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Quality Improvement Project to increase pneumococcal vaccination rates in adults with inflammatory bowel diseases (IBD) being treated with immunosuppressants.

Le Yu Naing
leyu.naing@louisville.edu

Sheza Malik
Rochester Regional Health System, sheza.malik@rochesterregional.org

Jay Bapaye
jay.bapaye@rochesterregional.org

Nagesh Jadhav
Rochester General Hospital, nagesh.jadhav@rochesterregional.org

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Abstract

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Patients with inflammatory bowel diseases (IBD) are at an increased risk of pneumonia, and using immunosuppressive medications further increases this risk. Hospitalized patients with IBD have a significantly higher mortality rate from infections with pneumonia being one of them. The American College of Gastroenterology recommends pneumococcal vaccination for all IBD patients as a part of preventative care for IBD patients. However, compliance rates of pneumococcal vaccination in IBD patients have been very low. Quality improvement projects in this regard have been successful at demonstrating increased immunization rates. Our quality improvement project was aimed at increasing pneumococcal vaccination rates in these adult IBD patients by establishing a process to identify eligible patients in primary care clinics.

Methods:

A total of 95 adult patients (under age 65) with IBD who were treated with immunosuppressants and had clinic visits in 2 primary care clinics (one internal medicine residents' continuity clinic, and one primary care clinic without residents) from January 2010 to December 2020 were screened for their eligibility for pneumococcal vaccination and immunosuppressed status. Eligible patients were contacted via phone to schedule a clinic visit to receive pneumococcal vaccinations and reasons for refusal were documented. All the physicians, physician assistants, and nursing staff were informed of the project, and the plan was set up to identify yearly champions in each clinic whose patients are up to date with their pneumococcal vaccinations to ensure the project's sustainability. Data were collected and analyzed using descriptive statistics. Fisher's exact test compared patients with updated pneumococcal vaccination to those not up to date. McNemar's exact test compared the before and after vaccination status.

Results:

A total of 95 patients (28 patients with ulcerative colitis and 67 patients with Crohn's disease) treated with immunosuppressant medications were evaluated and only 10 patients (10%) were up to date with pneumococcal vaccination. 56 patients (58%) had not started pneumococcal vaccinations and were due to receive PCV 13 and 29 patients (30%) were due for PPSV 23. After the intervention, 32 patients (33.6%) had received pneumococcal vaccination at 6 months follow-up. 16 patients (16%) refused to get pneumococcal vaccination until after the consultation with their primary gastroenterologists and had not received the immunization at 6 months follow-up. The compliance rate of pneumococcal vaccinations was increased by 23% (p

Conclusion:

Patients with inflammatory bowel disease are at risk for vaccine-preventable illnesses, and pneumococcal vaccination rates are consistently low in this patient population. A simple primary care clinic-based intervention described in our project significantly improved the pneumococcal vaccination rate.

Conflict of Interest Statement

No conflict of statement

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ARTICLE

Quality Improvement Project to Increase Pneumococcal Vaccination Rates in Adults with Inflammatory Bowel Diseases (IBD) Being Treated with Immunosuppressants

Le Y. Naing [a], Sheza Malik [a,*], Jay Bapaye [b], Nagesh Jadhav [b]

[a] Rochester Regional Health System, USA
[b] Rochester General Hospital, USA

Abstract

Patients with inflammatory bowel diseases (IBD) are at an increased risk of pneumonia, and using immunosuppressive medications further increases this risk. Hospitalized patients with IBD have a significantly higher mortality rate from infections with pneumonia being one of them. The American College of Gastroenterology recommends pneumococcal vaccination for all IBD patients as a part of preventative care for IBD patients. However, compliance rates of pneumococcal vaccination in IBD patients have been very low. Quality improvement projects in this regard have been successful at demonstrating increased immunization rates. Our quality improvement project was aimed at increasing pneumococcal vaccination rates in these adult IBD patients by establishing a process to identify eligible patients in primary care clinics.

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Results: **A total of 95 patients (28 patients with ulcerative colitis and 67 patients with Crohn's disease) treated with immunosuppressant medications were evaluated and only 10 patients (10%) were up to date with pneumococcal vaccination. 56 patients (58%) had not started pneumococcal vaccinations and were due to receive PCV 13 and 29 patients (30%) were due for PPSV 23. After the intervention, 32 patients (33.6%) had received pneumococcal vaccination at 6 months follow-up. 16 patients (16%) refused to get pneumococcal vaccination until after the consultation with their primary gastroenterologists and had not received the immunization at 6 months follow-up. The compliance rate of pneumococcal vaccinations was increased by 23% ($p < 0.001$) in patients with inflammatory bowel disease treated with immunosuppressant drugs after the intervention.**

Conclusion: **Patients with inflammatory bowel disease are at risk for vaccine-preventable illnesses, and pneumococcal vaccination rates are consistently low in this patient population. A simple primary care clinic-based intervention described in our project significantly improved the pneumococcal vaccination rate.**

Keywords: Inflammatory bowel diseases, Immunosuppressive medications, Pneumococcal vaccination, Quality improvement, Compliance rate, Primary care, Intervention

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* Corresponding author.
E-mail address: Sheza.malik@rochesterregional.org (S. Malik).

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1. Introduction

In 2015–2016, around 3.1 million adults were estimated to have ever received a diagnosis of Inflammatory bowel disease (IBD).[1] Although the life expectancy of IBD patients is close to the average for the healthy population, it is generally associated with low health-related quality of life (QoL), emotional distress, and high medical costs.[2,3] IBD patients are also at increased risk for infectious complications, accounting for high morbidity and mortality, especially in older populations with multiple comorbidities.[4] Treatments with corticosteroids, immunomodulators or biologics, narcotics, and proton-pump inhibitors increase the predisposition for infections.[5] Furthermore, IBD patients have a high risk of infections due to disease-associated complications such as malnutrition, need for parenteral nutrition, multiple hospitalizations, and bowel surgeries.[6] Community-acquired pneumonia is one of the most common infections in patients with ulcerative colitis and Crohn's disease.[7] Infection-related hospitalizations, including pneumonia and sepsis, were reported to have four-fold greater mortality and more extended hospital stay in IBD patients.[8]

Immune response to immunizations depends on the degree of immunosuppression. Although the sequential vaccination schedule of PCV13 followed by PPSV 23 is safe and immunogenic for most IBD patients, a combination of immunomodulators and biologics can significantly impair the immune response to pneumococcal vaccinations.[9] So, ideally, vaccinations should be given before initiating immunosuppressants.

The American College of Gastroenterology recommends pneumococcal vaccination for all IBD patients.[10] The Infectious Diseases Society of America (IDSA) and the Centers for Disease Control and Prevention (CDC) recommend that patients on immunosuppressants be vaccinated once with the pneumococcal conjugate vaccine (PCV13) followed by pneumococcal polysaccharide vaccine (PPSV23) at least eight weeks later, the second dose of the PPSV23 5 years after the first dose and the third dose after the age of 65 years.[11,12] However, pneumococcal vaccination coverage rates are very low in this population, especially adults below 65. Some surveys have found vaccination rates as low as 9–11% in people with IBD.[13,14] Inadequate counseling of patients, physicians' uncertainty about vaccination recommendations in IBD, fears, concerns about the side effects of vaccination, and costs associated with vaccine storage and administration have been cited in the literature as the most common causes of suboptimal vaccination rates.[13,14] Quality improvement projects in this area have been successful in increasing vaccination rates.[15]

The target pneumococcal vaccination rate by Healthy People 2020 for high-risk adults 18 to 64 years old was set at 60%; however, the compliance rates were low.[16] Our quality improvement project aims to increase pneumococcal vaccination rates in adult patients under 65 diagnosed with IBD and treated with immunosuppressants. We implemented a process to identify appropriate patients in two outpatient clinics – one internal medicine residents-run continuity care clinic and one primary care clinic without residents' involvement.

2. Methods

2.1. Ethics statement

The Rochester General Hospital Institutional Review Board approved our quality improvement initiative, and patients were provided with Center for Diseases Control (CDC) information regarding pneumococcal vaccinations. The consent for vaccinations was obtained according to the CDC standards.

2.2. Study population

A total of 95 adult patients (male = 43, female = 52) were screened with the following criteria-with the ages below 65 years old, having IBD diagnosis, taking immunosuppressants, and having clinic visits in two primary care clinics (one internal medicine residents' continuity clinic, and one primary care clinic without residents) from January 2010 to December 2020. 28 patients had ulcerative colitis, and 67 patients had Crohn's disease. 85 out of 95 patients (89%) of patients were below the age of 60 years old. Patients requiring systemic corticosteroids of ≥10 mg prednisolone/day or equivalent, immunomodulators including methotrexate, thioguanine, biologics including anti-tumor necrosis factor (Anti-TNF) agents, or a combination of ≥1 immunosuppressive agents were included in the study. All patients were screened for their eligibility for pneumococcal vaccination, presence of chronic diseases (end-stage renal disease on hemodialysis, chronic kidney diseases, diabetes), presence of psychiatric diagnoses, active steroid use, alcohol use, tobacco use, and immunosuppressed status. Our study had only one patient with a solid organ transplant and did not include any patients with end-stage renal disease diagnosis requiring hemodialysis. The baseline characteristics of eligible patients are shown in Table 1.

Table 1. Baseline characteristics of patients with inflammatory bowel disease.

Pneumococcal immunization completion	Overall (95)	No (85)	Yes (10)	P-Value
Age (Years)				0.698
18–20	1 (1.1)	1 (1.2)	0 (0.0)	
21–30	17 (17.9)	15 (17.6)	2 (20.0)	
31–40	12 (12.6)	11 (12.9)	1 (10.0)	
41–50	27 (28.4)	25 (29.4)	2 (20.0)	
51–60	28 (29.5)	23 (27.1)	5 (50.0)	
61–65	10 (10.5)	10 (11.8)	0 (0.0)	
Sex = Male	43 (45.3)	40 (47.1)	3 (30.0)	0.504
Ulcerative colitis diagnosis	28 (29.5)	26 (30.6)	2 (20.0)	0.718
Need PCV 13 at the time of review	56 (58.9)	56 (65.9)	0 (0.0)	<0.001
Need PPSV 23 at the time of review	29 (30.5)	29 (34.1)	0 (0.0)	0.029
Presence of a psychiatric diagnosis	49 (51.6)	42 (49.4)	7 (70.0)	0.319
Smoking Status				0.676
Active	17 (17.9)	16 (18.8)	1 (10.0)	
Former	35 (36.8)	32 (37.6)	3 (30.0)	
Never	43 (45.3)	37 (43.5)	6 (60.0)	
Alcohol use				0.591
Active	49 (52.1)	42 (50.0)	7 (70.0)	
Former	15 (16.0)	14 (16.7)	1 (10.0)	
Never	30 (31.9)	28 (33.3)	2 (20.0)	
Active antibiotic use	2 (2.1)	1 (1.2)	1 (10.0)	0.2
Steroid active use	13 (13.7)	11 (12.9)	2 (20.0)	0.623
Hepatitis B vaccination completed	28 (30.1)	24 (28.9)	4 (40.0)	0.482
Influenza vaccination within the last year	37 (39.8)	32 (38.6)	5 (50.0)	0.512
Diabetes	9 (9.5)	7 (8.2)	2 (20.0)	0.24
Chronic kidney disease stage III or IV	6 (6.4)	6 (7.1)	0 (0.0)	1
No end-stage renal disease on dialysis	95 (100.0)	85 (100.0)	10 (100.0)	NA
Organ Transplant	1 (1.1)	0 (0.0)	1 (10.0)	0.105
No Chronic congestive heart failure	95 (100.0)	85 (100.0)	10 (100.0)	NA
Active Malignancy	2 (2.1)	1 (1.2)	1 (10.0)	0.2

2.3. Intervention implementation

Eligible patients were contacted by phone to schedule a nurse or clinic follow-up visit to receive pneumococcal vaccinations. Any reasons for refusal of the pneumococcal vaccination series were documented. All the physicians, physician assistants, and nursing staff were informed of the project, the algorithm to follow to identify eligible patients, and the list of eligible patients to follow up.

The process was set up for eligible patients to schedule a separate nurse visit or follow-up visits with the primary team to receive pneumococcal vaccination series. The primary care team was informed of eligible patients who refused vaccinations and could not be contacted via phone to follow up during upcoming clinic visits. At six months, the compliance rates of the pneumococcal vaccination series were reevaluated. A Plan-Do-Study-Act quality improvement model was used to improve communication between patients and the primary care team. The aim was to increase the proportion of vaccinated IBD patients on immunosuppressants.

We formulated the process algorithm as a reference for all the providers in both clinics to identify eligible patients (Fig. 1). If a patient had received one dose of PCV13 within eight weeks or PPSV23 within a year, then no intervention was required for our quality improvement, but primary care teams were informed of the need to follow up. The same process was executed if the patient had received PCV13, followed by PPSV23 within the last five years (Fig. 1).

The plan was set up to identify yearly champions in each clinic whose patients are up to date with their pneumococcal vaccinations to ensure the sustainability of the project.

2.4. Statistical analysis

Counts and percentages summarized outcomes. Fisher's exact test compared patients with updated pneumococcal vaccination to those not up to date. McNemar's exact test compared the before and after vaccination status.

3. Results

Out of 95 patients (28 patients with ulcerative colitis and 67 patients with Crohn's disease) who were treated with immunosuppressant medications, 10

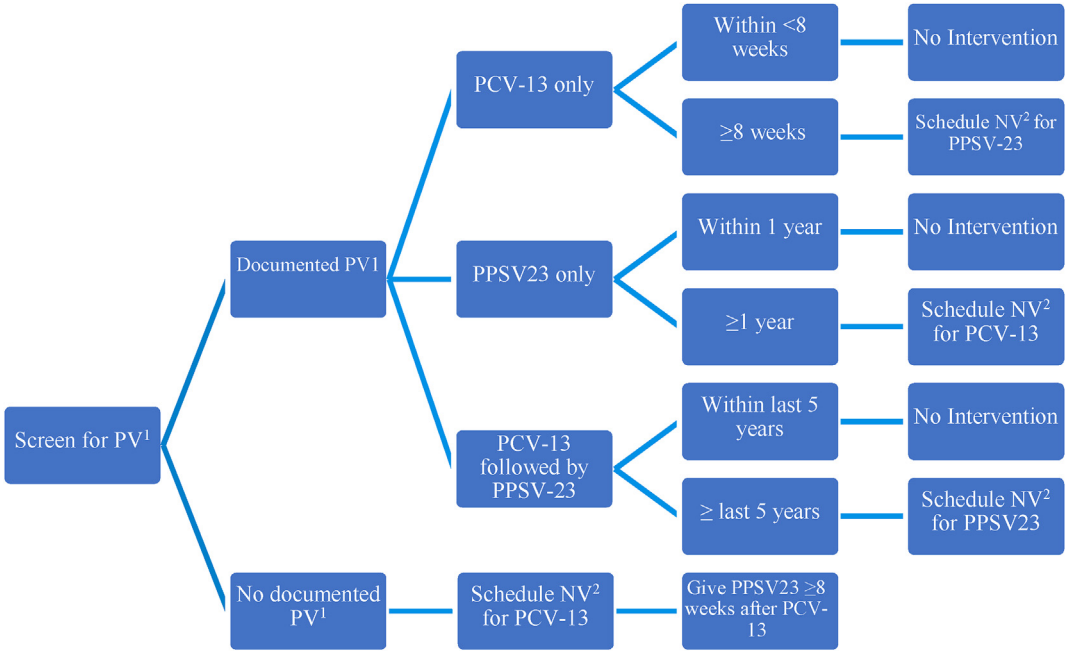

Fig. 1. Algorithm 1—A process algorithm for screening patients due for immunization. PCV-13 = Pneumococcal conjugate vaccine, PPSV23 = Pneumococcal polysaccharide vaccine, PV= Pneumococcal vaccine, NV= Nurse visit.

patients (10%) were up to date with pneumococcal vaccination, including one patient who had a solid organ transplant. 9 patients had diabetes, 49 patients had active alcohol use, and they all were not up to date with pneumococcal vaccination. 56 patients (58%) were eligible to receive PCV13 vaccinations, and 29 patients (30%) were due to receive PPSV23 immunizations. 37 patients (38.9%) received influenza vaccinations within the last year, while 56 Patients (58.9%) did not. 28 patients (29.4%) did not have a record of complete hepatitis B vaccinations. 16 patients (16%) refused to get pneumococcal vaccinations, 5 of them would like to discuss with their gastroenterologists to receive vaccinations, and the rest would like to postpone. None of those patients had received the pneumococcal vaccinations at six months follow-up.

Four patients out of 16 patients (25%) who refused to get pneumococcal vaccinations had records of hepatitis B vaccinations completed, and only 1 of them received influenza vaccination within the last year. 56 out of 95 patients (58%) did not have vaccination records of influenza vaccination within the past year, and 65 out of 95 patients (68%) did not have hepatitis B vaccination records. However, all patients were on immunosuppressant drugs at the time of review.

Forty one patients (43%) could not be reached, so the primary care team was informed of the plan and set up reminders to discuss the immunization plan during the upcoming appointment. At six months follow-up, 32 patients (33.6%) were up to date with pneumococcal vaccinations, whereas 63 patients (66.3%) were not (Table 2). The compliance rate of pneumococcal vaccinations was increased by 23% in patients with inflammatory bowel disease treated with immunosuppressant drugs.

4. Discussion

Optimizing the management of inflammatory bowel disease by decreasing vaccine-preventable infections is one of the most cost-effective and efficient ways to reduce the healthcare burden, morbidity, and mortality from IBD and complications from its treatments. Pneumonia is one of the most common extra-intestinal infections observed in patients with IBD.[7] Furthermore, a higher rate of complications from pneumonia is also observed in these IBD patients than in the general population. Anti-tumor necrosis factor medications (Anti-TNF) and steroid use were shown to be associated with an increased risk of developing pneumonia and pneumonia-related hospitalizations after adjusting age,

Table 2. Effect of intervention implementation on PCV immunization status.

PCV immunizations up to date	Before	After	P-Value
Yes	10 (10.5%)	32 (33.6%)	<0.001
No	85 (89.5%)	63 (66.3%)	

gender, and comorbidities, and the risk was higher compared to immunomodulators.[17,18]

The sequential vaccination schedule of PCV13 followed by PPSV23 is safe and immunogenic; however, the immune response in immunosuppressed patients varies depending on the use of conventional immunomodulators, including oral steroids, anti-TNF medications, and combination therapy.[9] Pneumococcal vaccinations should be administered preferably before the initiation of immunosuppressive therapy. However, the vaccination rates in IBD patients are significantly suboptimal.[19] A survey by Melmed et al. found that out of 146 IBD patients, only 13 (9%) reported being vaccinated against pneumococcal infections.[14] In another study by Jordan et al., 42.2% were vaccinated only with PPSV23, 19.27% were vaccinated only with PCV13, and only 16.5% received both vaccines.[20]

The compliance rate of pneumococcal vaccination in our study populations of immunosuppressed patients with IBD was very low. It was consistent with previous studies since only 10.5% of patients in our study had their pneumococcal vaccination up to date before intervention. The rates of pneumococcal vaccination were increased after a simple intervention such as contacting them to make an appointment for pneumococcal vaccination at the clinic and motivating healthcare professionals by identifying annual champions at the clinic whose patients have their pneumococcal immunization up to date.

Insufficient counseling by providers, ambiguity about indications, and fears concerning vaccine safety are the most common reasons for vaccination noncompliance among IBD patients.[13] Additionally, physician uncertainties over whether vaccination is indicated in IBD patients and uncertainty among primary care physicians and gastroenterologists about who is responsible for offering vaccination.[21,22] Wasan et al. reported that most of the gastroenterologists believed that the primary care providers should determine which vaccinations to give and to administer the vaccines.[23]

Quality improvement projects to improve pneumococcal vaccinations in patients with IBD vary depending on the clinic settings, resources available, and patients' cooperation with regular follow-up. Previous data have also shown that recommendations from health professionals are one of the most critical factors in the uptake of preventive health services such as vaccination and cancer screening.[24] A study by Parker et al. showed that vaccination rates were significantly improved in a high-risk IBD population after utilizing the Plan-Do-Study-Act quality improvement model.[15] Examples of successful quality improvement initiatives are setting up vaccination reminders in the progress note templates in electronic medical records, assigning a dedicated nursing staff to screen patients who are due to receive vaccinations and follow up with compliance rates, etc.[25,26]

In our study, the compliance rate for pneumococcal vaccination was increased to 20% even after simple active interventions such as directly asking patients to be vaccinated through phone calls and actively engaging healthcare professionals by identifying annual champions in the clinic whose patients are up to date on their pneumococcal vaccination. Our study found that the majority of patients who did not complete pneumococcal vaccinations also did not have hepatitis B and influenza vaccination records. So, we focused on raising awareness of the need for immunizations in adult patients with IBD who were already on immunosuppressant drugs. However, immunizations are preferable to be given before the initiation of immunosuppressants.

Our study has many strengths. Our study population's low vaccination rates underscore that interventions are needed to improve vaccination rates in patients with IBD. Addressing the benefits and safety of the vaccine for IBD-patients in clinical practice, direct invitations, and emphasizing immunosuppression as the main criterion for vaccination could be good starting points, although this should be verified by further research.[13,27,28] In addition, we targeted primary care clinics in our study. The most pressing need is raising awareness of recommended immunizations for immunosuppressed IBD patients among primary care physicians. However, the sample size of our research is limited, and data were collected in only two facilities. Larger multicenter quality improvement projects targeting primary clinics rather than specialty clinics are needed, as they are the primary venues to improve vaccination rates in patients with inflammatory bowel disease.

5. Conclusion

Patients with inflammatory bowel disease are at risk for vaccine-preventable illnesses, and pneumococcal vaccination rates in this population are consistently low. A simple primary care clinic-based intervention described in our project significantly improved the pneumococcal vaccination rate. Further quality improvement projects targeting primary care clinic sites to improve pneumococcal vaccination rates in inflammatory disease patients are needed.

Conflict of interest

The authors report there are no conflicts of interest.

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