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Pneumococcal Vaccination Rates in VHA Patients With Inflammatory Bowel Disease

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Abstract: Inflammatory bowel disease (IBD) is an inflammatory condition of the digestive tract not caused by infectious agents. Symptoms of IBD, such as diarrhea and pain, diminish one's quality of life. Underlying immune dysregulation may put IBD patients at risk for severe infectious disease making preventative vaccination highly recommended. Therefore, this study sought to assess rates of pneumococcal vaccination in patients with IBD.

A cross-sectional observational study was employed utilizing administrative data extracts from the Veterans Health Administration (VHA) to identify patients diagnosed with IBD per International Classification of Diseases, Version 9, Clinical Modification codes. Their pneumococcal vaccine histories were determined from Common Procedural Terminology codes. Data were aggregated to the patient level and subjected to multivariable logistic regression to assess factors associated with receipt of the vaccination and 1-year mortality; survival analyses extended follow-up to as much as 4 years following IBD diagnosis.

From October 2004 to September 2009, 49,350 patients were diagnosed with IBD in the VHA. Incidence was approximately 6000 cases/y. Patients averaged 62 years (±15, range 19–98) with 45% aged 65 or older. Approximately 6% were women, 21% were highly disabled from a military service-connected condition, 46% had hypertension, 38% dyslipidemia, and 18% diabetes. Only 20% of the cohort received pneumococcal vaccination including 5% vaccinated prior to IBD diagnosis, 2% on the date of diagnosis, and 13% subsequently. Being married, living outside the Northeast, and having more comorbidities were associated with vaccination before IBD diagnosis; models of vaccination at or after diagnosis demonstrated poor fit: little better than chance. Vaccinations before, after, and at diagnosis were protective against 1-year mortality adjusting for clinical and demographic covariates. Living in the South was an independent risk factor for death among IBD patients.

While vaccination for pneumococcus is a low-cost, low-risk recommendation for persons with IBD with an apparent survival benefit, vaccination rates were low.

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Abbreviations: IBD = inflammatory bowel disease, ICD9 = International Classification of Diseases, Version 9, Clinical Modification, STOPP = Surgical Treatment Outcomes for Patients with Psychiatric Disorders, SD = standard deviation, VHA = Veterans Health Administration.

INTRODUCTION

Patients with inflammatory bowel disease (IBD) have underlying immune dysregulation; they also frequently require exogenous immunosuppressive agents of different types both as induction and maintenance therapies for their disease state.[1] As a consequence, most patients with IBD are at increased risk of developing severe manifestations of infectious diseases.[2] Therefore, the proper use of vaccinations to protect against certain infectious conditions takes on added importance in the IBD patient population. In general, the vaccination schedule for adults with IBD is the same as that for the general adult population, with the caveat that live attenuated vaccines are contraindicated in patients already receiving biologic agents. Several studies and surveys have demonstrated suboptimal rates of vaccination in IBD patients,[3,4] despite fairly clear consensus on which vaccines are appropriate. Probable reasons for this underutilization include a lack of awareness of the problem on the part of clinicians, fear of potential adverse effects from vaccines, and ambiguity as to the role of the primary care provider versus the gastroenterologist in assuming responsibility for immunizations in this particular population.[5] Accordingly, it would seem there is a potential need for the development of systems, tools, and standardized processes for facilitating clinician adherence to recommendations regarding immunizations in IBD patients. Such processes may be more easily developed and more effective within large health care systems such as the Veterans Health Administration (VHA) system.

Pneumococcal infection causes more deaths annually in the United States than any other vaccine-preventable illness.[6] Current Centers for Disease Control and Prevention guidelines from 1997 recommend pneumococcal vaccination for all adults aged 65 years and older, adults on chronic immunosuppressive therapy, and those with chronic illnesses including IBD. This recommendation is echoed in the 2004 guidelines for IBD patients put forth by Sands et al,[7] in the 2009 guidelines from

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the European Crohn's and Colitis Organisation,[8] and in multiple reviews since that time.[9,10] In addition, a 1-time booster vaccination after 5 years is recommended for those patients on immunosuppressive medications.

Although, the VHA operates the nation's largest integrated health care system, IBD and compliance with the pneumococcal vaccination has not been sufficiently studied in this population. Accordingly, this study's aims were to describe the population of VHA patients with IBD as they appear in administrative databases and assess rates of compliance with pneumococcal vaccination in the VHA population of IBD patients.

METHODS

A cross-sectional study was conducted on system-wide data from the VHA to assess the proportion of patients diagnosed with IBD who have received the pneumococcal vaccine.

Sample

All VHA patients over the age of 18 diagnosed with IBD (International Classification of Diseases, Version 9, Clinical Modification [ICD9] diagnosis codes 555.0, 555.1, 555.2, 555.9, 556.0, 556.2, 556.3, 556.5, 556.6, and 556.9) during fiscal years (FYs) 2005–2009 (October 2004 through September 2009; FY2005–FY2009) with valid Veteran status per VHA Priority class (described below) were included.[11] A total of 49,350 veteran patients with IBD were identified.

Measures

Pneumococcal vaccination was identified by Common Procedural Terminology codes 90669, 90670, 90732, and G0009.[12] Covariates included age in years (also dichotomized as <65 vs 65 or older), sex, marital status, chronic disease burden (Selim physical comorbidity score, adapted to exclude IBD, and Selim mental comorbidity score which includes alcohol and drug use disorders),[13] Charlson comorbidity score (mortal illnesses including indicators for cirrhosis, myocardial infarct, human immunodeficiency virus, acquired immune deficiency syndrome, etc),[14,15] additional relevant comorbidities (frailty diagnoses [see Appendix for ICD9 codes],[16] diabetes [ICD9 249–250], chronic obstructive pulmonary disease [491, 492, 494, 495, 496, 500–505, and 506.4], congestive heart failure [428], and cirrhosis [571.2, 571.5, 571.6]). Receipt of immunosuppressive medications was also assessed per year. Death data were used to indicate death within 1 year post-IBD diagnosis and to generate survival in years through the end of the follow-up period on September 30 2010; patients diagnosed earlier in the study had longer follow-up. VHA priority status 1 to 8 defines "valid Veteran status." Priority is assigned by the VHA based on military experiences, disability, and poverty. Priority 1 means 50% to 100% disabled from a military service-related condition, Priority 2 indicates 30% to 40% service-connected disability, Priority 3 10% to 20% service-connected disability or special cohort, Priority 4 catastrophically disabled/homebound, Priority 5 very low income, Priority 6 special cohorts, Priority 7 and 8 are veterans who agreed to copayments for both pharmacy and care. VHA Priority 1 veterans have no copays. Veterans with VHA Priority 2 to 6 have pharmacy copays only.

Data Source

The Surgical Treatment Outcomes for Patients with Psychiatric Disorders (STOPP) data repository or STOPP Study extracted data from VHA administrative databases from VHA's all-electronic medical record system for 8 million patients treated during fiscal years FY2005 to FY2009 to examine surgical rates and outcomes of veterans with serious mental illness. Its data served as the basis for the STOPP Data Repository (Copeland – Principal Investigator, Protocols #00412 and #00532).[17] Data were derived from VHA inpatient, outpatient, vital statistics, pharmacy, and enrollment files, assured for quality through extensive data processing routines. The Data Repository was designed to provide for reuse of the STOPP study data in new protocols such as this study of IBD. This database-only study was approved by the Central Texas Veterans Health Care System Institutional Review Board via expedited review prior to initiation and exempted by the Scott & White Institutional Review Board.

Analysis

Rates of vaccination were determined and patient characteristics presented as counts (percentages) or means (standard deviations [SDs]). We modeled receipt of pneumococcal vaccine (at any time) in multivariable logistic regression models, to quantify the effects of demographic covariates, immunosuppressive medication, and comorbidity burden. Similar models assessed factors related to vaccination before IBD, at IBD diagnosis, and after IBD diagnosis, as well as 1-year post-IBD mortality. In these multivariable models, effects were reported as odds ratios with their 95% confidence intervals. Odds ratios <0.33 or >3.0 represent strong effect sizes.[18] Model fit for logistic regression was assessed by the c-statistic which ranges from 0.50 (for a model whose fit is no better than chance) to 1.0 (perfect prediction of the outcome). A proportional hazards model estimated the effect of vaccination on survival, adjusting for clinical and demographic covariates and censoring by the end of the observation period. Analyses were completed in SAS V9.2 (SAS Institute, Cary, NC), assuming a criterion significance level of .05.

RESULTS

There were 49,350 prevalent cases of IBD treated in the VHA during FY2005 to FY2009. Incidence was approximately 6000 new cases identified in medical records per year (see Table 1). Patients ranged in age from 19 to 98 years with a mean age of 62 (SD 15) years. About 45% of the IBD cohort was aged 65 or older. Approximately 1 in 20 patients was a female veteran, and 1 in 5 was VHA Priority 1 indicating 50% to 100% disability from a military service-connected condition. Comorbidity levels were modest, averaging 2 chronic physical conditions (SD 2). Specific comorbid conditions included hypertension (46%), dyslipidemia (38%), diabetes (18%), and anemia (11%). About 10% of the cohort was on immunosuppressive drugs in any year. Only 20% of the cohort received pneumococcal vaccination, with 5% being vaccinated prior to IBD diagnosis, 2% on the date of diagnosis with IBD, and 13% after diagnosis. In the first year after IBD diagnosis, 261 patients (1%) were hospitalized for pneumonia, 6317 (13%) for all-cause. Over the period of observation, 16% of the cohort died ($n = 7724$). One-year mortality was lower for those vaccinated relative to the unvaccinated (2.1% vs 4.5%, $\chi^2 = 127.9$, $df = 1$, $P < 0.001$).

Logistic regression models evaluated whether age, sex, married status, VHA Priority 1 (highly disabled) status, region of treatment (US Census regions Northeast, South, Midwest, West; or Puerto Rico/Virgin Islands where VHA also has

TABLE 1. Descriptive Statistics of Veterans Diagnosed with IBD During FY05 to FY09 (N = 49,350)

Characteristic	N or Mean (SD)	Percent, %, or Median (Min–Max)
Demographics		
Age	61.9 (15.0)	62.0 (19–98)
Age 65+	21,989	44.6
Female	2762	5.6
Married	21,605	43.8
South region		38.6
Northeast region		18.2
Midwest region		23.2
West region		18.7
Puerto Rico/Virgin Islands		1.4
Priority 1 status	10,154	20.6
Priority 2–6	26,475	53.6
Priority 7–8	12,721	25.8
FY		
2005	24,738	50.1
2006	6821	13.8
2007	6415	13.0
2008	5431	11.0
2009	5945	12.1
Comorbidities (1-year prior)		
Selim physical	1.9 (1.8)	2.0 (0–14)
Selim mental	0.3 (0.7)	0.0 (0–6)
Selim total	2.2 (2.0)	2.0 (0–16)
Charlson score	0.8 (1.4)	0.0 (0–19)
Diabetes	8909	18.1
COPD	6303	12.8
Congestive heart failure	1699	3.4
Cirrhosis	372	0.8
Dyslipidemia	18,498	37.5
Hypertension	22,704	46.0
Anemia	5485	11.1
Gait disorder	631	1.3
Falls	429	0.9
Weight loss	317	0.6
Coagulation	702	1.4
Other injury	418	0.9
Head injury	152	0.3
Fluid electrolyte imbalance	2297	4.7
Fractures	38	0.1
Frailty conditions	1668	3.4
Immunosuppressives		
Any prescription FY2005	4819	9.8
Any prescription FY2006	5049	10.2
Any prescription FY2007	5137	10.4
Any prescription FY2008	5284	10.7
Any prescription FY2009	5459	11.1
Vaccination measures		
Vaccinated during FY2005 to FY2009	10,043	20.4
Vaccinated Prior to IBD	2671	5.4
Vaccinated on date of IBD diagnosis	1148	2.3
Vaccinated after IBD diagnosis	6224	12.6
Year of vaccination		
2004	888	8.8
2005	2154	21.5
2006	1876	18.7
2007	1942	19.3
2008	1919	19.1
2009	1264	12.6
Died	7724	15.7
Years survival (censored on Sept 30, 2010)	4.0 (1.7)	4.4 (0–6.3)

COPD = chronic obstructive pulmonary disease, FY = fiscal year, IBD = inflammatory bowel disease.

TABLE 2. Logistic Regression Models of Pneumococcal Vaccination (N = 49,350)

Effect	Odds Ratio	95% Confidence Interval	
Dependent variable: pneumococcus vaccination (at any time)			
Age (effect per decade)	1.00	0.98 —	1.02
Female	0.81	0.73 —	0.90
Married	1.05	1.01 —	1.10
Priority 1	1.06	1.01 —	1.13
Census region (compared to Northeast)			
South	1.27	1.19 —	1.35
Midwest	1.17	1.09 —	1.25
West	1.18	1.10 —	1.28
Puerto Rico/Virgin Islands	1.38	1.15 —	1.66
Charlson Score (effect per additional point increase)	1.03	1.01 —	1.04
Selim physical (effect per additional comorbidity)	1.08	1.06 —	1.09
Selim mental (effect per additional mental illness)	1.14	1.11 —	1.18
Immunosuppressives prescribed in FY2005	0.90	0.82 —	1.00
Immunosuppressives prescribed in FY2006	1.08	0.97 —	1.20
Immunosuppressives prescribed in FY2007	1.17	1.05 —	1.30
Immunosuppressives prescribed in FY2008	1.18	1.06 —	1.31
Immunosuppressives prescribed in FY2009	1.08	0.98 —	1.18
c-statistic	0.57		
Dependent Variable: pneumococcus vaccination after IBD diagnosis			
Age (effect per decade)	0.99	0.97 —	1.01
Female	0.86	0.76 —	0.97
Married	0.95	0.90 —	1.01
Priority 1	1.19	1.11 —	1.27
Census region (compared with Northeast)			
South	1.23	1.14 —	1.34
Midwest	1.17	1.07 —	1.28
West	1.19	1.09 —	1.30
Puerto Rico/Virgin Islands	0.78	0.59 —	1.04
Charlson score (effect per additional point increase)	0.99	0.96 —	1.01
Selim physical (effect per additional comorbidity)	1.06	1.01 —	1.10
Selim mental (effect per additional mental illness)	0.96	0.94 —	0.98
Immunosuppressives prescribed in FY2005	1.08	0.97 —	1.21
Immunosuppressives prescribed in FY2006	1.16	1.03 —	1.32
Immunosuppressives prescribed in FY2007	1.16	1.03 —	1.32
Immunosuppressives prescribed in FY2008	1.24	1.10 —	1.40
Immunosuppressives prescribed in FY2009	1.07	0.97 —	1.20
c-statistic	0.57		
Dependent variable: pneumococcus vaccination at IBD diagnosis			
Age (effect per decade)	1.21	1.15 —	1.26
Female	0.69	0.50 —	0.96
Married	0.68	0.60 —	0.77
Priority 1	0.85	0.72 —	1.00
Census region (compared with Northeast)			
South	1.13	0.96 —	1.34
Midwest	1.02	0.85 —	1.23
West	0.96	0.78 —	1.17
Puerto Rico/Virgin Islands	1.76	1.13 —	2.74
Charlson Score (effect per additional point increase)	0.98	0.92 —	1.04
Selim physical (effect per additional comorbidity)	0.93	0.84 —	1.03
Selim mental (effect per additional mental illness)	0.92	0.88 —	0.96
Immunosuppressives prescribed in FY2005	0.67	0.50 —	0.90
Immunosuppressives prescribed in FY2006	1.13	0.83 —	1.54
Immunosuppressives prescribed in FY2007	0.97	0.71 —	1.33
Immunosuppressives prescribed in FY2008	0.99	0.73 —	1.35
Immunosuppressives prescribed in FY2009	1.00	0.77 —	1.31
c-statistic	0.61		
Dependent variable: pneumococcus vaccination before IBD diagnosis			
Age (effect per decade)	0.97	0.93 —	1.00
Female	0.82	0.67 —	1.01
Married	1.67	1.53 —	1.81
Priority 1	0.87	0.79 —	0.97
Census region (compared to Northeast)			
South	1.30	1.15 —	1.47
Midwest	1.16	1.02 —	1.33
West	1.21	1.05 —	1.39

TABLE 2. (Continued.)

Effect	Odds Ratio	95% Confidence Interval		
Puerto Rico/Virgin Islands	1.98	1.53	—	2.55
Charlson score (effect per additional point increase)	1.06	1.04	—	1.09
Selim physical (effect per additional comorbidity)	1.34	1.28	—	1.41
Selim mental (effect per additional mental illness)	1.31	1.28	—	1.34
Immunosuppressives prescribed in FY2005	0.53	0.42	—	0.67
Immunosuppressives prescribed in FY2006	0.79	0.63	—	0.99
Immunosuppressives prescribed in FY2007	1.18	0.96	—	1.45
Immunosuppressives prescribed in FY2008	1.00	0.82	—	1.22
Immunosuppressives prescribed in FY2009	1.05	0.88	—	1.25
c-statistic	0.75			

FY = fiscal year, IBD = inflammatory bowel disease.

facilities) were related to receipt of pneumococcal vaccine, with or without clinical covariates (Charlson Comorbidity Index, Selim physical and mental illness scores, receipt of immunosuppressive medication per year); the fit of the models was poor with c-statistic not exceeding 0.57. The model of vaccination after IBD was similarly uninformative as was a model of vaccination on the date of IBD diagnosis. However, the model of vaccination before IBD diagnosis had moderately good fit (c-statistic = 0.75) and positively related factors that included being married, living in the South, Midwest, or West, and having more comorbid conditions (see Table 2). In this model, older patients were relatively less likely to get vaccinated before IBD diagnosis.

One-year mortality was less for patients receiving pneumococcal vaccination at any time (Table 3). The survival analysis, however, identified only vaccination after IBD diagnosis, female sex, being married, and prescription immunosuppressives in FY2009 as protective factors (Table 4). Older, sicker, or highly disabled (Priority 1) veterans, as well as those living in the South, had increased risk of death over the long-term follow-up which ranged up to 4 years.

DISCUSSION

Patients with IBD are at an increased risk for pneumonia as compared with the general population, particularly when requiring medications such as steroids.[19] One recent study has demonstrated that *Streptococcus pneumoniae* is responsible for more pneumonia hospital admissions in IBD patients than either *Haemophilus influenza* or influenza virus.[20] These facts underlie the importance of adherence to the consensus recommendation for pneumococcal vaccination in IBD patients.[7–10] Unfortunately, multiple published reports indicate widespread difficulty in achieving this,[21] with reported pneumococcal vaccination rates as low as 31%[4] or even 9%.[3] Our data demonstrated a similarly low rate of pneumococcal vaccination for IBD patients in the VHA system (20%).

This study is unique in its broad and comprehensive scope of data collection from 140 VHA medical centers and hundreds of outpatient clinics across the United States. Limitations include reliance on administrative extracts of the electronic health records systems; lack of clinical notes; inability to

TABLE 3. Factors Associated with 1-Year Mortality for Patients with IBD (N = 49,350)

Effect	Odds Ratio	95% Confidence Interval		
Vaccination before IBD diagnosis	0.71	0.58	—	0.86
Vaccination at IBD diagnosis	0.54	0.36	—	0.82
Vaccination after IBD diagnosis	0.14	0.10	—	0.19
Age (effect per decade)	1.79	1.71	—	1.88
Female	0.72	0.52	—	0.99
Married	0.73	0.67	—	0.81
Priority 1	1.10	0.97	—	1.24
Census region (compared with Northeast)				
South	1.15	1.00	—	1.31
Midwest	1.14	0.99	—	1.32
West	1.07	0.91	—	1.25
Puerto Rico/Virgin Islands	1.42	1.04	—	1.94
Charlson score (effect per additional point increase)	1.40	1.37	—	1.44
Selim physical (effect per additional comorbidity)	1.25	1.17	—	1.34
Selim mental (effect per additional mental illness)	1.11	1.08	—	1.14
Immunosuppressives prescribed in FY2005	3.95	3.26	—	4.80
Immunosuppressives prescribed in FY2006	0.49	0.37	—	0.65
Immunosuppressives prescribed in FY2007	0.75	0.55	—	1.02
Immunosuppressives prescribed in FY2008	0.55	0.39	—	0.79
Immunosuppressives prescribed in FY2009	0.20	0.13	—	0.31
c-statistic	0.84			

FY = fiscal year, IBD = inflammatory bowel disease.

TABLE 4. Survival Analysis of Patients with IBD With Respect to Pneumococcal Vaccination and Adjusting for Clinical and Demographic Covariates (N = 49,350)

Characteristic	Hazard Ratio	95% Confidence Limits	
Vaccination before IBD diagnosis	0.94	0.85	— 1.04
Vaccination at IBD diagnosis	0.90	0.77	— 1.05
Vaccination after IBD diagnosis	0.53	0.49	— 0.58
Age (effect per decade)	1.92	1.88	— 1.96
Female	0.84	0.73	— 0.98
Married	0.80	0.77	— 0.84
Priority 1	1.11	1.05	— 1.18
Census region (compared with Northeast)			
South	1.11	1.04	— 1.18
Midwest	1.04	0.97	— 1.11
West	1.07	0.99	— 1.15
Puerto Rico/Virgin Islands	1.05	0.87	— 1.26
Charlson score (effect per additional point increase)	1.29	1.28	— 1.31
Selim physical (effect per additional comorbidity)	1.21	1.16	— 1.25
Selim mental (effect per additional mental illness)	1.05	1.04	— 1.07
Immunosuppressives prescribed in FY2005	1.79	1.63	— 1.96
Immunosuppressives prescribed in FY2006	1.16	1.04	— 1.30
Immunosuppressives prescribed in FY2007	1.10	0.98	— 1.24
Immunosuppressives prescribed in FY2008	0.94	0.83	— 1.07
Immunosuppressives prescribed in FY2009	0.37	0.32	— 0.42

IBD = inflammatory bowel disease.

capture out-of-system or undocumented vaccination, which could significantly increase the estimated rate of vaccination; and the restriction of the data to the years FY2005 to 2009. Recommendations regarding pneumococcal vaccination in the IBD population have not changed since that time frame.

Some centers have successfully undertaken quality improvement initiatives to try to increase compliance with vaccination recommendations. For 1 center's immunosuppressed IBD patients, the pneumococcal vaccination rate was increased from 31% to 54% simply through the use of a 1-page vaccination questionnaire distributed to all patients in the IBD clinic.[4]

A recent survey suggests that the majority of US gastroenterologists believe that the responsibility for vaccination of IBD patients should rest with the primary care physician.[5] The same survey results suggested that a knowledge deficit may be the primary reason why gastroenterologists feel this way. Regardless of one's belief in the theoretical role of primary care physician versus subspecialist, it seems clear that the status quo is unacceptable. We believe that gastroenterologists can and should take active roles in assuring that their IBD patients are appropriately immunized.

Health care systems should use all tools at their disposal to increase rates of vaccination among patients with IBD. These may include features of an electronic health records system, patient flyers or other low-cost interventional efforts, and academic detailing within clinical units. The primary determinants of success in delivering quality care will continue to be the clinician's knowledge of recommendations, and vigilance in following them, filtered through individual clinical experience and judgment. No mere tool, no matter how well developed, can be an adequate substitute for these qualities.

APPENDIX A. APPENDIX OF FRAILTY DIAGNOSES

276 – Disorders of fluid electrolyte and acid-base balance
280.0, 280.1, 280.8, 280.9, 281.xx, 285.9 – Anemia
800-804, 850-854 – head injury
805.6, 805.7, 806.6, 806.7, 807.0, 807.1, 808, 810-814, 818, 819, 821-825, 827-829 – Other injury
286, 287.1, 287.3, 287.4, 287.5 – Coagulation defects
260-263 – Malnutrition / weight loss
E880-E885, E887-E888 – Falls
781.2, 781.3, 719.7 – Gait disorders

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