for the secondary objective; however, these results did not show significance.

Conclusions: A pharmacist-directed Tdap immunization program is effective at increasing vaccination rates. Even though the change in education assessment data proved more observational, the education provided will empower subjects to make informed healthcare decisions.

Key Words: Pharmacists, vaccination, diphtheria-tetanus-acellular pertussis vaccines, population health

INTRODUCTION

Vaccinations are a cost-effective primary prevention service that help protect both adults and children against infectious diseases such as influenza, pneumonia, and polio. According to the Office of Disease Prevention and Health Promotion (ODPHP),¹ for each birth cohort immunized with the routine vaccination schedule, society saves 33,000 lives and saves upwards of \$9.9 billion on direct health care costs. Despite progress in immunization rates, 42,000 adults and 300 children die on average each year in the United States from a vaccine-preventable disease.

Two of the goals from Healthy People 2020² include increasing Tdap immunization rates and reducing the cases of pertussis among children less than 1 year of age and adolescents aged 11-18. Between the years of 2009 and 2013, there were 3,869 reported cases of pertussis in children under 1 year of age and 6,701 cases in adolescents aged 11-18 years.² These outbreaks could have been prevented with Tdap vaccination. It is anticipated that vaccinating adults would prevent transmission of pertussis to adolescents and young infants at highest risk for pertussis morbidity and mortality. Providing indirect protection through Tdap vaccination in adults creates herd immunity around at-risk individuals. Because of this, the Advisory Committee on Immunization Practices (ACIP)³ recommends that adults aged 19-64 years old receive a one-time dose of Tdap that would replace the usual decennial tetanus booster (Td). Among adults who are indicated by the ACIP to receive Tdap, only 20.1% actually receive it.³ Moreover, among the respondents that reported receiving a tetanus vaccination, 51.3% reported they were not informed of which vaccination they had received. Patient education plays an enormous role in identifying patients who are indicated to receive the Tdap vaccine.

There are multiple avenues available to increase vaccination rates and utilizing pharmacists has often been effective.⁴ One example of this was outlined in a study published in 2014 by Mills et al.⁵ They looked to increase Tdap vaccination rates in neonates by working with the birth families. During the study period, pharmacists and other healthcare professionals recommended the vaccine to close contacts of neonates. Pharmacists then held specific clinic hours dedicated to vaccinating these contacts. This method increased vaccination rates from 1.3 Tdap vaccinations per month to 85.2 vaccinations per month. The study concluded that the collaboration between health systems and pharmacists increased Tdap vaccination rates among close contacts of neonates; however, the impact was seen in a targeted population. Another study looking at Tdap immunization rates among a broader population was published in 2015 by Schultz et al.⁶ This study aimed to improve Tdap vaccination rates in family practice offices, but did not utilize a pharmacist to achieve this endpoint. Methods included an electronic prompt in the electronic medical record of each patient that did not have a documented Tdap vaccine. If this prompt appeared, a medical professional would recommend the vaccine. With this approach, Tdap vaccination rates increased from 33.8% to 68.0% during the first year of implementation. The study concluded that making a recommendation to patients about indicated vaccines increased vaccination rates in a medical office population. The most recent study looking at pharmacist impact on immunization rates was published by Sparkman et al. in 2017.⁷ They examined acceptance rates of vaccine recommendations made by pharmacists in a community setting and found a 35% vaccination acceptance rate for Tdap recommendations. The conclusion is that an immunization check-up performed by a pharmacist can lead to patient acceptance of recommendations of needed immunizations.

Pharmacist intervention has been shown to improve vaccination rates. Combining the approaches outlined by Schultz et al.⁵, Mills et al.⁶, and Sparkman et al.⁷ would create a program that would utilize a pharmacist to screen patients for indication, make vaccine recommendations, educate patients, and increase baseline vaccination rates across a broad population within a community. While the patient population studied had a higher baseline vaccination rate (37.4%) than the national average, there is still plenty of room to improve. There was also currently no education, other than the yearly influenza vaccine, provided to the study population prior to this intervention. The current study was designed to overcome low Tdap vaccination rates and to increase knowledge about the different tetanus vaccines in order to educate patients about the importance of their vaccine history and to know when to seek vaccination.

METHODS

Setting

The study took place in Ohio on a university campus within a pharmacist-directed, multidisciplinary, employee wellness clinic from September 2016 to April 2017. The employee wellness clinic partners with the Human Resources department at the university to provide free screenings, disease state management, and health education to employees insured through the university's health plan. As an incentive to participate in the campus wellness program, employees can accumulate points by attending health screenings, engaging in healthy activities, having lab values in range or achieving improvements in lab values, and attending educational programs. Once the employee reaches a predeter-

mined amount of points, they earn a discount on their insurance premium for the following year. This model increases participation in health activities, while providing a reward for individuals who make healthier choices.

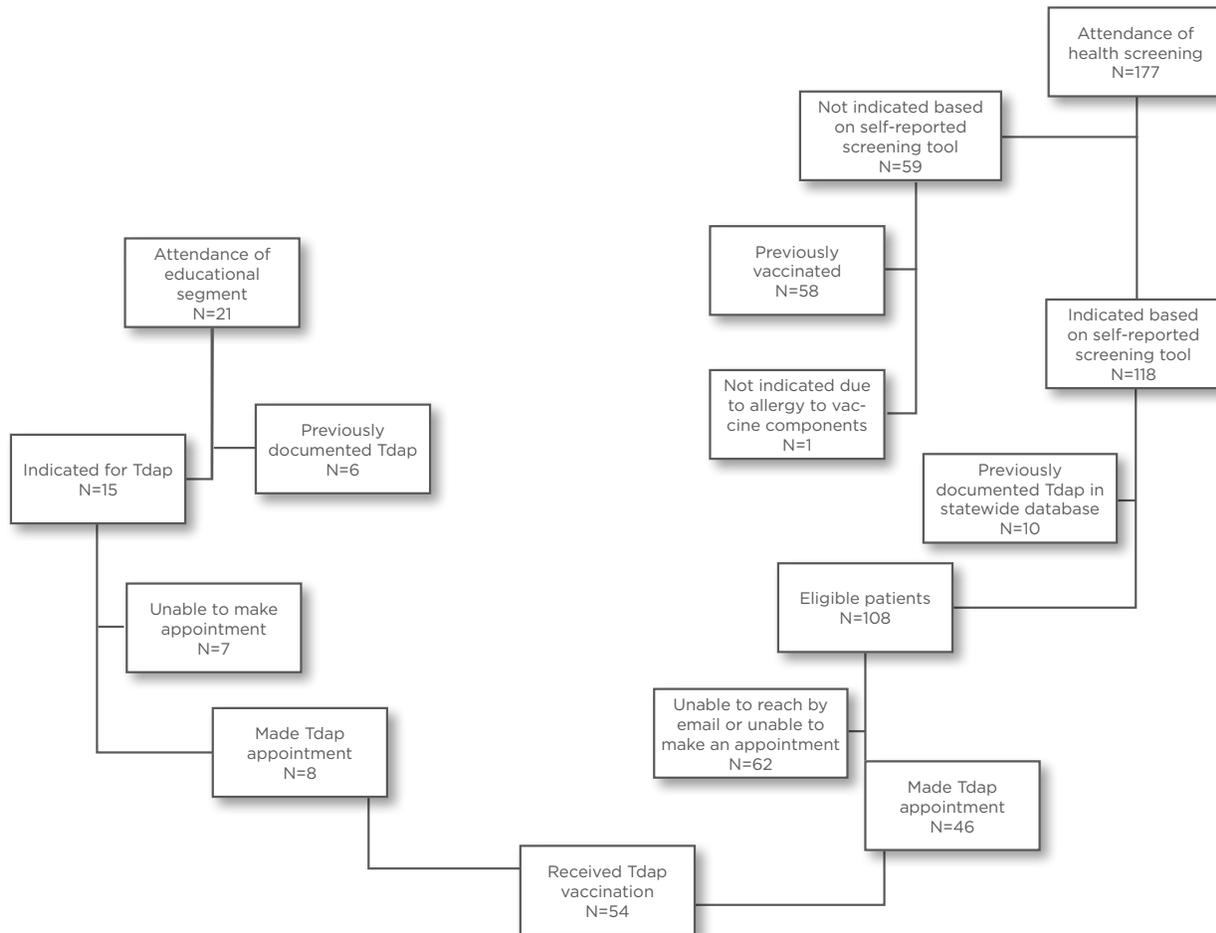
Design

This study was designed to be a prospective, observational study. Subjects were identified by a pharmacist via a health screening and an educational program. Subjects were screened for Tdap vaccination indication as defined by the ACIP and findings were cross-referenced against the state immunization database for accuracy. Subjects who had an indication for the vaccine were recommended to make an appointment with a pharmacist to receive the vaccination.

Participants

To be included in the study, patients had to be ≥ 18 years old, an employee or retiree of the university, and be indicated and willing to receive the Tdap vaccine. Each patient completed a Tdap Indication Screening Tool (TIST) assessment to determine if a Tdap vaccination was indicated. Patients were ineligible to participate if they had previously received Tdap as an adult, if they were ineligible based on ACIP recommendations, or if vaccination was contraindicated. A breakdown of patient enrollment is displayed in Figure 1. Patients that matched the inclusion criteria were identified in September 2016. Participants were notified of the opportunity by a pharmacist through a variety of routes, including a face-to-face screening and an educational presentation marketed through the wellness clinic.

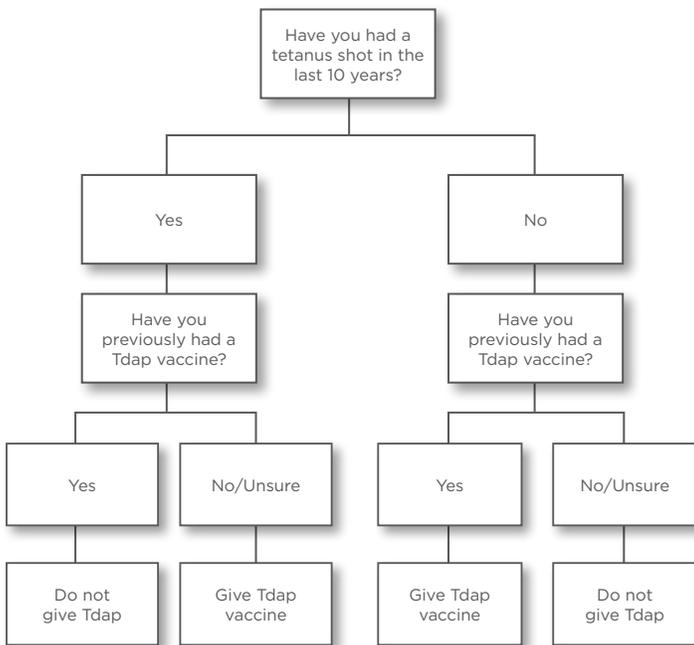
Figure 1. Breakdown of patient enrollment



Procedures

Subjects were screened for Tdap indication using a Tdap Indication Screening Tool (TIST) starting in September 2016 at a university health fair. Questions asked on the TIST were derived from the ACIP guidelines for Tdap recommendations. Based on the answers to the screening tool, an algorithm was developed to determine the need for vaccination. Figure 2 outlines the algorithm by which Tdap indication was determined. Pregnancy was not included in the algorithm due to specific timing of immunization in this population. No participants were found to be pregnant during this screening and follow-up would have occurred if found. A pharmacist was present during the screening to answer any questions. Subjects were indicated to report no previous Tdap vaccination if they were unsure of status. After all the participants were screened, all the TIST results were compared against the Ohio Statewide Immunization Information System (SIIS).⁸ A total of 177 patients were screened at the health fair. Of these, 68 were found to have previous Tdap vaccination and one was allergic to vaccine components. Initially, 58 self-reported as having previous Tdap vaccination. After cross referencing with the statewide vaccination data base, an additional 10 were identified as having a documented Tdap who were previously unsure of vaccination status. Subjects with a positive Tdap indication as determined by the ACIP guidelines were contacted via email to make an appointment to receive the vaccine.

Figure 2. Algorithm to determine Tdap indication derived from answers to self-reported screening questions



An educational program was developed and delivered by the pharmacist to employees of the university to address knowledge gaps about Tdap, the decennial Td booster, pertussis, and tetanus as previously identified by the ODPHP. A total of 21 subjects attended the educational program, where 6 were found to have previously received the Tdap vaccine. Participation was incentivized with healthy campus points and a pretest was given to subjects prior to the start of the program. There was no overlap of subjects between participants screened at the health fair and those who attended the educational program, even though participants at the health fair were invited to attend the education program.

Each Tdap clinic appointment was held at the on-campus health center and was led by a pharmacist with student pharmacists certified in immunizations available to administer the vaccine. After a safety assessment, the Tdap vaccine was administered and the patient was monitored for 10 minutes to ensure there were no adverse reactions. The posttest was administered at the time of vaccination for subjects who participated in the educational program. Both the pre-test and posttest consisted of the same four items pertaining to information covered during the educational program. The amount of time between pre-test and posttest varied among subjects, however, a minimum of 2 weeks between the assessments was applied, to limit short-term recall. All subjects were given written record of the given vaccine and all vaccinations were uploaded into the patient profiles on the state immunization database.

Outcomes

The primary objective of this study was to assess the effectiveness of a pharmacist-directed Tdap vaccination initiative. The primary outcome variable was the change from baseline vaccination rate compared to the change in post-intervention immunization rate with Tdap. A 20% increase in baseline vaccination rate within the study population was targeted based on evidence of change from baseline in previous literature. Studies of comparable target populations found increases between 30-35% within a year of implementation. With a shorter timeframe to make an impact, a goal of 20% was derived.^{6,7} The secondary outcome assessed the change in patient knowledge of pertussis and the Tdap vaccine through education delivered by a pharmacist during the immunization initiative. It was hypothesized that utilizing an ambulatory care pharmacist to educate and screen patients and administer vaccines would increase vaccination rates and improve patient knowledge.

Statistical Analysis

Data was analyzed using descriptive and inferential statistics. SPSS version 22 (IBM, New York) was utilized for statistical analysis. A McNemar's test was used to analyze the difference between those eligible for the vaccine at baseline and those who then received the vaccine. The mean percentage change in Tdap immunizations from baseline compared to the mean percentage in post-intervention group was provided as descriptive data. Fisher's Exact Test was utilized to compare the pre and post educational scores. Alpha was set at 0.05 for the primary outcome variable.

Institutional Review Board Approval

The university's Institutional Review Board approved the study. Patients were required to sign an informed consent form prior to inclusion into the study.

RESULTS

After administering the TIST and comparing those results to Ohio Impact SIIS, a total of 198 patients were included in the study, which revealed a baseline vaccination rate of 37.4% (74/198). The majority of subjects were female (70%) and age ranged from 23-83 years old with an average age of 50. A total of 177 subjects were screened at the health fair and 108 were found to be indicated for the Tdap vaccination. Of the 21 subjects participating in the educational segment, 15 were identified as having an indication for Tdap. Of the 108 subjects that were eligible for vaccination from the health fair, 46 went on to make an appointment and receive the vaccine. A total of 8 subjects of the 15 identified as eligible from the educational segment went on to make appointments and receive the vaccine. The pharmacist-directed clinic administered the Tdap vaccine to 52 of the 123 eligible subjects. Two individuals received their vaccine at their local pharmacy after recommendations encountered during the program. This led to a final vaccination rate of 64.6% (128/198), an increase of 27.2%

from baseline vaccination rate. An acceptance rate of 43.9% in vaccination recommendation was also achieved. McNemar's test of the primary outcome variable of vaccine acceptance in the eligible population was statistically significant at a p value of < 0.001.

Of the 8 assessments completed, a total of 6 assessments were available for analysis due to lack of completion of the full assessment by 2 individuals. A limited number of assessments were available due to a small sample attending the educational program and a smaller subset of attendees going on to receive the Tdap vaccine. Table 1 outlines questions asked on both pre and posttest and the respective number of correct answers. All questions improved following the educational program, except one. The trend in change on question 4, which asked the difference between the decennial Td booster and the Tdap vaccine, demonstrated improvement, although the sample size was inadequate to confirm this finding statistically.

Table 1. Questions utilized to assess patient knowledge and the number of correct responses on the pre and posttest

Question Number	Pre and Post Assessment Questions	Number of correct responses on pretest	Number of correct responses on posttest	p-value (n=6)
1	What diseases does the Tdap vaccine protect against?	3	5	0.27
2	Who needs to get the Tdap vaccine?	5	4	0.5
3	How often do you need a Td vaccine?	3	5	0.27
4	What is the difference between the Tdap and the Td?	1	5	0.04

DISCUSSION

Prior to this study, there was limited evidence demonstrating the benefit of a pharmacist-directed Tdap immunization program in a generalized population setting. Immunizations were offered through the health and wellness clinic prior to this study; however, the service was not routinely utilized by patients for vaccines other than the yearly influenza vaccine. This program provided evidence that a pharmacist-directed vaccination program would increase Tdap vaccination rates and could increase patient knowledge about Tdap vaccinations.

There were many strengths to this study, including the demonstration of effectiveness of a pharmacist-directed immunization program. This program provides data outside of a specialized population and provided a necessary service for improving public health. All patients that were enrolled into the program were screened for indication and verified through the statewide immunization database. This added a level of validity to the self-reported nature of the screening tool. In addition, all subjects were provided with written vaccination record and all vaccinations given were uploaded into the patient profiles on the statewide database.

This study was found to have similar efficacy as other previously published studies. The study performed by Schultz et al.⁶ found a 34.2% increase from the baseline vaccination rate in a one-year time frame. While utilizing similar methodology of making vaccination recommendations to indicated patients, this study found a 27.2% increase from the baseline vaccination rate within a shorter study duration of 7 months. This study also found higher vaccination acceptance rates than the study performed by Sparkman et al. with 43.9% of participants in this study accepting the recommendation compared to 35% seen in the previous study.⁷

This measure could also be due to the nature of the wellness clinic and how participation is incentivized through deductions in health insurance premiums.

There were some limitations in relation to this study. Even though the statewide database was utilized to ensure vaccine indication, the screening tool relied heavily on self-reported data. This presented some challenges, as several subjects were unsure when they received a Td booster or if they had ever received a Tdap. The pharmacists tried to account for this in the algorithm. If patients reported having a Tdap, but received a tetanus shot more than 10 years ago, the likelihood they actually received a Tdap vaccine as an adult is very unlikely. This is due to the fact that the Tdap vaccine was first approved in 2005 and was recommended for routine adult vaccination by the ACIP guidelines starting in 2006.⁹ It was estimated that only 5.9% of the United States population had received a Tdap vaccine in 2008¹⁰ and 17.2% in 2013.⁵ With this information, it is highly unlikely that the tetanus shot the patient received as an adult more than 10 years ago was indeed Tdap. The younger employee population did have individuals who reported no previous Tdap vaccine who indeed did receive it as adolescents. However, they were still indicated to receive the vaccine as an adult. The state database was especially helpful in this population as their records were up to date. While cross-referencing the statewide database, it was found that individuals born before the late 1980's had incomplete or no records uploaded into the database.

Power was not met for the secondary endpoint; however, with more participants in the educational program, significant changes could have been seen. This was evidenced by the fact most assessments improved, but only one question was found to be statistically significant. However, conclusions cannot be drawn from this due to the low number of assessments. Even if all participants from the educational program completed pre and post assessment data, power would still not have been met. Improvements to future studies would have multiple education programs to capture more subjects or administering the posttest online to capture all attendees regardless of vaccination status. Another limitation to the educational assessment relates to the education level of the participants. The majority of the participants were college professors that teach subjects such as chemistry, biology, and pharmaceutical sciences. While some of the participants were not faculty members, the education level of the population could be higher than a different population who would take this assessment.

PUBLIC HEALTH IMPLICATIONS

A pharmacist-directed Tdap immunization program is effective at increasing vaccination rates. With the implementation of the program, immunization rates increased by 27.2% from baseline within the study population with a statistically significant acceptance rate of Tdap vaccination in the eligible population ($p < 0.001$). With these results, more patients will be protected from the transmission of pertussis. Knowledge about tetanus, pertussis, Tdap and the decennial Td booster increased even though these results proved more observational. While not statistically significant, the increase in knowledge is successful at empowering the subjects to make informed healthcare decisions, which in turn may result in making vaccination recommendations to friends and colleagues, further increasing vaccination rates.

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APhA-ASP Operation Immunization

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