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The Use of DMAIC to Improve Quality Vaccination Recommendations in Chain Community Pharmacies

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Abstract

Community pharmacies provide the convenience and ease of administrating vaccinations outside traditional settings. Vaccinations are health initiatives that protect communities and improve health outcomes in all populations. Despite their accessibility and supporting clinical data, various influential factors contribute to the current suboptimal rates of vaccine administration. Given the common barriers to vaccine administration, this research narrows down to address a specific barrier and attempts to implement a method that focuses on improving vaccine rates in community pharmacies. This research is a case study that utilizes the DMAIC model of lean six sigma and aims to use this quality improvement process to identify, measure, analyze, and implement a training program to facilitate pharmacists in high-quality vaccine recommendations to promote higher rates of pneumococcal vaccinations in community settings.

Keywords*: pneumococcal vaccine, vaccine hesitancy, lean six sigma, DMAIC, pharmacists, Walgreens, quality improvement.*

<u>Abbreviations:</u>

LSS: Lean Six Sigma

DMAIC: Define, Measure, Analyze, Implement, Control

PCV13: pneumococcal conjugate vaccine

PPSV23: pneumococcal polysaccharide vaccine

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Chapter 1: Introduction

Vaccinations are vital preventative tools to help protect and significantly reduce the risk of various medical illnesses and disease states in the community. Pharmacists play a crucial role in impacting vaccination rates as certified immunizers and patient health advocates. Seen in multiple settings, 50%-90% of patients follow a pharmacist's advice and accept the recommended vaccine (Grabenstein, 1998). A 2011 study conducted by Taitel et al. showed that 4.88% of the 1.3 million high-risk patients immunized by a pharmacist received a pneumococcal vaccine; this value is significantly greater than the national mark 2.90% (2011). However, one significant barrier to utilizing a new pharmacy service is the lack of time for pharmacists to implement and monitor the service (Powers & Bright, 2008). One way to overcome this barrier is to utilize technicians for tasks that do not require a pharmacist's professional training. Another barrier specific to a new vaccination service within a pharmacy is the design of reimbursement. Many patients do not have health insurance plans that cover the cost of vaccinations administered outside of a primary care provider's office (“Addressing barriers,” 2018). This may limit the number of patients eligible to receive a vaccination within the pharmacy. Health practitioners have tried to understand the basis of vaccination hesitancy and found several strategies have been implemented to reduce hesitancy, such as improving the quality of vaccine education to patients, clearing misconceptions, decreasing wait times, improving accessibility, and making strong recommendations. In many community pharmacy settings, while pharmacists are the first-line practitioners to advocate for providing scheduled vaccinations, a deeper layer of hesitancy has been observed. In many instances, within such patient-driven yet dynamic environments, passive pharmacist engagement and the lack of active attention in recommending vaccinations to patients have been observed. They have contributed to current suboptimal pneumococcal vaccination rates.

Despite having clinically available and effective vaccinations to protect and prevent the public and susceptible patient populations, barriers exist that prevent immunization rate goal achievement of 90% established by Healthy People 2020. These barriers include but are not limited to vaccine hesitancy, lack of access, high costs, vaccine misconceptions, lack of education, fear of needles, and related factors (MacDonald et al., 2018). Many approaches have been proposed to overcome these barriers, including providing patient educational material, using proven communication strategies, understanding and clearing misconceptions, improving accessibility for vaccination, increasing provider engagement, and making strong recommendations.

This study aims to report how a lean six sigma (LSS) DMAIC approach can be used to address specific barriers of hesitancy and vaccination rates, mainly focusing on pneumococcal vaccination rates. An assertive training program to educate and train community pharmacists on vaccine assertiveness techniques and skills focusing on increasing pneumococcal vaccination recommendations in adult patient populations will be described. The primary outcome is the positive change in pneumococcal vaccination rates before and after the intervention.

Background

Pneumococcal disease, an infectious disease caused by the bacteria *Streptococcus pneumonia* (*S. pneumoniae*), is responsible for high incidences of morbidity and mortality each year in the United States and worldwide. Pneumococcal disease has the ability to cause sinusitis, otitis media, pneumonia, meningitis, and sepsis leading to severe and detrimental outcomes. The clinical presentation of pneumococcal disease typically results from bacterial colonization of the upper respiratory tract primarily via respiratory droplets from human to human through close contact. Populations at highest risk of developing pneumococcal infection include patients with high risk factors and health comorbidities. Patients who have any history of immunosuppression, chronic obstructive pulmonary disease, asplenia, and other chronic disease states are at high risk for developing pneumococcal infection.

Specifically, pneumococcal vaccinations provide preventative measures in protecting patients of all ages and those at high risk for acquiring the disease. The two pneumococcal vaccinations available in the United States are the pneumococcal conjugate vaccine (PCV13) and pneumococcal polysaccharide vaccine (PPSV23). Current recommendations for pneumococcal vaccinations provided by Center for Disease Control include the PPSV23 in high-risk adults from 18-64 years of age and for all adults 65 and older, and the PCV13 in certain high-risk populations in the United States (Centers for Disease Control and Prevention [CDC], 2017). Studies relating to PPSV23 and PCV13 efficacy demonstrate high estimates of clinical effectiveness and safety for both vaccines. Overall, the PPSV23 vaccine has shown approximately 70% clinical effectiveness and PCV13 has shown 75% clinical effectiveness in preventing invasive disease caused by the bacterial serotypes (CDC, 2017).

Even with such high levels of efficacy in these vaccines, pneumococcal vaccination rates in both the U.S. and the state of Tennessee are currently below the desired benchmarks to improve health outcomes. A number of factors contribute to such suboptimal vaccination rates with vaccine hesitancy being a top priority on the list. The World Health Organization lists vaccine hesitancy as one of the top 10 threats to global health outcomes in 2019 (Lo & Hotez, 2017). Vaccine hesitancy has been defined as "a delay in vaccination or a refusal to vaccinate in spite of vaccine availability" (Reifler et al., 2016). The majority of vaccine hesitancy research has been conducted in the pediatric population; however, there has been a growing interest in hesitancy in the adult population, a field that is currently under researched.

Chapter 2: Review of the Literature

The National Health Interview Survey (NHIS) is one of the major health surveys of the National Center for Health Statistics, which is a principal source for gathering information on the health of the noninstitutionalized civilian population of the United States (2020). NHIS collects data on a broad range of health topics by conducting personal interviews in households with adults throughout the U.S. to express a sample size representative of the national population. The methods and design for the NHIS are continuously reevaluated and refined to assure accurate data representation. The 2017 NHIS data show that pneumococcal vaccination coverage among adults aged 19-64 years at high risk for pneumococcal disease is 24.5% and 69.0% among adults aged 65 years and older in the U.S.

According to Healthy People 2020, the national objective is to increase the percentage of pneumococcal vaccinations in noninstitutionalized high-risk adults aged 19-64 years of age by 90% and in noninstitutionalized adults aged 65 and older by 60%. In 2017, 74.1% of adults sixty-five or older received the PPSV23 vaccine in Tennessee. This number was above the national average of 72.4% for adults sixty-five or older (CDC, 2020). In 2017, 34.9% of high-risk individuals less than sixty-five years old received the pneumococcal vaccine in Tennessee. This number was below the national average of 36.1% of high-risk individuals less than sixty-five years old. As the current rates in both the U.S. and the state of Tennessee are currently below this metric, a number of factors contribute to such suboptimal vaccination rates. These factors include, but are not limited to, patient hesitancy, lack of strong provider recommendation, lack of access due to high costs, and lack of health awareness and information. The majority of these factors exist primarily in the outpatient setting. The high prevalence of such factors to exist has led to vaccines incompliance and is responsible for current, suboptimal pneumococcal vaccination rates. Researchers have tried to understand the basis of vaccination incompliance and found that to improve vaccine compliance, the following actions must be taken by health providers: provide patients educational material, use proven communication strategies, understand and clear misconceptions, improve accessibility for vaccination, make strong recommendations, and provide evidence that support the safety and effectiveness of vaccinations (Ventola, 2016).

Various studies have been conducted to determine the relationship between the strength of the provider's recommendation for vaccinations and patient intentions to receive a vaccine, and these studies found a strong association correlating strength of provider recommendation to patient vaccinations. Many other studies also show that strong recommendation technique is highly critical for the protection and prevention for all populations, especially the high risk for pneumococcal related diseases and outcomes.

Chapter 3: Methodology

Research question

How can the use of Lean Six Sigma and the DMAIC process help improve pneumococcal vaccination rates in community pharmacy settings?

Population

The research includes gathering patient vaccination data from 54 community Walgreens pharmacies in the West Tennessee area. As part of this research, qualitative data through phone interviewing from community pharmacists in the selected Walgreen pharmacies were conducted.

Study Methods

Data collection used a multi-methods approach, including pharmacy dispensing data and in-depth, semi-structured interviews with pharmacist key informants from the study sites. The design and implementation of the training program is geared towards Walgreens community pharmacists. Pneumococcal vaccination data were collected before and after the implementation of the training program followed by data analysis to determine the impact of the implementation. Qualitative data analysis included interviews that were conducted by trained student research assistants over the telephone, recorded, and subsequently transcribed verbatim by a third-party transcription service to evaluate the usefulness of the skills learned from the training. Quantitative data analysis included both descriptive and inferential statistics, including chi-square to test the primary objective. This research will utilize a quality improvement process and lean six sigma methodologies to assist with the primary objective.

Chapter 4: LSS and The DMAIC Methodology

LSS and DMAIC (Define, Measure, Analyze, Improve, Control) methods have been used in this research to focus on improving specific existing challenges in the vaccine recommendation process. LSS methods have been more commonly integrated within healthcare in the past decade. In an early 2020 study, LSS has been used to improve access to care in surgical subspecialty clinics (Flanary et al., 2020). In an area where a delay to new patient visits and consults challenged the care for patients, LSS was implemented to improve the timeliness of care for patients and reduce its variation by improving clinic processes and scheduling.

LSS has been a model used in other aspects of healthcare as well such as pharmacy. While pharmacy is a demanding, patient- driven field, many of its issues lie within patient experiences and inefficiencies that ultimately lead to patient dissatisfaction. Recently in a 2018 study, LSS was incorporated into pharmacy practice to reduce pharmacy wait time. LSS methods in this study were used to identify potential problems associated with increased wait times and found that implementations such as automated queuing technology, pharmacy devices for quick and accurate filling and dispensing, and computer simulation modeling for smooth workflow were solutions to the issue (Alam, 2018). LSS methodologies have been utilized in several settings to reduce patient wait time, attract new customers, decrease workload and improve the overall efficiency within the organization.

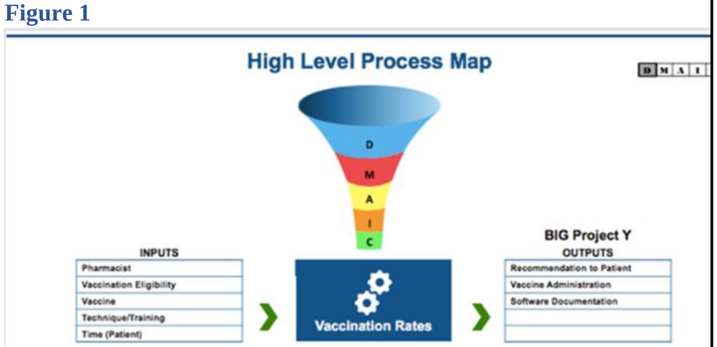
DMAIC is an aspect within LSS that includes defining a problem, quantifying the problem, analyzing the cause of the problem, implementing a feasible solution, and maintaining the solution. The integration of DMAIC in this research provides a well-guided approach to help improve the efficiency and performance within the process of vaccination recommendation and assertiveness. The implementation of the DMAIC process has been utilized to address the standards and approach currently used in the pneumococcal vaccination recommendation process at participating Walgreens pharmacies.

Chapter 5: DMAIC Case Study

Define

The problem of interest is pneumococcal vaccine rates below specification in community pharmacies. Specifications were based in Healthy People 2020, rather than traditional voice of consumer (VoC) analyses given the uniqueness of the product of interest (i.e. a vaccine). A high-level map of vaccine recommendation processes, as shown in Figure 1, was conducted to determine the key factors affecting vaccine recommendation. With Walgreens divisional leadership, the objective to increase pneumococcal vaccination rates across Tennessee by 20% year-over year was set and tested in study site pharmacies.

Figure 1



Measure

Base line (e.g. "current state") data from the dispensing history for pneumococcal vaccinations administered was gathered from each pharmacy and was compared across the pharmacy division. Key informant interviews were conducted to provide context on processes in community pharmacy workflow.

Analyze

Baseline data from historical pharmacy dispensing data was used to understand correlations between staffing and hours of operations and vaccination rates, but no significant correlations were identified after conducting a regression analysis. Content analysis of interview transcriptions highlighted vaccination hesitancy and related barriers present during pharmacist recommendations. A cause-and-effect matrix along with a failure modes and effects analysis (FMEA) were conducted to determine the potential root cause and determinant to the overarching issue and are shown in Figures 2 and 3, respectively. As a result, the vaccine recommendation communication technique used by the pharmacist was selected as the root cause hypothesis.

Figure 2

Cause and Effect Matrix

		Rating of Importance to Customer >>	10	
	Process Step	Process Inputs	Number of Vaccines	Total
1	Process Step 1	Initial Vaccine Eligibilty	9	90
2	Process Step 1	Recommendation of Vaccine	9	90
3	Process Step 1	Vaccine cost (Hesitant Patient)	6	60
4	Process Step 1	Patient Objective Information (Hesitant Patient)	9	90
5	Process Step 1	Patient Subjective Information (Hesitant Patient)	3	30
6	Process Step 2	Needle & Syringe	3	30
7	Process Step 2	Vaccine	9	90
8	Process Step 2	Technique/Training	3	30
10	Process Step 2	Pharmacist Experience	3	30
11	Process Step 2	Time (Pharmacist)	3	30
12	Process Step 2	Time (Patient)	9	90
13	Process Step 3	Informational Pamphlet	3	30
14	Process Step 3	Patient education	3	30
15	Process Step 3	Counseling	3	30
Total			75	

Figure 3

Process/Product Failure Modes and Effects Analysis (FMEA)

Process Step	Key Process Input	Potential Failure Mode	Potential Failure Effects	SEV	Potential Causes	OCC	Current Controls	DET	RPN	Actions Recommended	Resp.	Actions Taken	SEV	OCC	DET	RPN
What is the Process Step	What is the Key Process Input?	In what ways does the Key Input go wrong?	What is the impact on the Key Output Variables (Customer Requirements) or internal requirements?	How Severe is the effect to the customer?	What causes the Key Input to go wrong?	How often does cause or FM occur?	What are the existing controls and procedures (inspection and test) that prevent either the cause or the Failure Mode? **Should include an SOP number.**	How well can you detect cause or FM?		What are the actions for reducing the occurrance of the Cause, or improving Detection? **Should have actions only on high RPN's or easy fixes.**	Whose Responsible for the recommended action?	What are the completed actions taken with the recalculated RPN? **Be sure to include completion month/year**				
Determine vaccine eligibility	Initial Eligibility	Patinet is ineligbile to receive vaccine	Patient cannot receive vaccine	9	Uncontronalble	1	Vaccine is only recommended to patientsts eleigible to receive it	3	27	None	None	None				0
Lead with assertive recommendation	Patient Subjective Information (Hesitant)	Recommendation increases patient's hesitancy	Patient elects to not receive vaccine	9	Pharmacist is not properly trained	7	None	9	567	Pharmacists receive training on how to address vaccine hesitant patients	Pharmacist	Pharmacists receive virtual and inperson training on how to handle hesitant patients (3/20)	9	3	3	81
Assess	Initial Eligibility	Patinet is ineligbile to receive vaccine	Patient cannot receive vaccine	9	Uncontronalble	1	Vaccine is only recommended to patientsts eleigible to receive it	3	27	None	None	None				0
Plan	Time	Patient does not have enough time to receive vaccine	Patient cannot receive vaccine	7	Pharmacy is understaffed	3	None	5	105	None	None	None				0
Implement (Administer)	Pharmacist Experience	Pharmacist does not know how to address hesitancy	Patient elects to not receive vaccine	9	Pharmacist is not properly trained	7	None	9	567	Pharmacists receive training on how to address vaccine hesitant patients	Pharmacists receive training on how to address vaccine hesitant patients	Pharmacists receive virtual and inperson training on how to handle hesitant patients (3/20)	9	3	3	81
Follow-up/Document	Patient Education	Patient does not receice any follow-up or counseling	Patient is misinformed	5	Pharmacist is too busy	3	None	3	45	None	None	None				0

Implement

To improve the recommendation communication technique, implementing a training program has been decided to potentially be the most feasible and sound way to educate and improve vaccine rates in pharmacies. The intent of the training program is to focus on educating and training pharmacists on vaccine assertiveness technique and will be implemented within the community pharmacies study sites. The training was directed towards study site pharmacists representing and consisted of both online and live training sessions. The training program centered on the concept of "presumptive" vaccine recommendations motivational interviewing and the transtheoretical model to guide pharmacists through behavior change toward vaccine recommendation acceptance. The live sessions were led by faculty facilitators and included practice of key verbiage and mock sessions to practice improving the communication of vaccine recommendations.

Results of the Implementation

The results of the study were gathered through a variety of statistical tests to test the effectiveness of the training program. The Chi Square test, represented in Figure 4, was used for unpaired, bivariate data which represents the dataset of pneumococcal vaccines pre-implementation and post implementation. Thereafter, a capability analysis test was conducted to evaluate the process capability, Cp, Cpk, and p-value. A total of 54 pharmacies completed the experiment, including 25 intervention sites. Of these, 8 increased by 20%. Of the 29 control sites that did not receive training, 4 increased by the specification of 20%. Year-over-year comparison of mean pneumococcal vaccination rates showed no significant difference ($p<0.05$). The new processes capability analysis was run as a one-sided analysis with a goal and LSL of 20% to compare the 2018 vs 2019 vaccination rates, as shown in Figure 5. The analysis revealed 70.49% of the stores fell below the LSL and did not achieve the goal of increasing vaccinations by 20%, as displayed in the process capability report in Figure 6. To show the results in a simpler format, refer to Graph A below.

Graph A

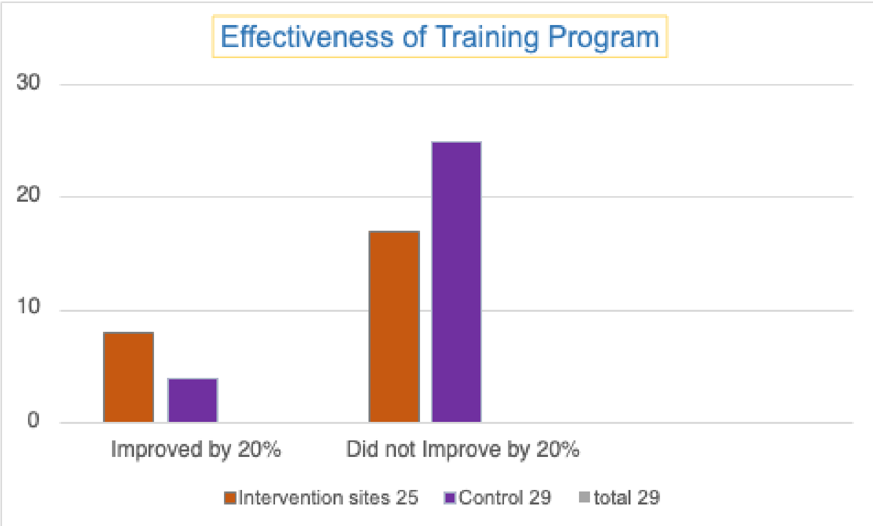


Figure 4

Chi-Square Two-Way Table Statistics		
Observed Counts	**Achieved Goal**	**Below Goal**
Intervention	8	17
Control	4	25
Expected Counts	**Achieved Goal**	**Below Goal**
Intervention	5.556	19.444
Control	6.444	22.556
Std. Residuals	**Achieved Goal**	**Below Goal**
Intervention	1.037089946	-0.554348
Control	-0.962914	0.514699
Chi-Square	2.575	
DF	1	
P-Value	0.1086	

Figure 5

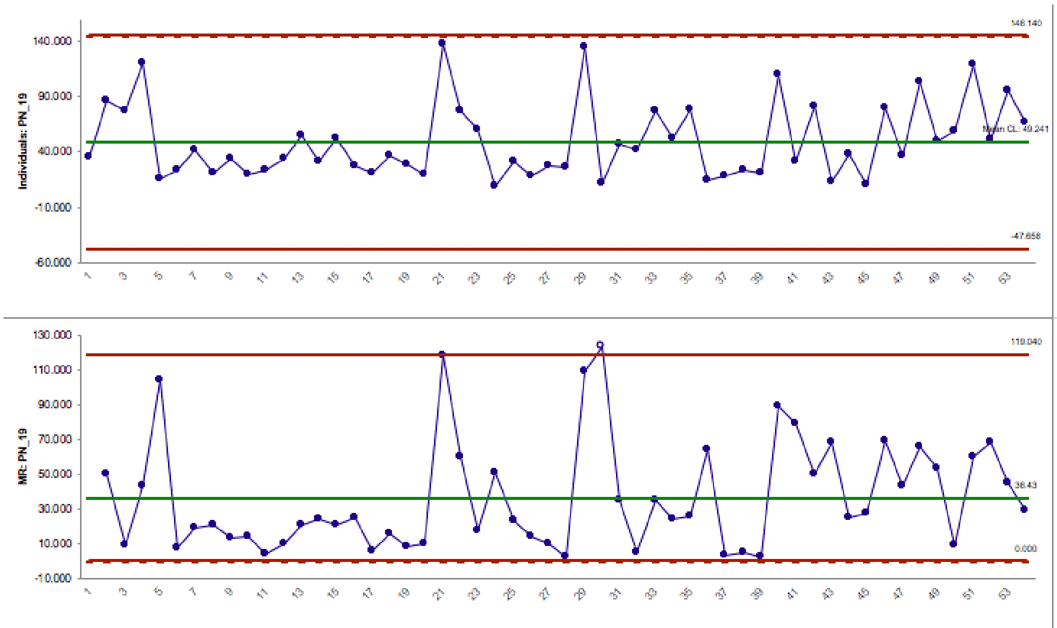
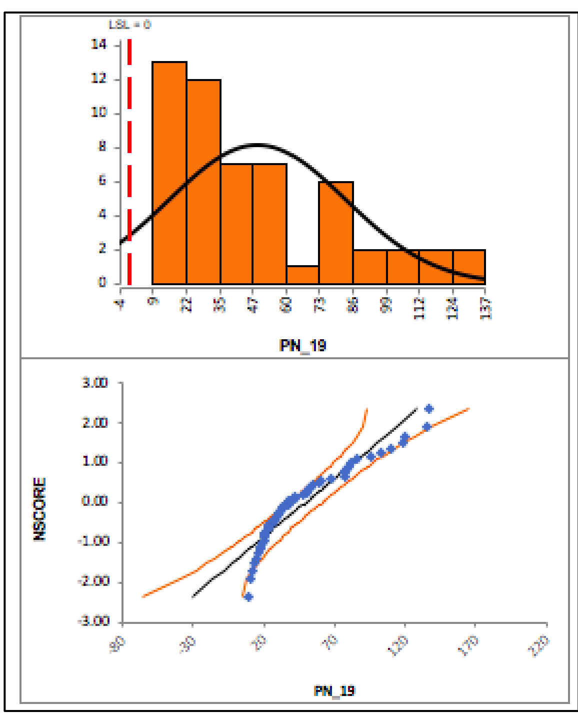


Figure 6

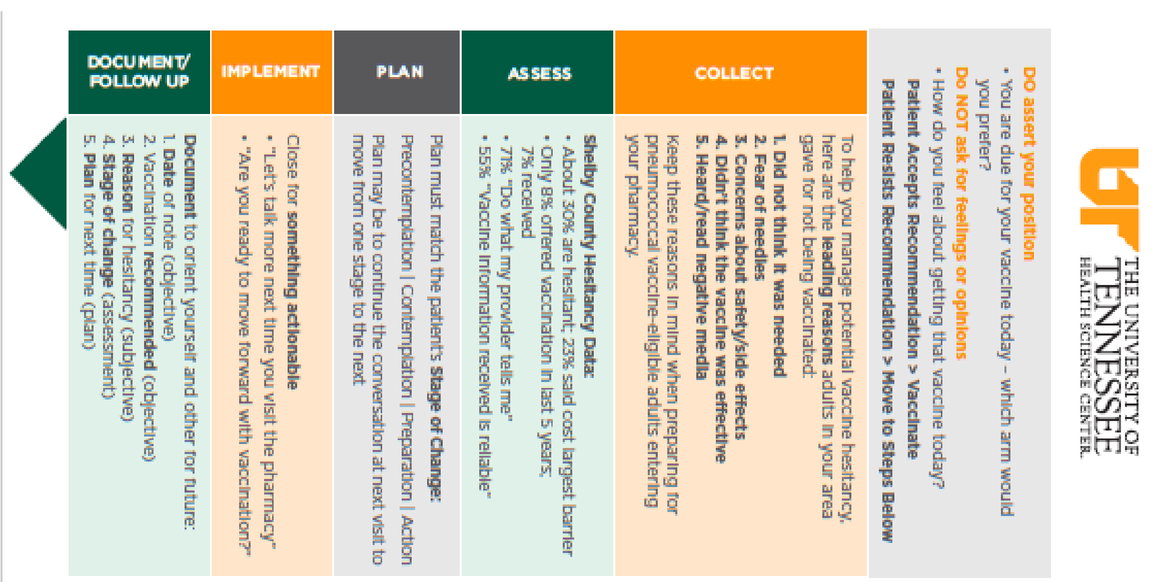


Process Capability Report: Pn % change	
Count	54
Mean	-8.054
StDev (Overall, Long Term)	52.093
StDev (Within, Short Term)	40.339
USL	
Target	20
LSL	20
Capability Indices using Overall StDev	
Pp	
Ppu	
Ppl	-0.18
Ppk	-0.18
Cpm	
Potential Capability Indices using Within StDev	
Cp	
Cpu	
Cpl	-0.23
Cpk	-0.23
Expected Overall Performance	
ppm > USL	
ppm < LSL	704896.1
ppm Total	704896
% > USL	
% < LSL	70.49%
% Total	70.49%
Actual (Empirical) Performance	
% > USL	
% < LSL	79.63%
% Total	79.63%
Anderson-Darling Normality Test	
A-Squared	3.014
P-Value	0.0000

Control

After conducting the training program with pharmacists, trends in pneumococcal vaccination rates over the course of a year at each pharmacy will be monitored. This will help evaluate the skills and assertive techniques that were adapted and integrated by each pharmacist at each Walgreens pharmacy. At the end of the training program, pharmacists will be provided "Reference Guides" of the vaccine recommendation process, as represented in Figure 7, to attach to their computer monitors at their respective sites to remind and ensure each eligible vaccine recommendation is strong and assertive. Adherence to these guides will be a fidelity outcome and will help to evaluate the extent to which each pharmacy adapted to the lessons learned from the training. Finally, follow up interviews will be performed with pharmacists post-implementation to discuss the strengths and weaknesses of the training and evaluate the usefulness of the skills learned from the training sessions.

Figure 7



Chapter 6: Discussion

The primary focus of training program was to improve the quality of pneumococcal vaccine recommendations pharmacists provide in the community setting to increase the overall rates of vaccinations and optimize health outcomes. Research has suggested that the influence of quality recommendations has a significant impact on vaccine behaviors and vaccine initiation. In a prior research study examining the correlation between the quality of a vaccine recommendation to vaccine initiation, researchers found that receiving a high-quality recommendation versus no recommendation was associated with over nine times the odds of having received the vaccination and four times the odd compared to a low-quality recommendation (Gilkey et al., 2016). The study also found that higher recommendation quality was associated with less vaccination refusal and delay. It is quite evident that higher quality recommendations significantly influenced the decision making of receiving the vaccination and led to higher overall initiation rates.

Limitations and Insights

While the outcomes of the training program did not result as expected a discussion to help identify various factors that may have contributed to the variable outcomes of the training program can help understand and address the shortcomings of this research. To understand both the factors of success and the potential barriers to implementing and sustaining the implementation of the training program, we used the Consolidated Framework for Implementation Research (CFIR) to help evaluate various factors in a systematic approach. We examined each domain of the CFIR construct such as intervention characteristics, outer setting, inner setting, characteristics of individuals, and process of implementation to consider issues that both facilitated and hindered implementation.

When considering intervention characteristics, several relative advantages of the implementation were noted. The training program intended to equip pharmacists with stronger skills in their communication and assertive techniques to improve pneumococcal vaccine rates and improve overall patient health. The training program was adaptable to all community pharmacies where there is convenience in providing vaccinations and feasibility to implement in routine practice.

Regarding outer setting, patient resources were considered in terms of if there was a willingness for patients to engage in active discussion during a vaccine recommendation. External policies such as insurance coverage can influence patients' decision to receive vaccinations. Another important consideration is the pre-administration processing time of a vaccination which can influence and defer patients from receiving vaccinations at the pharmacy

In terms of inner setting, understanding the culture, implementation climate, and readiness for implementation were critical. Community pharmacies, in general, are sometimes perceived as environments of high tension where pharmacists are challenged with multiple initiatives and benchmarks that are considered more important than others. And as a common result, more efforts are typically directed to initiatives that are incentivized versus those that are not. Time and workload were other barriers commonly seen that may have impacted the climate of learning new vaccine recommendation techniques and integrating within practice.

In terms of characteristics of individuals, it is valuable to consider the knowledge and beliefs about the intervention, and vaccinations in general. The intended purpose of the training program was to improve pharmacist recommendation technique, expand patient education, and help dissolve several hesitancy factors including culture and misconceptions. While acquiring new knowledge and further solidifying important strategies, attitudes and perception play an important role in a new implementation. That is why we may consider another barrier to successful implementation: the resistance to change in routine and resolute perceptions.

Lastly, we may reassess the process of implementation: the planning and execution of the training program. Perhaps another reason for unsuccessful improvement was simply a weak implementation of the program or weak integration of techniques within the pharmacies after implementation. Perhaps, our strategies may have not been strong enough to adapt firmly and integrate within the participating pharmacies. As a means of reflecting and evaluating the effectiveness of the training program, we conducted interviews with pharmacists that participated in the training post implementation. From the interviews, we acquired qualitative data and gained perspective on aspects of the program that were integrated successfully as well as measures for quality improvement. Future studies may focus on the strategy of implementation and improvement to better correlate an assertive training program for pharmacists to improve vaccination rates in the community setting.

Conclusion

Though quantitative data did not suggest a strong enough correlation to determine the impact of the training program to the overall increase in pneumococcal vaccination rates, this research provides future direction on how community pharmacists can better facilitate vaccine recommendations and be key players in improving overall vaccination rates to better patient outcomes. In regard to the data analysis, we found settings where the training program was beneficial and others where they were not. Considering several influential factors that may be outside of the study's control, it is difficult to determine whether or not the training program positively or negatively impacted pneumococcal vaccination rates in community pharmacies. Perhaps, the lessons learned from this research study can provide future researchers and pharmacy practitioners a direction for the future to overcome vaccine hesitancy and improve quality recommendations.

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