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Improving Vaccination Rates in Adults with Type II Diabetes in a Family Practice Setting: An Evidence-based Quality Improvement Project

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IMPROVING VACCINATION RATES IN
ADULTS WITH TYPE II DIABETES IN A FAMILY PRACTICE
SETTING: AN EVIDENCE-BASED QUALITY IMPROVEMENT PROJECT

by

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Abstract

The purpose of this evidenced-based quality improvement project is to implement processes to facilitate providers' adherence to the American Diabetes Association (2017), American Association of Clinical Endocrinologist (2015), and American College of Endocrinology (2015) immunization guidelines for adults with type II diabetes. Presently, diabetes is the 7th leading cause of death in the United States contributing to serious complications throughout the body as a result of poor glucose control. Adults with diabetes are at increased susceptibility to infectious disease because of hyperglycemia, poor glucose control, and decreased immunity. A protocol was created using The Four Pillars Transformation Program™ to align provider practices at a family practice clinic with recommended guidelines. Interventions aimed at improving recommended vaccination rates in adults with type II diabetes mellitus include standing orders for all immunizations, a vaccine clinic that operates simultaneously during office hours, vaccine needs screening, patient education, flyers, electronic medical record alerts, an appointed immunization champion, and quality improvement meetings. At project completion 62% of eligible patients had been screened for vaccine need and 62% received education. Ten weeks post project implementation, 64% of the eligible patients had been vaccinated with pneumococcal polysaccharide vaccine 23, 86% pneumococcal conjugate vaccine, 89% tetanus, and 54% herpes zoster. Thirty-seven out of 49 (76%) eligible patients who received education received all recommended vaccines indicating a need for continued work on staff and patient education that will facilitate patient consent for recommended vaccines.

Keywords: Diabetes Mellitus, Pneumovax 23, Tetanus, Herpes Zoster

Type II diabetes negatively affects cells within muscles, liver, and fat tissue which results in inappropriate use of insulin (Pratley, 2013). The body's need for insulin increases and beta cells located within the pancreas begin to lose the capability to produce adequate amounts of insulin over time (Pratley, 2013).

Presently, diabetes is the 7th leading cause of death in the United States (Centers for Disease Control & Prevention [CDC], 2014). Approximately 30 million people in the United States have diabetes. Death associated with diabetes is 1.5 times higher in adults age 18 or older with diabetes than those without diagnosed diabetes (CDC, 2014). The direct and indirect cost of diabetes is estimated to be \$245 billion annually in the United States (CDC, 2014). Diabetes contributes to serious complications throughout the body, as a result of poor glucose control (CDC, 2014). Adults with diabetes are at increased susceptibility to infectious disease because of hyperglycemia, poor glucose control, longer duration of diabetes, decreased immunity, and impaired pulmonary, renal, and liver function.

Statement of the Problem

It is estimated that 29.1 million Americans have diabetes (CDC, 2014). Adults age 65 or older account for 11.8 million of the estimated population of adults with diabetes (CDC, 2014). Adults with type II diabetes mellitus acquire infectious diseases more frequently and severely than adults without diabetes because of the hyperglycemic environment which causes a reduction in T cell response, neutrophil functioning, and humoral immunity disorders (Casqueiro, Casqueiro, & Alves, 2012). Herpes zoster, tetanus, and pneumococcal disease commonly occur in adults with type II diabetes, but each of these diseases is preventable through the use of recommended vaccinations. Presently there is a lack of adherence to immunization guidelines in family practice settings (Alcuskys & Pawasauskas, 2015).

Background and Significance

The most frequently occurring infectious diseases in patients with type II diabetes are *Streptococcus pneumonia* and influenza virus (Casqueiro et al., 2012). Individuals with type II diabetes who acquire pneumonia or influenza are six times more likely to require hospitalization than non-diabetics (Casqueiro et al., 2012). Yende et al. (2010) conducted a retrospective analysis on two multicenter cohorts to help determine the effect pre-existing diabetes has on morbidity and mortality after a patient is infected with community acquired pneumonia. The study found diabetes increases the rate of mortality within the 1st year following infection with community acquired pneumonia (Yende et al., 2010). Yende et al. (2010) also found adults with diabetes have a higher risk of acute kidney injury during hospitalization for community acquired pneumonia (39.3%) vs 31% of adults without diabetes. It is estimated that pneumococcal vaccines are 84% effective in patients with diabetes age 18-64 and 44% effective in adults age 65 or older against pneumococcal bacteremia (Kesavadev et al., 2012). The pneumococcal polysaccharide vaccine 23 (PPSV23) and pneumococcal conjugate vaccine (PCV13) contain polysaccharide antigens that induce an antibody response which destroys pneumococcus seven to 10 days after vaccination (Kesavadev et al., 2012). In 2014, the National Health Interview Survey (NHIS) conducted a cross-sectional household survey and found the national vaccine rate for PPSV23 and PCV13 was 20.3% (Williams et al., 2016). Similarly, Alcusky and Pawasauskas (2015) found adherence to national pneumococcal vaccine guidelines was 37% in a single-center, cross-sectional study conducted on 100 medical records.

Herpes zoster virus presents as a painful, vesicular rash, which can be complicated by secondary infections (Karla & Chawla, 2016). It commonly occurs in adults with diabetes because of the immune-compromised state (Karla & Chawla, 2016). A decline in varicella zoster

virus related cell-mediated immunity is seen in adults with diabetes which results in a higher incidence of herpes zoster virus in these individuals (Karla & Chawla, 2016). Post-herpetic pain has a higher prevalence in adults with diabetes as well (Karla & Chawla, 2016). Diabetes increases the risk of acquiring herpes zoster by 2.1% (Aldaz et al., 2013). The 2014 NHIS survey found that herpes zoster vaccination coverage amongst adults age 60 and older was 27.9% (Williams et al., 2016). The Center for Disease Control and Prevention analyzed data from the 2014 NHIS and found Whites have the highest rate of herpes zoster vaccine coverage at 32%, with Blacks 11.6%, Hispanics 14.6%, Asians 16.5%, and those reporting other race 16.2% (Williams et al., 2016). The herpes zoster vaccine (Zostavax®) reduces the risk of developing shingles by 51% and post-herpetic neuralgia by 67% (CDC, 2016). The herpes zoster vaccine is thought to stimulate the body's immune system through a weakened strain of the chickenpox virus which helps keep the virus dormant (CDC, 2016).

Tetanus is a vaccine-preventable disease that is life-threatening (Williams et al., 2016). *Clostridium tetani*, the bacteria causing tetanus, is found in high concentrations in soil and animal excrement (Williams et al., 2016). It presents with acute onset of hypertonia and painful muscle contractions that have no obvious cause (Williams et al., 2016). Adults with diabetes are at an increased risk of acquiring tetanus (Williams et al., 2016). The prevalence of tetanus in individuals with diabetes is three times higher than those without diabetes (Williams et al., 2016). Chronic wounds or infections which are common in diabetes increase the risk by 13% (Williams et al., 2016). The 2014 NHIS survey found that only 64.7% of adults aged 50-64 and 57.7% of adults age 65 or older had received any tetanus toxoid containing vaccine within the past 10 years (Williams et al., 2016). There are four vaccines which protect against tetanus in combination with other vaccines: DT (diphtheria and tetanus), DTaP (diphtheria, tetanus, and

pertussis), Td (tetanus and diphtheria), and Tdap (tetanus, diphtheria, and pertussis) (CDC, 2016). The vaccines offer protection from tetanus due to the neutralizing antibodies from the tetanus toxin and as a result cause a rise in tetanus antibody concentration after vaccination (CDC, 2016).

Assessment

A pre-intervention retrospective medical record review of 155 adults with type II diabetes was conducted from November 1, 2016, through January 31, 2017, at a family practice clinic. The majority of the patients were privately insured (60%), white (91%), and non-Hispanic (60%). Fifty-nine (38%) of the adult patients with type II diabetes were age 30 to 49, 25 (16%) age 50-64, and 70 (45%) age 65 or older.

The pre-intervention retrospective chart review demonstrated that ninety (58%) of the adult patients with type II diabetes had a HbA1c greater than or equal to 6.5 placing them at high risk for acquiring infectious disease. Thirty-seven (41%) of the ninety patients at high risk for infectious disease were treated with antibiotics for bacterial infections within the past year. The clinic vaccination rates in adults with type II diabetes were influenza PVC13 (49%), PPSV23 (21%), tetanus (24%), and herpes zoster (17%) which further increases the susceptibility of disease in this already vulnerable population (Table 1).

Readiness for Change

A review of the ADA, AACE, and ACE guidelines and the results of the December 2016 microsystem assessment with key stakeholders at the family practice clinic resulted in a determination that the clinic does not have a process in place to facilitate immunizing adults with type II diabetes. Prior to the review of the guidelines the providers and staff were unaware of the high risk of morbidity and mortality associated with vaccine preventable infectious disease and

the current immunization guidelines for adults with type II diabetes. Following the guideline review it was determined that a process improvement project would be created to align the practice with the ADA, AACE, and ACE guidelines and all providers and staff expressed a desire to improve the immunization rates for adults with type II diabetes. The clinic's resources are able to support the performance improvement project through the use of space, technology, training, and organizational structure.

Table 1

Clinical Characteristics of Pre-intervention Patient Population

Demographics	Percentage
Hemoglobin A1c	58%
≥ 6.5	42%
<6.5	
Infectious Disease Treated with Antibiotics	
Upper Respiratory Infection	20%
Bronchitis	14%
Sinusitis	35%
Cellulitis	26%
Conjunctivitis	16%
Pharyngitis	39%
Otitis	27%
Pneumonia	5%
Folliculitis	6%
Recommended Immunizations Administered	
PVC13	49%
PPSV23	21%
Tetanus	24%
Herpes Zoster	17%

Project Purpose and Objectives

The purpose of this quality improvement project was to implement processes to facilitate providers' adherence to the ADA (2017), AACE (2015), and ACE (2015) immunization

guidelines for adults with type II diabetes at a family practice clinic. The ADA (2017) recommends all adults with type II diabetes receive by age group:

- 19-64: PPSV23
- 65 or older: PVC13 and PPSV23

The AACE (2015) and ACE (2015) also support the above recommendations, but in addition these two organizations recommend all adults with type II diabetes receive by age group:

- 18 and older: tetanus-diphtheria booster every 10 years
- 60 and older: varicella zoster (Handelsman et al., 2015).

The objectives of this evidence-based quality improvement project are to increase the percentage of adult patients with type II diabetes who receive vaccine needs screening, education, and recommended vaccines (Table 2).

Table 2

Objectives and Anticipated Outcomes

Project Objectives	Anticipated Outcomes
Screening for Vaccine Need	Increase from 0% to 60%
Patient education	Increase from 0% to 60%
Administration of PPSV23	Increase from 21% to 41%
Administration of PVC13	Increase from 49% to 69%
Administration of tetanus	Increase from 21% to 41%
Administration of herpes zoster	Increase from 21% to 41%

Summary and Strength of the Evidence

Methods which can improve immunization rates are vaccine needs screening, patient education, immunization access, and education. Studies that implemented or analyzed The Four Pillars Practice Transformation Program™ were synthesized and resulted in the information used to create the immunization protocol for adults with type II diabetes in the clinic.

Lin et al. (2016) conducted a randomized cluster trial of 70,549 adults seen in twenty-five primary care clinics over a 1 year period. The study used The Four Pillars Practice Transformation Program™ to increase adult influenza vaccination rates and reduce missed opportunities to vaccinate patients. The program included provider and staff education on the importance of protecting patients from vaccine preventable diseases and strategies to overcome common barriers patients and providers often face (Lin et al., 2016). The study also identified an immunization champion who was responsible for updating the project outcome dashboard, assuring the strategies were implemented, and providing motivation for the staff (Lin et al., 2016). During the study, access to vaccinations was increased by using each patient visit as an opportunity to vaccinate, holding express vaccination clinics outside of normal clinic hours, and creating a dedicated vaccination station (Lin et al., 2016). Communication with patients about the importance of vaccination was done by using posters, fliers, social media vaccination prompting, and outreach email and phone calls (Lin et al., 2016). Office systems were enhanced to facilitate adult vaccinations by assessing immunizations as part of vital signs, incorporating standing order procedures (SOP), and promoting simultaneous vaccination. One year after initiating these interventions, the influenza vaccination rate increased by 2.7% to 6.5% from baseline per practice (Lin et al., 2016). Similarly, Nowalk et al. (2014) conducted a qualitative, triangulated, mixed method design study using the 4 Pillars Practice Transformation Program™

to improve influenza and pneumococcal vaccination rates in adults (Nowalk et al., 2014). The study was conducted at four primary care practices within the same county of Pennsylvania (Nowalk et al., 2014). Each clinic was encouraged to implement interventions from The Four Pillars Practice Transformation Program™ that best fit their practice. In the 1st year pneumococcal vaccination rates increased significantly by 25% and in the 2nd year the rates increased by 40% from baseline. Three of the four clinical sites saw improved influenza vaccination rates. The overall improvement rate for influenza vaccination was 22% during the 1st year and 33% during the 2nd year. The study found the greatest rates of improvement were seen in clinics that more fully implemented The Four Pillars Practice Transformation Program™.

Zimmerman et al. (2017) also conducted a cluster randomized trial using The Four Pillars Practice Transformation Program™ to determine if it would increase pneumococcal immunization rates in older adults (Zimmerman et al., 2017). This study used a sample from twenty-five primary care practices with 18,107 participants age 65 or older. The study implemented interventions which included convenient vaccination services, communication with patients about the importance of immunizations, enhanced office systems, and motivation through an office immunization champion (Zimmerman et al., 2017). Like previous studies, during the 1st year vaccination rates increased 6.5% to 8.7% per practice (Zimmerman et al., 2017). By the end of the 2nd year, 79% of participating primary care practices had PPSV23 rates at or above 70% (Zimmerman et al., 2017). The Four Pillars Practice Transformation Program™ uses an evidence-based method to systematically improve immunization rates. The program was not found in a published study of adults with type II diabetes or for improving tetanus and herpes zoster immunization rates, but multiple studies have proven its efficacy making it feasible in these situations.

Methods

Project Intervention

The project setting is a privately owned family practice clinic located in a small Texas suburb. The providers currently care for 12,059 patients. Over the past year, 512 clinic patients were adults with type II diabetes. The clinic has been owned and operated by the lead physician for the past 22 years. The clinic is staffed with five providers, five medical assistants (MA), two receptionists, one office manager, one biller/coder, and one information technologist. The top five ICD-10 diagnoses in the clinic are essential hypertension, type II diabetes, generalized atherosclerosis, disorder of lipid metabolism, and adult health exam.

An evidence-based practice project was implemented to increase provider and MA adherence to ADA (2017), AACE (2015), and ACE (2015) guidelines for immunizations in adults with type II diabetes. The project interventions designed to increase adherence included an education/discussion session for providers and staff, using a vaccine needs assessment (Appendix A), implementing standing orders, appointing an immunization champion, building an electronic medical record (EMR) alert, providing patient education (Appendices B & C), and bi-weekly quality improvement meetings (Table 3).

Prior to project implementation, an interactive group education session was conducted with all providers and MAs. The education session provided information on type II diabetes and guidelines for recommended vaccines including background, significance, vaccine needs assessment screening, and The Four Pillars Practice Transformation Program™.

The clinic presently has an SOP for influenza, PVC13, and PPSV23 immunizations. Prior to project implementation the clinic adopted an SOP for tetanus and herpes zoster vaccines. The clinic selected to use pre-printed standing orders provided by the Immunization Action Coalition

Table 3

Interventions Based on The Four Pillars Practice Transformation Program™.

Intervention	Responsible Party
Pillar 1: Convenient Vaccination Services	
Standing Orders for all Immunizations A vaccine clinic that runs simultaneously during office hours	Physician, Project Leader Medical Assistants
Pillar 2: Communication with Patients About the Need for Vaccinations and Availability	
Vaccine needs screening Patient education Flyers	Receptionist, Medical Assistant, Providers Medical Assistants, Providers Medical Assistant
Pillar 3: Enhanced Electronic Office Systems to Facilitate Immunizations	
Electronic medical record alert for influenza, PVC13, PPSV23, tetanus, and herpes zoster vaccines	Physician Owner, Project Leader
Pillar 4: Motivation Through the Use of an Immunization Champion	
Pre-intervention interactive group education Appointment of an immunization champion Biweekly Quality Improvement meetings	Project Leader Physician Owner Providers, and Project Leader

(n.d.) which include *Standing Orders for Administering Tdap/Td Vaccine to Adults* (Appendix D), and *Standing Orders for Administering Zoster Vaccine to Adults* (Appendix E). The SOPs

were reviewed by the project leader, all providers, MAs, and the office manager. The medical director signed the SOPs and added them to the facility's SOP manual.

Prior to implementation of the project, the EMR was reconfigured to include quality indicator alerts for tetanus and herpes zoster vaccines for all adults with type II diabetes. Influenza, PVC13, and PPSV23 alerts were already programed into the EMR. All recommended immunization identifiers are located under the quality tab and have a red alert that indicates attention is required.

On the 1st day of implementation each patient age 18 or older entering the clinic was given by the receptionist a copy of the vaccine needs assessment to complete. After completion, the patient gave the form to the MA. The MA used the vaccine needs assessment to identify which vaccines were recommended and documented the vaccine administration in the electronic medical record. All adult patients with type II diabetes were given the handout *What You Need to Know About Diabetes and Adult Vaccines* in English or Spanish based on the language of their choice (U.S. Department of Health and Human Services Centers for Disease Control and Prevention, 2015). The MA initialed the vaccine needs assessment indicating it was reviewed and initialed the box on the vaccine needs assessment indicating patient education was presented. The MA answered any patient questions. The MA then placed the vaccine needs assessment in the designated file folder in the patient room for the provider.

The provider reviewed the vaccine needs assessment with the patient and discussed recommended vaccinations with the patient. The provider answered any patient questions. The provider initialed the vaccine needs assessment indicating it had been reviewed and documented any vaccine orders, refusal, or contraindications to the recommended vaccine in the electronic

medical record. Upon leaving the patient's room the provider handed the vaccine needs assessment to the MA, and discussed recommended vaccines.

The MA prepared the recommended vaccines at the vaccine station. The MA entered the patient's room and handed the patient a copy of each vaccine's information sheet. The MA answered patient questions and administered the vaccines. The MA documented vaccine administration in the electronic medical record.

The patient then checked out at the front receptionists' desk. The receptionist viewed upcoming immunization recommendations in the electronic medical record. The receptionist scheduled an appointment for the patient to see the MA for future immunizations.

Organizational Barriers and Facilitators

The organization had multiple challenges to overcome during the implementation of the new protocol. Barriers included staff turnover, immunization stock, and insurance coverage. Following staff education but prior to project implementation, one provider and one MA left the practice. During the project these positions were not filled. This resulted in higher patient volumes for both providers and MAs. During the 2 weeks post implementation quality improvement meeting staff reported it was difficult to assess immunization status on acute patient visits because acute patient visits were only scheduled for fifteen minute blocks. To overcome this problem the MAs began using the SOPs and administered the patient's recommended vaccine prior to having the provider enter the room. This eliminated the need to have the MA return to the patient's room a 2nd time. During the 4th and 6th week's quality improvement meetings all three MAs reported time was no longer an issue for acute visits.

The implementation of screening all patients through the use of a vaccine needs assessment resulted in increased vaccination rates for all patients including those without type II

diabetes. Though an increase was anticipated, the clinic did not fully predict the degree of increase. During the 1st 2 weeks of project implementation the clinic ran out of the tetanus vaccine. During this time two patients were not vaccinated and instructed to return to the clinic at their next scheduled visit for the vaccine. A written vaccine reminder was also placed in both patients' medical records. Both patients returned to the clinic within 4 weeks and received the recommended vaccine. During the 6th week the clinic again ran out of tetanus vaccine. One patient did not receive the vaccine at this time and was instructed to return to the clinic in 4 weeks to receive the vaccine. The patient did return to the clinic for his scheduled vaccine. During the 6th week's quality improvement meeting it was noted that all vaccine administrations were being logged but it was still impossible to predict how many vaccines might be administered in one week. The rate ranged from one to 20 vaccines per week. The clinic agreed to keep 20 doses in stock for the remainder of the project.

Despite ADA, AACE, and ACE recommendations to vaccinate all adults with type II diabetes with herpes zoster vaccine at age 50, the Center for Disease Control does not recommend vaccination until age 60. The CDC (2016) reports protection from shingles vaccine only lasts about 5 years and the risk of complicated shingles occurs later in life. Following project implementation the clinic found most commercial insurances would not cover herpes zoster vaccination until the patient is age 60. During week two's quality improvement meeting the clinic decided to only offer the vaccine to patients age 60 or older for the remainder of the project.

Facilitators of the new protocol included the familiarity of the clinic staff with vaccine administration and standing orders, an affiliation with drug companies that produce vaccines, increased revenue from enactment of the vaccine protocol, and patient willingness to participate

in the project. The expertise of the clinic staff with the process of scheduling patients for immunization appointments and the use of SOPs were additional facilitators.

The clinic received increased revenue based on increased immunization visits and billable procedures involved in the operationalization of the vaccine protocol. The use of national guidelines for immunizations in adults with type II diabetes increased insurance reimbursement, decreased the chance for denial of benefits, and improved adherence to government sanctioned quality measures.

Ethical Considerations

The herpes zoster vaccine was created using descendant cells taken from an electively aborted fetus approximately 40 years ago (The College of Physicians of Philadelphia, 2017). The official position of the National Catholic Bioethics Center (2006) is complex and multifaceted and requires individuals to examine the problem and history, moral and ethical considerations, and use these factors to guide their decisions on the use of herpes zoster vaccine.

The Catholic Church acknowledges that some vaccine-preventable illnesses are epidemic in certain parts of the world and can cause serious adverse effects and even lead to death (National Catholic Bioethics Center, 2006). Vaccines are created by growing a weakened viral strain in a medium or cell culture (The Right to Life of Michigan, n.d.). The virus then invades the culture, grows, and multiplies resulting in a weakened vaccine (The Right to Life of Michigan, n.d.). In the case of herpes zoster vaccine, cells were obtained from cell line MCR-5 from an aborted fetus (The Right to Life of Michigan, n.d.). Cell line MCR-5 originated from fetal lung tissue taken from a 14 week gestation male fetus that was aborted for psychiatric reasons in 1966 (The Right to Life of Michigan, n.d.). The aborted fetus was healthy and had no life-threatening conditions (The Right to Life of Michigan, n.d.).

People are justified in wanting to protect themselves, their children, and their community from potentially life-threatening diseases (The Right to Life of Michigan, n.d.). There is also a moral obligation within society to prevent disease epidemics (National Catholic Bioethics Center, 2006). The Right to Life of Michigan (n.d.) states, people who morally oppose the use of a vaccine created from an aborted stem cell line are justified in their opposition. In the case of herpes zoster vaccine, researchers did not obtain consent from the subjects and knowingly and purposefully ended the life of the fetus (The Right to Life of Michigan, n.d.). The ultimate ethical issue is how people should morally handle using a vaccine to protect people from disease when the vaccine originated from an immoral act of aborting a child.

The Catholic Church has decided that using vaccines is morally permissible, but when possible, providers should use vaccines not developed using cell strains obtained from an aborted fetus (National Catholic Bioethics Center, 2006). The Catholic Church also recommends seeking ethical alternative vaccines and pressuring vaccine manufactures to research and produce vaccines through morally acceptable means (National Catholic Bioethics Center, 2006). Due to moral and ethical concerns, the physician owner has chosen not to recommend herpes zoster vaccine to his patients. He has agreed to order the vaccine if the patient requests the it and he is allowing the other providers the free will to prescribe the vaccine at their discretion.

Results

The total number of adults with type II diabetes that entered the clinic during the ten weeks of project implementation was 182. Ninety-seven of the patients were male and 85 were female. The majority of the patients were privately insured (62%), white (91%), and non-Hispanic (60%). Thirty-two (18%) of the adult patients with type II diabetes were age 30 to 49, 68 (37%) age 50-64, and 82 (45%) age 65 or older. One-hundred seven (94%) of the adult

patients with type II diabetes race were white and 79 (43%) of the patients were Hispanic. The mean HbA1c was 7.4 and the mean BMI was 32.2 for all eligible patients (Table 4).

Table 4

Post-Intervention HbA1c and BMI Rates

HbA1c		BMI	
Mean	7.351	Mean	32.186
Median	6.7	Median	31.050
Std. Deviation	1.9526	Std. Deviation	7.47709
HbA1c \geq 6.5	108 (59%)	BMI \geq 30	99 (54%)
HbA1c < 6.5	74 (41 %)	BMI \geq 25 & <30	62 (34%)
		BMI < 25	21 (12%)

Of the 182 adult patients diagnosed with type II diabetes co-morbid conditions included 148 (81%) cardiac, 20 (11%) pulmonary, 32 (17%) endocrine, 24 (13%) psychiatric, 48 (26%) gastrointestinal, 26 (14%) renal, and 4 (2%) renal. One hundred four (73%) had no history of smoking, 17 (9%) were current smokers, and 30 (17%) were former smokers.

Of the 182 eligible patients, 100 (55%) were screened over 10 weeks using the vaccine needs assessment. Vaccine needs assessment screening was completed during 1st and 2nd weeks 39 out of 62 times (63%), the 3rd and 4th weeks had 15 out of 34 (44%), the 5th and 6th weeks had 16 out of 36 (53%), the 7th and 8th weeks had 12 out of 23 (52%), and the 9th and 10th weeks had 18 out of 29 (62%) (Figure 1). The screening percentage fluctuated throughout the project. During the 3rd and 4th weeks the staff thought the project had completed and stopped handing out the screening tool 1 month early. The screening tool was re-implemented in the 5th week. Reported reasons for not using the vaccine needs screening tool included:

- “I forgot.”

- “The patient wasn’t given one at check-in and I didn’t have time to get one.”
- “I use the quality tab to notify me when patient’s need vaccines.”
- “I’m too busy.”

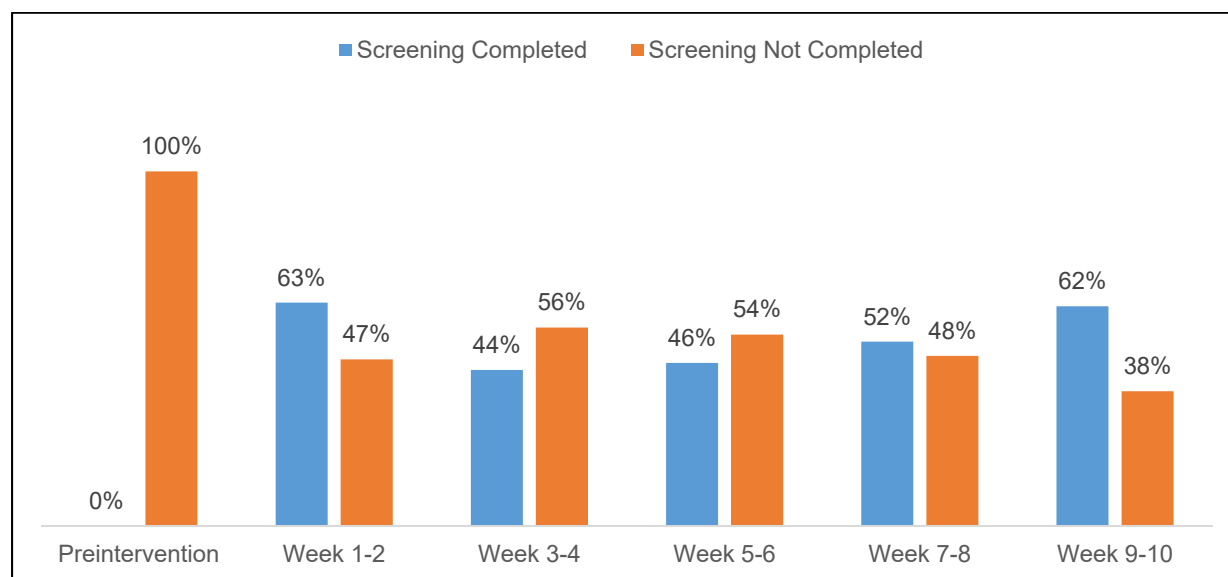


Figure 1. Pre and post-intervention vaccine needs screening. This figure illustrates the changes in pre and post-intervention vaccine needs screening.

A Spearman’s rho coefficient was performed on post-intervention data to examine the relationship between screening patients for vaccine need and patient receipt of the herpes zoster vaccine. The relationship between these variables was significant, $r = .20$, $p < .01$ (Table 5).

Formal vaccine education was done during the 1st and 2nd weeks four out of 62 times (6%), during the 3rd and 4th weeks six out of 34 times (18%), during the 5th and 6th weeks 10 out of 36 times (28%), during the 7th and 8th weeks 11 out of 23 times (43%), and during the 9th and 10th weeks nine 18 out of 29 times (62%) (Figure 2). During the initial phase of the project, the education handout was not being utilized. During the 6th week of project implementation two of the providers reported they preferred to give verbal education as opposed to the handout, but

agreed to provide printed education. At project completion 37 out of 49 (76%) patients who received formal printed education on vaccines and diabetes received all recommended vaccines.

Table 5

Relationship Between Screening and Administration of Herpes Zoster Vaccine (HZV)

Relationship	Test	Received HZV	Screening
Received HZV	Correlation Coefficient	1.000	.204*
	Sig. (2-tailed)	.	.006
	N	182	182
Screening	Correlation Coefficient	.204*	1.000
	Sig. (2-tailed)	.006	.
	N	182	182

Note. *Correlation is significant at the 0.01 level (2-tailed).

Many patients were unaware that specific immunizations are recommended for patients with type II diabetes. They were also unaware that elevated blood glucose decreases immunity and places the patient at increased risk of acquiring vaccine preventable diseases. Patients received PVC13 (81%), PPSV23 (82%), tetanus (76%), and herpes zoster (60%) vaccines after they received formal printed education indicating a direct correlation between vaccine administration and patient education. Reported reasons for not using the printed education on diabetes and vaccines included:

- “I forgot.”
- “I couldn’t find it.”
- “I prefer to do verbal education.”

A Spearman's rho coefficient was performed on post-intervention data to examine the relationship between using formal printed education and the patient receipt of a vaccine. The relationship between these variables was significant, $r = .17, p < .05$ (Table 6).

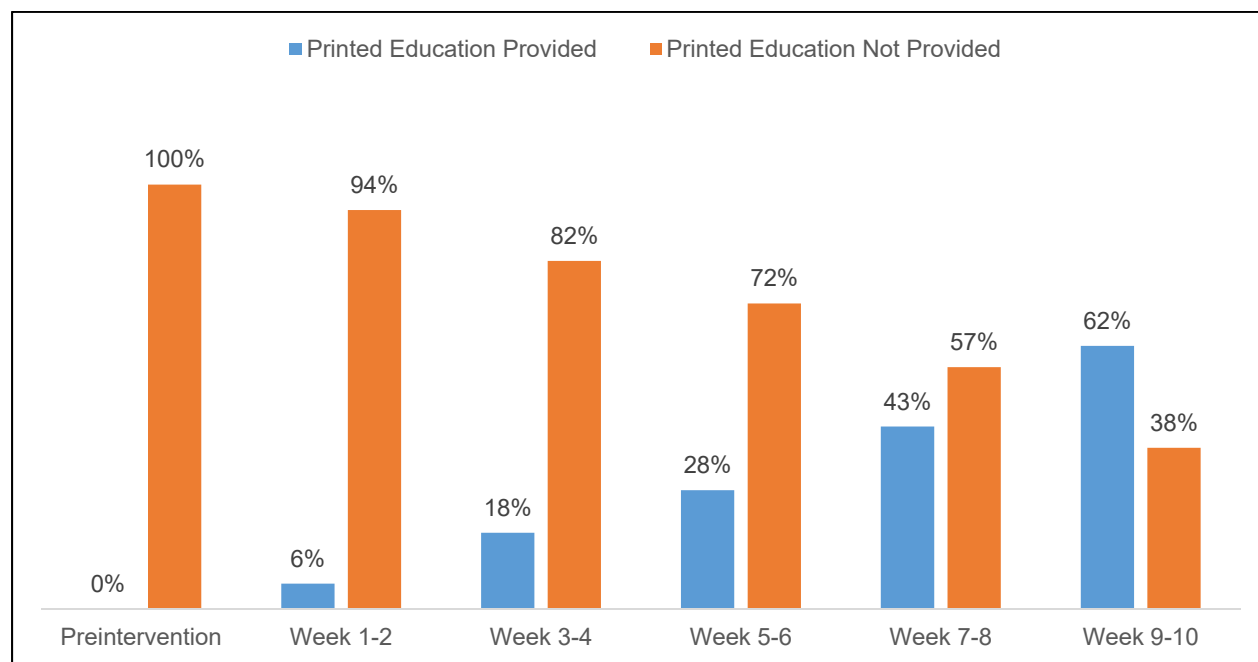


Figure 2. Pre and post-intervention patient education. This figure illustrates pre and post-intervention receipt of patient education.

A chi-square test of independence was performed, including both the pre-intervention and post-intervention data, to examine the relationship between implementation of The Four Pillars Transformation Program™ and administration of one or more recommended vaccines. The relationship between these variables was significant, $\chi^2(1, 335) = 25.78, p < .05$ (Table 7).

At project completion all vaccine administration rates exceeded the project goal of 20% improvement from pre-intervention rates. Pneumococcal polysaccharide vaccine rates increased from 21% to 64%, PVC13 rates increased from 49% to 86%, tetanus rates increased from 24% to 89%, and herpes zoster vaccine rates increased from 17% to 54% after 10 weeks of project implementation (Table 8). Pre-intervention data revealed 79 out of 153 (52%) adults with type II

Table 6

Relationship Between Education and Vaccination

Relationship	Test	Received at least 1 vaccine	Education
Received at least 1 vaccine	Correlation Coefficient	1.000	.173*
	Sig. (2-tailed)	.	.020
	N	182	182
Education	Correlation Coefficient	.173*	.033
	Sig. (2-tailed)	.020	.
	N	182	182

Note. * Correlation is significant at the 0.05 level (2-tailed).

diabetes received one or more recommended vaccines. Post-intervention 142 out of 182 (78%) adults with type II diabetes received one or more recommended vaccines.

During the 10 weeks of project implementation multiple patients declined the recommended vaccines. Three patients declined PVC13, eight patients declined PPSV23, two patients declined the tetanus vaccine, and two patients declined the herpes zoster vaccine. Overall, 15 (8%) of the eligible patients with type II diabetes declined the recommended vaccines. Reported reasons for patients refusal of vaccines included:

- “I don’t believe in vaccines.”
- “I always get sick after I have a vaccine.”
- “I think I have had this vaccine but I don’t remember.”
- “I’m sick so I don’t want the vaccine.”
- “I’ll get the vaccine at my next appointment.”

- “Vaccines cost too much.”

Table 7

Relationship Between Implementation of The Four Pillars Transformation Program™ and Administration of One or More Vaccines

Test	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2- sided)	Exact Sig. (2- sided)
Pearson Chi- Square	25.782 ^a	1	.000		
Continuity Correction ^b	24.620	1	.000		
Likelihood Ratio	25.993	1	.000		
Fisher's Exact Test		1		.000	.000
Linear-by-Linear Association	25.705	1	.000		
N of Valid Cases	335				

Note. ^a (0.0%) have expected count less than 5. The minimum expected count is 52.07.

^b Computed only for a 2X2 table

Discussion

The vaccine needs assessment was not consistently administered to all patients that entered the practice during the project. The absence of completed vaccine needs assessment tools limited identification of patients who required education and vaccinations. In a study conducted by Lu, O'Halloran, Ding, Srivastav, & Williams (2016), 87% of unvaccinated high risk adults attended at least one provider visit in the past year where a vaccine could have been administered but was missed. At the end of project implementation, 62% of eligible patients were screened using the vaccine needs assessment tool indicating missed opportunities occurred in 38% of the eligible patients. In this project screening was shown to have a significant relationship to herpes

Table 8

Pre and Post-intervention Vaccine Administration Rate

Date	PPSV23	PVC13	Tetanus	Herpes Zoster
Pre-intervention	21%	49%	24%	17%
5/31/17- 6/14/17	64%	83%	62%	44%
6/15/17- 6/28/17	78%	69%	62%	44%
6/29/17-7/12/17	64%	100%	85%	59%
7/13/17- 7/26/17	88%	75%	88%	57%
7/27/17- 8/9/17	64%	86%	89%	54%

zoster vaccine administration. The screening tool served as a way to educate staff and help with patient decision making while limiting the number of missed opportunities for vaccine uptake.

At 10 weeks post initiation of the interventions, 62% of eligible patients received formal education. After receiving printed education on diabetes and vaccines 76% of eligible patients received all recommended vaccines. There was a significant correlation between patient education and patient consent to vaccines during the project. In a 2012 study of adults age 60 and older only 14% reported a medical provider discussed the herpes zoster vaccine with them and 59% of the unvaccinated patients reported they would consent to the vaccine after education was delivered by the provider (Lee et al., 2013). The education flyer served as a way to educate staff and patients on recommended vaccines and their risks associated with diabetes and vaccine-preventable infectious diseases.

Type II diabetes restricts insulin's ability to work in the body because the body has become resistant to insulin, or the body cannot produce enough insulin to lower blood glucose levels (Knapp, 2013). Chronic hyperglycemia creates an altered immune response making

susceptibility to infection more common in adults with type II diabetes (Knapp, 2013). The risk for mortality related to infectious disease is doubled for individuals with a 6.5 HbA1c or higher compared to those with a 5.2 or lower HbA1c (Breitling, 2016). The post-intervention data revealed 108 of the 182 (59%) adults with type I diabetes had HbA1c levels greater than or equal to 6.5, making them highly susceptible to morbidity and mortality associated with vaccine-preventable infectious diseases.

Elevated BMIs place adults with type II diabetes at greater risk for adverse outcomes. Cardiovascular complications occur in 70.3% of adults with diabetes (Gray, Picone, Sloan, & Yashkin, 2015). Women have a 1.34 times higher risk of cardiovascular complications when their BMI is slightly over 25 (Gray et al., 2015). Men have a 1.22 increased risk of cardiovascular complications when they have a BMI of 27-29 (Gray et al., 2015). The risk increases with BMIs 30 or higher for both women and men (Gray et al., 2015). Of the 182 adults with type II diabetes that participated in the quality improvement project, 21 (12%) had a BMI less than 25, 62 (34%) had a BMI of 25 or greater but less than 30, and 99 (54%) had a BMI of 30 or higher. The post-intervention data also revealed 148 of the 182 (81%) patients had cardiovascular complications.

The protocol is a practical method for screening, educating, and vaccinating patients with type II diabetes at risk for acquiring vaccine-preventable diseases. In previous studies, the use of The Four Pillars Transformation Program™ improved vaccination rates by 2.7% to 25% from baseline over 1 year (Lin et al., 2016; Nowalk et al., 2014; Zimmerman et al., 2017). Over a 10 week period of time this quality improvement project saw a 37% to 65% improvement from baseline in PPSV23, PVC13, tetanus, and herpes zoster vaccination rates. The use of The Four Pillars Transformation Program™, an immunization champion, and biweekly quality

improvement meetings was a sustainable way to keep all providers and staff informed about immunizations and the tools needed to complete the project. Provider adherence to screening, education, and immunizing patients improved over the course of the project which enabled more patients to receive recommended vaccinations than prior to project implementation. The Four Pillars Transformation Program™ has been previously used in other quality improvement projects and is transferable to additional practices and other patient populations. The project can easily be replicated and altered by any medical practice to meet the needs of the clinic.

A significant component of success was the diverse care team, facility culture that emphasized systems behavior, and motivation from the immunization champion. Both MAs and providers facilitated communication about immunization needs to patients, families, and each other. Two weeks post interactive group education all immunization rates increased by 27%-43% from baseline. Biweekly quality improvement meetings were initially led by the project leader then taken over by the providers in the 4th week. Quality meetings allowed providers and staff the ability to see real-time feedback on the progress made in screening, educating, and immunizing adults with type II diabetes. During the quality meeting staff roles and responsibilities were occasionally redefined to support improved processes. Quality meetings also served as continued reminders to sustain the improvement and as additional motivation for the providers and staff.

Limitations

The quality improvement project had several limitations as a result of the complexity of managing multiple interventions including group education, EMR alerts, flyers, standing orders for all immunizations, a vaccine clinic that runs during office hours, vaccine screening, patient education, a facility immunization champion, and biweekly quality improvement meetings. The

multifaceted quality improvement approach for improving immunizations of patients with type II diabetes did not allow for interventions such as an immunization champion, EMR alerts, quality meetings, and flyers to be rigorously tested for significance. The project goal was to significantly improve vaccination rates in an at risk-population therefore making it a priority to create a robust intervention program with greater likelihood of success as opposed to testing each intervention separately.

An additional limitation was the time restriction on project implementation. During the 10 week period of time 182 adults with type II diabetes entered the clinic. A longer time period for project implementation may have increased the number of eligible patients and further tested the project's sustainability through bi-weekly quality meetings, and supervision and motivation from the immunization champion.

The majority of the patients were privately insured (62%), white (91%), and non-Hispanic (60%) which does not include marginalized or underserved populations. This project was limited in the ability to directly implement the project in another setting as the population and providers were limited in diversity. The clinic is a small privately owned practice and more diversity may be seen in large corporately owned practices or government run facilities.

Another limitation is this project was conducted with readily available vaccines purchased by the clinic. Many practices have limited finances to purchase vaccines, and must follow regulations provided by government programs and grants with the consideration of vaccine purchasing. The project intervention strategies did not consider inadequate or limited vaccine supplies.

Recommendations

The clinic's pre-intervention immunization rate for adults with type II diabetes mirrored local and national averages indicating a significant need for quality improvement projects aimed at improving vaccination rates in the family practice setting. This project focused on improving PPSV23, PVC13, tetanus, and herpes zoster vaccination rates in adults with type II diabetes. The processes and interventions can be applied to any quality improvement initiative focused on improving vaccination rates. In this project the key interventions implemented for improving administration of recommended vaccines were vaccine needs assessment screening and providing education to facilitate patient's informed decision making. Further exploration into additional interventions is necessary to identify why 24% of the patients with diabetes who received printed education chose not to receive recommended vaccinations. In a triangulated, mixed methods study conducted by Nowalk et al. (2014), using The Four Pillars Transformation ProgramTM, it was discovered that despite education staff generally feel unprepared to deal with patient's refusal of vaccines. Nowalk et al. (2014) suggests creating prewritten staff responses for patients who refuse vaccines. During this project, reasons for refusal were not documented in the EMR and may have helped staff and providers understand patient's fear, knowledge, and misinformation about specific vaccines. Modifications to the current EMR quality indicators should be considered and include a section that lists reasons for vaccine refusal. An additional next level alert that indicates the patient needs further education on vaccines could also benefit this population. During future appointments the alert will remind the provider to revisit the immunization discussion which should include benefits of each vaccine and risks associated with diabetes and vaccine-preventable disease.

Though interventions such as an immunization champion and biweekly quality meetings were not rigorously tested for significance in this project, they served as a way to facilitate a

systems culture within the practice. The immunization champion served as a resource and motivation for the team. The immunization champion selected was an MA who understood all staff roles within the practice. Biweekly quality meetings facilitated teamwork, increased awareness and accountability, and served as motivation to improve vaccination rates. Daily team huddles were not used in this project, but have been proven to be a useful way to improve communication, team work, patient flow, and quality of care delivered. A team huddle could be an effective way to review patients' missing immunizations before the patients arrive for the day and identify potential issues with vaccine stock or educational materials.

During the project multiple patients reported they believed they had received a specific vaccine but did not have a record for it. In future projects the implementation of a health information exchange program prior to project implementation would allow for online movement of patient's health information amongst healthcare providers. Patient information from previous medical visits or hospitalizations can be accessed by the provider regardless of where the patient seeks care which can reduce fragmented care. This intervention could eliminate redundancy in patient's immunizations and minimize the risk of patients not receiving recommended vaccines.

Implications for Practice

Vaccine-preventable infectious disease morbidity and mortality can be prevented through the use of recommended vaccines. This project has far-reaching public health implications, as it can provide a path for improving all vaccination rates and thereby increasing herd immunity and decreasing morbidity and mortality in high-risk populations. Government sanctioned quality measures currently track PPSV23 and PVC13 vaccination rates for adults with type II diabetes yet the national and local rates are far below Healthy People 2020's goal of 60% immunization

of high-risk adults aged 19-64 and 90% for adults aged 65 and over. These intervention strategies need to be disseminated to providers to improve the health of adults with type II diabetes.

This project was implemented in a family practice setting and focused on adults with type II diabetes, but similar quality improvement projects could be implemented in other specialty practices for patients at risk for acquiring vaccine-preventable diseases. The Four Pillars Transformation ProgramTM allows the practice the ability to modify and select interventions that best suit the practice's needs making it a feasible tool for any specialty clinic.

Advance Practice Registered Nurses (APRN) with a Doctor of Nursing Practice (DNP) degree have training and preparation in leadership roles, evaluation and application of evidence-based practice, quality improvement, and organization and systems impact on practice change. A DNP APRN is uniquely qualified to critique practice and redesign care delivery which can significantly impact healthcare outcomes such as improving vaccination rates in adults with type II diabetes. The leadership and clinical skills of a DNP APRN allows for implementation of evidence-based practice guidelines, such as The Four Pillars Transformation ProgramTM, beyond the individual providers by focusing on micro and macrosystems.

Conclusion

Type II diabetes remains one of the leading causes of death in the United States. Elevated blood glucose levels increase the risk of acquiring vaccine-preventable infectious diseases and accelerates complications in adults with type II diabetes. Despite readily available immunizations and recommendations from ADA, AACE, and ACE, the national and local PPSV23, PVC13, tetanus, and herpes zoster vaccination rates in adults with type II diabetes remain low. This quality improvement project showed significant improvement in PPSV23, PVC13, tetanus, and herpes zoster vaccination rates in adults with type II diabetes. Interventions based on The Four

Pillars Transformation Program™ were implemented and sustained over 10 weeks. The successful implementation of these interventions led to a significant increase in post-intervention screening (62%) and education (62%) rates. At project completion PPSV23 (64%), PVC13 (86%), tetanus (89%), and herpes zoster (54%) vaccination rates also increased in adults with type II diabetes. The results indicate that formal printed education on diabetes and vaccines increased vaccine uptake in eligible patients by 76% but further exploration into additional interventions is necessary to identify why 24% of the adult patients with type II diabetes chose not to receive recommended vaccinations.

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Appendix A: Vaccine Needs Assessment

<input type="text"/>	Provider Initials	Patient Name: _____ Date: _____
<input type="text"/>	MA Initials	
<input type="text"/>	Education Given	

We believe that getting vaccinated is a critical step in protecting your health. Vaccines can help prevent common diseases that can be serious and costly for you or your loved ones.

Each year, thousands of adults in America suffer serious health problems (and some even die) from diseases they could be vaccinated against like whooping cough, hepatitis A and B, flu and pneumococcal diseases, and shingles. Older adults and those with chronic health conditions are at increased risk for complication from certain diseases.

Together, let's take an active role in helping you and your loved ones stay healthy. To learn more about vaccines for adults, visit www.cdc.gov/vaccines/adults or take a quick vaccine quiz at www.cdc.gov/vaccines/adultquiz.

Please take a moment to fill out the questionnaire below to help us determine which vaccines may be recommended for you based on your specific health status, age, and lifestyle. Keep in mind that this list may not include every vaccine you need.

Check all that apply to you	Let's discuss these recommended vaccines	Office Use Only
<input type="checkbox"/> I am 19 years or older	<ul style="list-style-type: none"> Seasonal Flu (Influenza) vaccine every year Tetanus (Td) vaccine every 10 years One time dose of whooping cough (Tdap) vaccine for all adults who have never received Tdap vaccine <div>PREGNANT WOMEN SHOULD GET A Tdap VACCINE DURING EACH PREGNANCY</div>	<input type="checkbox"/> influenza <input type="checkbox"/> Td
<input type="checkbox"/> I am 60 years or older	<ul style="list-style-type: none"> Shingles (Zoster) vaccine* 	<input type="checkbox"/> zoster
<input type="checkbox"/> I am 65 years or older	<ul style="list-style-type: none"> Both types of pneumococcal vaccines (one dose of conjugate first, then one dose of polysaccharide 6-12 months later) 	<input type="checkbox"/> 23 or 13
<input type="checkbox"/> I didn't receive the Human papillomavirus (HPV) vaccine series as a child	<ul style="list-style-type: none"> HPV vaccine series (3 dose series) <ul style="list-style-type: none"> Female age 26 or younger Male age 21 or younger Male age 22-26 who has sex with men, who has a weakened immune system, or who has HIV 	
<input type="checkbox"/> I was born in the US in 1957 or after and don't have immunity against measles, mumps, and rubella	<ul style="list-style-type: none"> Measles, mumps, rubella (MMR) vaccine* (one dose) 	
<input type="checkbox"/> I was born in the US in 1980 or after and don't have immunity against chickenpox	<ul style="list-style-type: none"> Varicella "chickenpox" vaccine* 	
<input type="checkbox"/> I am a healthcare worker	<ul style="list-style-type: none"> Hepatitis B vaccine series Measles, mumps, rubella (MMR) vaccine* Varicella "chickenpox" vaccine* 	
<input type="checkbox"/> I have heart disease, asthma or chronic lung disease	<ul style="list-style-type: none"> Pneumococcal polysaccharide vaccine 	

Flip page to continue questionnaire →



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Healthcare Provider Office Information

Check all that apply to you	Let's discuss these recommended vaccines	Office Use
<input type="checkbox"/> I have type 1 or type 2 diabetes	<ul style="list-style-type: none"> Hepatitis B vaccine series Pneumococcal polysaccharide vaccine 	<input type="checkbox"/> # 1- 2- 3 <input type="checkbox"/> 23
<input type="checkbox"/> I have a weakened immune system	<ul style="list-style-type: none"> Both types of pneumococcal vaccines (one dose of conjugate first, then one dose of polysaccharide ≥ 8 weeks later) HPV vaccine series (if 26 years of age or younger and not previously vaccinated) Hib vaccine (post-hematopoietic stem cell transplant only) 	
<input type="checkbox"/> I have HIV	<ul style="list-style-type: none"> Hepatitis B vaccine series Both types of pneumococcal vaccines (one dose of conjugate first, then one dose of polysaccharide ≥ 8 weeks later) HPV vaccine series (if 26 years of age or younger and not previously vaccinated) 	
<input type="checkbox"/> I have chronic liver disease	<ul style="list-style-type: none"> Hepatitis A vaccine series Hepatitis B vaccine series Pneumococcal polysaccharide vaccine 	
<input type="checkbox"/> I do not have a spleen or my spleen does not work well	<ul style="list-style-type: none"> Hib vaccine Meningococcal vaccine Both types of pneumococcal vaccines (one dose of conjugate first, then one dose of polysaccharide ≥ 8 weeks later) 	
<input type="checkbox"/> I am a man who has sex with men	<ul style="list-style-type: none"> Hepatitis A vaccine series Hepatitis B vaccine series HPV vaccine series (if 26 years of age or younger and not previously vaccinated) 	
<input type="checkbox"/> I am a laboratory worker and may be routinely exposed to isolates of <i>Neisseria meningitidis</i> , or specimens potentially containing hepatitis A or hepatitis B virus	<ul style="list-style-type: none"> Hepatitis A vaccine series Hepatitis B vaccine series Meningococcal vaccine 	
<input type="checkbox"/> I am a college freshman living in a residence hall	<ul style="list-style-type: none"> Meningococcal vaccine Measles, mumps, rubella (MMR) vaccine* 	
<input type="checkbox"/> I am planning to travel out of the U.S.	Talk to your healthcare professional to learn which vaccines you may need based on locations of travel.	

*This is a live vaccine and should not be given to people who have a very weakened immune system, including those with a CD4 count less than 200, or to pregnant women.



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Appendix B: What You Need to Know About Diabetes and Adult Vaccines

INFORMATION SERIES FOR ADULTS

What You Need to Know About Diabetes and Adult Vaccines

Each year thousands of adults in the United States get sick from diseases that could be prevented by vaccines — some people are hospitalized, and some even die. People with diabetes (both type 1 and type 2) are at higher risk for serious problems from certain vaccine-preventable diseases. **Getting vaccinated is an important step in staying healthy.**

Why Vaccines are Important for You

- Diabetes, even if well managed, can make it harder for your immune system to fight infections, so you may be at risk for more serious complications from an illness compared to people without diabetes.
 - Some illnesses, like influenza, can raise your blood glucose to dangerously high levels.
 - People with diabetes have higher rates of hepatitis B than the rest of the population. Outbreaks of hepatitis B associated with blood glucose monitoring procedures have happened among people with diabetes.
 - People with diabetes are at increased risk for death from pneumonia (lung infection), bacteremia (blood infection) and meningitis (infection of the lining of the brain and spinal cord).
- Immunization provides the best protection against vaccine-preventable diseases.
- Vaccines are one of the safest ways for you to protect your health, even if you are taking prescription medications. Vaccine side effects are usually mild and go away on their own. Severe side effects are very rare.

Getting Vaccinated

You regularly see your provider for diabetes care, and that is a great place to start! If your healthcare professional does not offer the vaccines you need, ask for a referral so you can get the vaccines elsewhere.

Adults can get vaccines at doctors' offices, pharmacies, workplaces, community health clinics, health departments and other locations. To find a place near you to get a vaccine, go to <http://vaccine.healthmap.org>.

Most health insurance plans cover recommended vaccines. Check with your insurance provider for details and for a list of vaccine providers covered by your plan. If you do not have health insurance, visit www.healthcare.gov to learn more about health insurance options.

For more information on vaccines, go to www.cdc.gov/vaccines/adults.



What vaccines do you need?

- **Flu vaccine** every year to protect against seasonal flu
- **Pneumococcal vaccines** to protect against serious pneumococcal diseases
- **Hepatitis B vaccine series** to protect against hepatitis B
- **Tdap vaccine** to protect against tetanus, diphtheria, and pertussis (whooping cough)
- **Zoster vaccine** to protect against shingles if you are 60 years or older

There may be other vaccines recommended for you so be sure to talk with your healthcare professional about what is right for you.

DON'T WAIT. VACCINATE!



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Appendix C: Lo Que Necesita Saber Sobre la Diabetes y Vacunas para los Adultos

SERIE INFORMATIVA PARA ADULTOS

Lo que necesita saber sobre la diabetes y las vacunas para los adultos

Cada año, miles de adultos en los Estados Unidos contraen enfermedades que se pueden prevenir con vacunas; algunos de ellos son hospitalizados y otros incluso mueren. Las personas que tienen diabetes (tanto tipo 1 como tipo 2) están en mayor riesgo de tener problemas graves con ciertas enfermedades que se pueden prevenir con vacunas. Vacunarse es una medida importante para mantenerse sano.

Por qué es importante que se vacune

- La diabetes, aunque esté bien controlada, puede hacer que le sea más difícil a su sistema inmunitario luchar contra las infecciones, por lo tanto, usted podría estar en riesgo de complicaciones más graves por una enfermedad, comparado con las personas que no tienen diabetes.
- Algunas enfermedades, como la influenza (gripe), pueden elevar los niveles de glucosa en la sangre a niveles peligrosamente altos.
- Las personas que tienen diabetes tienen tasas más altas de hepatitis B que el resto de la población. Se han producido brotes de hepatitis B asociada a procedimientos de medición de glucosa entre las personas con diabetes.
- Las personas que tienen diabetes están en mayor riesgo de morir de neumonía (infección de los pulmones), bacteremia (infección de la sangre) o meningitis (infección del recubrimiento del cerebro y la médula espinal).
- Las vacunas proporcionan la mejor protección contra las enfermedades que se pueden prevenir.
- Vacunarse es una de las maneras más seguras en que usted puede proteger su salud, incluso si está tomando medicamentos recetados. Los efectos secundarios de las vacunas generalmente son leves y desaparecen solos. Es muy raro que se produzcan efectos secundarios graves.


Vacunarse

Quizás vea regularmente a su proveedor de atención para la diabetes, ¡y él o ella puede ayudar! Si su profesional de la salud no ofrece las vacunas que usted necesita, pídale una remisión para poder ponérselas en otro lado.

Los adultos pueden vacunarse en un consultorio médico, una farmacia, su lugar de trabajo, un centro de salud comunitario, el departamento de salud y en otros lugares. Para encontrar un lugar cercano de vacunación, consulte <http://vaccine.healthmap.org> (en inglés).

La mayoría de los planes de los seguros médicos cubren las vacunas recomendadas. Consulte los detalles con su seguro médico y pida una lista de proveedores de vacunas que estén cubiertos por su plan. Si no tiene seguro médico, visite www.cuidadoesalud.gov/es/ para obtener más información sobre las opciones de seguro médico.

Para obtener más información acerca de las vacunas, visite www.cdc.gov/vaccines/adults/espanol.




¿Qué vacunas necesita?

- La vacuna contra la influenza (gripe) todos los años para protegerse contra la influenza estacional.
- Las vacunas antineumocóccicas para protegerse contra las enfermedades neumocóccicas graves.
- La serie de vacunas contra la hepatitis B para protegerse contra esta enfermedad.
- La vacuna Tdap para protegerse contra el tétanos, la difteria y la tosferina (whooping cough).
- La vacuna contra el herpes zóster para protegerse contra la culebrilla (shingles), si es mayor de 60 años.

Es posible que haya otras vacunas recomendadas para usted, así que asegúrese de hablar con su profesional de la salud sobre cuáles son adecuadas para usted.

NO ESPERE. ¡VACÚNESE!



U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

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Appendix D: Standing Orders for Administering Tdap/Td Vaccine to Adults

Standing orders for other vaccines are available at www.immunize.org/standing-orders.
 NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR Administering Tdap/Td Vaccine to Adults

Purpose

To reduce morbidity and mortality from tetanus, diphtheria, and pertussis infection by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1 Assess Adults for Need of Vaccination against tetanus, diphtheria, and pertussis based on the following criteria:

- Lack of documentation of ever receiving a dose of tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap) as an adolescent or adult
- Currently pregnant and no documentation of Tdap given during current pregnancy
- Lack of documentation of receiving at least 3 doses of tetanus- and diphtheria-containing toxoids (Tdap/Td)
- Completion of a 3-dose primary series of tetanus- and diphtheria-containing toxoids with no documentation of receiving a booster dose in the previous 10 years
- Recent deep and dirty wound (e.g., contaminated with dirt, feces, saliva) and lack of evidence of having received tetanus toxoid-containing vaccine in the previous 5 years

2 Screen for Contraindications and Precautions

Contraindications

- Do not give Tdap or Td to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of either vaccine or to any of its components. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf.
- Do not give Tdap to a person who has experienced encephalopathy within 7 days following DTP/DTaP/Tdap not attributable to another identifiable cause.

Precautions

- History of Guillain-Barré syndrome within 6 weeks of a previous dose of tetanus toxoid-containing vaccine
- History of an Arthus-type hypersensitivity reaction after a previous dose of tetanus or diphtheria toxoid-containing vaccine; in such cases, defer vaccination until at least 10 years have elapsed since the last tetanus toxoid-containing vaccine
- Moderate or severe acute illness with or without fever
- For Tdap only, progressive or unstable neurologic disorder, uncontrolled seizures or progressive encephalopathy until the patient's treatment regimen has been established and the condition has stabilized

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

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4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

GENDER AND WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Female or male less than 130 lbs	22–25	5/8"–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm

* A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin.

5 Administer Tdap or Td Vaccine, 0.5 mL, via the intramuscular (IM) route, according to the following criteria and schedule:

The routine schedule for Tdap/Td vaccination is to administer a 3-dose series at 0, 1, and 6–12 month intervals, including one dose of Tdap, preferably as the first dose, followed by a Td booster every 10 years. If Td is indicated but not available, Tdap may be substituted.

HISTORY OF PREVIOUS Tdap/Td VACCINATION	DOSE AND SCHEDULE FOR ADMINISTRATION OF Tdap AND Td
0 documented doses, or none known	Give 0.5 mL Tdap as dose #1. Give dose #2 (Td) at least 4 weeks later, and dose #3 (Td) 6–12 months after dose #2.
1 previous dose, Td	Give 0.5 mL Tdap as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td) 6–12 months after dose #2.
1 previous dose, Tdap	Give 0.5 mL Td, as dose #2 at least 4 weeks after dose #1. Give dose #3 (Td) 6–12 months after dose #2.
2 previous doses, both Td	Give 0.5 mL Tdap as dose #3 at least 6 months after dose #2.
2 previous doses, 1 Td and 1 Tdap	Give 0.5 mL Td at least 6 months after dose #2.
3 or more previous doses, Td only	Give 0.5 mL Tdap as soon as possible. (You do not need to wait 10 years from previous dose.)
3 or more previous doses, including 1 dose of Tdap	Give 0.5 mL Td booster every 10 years unless patient needs prophylaxis for wound management sooner.

Tdap vaccination for pregnant women

Pregnant women should receive Tdap during **each** pregnancy, preferably early during the window of 27 through 36 weeks' gestation, regardless of number of years since prior Td or Tdap vaccination.

6 Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

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7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8 Report all Adverse Events to VAERS

Report all adverse events following the administration of tetanus-, diphtheria-, and pertussis-containing vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Forms are available on the website or by calling (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____		
<small>NAME OF PRACTICE OR CLINIC</small>		
until rescinded or until _____		
<small>DATE</small>		
Medical Director's signature _____	Signature date _____	Effective date _____

Appendix E: Standing Orders for Administering Zoster Vaccine to Adults

Standing orders for other vaccines are available at www.immunize.org/standing-orders.
NOTE: This standing orders template may be adapted per a practice's discretion without obtaining permission from IAC. As a courtesy, please acknowledge IAC as its source.

STANDING ORDERS FOR Administering Zoster Vaccine to Adults

Purpose

To reduce morbidity and mortality from herpes zoster infection (shingles) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

- 1 **Assess Adults Age 60 Years and Older for Need of Vaccination** against herpes zoster virus infection. Documentation of prior receipt of a single dose of zoster vaccine is evidence of immunity.

- 2 **Screen for Contraindications and Precautions**

Contraindications

- Do not give zoster vaccine to a person who has experienced a serious systemic or anaphylactic reaction to a vaccine component, including gelatin and neomycin. For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/packageinserts) or go to www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/exciptient-table-2.pdf.
- Do not give zoster vaccine to a person who has primary or acquired immunodeficiency, including:
 - leukemia, lymphomas, or other malignant neoplasms affecting the bone marrow or lymphatic system
 - AIDS or other clinical manifestations of HIV, including persons with CD4+ T-lymphocyte values ≤ 200 per mm^3 or $\leq 15\%$ of total lymphocytes
 - current immunosuppressive therapy, including high-dose corticosteroids (≥ 20 mg/day of prednisone or equivalent) lasting two or more weeks, or current receipt of recombinant human immune mediators and immune modulators, especially the antitumor necrosis factor alpha agents adalimumab, infliximab, and etanercept
 - clinical or laboratory evidence of other unspecified cellular immunodeficiency
 - history of hematopoietic stem cell transplantation
- Do not give zoster vaccine to a patient who is pregnant or has a possibility of pregnancy within 4 weeks of receiving the vaccine.

Precautions

- Moderate or severe acute illness with or without fever
- History of having received specific antivirals (i.e., acyclovir, famciclovir, or valacyclovir) within the previous 24 hours. Delay resumption of these antiviral drugs for 14 days after vaccination.

- 3 **Provide Vaccine Information Statements**

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

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4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

AGE OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
60 years or older	23–25	5/8"	Fatty tissue overlying triceps muscle

For details on preparing to administer zoster vaccine, see the package insert. Once reconstituted, the vaccine must be used within 30 minutes.

5 Administer Zoster Vaccine, 0.65 mL, Subcut, according to the information in the package insert and the table below:

AGE OF PATIENT	DOSE	ROUTE	INSTRUCTIONS
60 years or older	0.65 mL (entire amount in vial)	Subcutaneous (Subcut)	Administer vaccine in fatty tissue overlying triceps muscle.

6 Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Document the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS, if available.

7 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications. For IAC's "Medical Management of Vaccine Reactions in Adults," go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8 Report All Adverse Events to VAERS

Report all adverse events following the administration of zoster vaccine to the federal Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov. Forms are available on the website or by calling (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____		
<small>NAME OF PRACTICE OR CLINIC</small>		
until rescinded or until _____.		
<small>DATE</small>		
Medical Director's signature _____	Signature date _____	Effective date _____