Implementation of a Pneumococcal Immunization Standing Order Protocol in Long-Term Care

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Abstract

Problem & Purpose

Streptococcus pneumonia is a significant cause of morbidity and mortality of adults who are immunocompromised and of advanced age. It is the standard of care to vaccinate all high-risk adults (18-64 years) and adults 65 years and older with two pneumococcal vaccines (Centers for Disease Control and Prevention [CDC], 2015). However, pneumococcal immunization rates remain below the HeathyPeople2020 target goal of 90% nationally and locally (Office of Disease Prevention and Health Promotion [ODPHP], 2019). The objective of this quality improvement (QI) project was to implement the Immunization Action Coalition (2017) pneumococcal standing order protocol to increase the percentage of adult patients screened for vaccine need by 90%, and percentage of total residents vaccinated according to CDC recommendations by 10%.

Methods

The strategy of this QI project was to educate registered nurses to implement a pneumococcal standing order protocol, in a privately owned, 120-bed, long-term care (LTC) center in suburban Maryland. The design of this QI project was based on the diffusion of innovation theory, the 4 pillars practice transformation program (4 Pillars), and the Mobilize-Assess-Plan-Implement-Track (MAP-IT) process model. Weekly frequency distributions were used to examine the screening and vaccination rates, and a chi squared (X_2) test was performed post intervention to examine the significance of intervention on vaccination rates.

Results

The total number of LTC residents (n=100) were White (66%), Black (32%), other (2%), with an average age of 83 years. Pneumococcal immunization rates increased from 56% pre-intervention to 82% post-intervention, and screening rates for vaccination need increased from 0% to 100%. A chi-squared test for independence indicated a significant relationship between vaccination status and implantation of the SOP intervention ($p = 0.046$, d$f = 1$, n = 100).

Conclusions

This QI initiative showed that a systematic process change is feasible and can improve pneumococcal vaccination rates in a single institution. The findings may not be applicable to centers without an electronic medical record software to document immunizations or dedicated QI team. Ongoing work should focus on the perceived self-efficacy of LTC nursing staff to effectively implement a behavior change, and skills to provide strong recommendations for immunizations.

Introduction

Streptococcus pneumonia, a vaccine-preventable disease, was rated the eighth-leading cause of death with nearly 51,000 adult deaths annually (Centers for Disease Control and Prevention [CDC], 2016). Immunizations are a clinically beneficial, safe, and cost-effective intervention to prevent infectious disease, and the Office of Disease Prevention and Health Promotion (ODPHP, 2019) set a national goal to have 90% of adults aged 18 years and older, in long-term care (LTC) facilities, vaccinated against pneumococcal disease by 2020. However, pneumococcal vaccination rates of persons living in LTC remained below the national target at approximately 70% nationally in 2015 (ODPHP, 2019) and 60% locally in a 120-bed LTC facility in 2018. Organizational stakeholders at this suburban LTC facility identified inconsistent administration of the vaccines was the primary cause for suboptimal coverage rates.

Improving adult vaccine uptake is encouraged by the Centers for Medicare and Medicaid Services (2019) minimum data set (MDS 3.0), which outlines quality measures for residents in LTC facilities, including the percentage of residents assessed and appropriately given the pneumococcal vaccine. In addition to the low vaccination rates, the facility's internal QI team completed a chart audit which revealed there was no standardized vaccine screening protocol, and there were inconsistencies with vaccine administration documentation. Implementing an evidence-based structure and process to avoid missed opportunities to vaccinate residents against pneumococcal pneumonia can help promote positive patient outcomes and increase organizational quality ratings. The purpose of this Doctor of Nursing Practice (DNP) quality improvement (QI) project was to implement an evidence-based standing order protocol (SOP) to increase the percentage of adult patients in LTC appropriately screened and vaccinated against *streptococcus* pneumonia according to CDC recommendations.

Literature Review

Suboptimal vaccination rates in adults suggest there is a systematic failure to address immunization needs across the lifespan (de Gomensoro, Del Giudice, & Doherty, 2018). The 4 Pillars practice transformation program (4 Pillars™) is an evidence-based model shown to increase adult vaccination rates based on four strategies—Pillar 1: convenient vaccination services, Pillar 2: improved patient communication, Pillar 3: enhanced office systems, and Pillar 4: organizational motivation (Zimmerman et al., 2017). This review is a discussion of the evidence (see Appendix A) to support selected strategies for increasing adult vaccination rates.

Improved Patient Communication

Implementing an SOP provides nurses with language appropriate education materials to help improve and facilitate communication on pneumococcal vaccines with residents and family members. Chan et al. (2015) conducted a single-blinded cluster RCT to determine if a multi-component health education intervention (e.g., promotional leaflets, poster displays, and educational videos) increased PPSV23 vaccination rates and found the health education intervention significantly increased PPSV23 vaccine uptake in older adults. A systematic review and meta-analysis by Lau et al. (2012) also found educating patients about the pneumococcal vaccine through print materials and in-person education sessions improved PPSV23 vaccination rates. Nurses can use the CDC (2015) Vaccine Information Statement to provide standardized education to patients to help increase vaccination rates (Chan et al., 2015; Lau et al., 2012; Nowalk et al., 2014; Zimmerman et al., 2017).

Enhanced Systems

Standing orders are a part of an enhanced system that allows non-prescribing health care workers to independently administer recommended vaccinations, according to an approved

protocol (Community Preventative Services Task Force [CPSTF], 2015). The CPSTF (2015) supports standing orders for vaccinations based on a high-quality systematic review of 35 studies, including randomized controlled trials, showing an increase in overall vaccination rates with effective use of SOPs. Lau et al. (2012) conducted a systematic review and meta-analysis of 106 studies and found nurse-driven immunization SOPs were associated with increased pneumococcal vaccination rates. Zimmerman et al. (2017) conducted a 2-year randomized controlled cluster trial with over 18,000 patients aged 65 years and older and found implementation of the 4 Pillars showed a statistically significant increase in the PPSV23 and PCV13 vaccination rates for the control group. The studies to support the implementation of an SOP were conducted in the outpatient setting, which deserves consideration when expanding the application to an LTC setting as results may not be generalizable and may pose a threat to external validity.

Organizational Motivation

An immunization champion (IC) is an individual in the practice who facilitates and promotes the project through motivation (Zimmerman et al., 2017). Zimmerman et al. (2017) and Nowalk et al. (2014) saw increased immunization rates with the implementation of the 4 Pillars, which included one-on-one coaching of practice-based ICs. A qualitative study by Hawk et al. (2017) found practices were more likely to implement an SOP successfully when there was support through a facilitator such as an IC. Consistent use of vaccination SOPs was associated with greater provider awareness of the Advisory Committee on Immunization Practices (ACIP) recommendations and Medicare regulations for adult vaccines (Albert et al., 2012). ICs can support a successful SOP implementation by providing updated ACIP and Medicare guidelines to implementers (Nowalk et al., 2014; Zimmerman et al., 2017).

Theoretical Framework

Organizational change theories have a long history, and Rogers' diffusion of innovations (DOI) theory is widely cited in preventative health and health promotion literature (Goodroad, Webb, & Bredow, 2017). Rogers (2004) defined diffusion as "the process by which an innovation, defined as an idea perceived as new, spreads via certain communication channels over time among the members of a social system" (p.13). Diffusion occurs when there is an alteration in the structure and function of a social system, resulting in change (Rogers, 1983).

The DOI theory describes an innovation-decision process in which change agents move through an organizational system to implement new knowledge and mitigate uncertainty among program adopters (Goodroad et al., 2017). The five concepts of the innovative-decision process include knowledge, persuasion, decision, implementation, and confirmation (Rogers, 1983). The DOI theoretical concepts underpin the three main components of this DNP project: (a) determining the LTC units current pneumococcal vaccination rate (knowledge), (b) identifying and presenting high-quality evidence-based strategies for improvement to key stakeholders (persuasion), (c) accepting or rejecting the proposed practice change (decision), (d) testing the SOP (implementation), and (e) evaluating the results of the intervention (confirmation). Rogers' (1983) theory was chosen for this DNP project because it describes the influential factors that determine evidence-based practice change, and it was used in the design of essential studies including a landmark study examining the 4 Pillars intervention (Zimmerman et al., 2017).

Methods

This QI project was executed on two LTC units within a 4-unit rehabilitation facility from September to November 2019. The privately owned, suburban Maryland facility provides both short-term rehabilitation and long-term care services to residents with Medicare, Medicaid,

and private insurance. Inclusion criteria for this project were adult residents aged 65 years and older and residents aged 19-64 years with high-risk medical conditions (see section 1 in Appendix B). Exclusion criteria included residents with a documented contraindication to either pneumococcal vaccine or receipt of all pneumococcal vaccinations per CDC recommendations. Based on the population criteria outlined above, this DNP project impacted 100 eligible residents to be screened and appropriately vaccinated against *Streptococcus pneumoniae*.

The CDC (2015) pneumococcal vaccine recommendations support the goals of this QI project. The objective of this QI project was to implement the Immunization Action Coalition (2017) pneumococcal SOP, to increase the percentage of adult patients screened for vaccine need by 90% and vaccinated according to CDC recommendations by 10%.

Implementation Procedures

This DNP project was conducted over a 90-day pre- and postimplementation period. The intervention was employed to change current practice and initiate standardized pneumococcal screening and increase low vaccination rates in adult long-term care patients. Evidence-based strategies from the 4 Pillars included using all opportunities to vaccinate through the use of standing orders, immunization champions, progress charts, and staff education. The DNP student served as the project leader and introduced the structural changes, pneumococcal vaccination SOP and education training to nursing staff. Implementation tools include the Immunization Action Coalition: Standing Orders for Administering Pneumococcal Vaccines (see Appendix B), Practice Site Pneumococcal Vaccine Consent Form (see Appendix C), Vaccine Information Statement for PPSV23 (see Appendix D) and PCV13 (see Appendix E), and Medical Management of Vaccine Reactions in Adult Patients (see Appendix F). The implementation team used the Mobilize-Assess-Plan-Implement-Track (MAP-IT) QI process

methodology. Following the Institutional Review Board (IRB) non-human subjects research determination, trained nurses used the SOP to assess each resident's vaccination status weekly and appropriately vaccinate based on the residents' needs.

Measures Collected

The DNP project leader used a combination of electronically generated reports and manual chart audits (see Appendix G) to collect the following data: (a) demographics (age, gender, ethnicity), (b) pre- and postimplementation pneumococcal immunization status, (c) screening via SOP, and (d) immunization receipt via SOP. Retrospective electronic medical record reviews from all long-term care residents were conducted at the start of the project and continued weekly throughout the implementation phase. The DNP project leader and ICs shared outcome data points (immunization screening and administration rates) with nursing staff every week via graphical representation. Final data analyses will be presented to the administrative and clinical leaders, post-implementation, in the spring of 2020.

Data Analysis Plan

Microsoft Excel software was used to analyze data through descriptive statistics and statistical testing of pre- and postintervention. Frequency statistics were used to calculate the percentage of residents screened using the SOP; the number of LTC residents screened will be the numerator statement, and the total number of LTC residents will be the denominator statement. To measure the outcome goal, the number of eligible residents with documentation of both PPSV23 and PCV13 is the numerator statement, and the total number of eligible residents is the denominator statement. The statistical process control run chart was used for weekly screening and immunization rates. A chi-squared (x_2) statistical test was used to examine the relationship between residents screened and residents appropriately vaccinated.

Results

A total of 100 LTC residents were included in the project cohort. The average age of the entire cohort was 83 years, 77% were female, and 66% were non-Hispanic White. Key structure change includes education on the SOP tool and process change includes use of the SOP to screen and appropriately vaccinate adult LTC residents. The facility did not have a formal immunization screening tool; therefore, at baseline there was a 0% rate of pneumococcal immunization screening, with no change throughout the pre-intervention phase. Baseline vaccination rate was 56% and increased to 65% at the end of the pre-intervention stage, a consequence of nurses' heightened awareness of vaccination recommendations after the education session. Due to nearly meeting the project goal of a 10% increase from pre-intervention rates, the DNP project leader and implementation team increased the project goal to a total vaccination rate of 90%, per the HealthyPeople 2020 benchmark. Throughout the active intervention stage, screening rates increased to 100%, surpassing the 90% project goal. Post-intervention pneumococcal immunization rates were 85%, and a chi-squared test for independence indicated a significant relationship between vaccination status and the SOP intervention ($p = 0.046$, d$f = 1$, n =100).

Weekly QI meetings identified barriers associated with the implementation of the SOP intervention: (a) systems—inability to integrate the SOP into the electronic medical record, (b) resources—limited patient education resources and mediums of education materials, (c) staff—low priority for change among the unit nurses and perceived low self-efficacy of unit nurses to use SOP independently. To mitigate the staff barriers, the implementation team provided weekly education and motivation to staff nurses. After feedback from the staff nurses that there was perceived low self-efficacy with use of the SOP, the DNP project leader further simplified the

intervention by color coding the SOP. Color coding the tool allowed nurses to more clearly visualize the screening and vaccination procedure for each target group (e.g., green group represents patients 65 and older, yellow group represents 19-64 years with specific chronic conditions, and red group represents 19-64 years with high risk immunosuppressive disease states), while keeping the original evidence-based tool intact. Additionally, the DNP project leader trained nurses on how to educate patients on the necessity of the pneumococcal vaccines by using the CDC's Vaccine Information Statement. Lastly, the implementation team motivated the floor nurses to continue to buy into the change by showing the SOP helps to empower nurses, allows floor nurses to function to the full extent of their license, and includes simple step-by-step directions to appropriately screen and vaccinate adult residents. For this DNP project, we were not able to integrate the SOP into the electronic medical record and address the systems barrier.

The primary facilitator that led to the unexpected benefit of 100% screening rates and statistically significant vaccination rates was a process change during MAP-IT Cycle 3. The implementation team encouraged shared dialogue during weekly QI updates and, to overcome the staff barriers, the team changed the process to have the nurse managers screen and vaccinate residents. The nurse managers decided to integrate the SOP tool into the preexisting weekly audits required by organization administration. The implementation team, organizational leadership, and staff nurses collectively agreed on this process change. Additional facilitators were low cost of implementation because the facility already stocked both pneumococcal vaccines and the minimal cost of printing the SOP. The project site had a designated quality manager to help facilitate education, data collection, leadership buy-in, and team motivation.

Discussion

Patients in a suburban long-term care facility had low baseline rates of pneumococcal immunization and screening documentation. After implementing a QI initiative and conducting a number of improvement cycles, our analysis showed there was a significant increase in vaccination rates, from 56% to 85%, in 90-days. In addition, after Cycle 3 of our intervention, there was evidence of significant increase in vaccination screening rates, from 0% to 100%. Similar improvement rates have been shown by implementing the 4 Pillars in outpatient settings. In the 2018 study by Gottlieb and Dohls, PPSV23 vaccine rates increased from 21% to 64%, PCV13 rates increased from 49% to 86%, and the relationship between the 4 Pillars program and recommended vaccines was significant (Gottlieb & Dohls, 2018). Pennant et al. (2015) described implementing a nurse-driven model, which gave nurses complete autonomy over vaccine eligibility screening and administration. Pneumococcal vaccine rates increased from 52% to 79% in a pulmonology practice and from 50% to 87% in a rheumatology practice. The results of the vaccination rates of this DNP project compare favorably to these studies; however, differences in the screening rates may be influenced by the context of LTC versus ambulatory outpatient centers.

The initial modest improvement in the vaccine screening rates by the unit staff nurses suggested there is room for improvement in this area. Although a process change allowed for increased screening rates, additional strategies like clinical reminders (Pennet et al., 2015) may help staff nurses adherence to the SOP. Additionally, the lack of integration of the SOP into the EMR made the screening data in this DNP project less reliable, as there was no way to electronically capture screening data reports. Pennet et al. (2015) discussed how QI measures are more quickly adopted if the process is customizable and the data are reliable, highlighting a strength and weakness of this DNP project respectively. Gottlieb and Dohls (2018) found to

facilitate the patient education barrier, designated handout locations should be identified and labeled prior to project implementation. To aid in staff nurse perceived self-efficacy and low priority for change, the project leader should have all stakeholders complete a cultural assessment and readiness for change evaluation prior to project planning.

Quality improvement is not a new concept in this facility, but staff nurses were unfamiliar with the process of reviewing quality measures and participating in quality meetings. It took 4 weeks for the staff nurses to become acclimated with the QI process; therefore, initiating QI process training and meetings a month before project initiation may result in improved outcomes. At the end of this QI project, unit managers assumed ownership over the quality process from the DNP project leader, which was a mechanism for sustainability of the practice change. Furthermore, as change champions, nurse managers can use incentives to motivate staff nurses to use the SOP and coach their team members through barriers and facilitators that will be encountered with successfully implementing the process change.

The results of this DNP project must be interpreted in the context of methodological limitations. Because there is a low turnover rate in the LTC setting, the project design easily identified eligible patients on admission to be screened, educated, and appropriately vaccination. However, this left an unequal opportunity for existing patients to have vaccination education and substantial conversations on reasons for refusal. Another limitation was the use of manual and electronic chart audits with significant discordance between the two reports. Although the DNP project leader ensured concordance between the two reports, the lack of a fully integrated information technology system for data collection may leave room for measurement error.

Conclusion

The American Association of Colleges of Nursing (AACN) developed eight essentials to guide DNP education, and this DNP project focuses on essential V—health care policy for advocacy in health care and essential VII—clinical prevention and population health for improving the nation's health. This DNP project significantly impacted a process change that allowed nurses to autonomously assess and administer routine pneumococcal immunizations to help prevent pneumococcal pneumonia in a vulnerable population. Pneumococcal pneumonia remains one of the leading causes of death in the United States (CDC, 2016), and advanced age and comorbidities increases the risk of acquiring vaccine-preventable infectious diseases. Despite readily available immunizations and recommendations from the CDC, national and local pneumococcal vaccination rates in adults in LTC remain low.

This QI project showed significant improvement in PPSV23 and PCV13 screening and vaccination rates in adults in a suburban LTC facility. The successful implementation of the evidence-based SOP led to a significant increase in post intervention screening rates and pneumococcal immunization rates. The results indicate a pneumococcal SOP increased vaccine administration in eligible patients by 30%, far surpassing the project goal. The success of this DNP project allowed for the spread of implementation of the SOP to the sub-acute rehabilitation units in this organization. Additionally, organizational leadership plans to make the SOP a part of the standard admission process, to ensure all residents in the facility are appropriately vaccinated against *Streptococcus pneumonia*.

Key features of this DNP project that contributed to the sustainability of the SOP structure change include active engagement of administrative and clinical leaders, inclusion of champions to facilitate the process change, availability of facility-based stock of pneumococcal vaccines, standardized education, and a defined measurement plan for continuous data collection.

The champions will continue to informally query the staff nurses to identify barriers to compliance with the SOP during weekly huddle meetings. To ensure the sustainability of this QI intervention, future projects should aim to integrate the use of information technology and strategies to promote nurses' competency in patient education on recommended vaccinations.

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Appendix A

Evidence Review Table

Author, year	**Study objective/ Intervention compared**	**Design**	**Sample (n)**	**Outcomes studied (how measured)**	**Results**	**Level/ Quality**
Albert, S. M., Nowalk, M. P., Yonas, M. A., Zimmerman, R. K., & Ahmed, F. (2012).	To identify factors that impede or promote consistent use of standing order protocols (SOPs) for adult vaccination and correlate factors of providers who use or do not use SOP for influenza and pneumococcal vaccines.	Descriptive study of a national survey of U.S. primary care physicians. Development of the survey questionnaire guided by the awareness-to-adherence model, diffusion of innovation theory, and PRECEDE-PROCEED.	Primary care physicians (n = 880). A power analysis was completed.	Number of providers who use of SOPs for influenza or pneumococcal immunization. Practice characteristics associated with use of SOPs. Outcomes measured by survey data extraction.	No use of SOPs for either vaccination (n = 502, 57%) Consistent use of SOPs for influenza vaccination only (n = 175, 19.9%) Consistent use of SOPs for both vaccines (n = 203, 23.2%). Consistent use of SOPs for both influenza and pneumococcal vaccine was associated with the following factors: 1) Awareness of ACIP recommendation and/or Medicare regulations (OR 4.46, 95% CI, 2.91-6.85) 2) Presence of an immunization champion in the practice (OR 1.94, 95% CI, 1.27-2.98) 3) Access to an electronic medical record (OR 1.90, 95% CI, 1.22-2.96)	VI/B
Chan, S., Leung, D., Leung, A., Lam., C., Hung, I., Chu, D., …Yuen, K. Y. (2015).	To determine if a multi-component health education intervention increases the rate of 23-valent pneumococcal polysaccharide vaccine (PPV) vaccination among older patients with chronic disease. **Intervention:** Brief health education via	Single-blinded cluster randomized controlled trial. 10-week duration with each week randomized to either intervention or control.	Practice sites (n = 5). Participants aged 65 years and older (n = 2517). Power analysis completed	Recorded uptake rate of PPV post intervention. Measured by data extraction from the hospital authority clinical management system. Awareness of PPV at 3-month follow-up.	Pneumococcal vaccine received in the intervention group (n = 716; 57%) and the control group (n = 609, 48%). The intervention effect was significant (ARR = 1.3, 95% CI, 1.09-1.45). Awareness of PPV at the 3-month follow-up was insignificant (ARR = 1.06, 95% CI, 0.94-1.20).	II/C

	telephone and in-person at medical appointment (3-minutes each).		Intervention and control practices were similar outpatient clinics.	Measured by baseline and follow-up questionnaires.		
Communty Preventative Services Task Force. (2015).	Evaluation of the effectiveness of standing order vaccination program interventions across various settings, healthcare workers, and patient populations. **Intervention description:** Standing orders authorizing nurses, pharmacists, and other health care personnel to assess a patient's immunization status and administer vaccinations according to a protocol approved by an institution or authorized provider	Systematic Review	n = 35 studies Including randomized controlled trials and observational studies Various study populations and settings: Pediatric to older adults; clinics, hospitals, long-term care facilities	Effectiveness of standing orders to change vaccination rates of all CDC recommended immunizations. Outcomes measured by vaccination rates and percentage point (PP) changes in vaccination rates of included studies.	Nine studies examining standing orders alone: Median increase of 16 PP (interquartile interval [IQI]: 9 to 29 PP) Nineteen studies evaluating standing orders with additional interventions: Median increase of 27 PP (IQI: 13 to 40 PP) Seven studies did not provide a common measure of change for vaccination rates, but reported favorable results after implementation of standing orders	I/A
Hawk, M., Norwalk, M. P., Moehling, K. K., Pavlick, V., Raviotta, J. M., Brown, A. E., …Ricci, E. M. (2017).	To examine practice characteristics associated with implementation of and immunization intervention using the Four Pillars Program. **Intervention:** The 4 Pillars Program, provider education, and one-on-one coaching of practice-based immunization champions.	Mixed methods with qualitative data collected to examine implementation success of the 4 pillars practice transformation program RCCT conducted by Zimmerman et., 2017.	Practice sites who completed the 2-year RCCT (n = 14). Studied staff members included immunization champions, physicians, medical	Year 1: The degree to which implementation of the 4 Pillars program took place. Measured by qualitative interviews. Year 2: How implementation took place and why variance in rates of application occurred. Measured by qualitative evaluation:	Thematic analysis revealed four practice characteristics that were integral to implementation of a toolkit: degree of quality improvement history, communication and practice leadership, immunization champion leadership effectiveness, and organizational flexibility. Practices that were stratified as high implementers were more likely to have fully implemented standing	VI/C

		Qualitative researchers reviewed data to generate a thematic analysis	assistants, and managers.	onsite observation, interviews, and a RE-AIM-based framework protocol	order protocols and immunization champions (IC) with clinical responsibility and authority in the practice.	
Lau, D., Hu, J., Majumdar, S. R., Storie, D. A., Rees, S. E., & Johnson, J. A. (2012).	Systematically review the effectiveness of quality improvement interventions for increasing the rates of influenza and pneumonia vaccinations **Intervention descriptions:** Team change interventions include nurses assuming autonomous responsibility for administering vaccinations Patient outreach interventions include brochures, print material, in person education	Systematic review and meta-analysis of RCT and nonrandomized studies with a control group. Downs and Black quality assessment tool used on all included studies, median score 21. No evidence of heterogeneity based on Cochran's Q and I_2 statistics.	n = 106 studies included in qualitative synthesis and n = 77 studies included in quantitative synthesis Community – dwelling adults aged 65 years and older included in the studies (n = 470,175).	Effectiveness of interventions that improved pneumococcal vaccinations rates. Outcomes measured by random-effects meta-analysis of log ratios. All data studied in this systematic review and meta-analysis were extracted from included studies.	1) Clinician reminders (OR = 2.13; 95% CI, 1.50-3.03, I_2 = 75%) 2) Pt outreach (OR = 1.80; 95% CI, 1.54-2.11, I_2 = 67%) 3) Team change (OR = 2.09; 95% CI, 1.48-2.95, I_2=51%) 4) Clinician education (OR = 1.54; 95% CI, 1.19-1.99, I_2 = 72%)	I/B
Nowalk, M. P., Nolan, B. A. D., Nutini, J., Ahmed, F., Albert, S. M., Susick, M., & Zimmerman, R. K. (2014).	Evaluate the acceptance and implementation of the 4 Pillars toolkit and its effectiveness on increasing adult PPSV23 and influenza vaccination rates Intervention: standing order programs allowing nonphysician personnel to assess patient immunization status and	Pre-post experimental study. Triangulated mixed methods	Three internal medicine practices and one family practice with various patient (n) census range: Practice 1 (n = 453) Practice 2 (n = 1021)	PPSV23 and Influenza vaccination rates. Outcomes measured by EMR data extraction	Influenza vaccination rates significantly improved in older adults in sites 2 and 4 ($p < 0.01$) Over all sites, influenza vaccination increased from 22% preintervention to 33% postintervention ($p < 0.001$) Sites 3 and 4 significantly increased PPSV23 vaccination rates in high-risk and older adults ($p < 0.05$) Overall PPSV rates increased from 24.6% to 40.1% ($p = 0.02$) for high	IV/B

	administer vaccines without a provider order		Practice 3 (n = 1910) Practice 4 (n = 2208)		risk adults <65 years, and from 43.7% to 52.1% (p=2.26) for adults 65 years and older	
Zhang, Y., Tang, X., Du, C., Wang, B., Bi, Z., & Dong, B. (2016).	To compare the effectiveness of influenza vaccination alone versus influenza plus pneumococcal dual vaccination for the prevention of pneumonia and mortality in adults 65 years and older. **Intervention reviewed:** receipt of the influenza alone or dual pneumococcal and influenza vaccination.	Meta-analysis including RCTs, 2-arm prospective studies, retrospective cohort studies. Newcastle-Ottawa Scale assessment concluded the overall quality of the studies was good. No evidence of heterogeneity based on Cochran's Q and I_2 statistics.	Studies included in the meta-analysis (n = 5). All study participants were 65 years and older. Patients who received influenza vaccine alone (n = 53,107). Patients who received dual vaccination (n = 102,068)	Incidence of pneumonia measured by a fixed-effects analysis model. All-cause mortality rates measured by a fixed-effects analysis model. All data studied in this meta-analysis was extracted from included studies.	Influenza plus pneumococcal vaccination was associated with a significantly lower pneumonia rate than influenza vaccine alone (RR = 0.835, 95% CI, 0.718-0.971, p = 0.019) and a significantly lower all-cause mortality rate (RR = 0.771, 95% CI, 0.707-0.842, p = 0.001)	I/B
Zimmerman, R. K., Brown, A. E., Pavlik, V. N., Moehling, K. K., Raviotta, J. M., Lin, C. J., … Nowalk, M. P. (2017).	To test the effectiveness of an evidence-based guide to increase adult pneumococcal vaccination. **Intervention:** The 4 Pillars Program, provider education, and one-on-one coaching of practice-based immunization champions.	Randomized controlled cluster trial (RCCT). Year 1: Intervention and control group Year 2: Intervention group became maintenance group and control group received intervention	Practice sites (n = 25) Participants were aged 65 years and older (n = 18,107) Power analysis completed. Intervention and control practices were similar primary care,	23-valent pneumococcal polysaccharide vaccine (PPV) and pneumococcal conjugate vaccine (PCV) vaccination rates and percentage point (PP) changes in vaccination rates. Outcomes measured by EMR data extractions.	Year 1 RCCT analysis – PPSV-23 vaccination rates increased in intervention and control groups, with an average increase from 6.5 to 8.7 PP (p < 0.001). The differences in PP changes in the intervention group and control group were significant for one practice site (p < 0.001). Year 2 pre-post analysis – data were analyzed using a pre-post design, and PPSV-23 and PCV-13 vaccination was significantly higher in the active intervention group,	II/A

			family medicine or internal medicine.		than the maintenance group ($p < 0.001$).	

Rating System for Hierarchy of Evidence

Level of the Evidence	Type of the Evidence
I (1)	Evidence from systematic review, meta-analysis of randomized controlled trails (RCTs), or practice-guidelines based on systematic review of RCTs.
II (2)	Evidence obtained from well-designed RCT
III (3)	Evidence obtained from well-designed controlled trials without randomization
IV (4)	Evidence from well-designed case-control and cohort studies
V (5)	Evidence from systematic reviews of descriptive and qualitative studies
VI (6)	Evidence from a single descriptive or qualitative study
VII (7)	Evidence from the opinion of authorities and/or reports of expert committees

Melnyk, B.M. & Fineout-Overholt, E. (2014). *Evidence-based practice in nursing & healthcare: A guide to best practice* (3rd ed.). New York: Lippincott, Williams & Wilkins.

Rating Scale for Quality of Evidence

A: High – consistent results with sufficient sample, adequate control, and definitive conclusions; consistent recommendations based on extensive literature review that includes thoughtful reference to scientific literature

B: Good – reasonably consistent results; sufficient sample, some control, with fairly definitive conclusions; reasonably consistent recommendations based on fairly comprehensive literature review that includes some reference to scientific evidence

C: Low/major flaw – Little evidence with inconsistent results; insufficient sample size; conclusions cannot be drawn

Newhouse, R.P. (2006). Examining the support for evidence-based nursing practice. *Journal of Nursing Administration*, *36*(7-8), 337

Appendix B

Immunization Acion Coalition: Standing Orders for Administering Pneumococcal Vaccines

STANDING ORDERS FOR
Administering Pneumococcal Vaccines (PCV13 and PPSV23) to Adults

Purpose

To reduce morbidity and mortality from pneumococcal disease 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 *Streptococcus pneumoniae* (pneumococcus) infection according to the following criteria:

Routine pneumococcal vaccination
Assess adults age 65 years or older for need of pneumococcal vaccination. Pneumococcal conjugate vaccine (PCV13) should be administered routinely to all previously unvaccinated adults age 65 years and older. Pneumococcal polysaccharide vaccine (PPSV23) is recommended for all adults ages 65 years or older. For complete details, see section 5 (page 3).

Risk-based pneumococcal vaccination
Age 19 through 64 years with an underlying medical condition or other risk factor as described in the following table:

CATEGORY OF UNDERLYING MEDICAL CONDITION OR OTHER RISK FACTOR	RECOMMENDED VACCINES ARE MARKED "X" BELOW		
	PCV13	PPSV23	PPSV23 booster*
Chronic heart disease,[1] chronic lung disease[2]		x	
Diabetes mellitus		x	
Chronic liver disease, cirrhosis		x	
Cigarette smoking		x	
Alcoholism		x	
Cochlear implant, cerebrospinal fluid leak	x	x	
Sickle cell disease, other hemoglobinopathy	x	x	x
Congenital or acquired asplenia	x	x	x
Congenital or acquired immunodeficiency,[3] HIV	x	x	x
Chronic renal failure, nephrotic syndrome	x	x	x
Leukemia, lymphoma	x	x	x
Generalized malignancy, Hodgkin disease	x	x	x
Iatrogenic immunosuppression[4]	x	x	x
Solid organ transplant, multiple myeloma	x	x	x

* a second dose 5 years after the first dose of PPSV23

1 Excluding hypertension
2 Including asthma
3 Including B- (humoral) or T-lymphocyte deficiency, complement deficiencies (particularly C1, C2, C3, and C4 deficiencies), and phagocytic disorders (excluding chronic granulomatous disease)
4 Diseases requiring treatment with immunosuppressive drugs, including long-term systemic corticosteroids and radiation therapy

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Technical content reviewed by the Centers for Disease Control and Prevention
IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org
www.immunize.org/catg.d/p3075.pdf • Item #P3075 (1/17)

2 Screen for Contraindications and Precautions

Contraindications

Do not give pneumococcal vaccine (PCV13 or PPSV23) to a person who has experienced a serious systemic or anaphylactic reaction to a prior dose of the 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.

Precautions

Moderate or severe acute illness with or without fever

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.")

4 Prepare to Administer Vaccine

PCV13 must be given intramuscularly (IM). PPSV23 may be administered either IM or subcutaneously (Subcut). **For vaccine that is to be administered IM,** 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	⅝"*–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 ⅝" 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.

If you prefer Subcut injection of PPSV23, choose a 23–25 gauge, ⅝" needle for injection into the fatty tissue overlying the triceps muscle.

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5 Administer PCV13 or PPSV23, 0.5 mL, according to the following dosing information and schedule:

- PCV13 must be administered by the IM route.
- PPSV23 may be administered either IM or Subcut.

Routine vaccination for all adults ages 65 years and older

AGE OF PATIENT	VACCINE(S) INDICATED (SEE TABLE ON PAGE 1)	HISTORY OF PRIOR VACCINATION	SCHEDULE FOR ADMINISTRATION OF PCV13 AND PPSV23
65 yrs or older	PPSV23 and 1-time dose of PCV13	None or unknown	Administer PCV13 followed in 1 year* by PPSV23.
		PPSV23 when younger than age 65 years; 0 or unknown PCV13	Administer PCV13 at least 1 year after previous PPSV23. Administer another PPSV23 at least 5 years after previous dose of PPSV23 and at least 1 year* after PCV13.
		PPSV23 when younger than age 65 years; PCV13	Administer another PPSV23 at least 5 years after previous dose of PPSV23 and at least 1 year* after previous dose of PCV13.
		PPSV23 when age 65 years or older; 0 or unknown PCV13	Administer PCV13 at least 1 year after PPSV23
		0 or unknown PPSV23; PCV13	Administer PPSV23 at least 1 year* after PCV13.

* For adults age 65 years and older with immunocompromising conditions, functional or anatomic asplenia, cerebrospinal fluid leaks, or cochlear implants, the interval between PCV13 and PPSV23 should be shortened to 8 weeks.

Risk-based vaccination for adults ages 19–64 years

AGE OF PATIENT	VACCINE(S) INDICATED (SEE TABLE ON PAGE 1)	HISTORY OF PRIOR VACCINATION	SCHEDULE FOR ADMINISTRATION OF PCV13 AND PPSV23
19–64 years	*For medical conditions in which only PPSV23 is indicated*		
	1 dose PPSV23	None or unknown	Administer PPSV23.
	For medical conditions in which both PCV13 and PPSV23 (1 or 2 doses) are recommended		
	1 dose PCV13 and 1 dose PPSV23 (i.e., cochlear implant; CSF leak)	None or unknown	Administer PCV13 followed in 8 weeks by PPSV23.
		0 or unknown PPSV23; 1 dose PCV13	Administer PPSV23 at least 8 weeks after PCV13.
		1 dose PPSV23; 0 or unknown PCV13	Administer PCV13 at least 1 year after PPSV23.
	1 dose PCV13 and 2 doses PPSV23 (e.g., immuno-compromised)	None or unknown	Administer PCV13 followed in 8 weeks by PPSV23 #1. Administer PPSV23 #2 at least 5 years after PPSV23 #1.
		1 dose PPSV23; 0 or unknown PCV13	Administer PCV13 at least 1 year after PPSV23 #1. Administer PPSV23 #2 at least 5 years after PPSV23 #1 and at least 8 weeks after PCV13.
		0 or unknown PPSV23; 1 dose PCV13	Administer PPSV23 #1 at least 8 weeks after PCV13. Administer PPSV23 #2 at least 5 years after PPSV23 #1.
		1 dose PPSV23; 1 dose PCV13	Administer PPSV23 #2 at least 5 years after PPSV23 #1 and at least 8 weeks after PCV13.
		2 doses PPSV23; 0 or unknown PCV13	Administer PCV13 at least 1 year after PPSV23 #2.

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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 pneumococcal 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 _____ (NAME OF PRACTICE OR CLINIC)

until rescinded or until _____ (DATE).

Medical Director's signature _____ Signature date _____ Effective date _____

Appendix C

Practice Site Pneumococcal Vaccine Consent Form

RESIDENT VOLUNTARY CONSENT/DECLINATION FOR PNEUMOCOCCAL-23 VACCINE

Resident Name_____ Resident #_____

Check the appropriate box:

- ☐ I hereby give the Center permission to administer a Pneumococcal-23 vaccination. I have not had an allergic or anaphylactic* reaction to the Pneumococcal vaccine. I have been instructed that as a result of this vaccination, I may experience some side effects such as:
  - Slight discomfort
  - Soreness or redness of the injection site
  - Slight fever
  - Muscle aches
  - Fatigue
  - Headaches
- ☐ I have received the Pneumococcal-23 Vaccine and therefore decline it now.
  Date received: _____
- ☐ To the best of my knowledge, I have had an allergic reaction or anaphylactic* reaction from the Pneumococcal-23 vaccination in the past and therefore decline it now.
- ☐ For religious reasons, I decline to have the Pneumococcal-23 vaccination.
- ☐ I decline to have the vaccination due to _____

As indicated by my signature below, I have read or had explained to me the Vaccination Information Statement about Pneumococcal-23 vaccination, and I understand the benefits and risks of pneumococcal-23 vaccination.

_____ _____
Date Resident/Resident Representative Signature

_____
Resident/Resident Representative Printed Name

_____ _____
Date CCRC Representative Signature

_____
CCRC Representative Printed Name

RESIDENT VOLUNTARY CONSENT/DECLINATION FOR PREVNAR-13 VACCINE

Check the appropriate box:

- ☐ I hereby give the Center permission to administer a Prevnar-13 vaccination. I have not had an allergic or anaphylactic* reaction to the Pneumococcal vaccine. I have been instructed that as a result of this vaccination, I may experience some side effects such as:
  - Slight discomfort
  - Soreness or redness of the injection site
  - Slight fever
  - Muscle aches
  - Fatigue
  - Headaches
- ☐ I have received the Prevnar-13 Vaccine and therefore decline it now.
  Date received: _____
- ☐ To the best of my knowledge, I have had an allergic reaction or anaphylactic* reaction from the Prevnar-13 vaccination in the past and therefore decline it now.
- ☐ For religious reasons, I decline to have the Prevnar-13 vaccination.
- ☐ I decline to have the vaccination due to _____

As indicated by my signature below, I have read or had explained to me the Vaccination Information Statement about Prevnar-13 vaccination, and I understand the benefits and risks of Prevnar-13 vaccination.

_____ _____
Date Resident/Resident Representative Signature

_____
Resident/Resident Representative Printed Name

_____ _____
Date CCRC Representative Signature

_____
CCRC Representative Printed Name

*An Anaphylactic reaction is a severe drug induced reaction causing such symptoms as severe difficulty in breathing, fainting, shock, severe hives or patches of fluid under the skin, and intense itching. It can be a life threatening response to a drug.

A copy of this consent/declination must be filed in the medical record.

RESIDENT VOLUNTARY CONSENT/DECLINATION FOR PNEUMOCOCCAL-23 VACCINE & PREVNAR-13 VACCINE
FORM: 6C011C

Appendix D

Vaccine Information Statement: Pneumococcal Polysaccharide Vaccine (PPSV23)

VACCINE INFORMATION STATEMENT

Pneumococcal Polysaccharide Vaccine

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect older adults (and some children and younger adults) from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis). Meningitis can cause deafness and brain damage, and it can be fatal.

Anyone can get pneumococcal disease, but children under 2 years of age, people with certain medical conditions, adults over 65 years of age, and cigarette smokers are at the highest risk.

About 18,000 older adults die each year from pneumococcal disease in the United States.

Treatment of pneumococcal infections with penicillin and other drugs used to be more effective. But some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 Pneumococcal polysaccharide vaccine (PPSV23)

Pneumococcal polysaccharide vaccine (PPSV23) protects against 23 types of pneumococcal bacteria. It will not prevent all pneumococcal disease.

PPSV23 is recommended for:

- All adults 65 years of age and older,
- Anyone 2 through 64 years of age with certain long-term health problems,
- Anyone 2 through 64 years of age with a weakened immune system,
- Adults 19 through 64 years of age who smoke cigarettes or have asthma.

Most people need only one dose of PPSV. A second dose is recommended for certain high-risk groups. People 65 and older should get a dose even if they have gotten one or more doses of the vaccine before they turned 65.

Your healthcare provider can give you more information about these recommendations.

Most healthy adults develop protection within 2 to 3 weeks of getting the shot.

3 Some people should not get this vaccine

- Anyone who has had a life-threatening allergic reaction to PPSV should not get another dose.
- Anyone who has a severe allergy to any component of PPSV should not receive it. Tell your provider if you have any severe allergies.
- Anyone who is moderately or severely ill when the shot is scheduled may be asked to wait until they recover before getting the vaccine. Someone with a mild illness can usually be vaccinated.
- Children less than 2 years of age should not receive this vaccine.
- There is no evidence that PPSV is harmful to either a pregnant woman or to her fetus. However, as a precaution, women who need the vaccine should be vaccinated before becoming pregnant, if possible.

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

4 Risks of a vaccine reaction

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

About half of people who get PPSV have mild side effects, such as redness or pain where the shot is given, which go away within about two days.

Less than 1 out of 100 people develop a fever, muscle aches, or more severe local reactions.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

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

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

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

VAERS does not give medical advice.

6 How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
PPSV Vaccine

4/24/2015

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Appendix E

Vaccine Information Statement: Pneumococcal Conjugate Vaccine (PCV13)

VACCINE INFORMATION STATEMENT

Pneumococcal Conjugate Vaccine (PCV13)

What You Need to Know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis

Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1 Why get vaccinated?

Vaccination can protect both children and adults from **pneumococcal disease**.

Pneumococcal disease is caused by bacteria that can spread from person to person through close contact. It can cause ear infections, and it can also lead to more serious infections of the:

- Lungs (pneumonia),
- Blood (bacteremia), and
- Covering of the brain and spinal cord (meningitis).

Pneumococcal pneumonia is most common among adults. Pneumococcal meningitis can cause deafness and brain damage, and it kills about 1 child in 10 who get it.

Anyone can get pneumococcal disease, but children under 2 years of age and adults 65 years and older, people with certain medical conditions, and cigarette smokers are at the highest risk.

Before there was a vaccine, the United States saw:

- more than 700 cases of meningitis,
- about 13,000 blood infections,
- about 5 million ear infections, and
- about 200 deaths

in children under 5 each year from pneumococcal disease. Since vaccine became available, severe pneumococcal disease in these children has fallen by 88%.

About 18,000 older adults die of pneumococcal disease each year in the United States.

Treatment of pneumococcal infections with penicillin and other drugs is not as effective as it used to be, because some strains of the disease have become resistant to these drugs. This makes prevention of the disease, through vaccination, even more important.

2 PCV13 vaccine

Pneumococcal conjugate vaccine (called PCV13) protects against 13 types of pneumococcal bacteria.

PCV13 is routinely given to children at 2, 4, 6, and 12–15 months of age. It is also recommended for children and adults 2 to 64 years of age with certain health conditions, and for all adults 65 years of age and older. Your doctor can give you details.

3 Some people should not get this vaccine

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine, to an earlier pneumococcal vaccine called PCV7, or to any vaccine containing diphtheria toxoid (for example, DTaP), should not get PCV13.

Anyone with a severe allergy to any component of PCV13 should not get the vaccine. *Tell your doctor if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is not feeling well, your healthcare provider might decide to reschedule the shot on another day.

4 Risks of a vaccine reaction

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

Problems reported following PCV13 varied by age and dose in the series. The most common problems reported among children were:

- About half became drowsy after the shot, had a temporary loss of appetite, or had redness or tenderness where the shot was given.
- About 1 out of 3 had swelling where the shot was given.
- About 1 out of 3 had a mild fever, and about 1 in 20 had a fever over 102.2°F.
- Up to about 8 out of 10 became fussy or irritable.

Adults have reported pain, redness, and swelling where the shot was given; also mild fever, fatigue, headache, chills, or muscle pain.

Young children who get PCV13 along with inactivated flu vaccine at the same time may be at increased risk for seizures caused by fever. Ask your doctor for more information.

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

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.
- Some older children and adults get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.
- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

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

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

5 What if there is a serious reaction?

What should I look for?

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

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

What should I do?

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

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

VAERS does not give medical advice.

6 The National Vaccine Injury Compensation Program

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

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

7 How can I learn more?

- Ask your healthcare provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
PCV13 Vaccine

11/05/2015

42 U.S.C. § 300aa-26

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Appendix F

Medical Management of Vaccine Reactions in Adult Patients

Medical Management of Vaccine Reactions in Adult Patients

All vaccines have the potential to cause an adverse reaction. In order to minimize adverse reactions, patients should be carefully screened for precautions and contraindications before vaccine is administered (see www.immunize.org/catg.d/p3072.pdf). Even with careful screening, reactions may occur. These reactions can vary from trivial and inconvenient (e.g., soreness, itching) to severe and life threatening (e.g., anaphylaxis). Vaccine providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction. Maintenance of the airway, oxygen administration, and intravenous normal saline might be necessary. The table below describes procedures to follow if various reactions occur.

REACTION	SYMPTOMS	MANAGEMENT
Localized	Soreness, redness, itching, or swelling at the injection site	Apply a cold compress to the injection site. Consider giving an analgesic (pain reliever) or antipruritic (anti-itch) medication.
	Slight bleeding	Apply an adhesive compress over the injection site.
	Continuous bleeding	Place thick layer of gauze pads over site and maintain direct and firm pressure; raise the bleeding injection site (e.g., arm) above the level of the patient's heart.
Psychological fright and syncope (fainting)	Fright before injection is given	Have patient sit or lie down for the vaccination.
	Extreme paleness, sweating, coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness, or visual disturbances	Have patient lie flat or sit with head between knees for several minutes. Loosen any tight clothing and maintain an open airway. Apply cool, damp cloths to patient's face and neck.
	Fall, without loss of consciousness	Examine the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated.
	Loss of consciousness	Check the patient to determine if injury is present before attempting to move the patient. Place patient flat on back with feet elevated. Call 911 if patient does not recover immediately.
Anaphylaxis	Sudden or gradual onset of generalized itching, erythema (redness), or urticaria (hives); angioedema (swelling of the lips, face, or throat); severe bronchospasm (wheezing); shortness of breath; shock; abdominal cramping; or cardiovascular collapse.	See "Emergency Medical Protocol for Management of Anaphylactic Reactions in Adults" on the next page for detailed steps to follow in treating anaphylaxis.

CONTINUED ON NEXT PAGE ▶

Technical content reviewed by the Centers for Disease Control and Prevention

IMMUNIZATION ACTION COALITION Saint Paul, Minnesota • 651-647-9009 • www.immunize.org • www.vaccineinformation.org

www.immunize.org/catg.d/p3082.pdf • Item #P3082 (7/16)

Suggested medications for a community immunization clinic

FIRST-LINE medication

☐ **Epinephrine**, aqueous 1:1000 (i.e., 1 mg/mL) dilution, in ampules, vials of solution, or prefilled syringes, including epinephrine autoinjectors (e.g., EpiPen and Auvi-Q). If autoinjectors are stocked, at least three should be available.

Optional medication: H_1 antihistamines

☐ Diphenhydramine (e.g., Benadryl) oral (12.5 mg/5 mL liquid, 25 or 50 mg capsules/tablets) or injectable (50 mg/mL solution).

☐ Hydroxyzine (e.g., Atarax, Vistaril) oral (10 mg/5 mL or 25 mg/5 mL liquid, 25 mg capsules).

Suggested supplies for a community immunization clinic

☐ Syringes (1 and 3 cc) and needles (22 and 25 g, 1", 1½", and 2") for epinephrine, diphenhydramine, or hydroxyzine. For ampules, use filtered needles.

☐ Alcohol wipes

☐ Tourniquet*

☐ Adult airways (small, medium, and large)

☐ Adult size pocket mask with one-way valve

☐ Oxygen (if available)

☐ Stethoscope

☐ Sphygmomanometer (blood pressure measuring device) with adult-size and extra-large cuffs

☐ Tongue depressors

☐ Flashlight with extra batteries (for examination of the mouth and throat)

☐ Wristwatch with a second hand or other timing device

☐ Cell phone or access to onsite phone

* Applied on the extremity above the injection site to slow systemic absorption of antigen and anaphylactic mediators.

REFERENCES

Simons FE, Camargo CA. Anaphylaxis: Rapid recognition and treatment. In: UpToDate, Bochner BS (Ed). UpToDate: Waltham, MA, 2013.

Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the Diagnosis and Management of Food Allergy in the United States: Report of the NIAID-Sponsored Expert Panel. *Allergy Clin Immunol* 2010; 126(6): S1–S57.

Emergency medical protocol for management of anaphylactic reactions in adults

1 If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.

2 If symptoms are generalized, activate the emergency medical system (EMS; e.g., call 911) and notify the patient's physician. This should be done by a second person, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Vital signs should be monitored continuously.

3 **DRUG DOSING INFORMATION: The first-line and most important therapy in anaphylaxis is epinephrine. There are NO contraindications to epinephrine in the setting of anaphylaxis.**

- **a First-line treatment:** Administer aqueous **epinephrine** 1:1000 dilution intramuscularly, 0.01 mL/kg/dose (adult dose ranges from 0.3 mL to 0.5 mL, with maximum single dose of 0.5 mL).
- **b Optional treatment: H_1 antihistamines** for hives or itching; you may also administer **diphenhydramine** (either orally or by intramuscular injection; the standard dose is 1–2 mg/kg every 4–6 hrs, up to 50 mg maximum single dose) or **hydroxyzine** (standard oral dose is 0.5–1 mg/kg every 4–6 hrs up to 100 mg maximum single dose).

4 Monitor the patient closely until EMS arrives. Perform cardiopulmonary resuscitation (CPR), if necessary, and maintain airway. Keep patient in supine position (flat on back) unless he or she is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs. Monitor blood pressure and pulse every 5 minutes.

5 If EMS has not arrived and symptoms are still present, repeat dose of epinephrine every 5–15 minutes for up to 3 doses, depending on patient's response.

6 Record the patient's reaction (e.g., hives, anaphylaxis) to the vaccine, all vital signs, medications administered to the patient, including the time, dosage, response, and the name of the medical personnel who administered the medication, and other relevant clinical information. Report the incident to the Vaccine Adverse Event Reporting System (VAERS).

7 Notify the patient's primary care physician.

These standing orders for the medical management of vaccine reactions in adult patients shall remain in effect for patients of the

_____ until rescinded or until _____
NAME OF CLINIC DATE

_____ _____
MEDICAL DIRECTOR'S SIGNATURE DATE OF SIGNING

Appendix G

Chart Audit Tool

Chart Audit Template

Subject ID# *(de-identified code)*

Retrospective Data:

Demographics:

- Age
  - 19-64 years (1)
  - 65 years and older (2)
- Gender
  - Male (1)
  - Female (2)
- Ethnicity
  - White (1)
  - Black (2)
  - Hispanic (3)
  - Asian or Pacific Islander (4)
  - Other (5)

Pre-implementation Baseline Pneumococcal Immunization Status

- Pneumococcal Vaccination series complete for aged and medical condition/ risk factor
  - Yes (1)
  - No (2)

Current Data:

Patient Screened for Pneumococcal vaccine need according to SOP

- Yes (1)
- No (2)

Patient immunized with PPSV23 or PCV13 based on need using SOP

- Yes (1)
- No (2)
- Not indicated per screening (3)

Post-implementation of SOP Pneumococcal Immunization Status

- Pneumococcal Vaccination series complete for aged and medical condition/ risk factor
  - Yes (1)
  - No (2)