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Immunization Rates and Vaccine Beliefs among Inflammatory Bowel Disease Patients: An Opportunity for Improvement

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Abstract

Background: Immunosuppressive agents used to treat inflammatory bowel disease (IBD) can increase the risk for infections, several of which are preventable through vaccination. Our study aimed to describe vaccine utilization by immunosuppression status, examine reasons for vaccine refusal, and identify characteristics associated with lack of influenza vaccination in IBD patients.

Methods: We administered an online survey between Feb 2012 and April 2012 to an internet-based cohort of IBD patients in the Crohn's and Colitis Foundation of America Partners program.

Results: During this time, 958 individuals completed the survey. The median age was 45, 72.8% were female, and 62.0 % had Crohn's disease. Self-reported vaccination rates were low. Those on immunosuppression (n=514) were more likely to be counseled to avoid live vaccines (p<0.01). However, counseling rates were low (3.5% to 19.1% for various live vaccines). Among the 776 individuals who received the influenza vaccine, maintaining health (74.1%), importance of prevention (66.1%), and provider recommendation (38%) were the most frequently cited motivations. Factors associated with lack of influenza vaccine included lower education level (p=0.01), younger age (p=0.02) and no chronic immunosuppression use (p<0.01). 570 (59.5%) individuals thought that patients were responsible for keeping track of their vaccines, while 428 (44.7%) placed responsibility on their gastroenterologist (GI) and 595 (62.1%) on their primary care physician (PCP).

Conclusions: Vaccine utilization remains sub-optimal in IBD patients. Educational interventions may increase vaccination rates by clarifying misconceptions. GIs can play a more active role in health care maintenance in IBD patients by counseling patients on which vaccines to receive or avoid.

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vaccine beliefs; immunization rates	

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Introduction

Current therapy for inflammatory bowel disease (IBD) patients often involves agents that suppress the immune system. These treatments put patients at an increased risk for developing infections, of which several are potentially preventable through timely vaccination. Prior work has shown a significantly increased risk of pneumonia among IBD patients, highlighting the importance of primary prevention via vaccination. Unfortunately, despite guidelines specifying appropriate vaccination strategies in immunosuppressed patients, 1, 2 many IBD patients are not being vaccinated appropriately. For example, in one tertiary care center study of vaccination efforts in IBD patients, only 28% received annual influenza vaccine and only 9% received pneumococcal vaccine. Reported barriers to vaccination include a lack of awareness and concern for side effects by patients, suggesting that providers may not appropriately educate patients as to the importance of these vaccines.

Similarly, gastroenterologist knowledge of the appropriate immunizations for the IBD patient is poor.^{5, 6} A recent survey demonstrated that nearly one third of gastroenterologists would mistakenly recommend live vaccines to their immunosuppressed IBD patients⁵. Up to one half of the gastroenterologists in this survey would incorrectly withhold inactivated vaccines to their immunocompromised patients. Additionally, nearly one third of gastroenterologists would avoid live vaccinations in their immunocompetent patients despite guideline recommendations that they can be safely administered, placing this patient group at a particularly high risk given the potential need for immunosuppression to treat their IBD at a later date. Given that physician knowledge is poor, it should therefore come as no surprise that patients are not being adequately immunized. Previous studies have emphasized the importance of provider recommendations in patient decisions to receive vaccines ^{7, 8}. However, if providers lack knowledge about and confidence in which vaccinations to recommend, patients will then be less likely to receive the appropriate vaccines.

While smaller surveys of patients have been done³, to date there have been no large studies examining vaccination perceptions among a diverse IBD population in the United States. Furthermore, little is known about the reasons behind suboptimal rates of vaccination in IBD patients and whether patient preferences, patient-provider interactions, or systems issues (e.g. access to care, insurance, cost) are the main driving force. The aims of our study were to: 1) describe vaccine utilization in individuals with IBD and whether this differs by immunosuppression status; 2) examine both the motivation and rationale for vaccine acceptance and refusal among individuals with IBD; and 3) identify characteristics associated with lack of influenza vaccination.

Methods

Crohn's and Colitis Foundation of America Partners

We used an internet-based cohort, the Crohn's and Colitis Foundation of America (CCFA) Partners, to investigate vaccine beliefs in individuals with self-reported inflammatory bowel disease (IBD). CCFA Partners follows individuals with self-reported IBD who were recruited from CCFA email lists and other social media outlets. Participants complete

baseline and semi-annual follow-up surveys regarding demographics, disease location and activity, medication use, prevention activities (such as screenings or vaccines) and quality of life measurements. Further details of the cohort and baseline characteristics of the population are described elsewhere⁹.

Vaccine beliefs survey

We developed a 7 question close-ended survey instrument about vaccine utilization and beliefs, including motivating factors and concerns (see Appendix 1). The survey was developed based on a prior survey study used to describe gastroenterologists behavior in prescribing vaccines⁵ and was piloted in five IBD patients seen in our gastroenterology office at Boston Medical Center. The vaccine beliefs survey module was then administered in all online follow up surveys to the CCFA Partners cohort that were completed between February 16, 2012 and April 24, 2012 until a total of at least 950 responses was obtained. This number was based on a power calculation to estimate the number of individuals required to be able to detect a 10% difference in influenza receipt amongst those on immunosuppresssion as compared to those not on immunosuppression.

Data Collection and Management

The data were collected entirely in a Web-based format, which allowed for real-time implementation of range and consistency checks. Therefore, missing data were minimized at point of entry. The data management system has previously been described⁹. The Web forms were accessible from any computer running a modern Internet browser with an active connection to the Internet; no special software was required. Data on demographics, disease type, medications and vaccination status were extracted from CCFA Partners core data for survey respondents

Statistical Analysis

All outcomes and characteristics were stratified by the primary categories of interest: use of immunosuppression and influenza vaccination within the prior 12 months. Descriptive statistics were used to characterize the population, including proportions, means and standard deviations (SD) for normally distributed variables, and medians and interquartile ranges (IQR) for nonparametic data. Chi-square, Fisher's exact, Wilcoxon rank sum, Student's t-test and oneway ANOVA were used to compare characteristics and beliefs by use of immunosuppression and by influenza vaccination. STATA version 10.0 (College Station, TX) was used for all analyses and p values less than 0.05 were considered statistically significant. The study protocol was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill.

Results

A total of 958 persons completed the vaccine survey. Those persons (n=33) who did not provide information on whether they had received vaccinations were excluded from the study. The median age of the surveyed group was 45 (IQ 31-57), 72.8% were female, and 62% had Crohn's disease (CD). Table 1 summarizes the characteristics of the study population. No differences in age, sex, race, ethnicity, education, IBD type, and rating of

general health were detected between vaccine survey participants compared to those participants in the CCFA cohort who were not given the vaccine survey.

Overall, self-reported vaccination rates were low (Figure 1). As noted in the vaccine module (Appendix 1), we used terminology that patients would understand and thus did not ask about specific brands or sub-types of vaccines, such as differentiating between the pneumococcal conjugate vaccine (PCV13) and the pneumococcal 23-valent polysaccharide vaccine (PPVSV23). Of the inactivated vaccines, the influenza vaccine (received in 2011, just prior to the survey) was most commonly received (81.5% of the population). Only 47.7% reported receiving the hepatitis B vaccine, 42.6% the pneumococcal vaccine, and 34.1% the hepatitis A vaccine. Among women under age 27, 50% reported that they had received the human papilloma virus (HPV) vaccine (vaccine only approved in women at the time of the survey). Of the live vaccines, 33.3% of those over age 60 recalled receiving the herpes zoster vaccine.

When asked who shared responsibility for vaccination efforts, 570 (59.5%) subjects thought that they (patients) were responsible for keeping track of their vaccines, while 428 (44.7%) placed the responsibility on their gastroenterologist and 595 (62.1%) on their primary care provider. Only 430 subjects (44.9%) recalled that their gastroenterologists had previously taken a vaccination history. Those patients on immunosuppression were significantly more likely to be counseled on avoidance of live vaccines (p<0.01). However, counseling rates as a whole were low, ranging from 3.5% to 19.1% for the various live vaccines (Table 2). There were no differences noted in the concerns about the vaccines effectiveness or the possible side effects of the vaccines by immunosuppression status.

Among the 776 individuals who received the influenza vaccine, maintaining health (74.1%), importance of prevention (66.1%), and provider recommendation (38%) were the most frequently cited motivations. Patients receiving the influenza vaccine were more likely to have a primary care provider than those who did not receive the vaccine (91.2% vs. 81.8%, p<0.01). There was also a higher rate of immunosupression use among those receiving the influenza vaccine when compared to those who did not receive the vaccine (55.8% vs. 44.9%, p<0.01). Age, gender, and smoking status did not differ by vaccination status.

Those not receiving the influenza vaccine (n=176) were significantly more concerned about side effects, effectiveness, and the worsening of their IBD by vaccines than those who received the influenza vaccine (p<0.01). Other factors associated with not receiving the influenza vaccine included lower education level (p=0.01), younger age (p=0.02) and absence of chronic immunosuppression use (p<0.01).

Discussion

Appropriate immunizations are an important component of routine preventive services in IBD patients. Immunosuppressive therapy puts patients at increased risk of developing infections which account for significant morbidity and mortality in IBD patients^{10, 11}. Active CD has also been shown to increase the risk for serious infections, ¹⁰ further supporting the crucial need for appropriate immunization to avoid potentially preventable

infections. A recent study demonstrated that patients with IBD are at increased risk for pneumonia, particularly among patients on corticosteroids and narcotics. Varicella infection 12 and herpes zoster 13 infection have also been found to be increased in immunosuppressed IBD patients, particularly in those on corticosteroids, thiopurines, anti-TNF agents, or combination immunosuppression. As demonstrated in this large, cross-sectional survey of IBD patients, however, vaccination rates for these preventable diseases remain suboptimal despite over a decade of data confirming that IBD patients are at an increased risk of vaccine preventable diseases. Patients who were most likely to receive the influenza vaccine were most concerned about maintaining their health, preventing disease, and followed their provider's recommendations. In contrast, patients who did not receive the vaccine had misconceptions about possible side effects of the vaccine or worsening of their IBD after vaccination. "Provider recommendation" was one of the most frequently cited motivations for receiving the influenza vaccine, the most commonly received vaccine in this study. Yet, only half of the patients recalled being asked by their gastroenterologist about their vaccination history.

Several prior studies have demonstrated that provider recommendations are a strong predictor for receipt of preventative health services including vaccination and cancer screening ¹⁴⁻¹⁶. Unfortunately, primary care clinicians are uncomfortable managing routine health maintenance issues in their IBD patients. For example, only 30% of family medicine doctors felt comfortable coordinating vaccinations for the immunosuppressed IBD patient ¹⁷. As primary care physicians may not adequately prescribe vaccines for immunosuppressed IBD patients, gastroenterologists should obtain a vaccine history and should accept the responsibility of either offering vaccinations in their office or providing recommendations to the primary care clinician for the appropriate vaccines to be adminsitered. ^{18, 19} Immunization status should be detailed during the first office visit and the required vaccines, especially the live attenuated vaccines, should be administered during the period before immunosuppressive medication is started. In one study, the influenza vaccine was offered and administered to eligible immunosuppressed IBD patients during their IBD office visit. Vaccination rates for influenza increased in this group from 54% to 81% suggesting that easy access to vaccines can also improve uptake.²³ In our study, rates of influenza vaccine were 81.5% which is higher than that reported in previous studies. This suggests that awareness for vaccinations in IBD patients has improved over time, possibly due to increased media focus, interventions in GI offices, and reminders for all patients regardless of IBD status.

Patients on immunosuppressive medications were more likely to be counseled to avoid live vaccines, but counseling rates overall were low, again suggesting that physicians are missing the opportunity to prevent potential infectious complications in their patients. Since provider recommendation was found to be an important reason why patients chose to receive a vaccine, spending time educating patients on the importance of vaccines during an office visit either through a face to face discussion with a member of the GI team or through a handout may be beneficial. Side effects, effectiveness, and worsening of their IBD by vaccines were cited as the biggest concerns among the 176 patients who did not receive the influenza vaccine. Although immunologic response to vaccination appears to be decreased in immunosuppressed patients, there is no convincing evidence to suggest that immunization

will lead to an exacerbation of IBD activity. These concerns emphasize the importance of intensive educational efforts, for both provider and patient, in order to ensure that misconceptions are clarified and that patients receive the appropriate vaccinations. It is important to remember that based on our results, in those patients who are younger or less educated, additional time discussing these misconceptions might increase vaccination rates.

The strengths of this study include the large number of surveyed participants who were geographically diverse and represent many different clinical practices. Additionally, we were able to obtain detailed information on demographics, disease status, and medication use. The anonymous nature of the survey may have allowed participants to honestly provide their views on recommended routine vaccinations.

The main limitation of this cross-sectional study was in its design as a self-administered electronic survey. Methods of recruitment included an interest in participating, requirement for the English language, and the technology to join the cohort. The sample therefore may not necessarily represent the US IBD population as a whole. In addition, all of the data collected were based on participant self-reporting rather than on audit of medical records. Reassuringly, a previous validation study has been completed on a subset of the study cohort. Within this group on whom physicians confirmed diagnoses via medical record review, 94% of patients have a diagnosis of IBD Additionally, other previously established associations were confirmed within this cohort, supporting the validity of this patient reported data. Vaccine utilization was also obtained via self-report which may be subject to under or over reporting. Because billing records would not contain information on vaccination through employers or at local pharmacies where no insurance billing occurs, self-report may actually be the best means at obtaining vaccine utilization information. Other studies of self-report of vaccine utilization have shown a high concordance between the medical records and patients' self-reported vaccine exposure to influenza, pneumococcal and HPV vaccines. ^{20, 21} However, because vaccines were self-reported, no distinction was made about which particular vaccine the patients had received. Another limitation of our study is that it did not include a pediatric/adolescent IBD subset, who have also been shown to have suboptimal immunization rates.²² We did find that the younger patients in this cohort were less likely to have received the influenza vaccine suggesting that we do need to improve our vaccination rates in our younger patients as well. Lastly, we could not control for other potential confounders in vaccination utilization such as other co-morbidites (e.g. asthma) or occupation since we did not have this information.

In summary, our study confirms prior reports that patients with IBD are not receiving counseling regarding appropriate vaccinations and are inadequately vaccinated. Importantly, we were also able to determine patient perceptions and rationales for avoiding vaccination, in order to target future educational efforts. The findings of this study thus serves as an important reminder that we need to continue to improve the education of this high risk population of patients and their primary health care providers regarding the safety of administering vaccinations while remembering to address possible misconceptions are paramount in increasing vaccine rates. Since physician recommendation for vaccinations is a primary motivation among IBD patients, future efforts should focus on education and systems-based practices to improve vaccination efforts. As a community of

gastroenterologists, we should play a more active role in the health care maintenance in our IBD patients.

Acknowledgments

This research was supported, in part, by a grant from the Crohn's and Colitis Foundation of America.

Appendix 1 Patient Vaccine Survey

1.	Who do you think is responsible for determining which vaccinations you should receive? (Check all that apply.)
	☐ Your gastroenterologist
	☐ Your primary care physician
	☐ I am responsible
	☐ Other
2.	Has your gastroenterologist ever asked you about your immunization history?
	○ Yes
	\bigcirc No
	○ Don't know
3.	Has your gastroenterologist told you that you need to avoid certain vaccines?
	○ Yes
	○ No (skips to 5)
	○ Don't know (skips to 5)
4.	Which of the following vaccines have you been told to avoid? (Check all that apply.)
	☐ Hepatitis
	☐ Influenza nasal mist
	☐ Influenza shot
	☐ Pneumonia (pneumococcal)
	☐ Zoster (shingles)
	☐ Varicella (chicken pox)
	☐ MMR (measles, mumps, rubella)
	☐ Tetanus
	☐ Other

5.	(If the respondent said YES to Q4440 at FOLLOW-UP): You told us that you received a flu shot this year. What motivated you to get your influenza vaccine (flu shot)? (Check all that apply.)
	☐ It is important for my health.
	\square I want to do what my doctor recommends.
	\square I like doing things that prevent future health problems.
	☐ It is readily available at my doctor's office.
	☐ Other
6.	The following questions will ask you to rate 3 possible concerns about vaccines, please answer the questions in general (not focusing upon a specific vaccine):
7.	Which of the following might influence your decision to avoid a vaccine? (Check all that apply.)
	☐ I don't think vaccines are important.
	$\hfill\Box$ I do not know where to get the vaccines recommended to me.
	☐ Vaccines are too expensive.
	Since <date a="" consented="" last="" started="" survey="" to="">did you receive a flu shot or flu mist (nasal vaccine)?</date>
	○ Yes [skips to Q4300]
	○ No
	○ Don't know [skips to Q4300]
	(Q4480) Why did you not receive a flu shot? (Check all that apply.)
	☐ Never offered flu shot
	☐ Allergy to eggs/vaccines
	☐ Did not think I needed it
	☐ Too expensive
	☐ Vaccine not available
	☐ Too busy/forgot
	☐ Concerned about side effects from the vaccine
	☐ Concerned that the vaccine would worsen my IBD
	☐ My doctor advised against a flu shot
	☐ Other reason
	□ Don't know

(Q4300) Have you had any other new vaccines since <DATE CONSENT/START LAST SURVEY>?

O Yes

○ No [skips to Q4520]

O Don't know [skips to Q4520]

Which of the following adult vaccines have you had since <DATE LAST STARTED/CONSENTED TO A SURVEY>:

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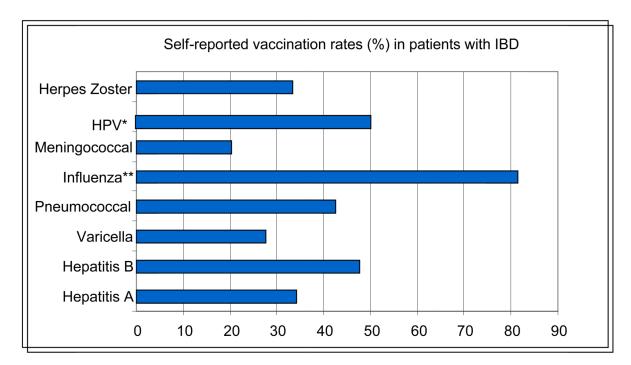
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^{*}Human papiloma virus (woman <age 27 only)

Of note, specific brand or sub-type of vaccine not specified as this was self report

Figure 1.
Self reported vaccination rates (%) in patient with IBD

^{**}Influenza within the past one year

Table 1

Characteristics of the population of patients with inflammatory bowel disease in the CCFA Partners cohort who reported information on vaccine utilization and beliefs (n=958)

Characteristic	N=958	% or median (IQR)
IBD type		
Crohn's disease	594	62.0
Ulcerative colitis	364	38.0
Age (median, IQR)	957	45 (31-57)
Sex (% female)	697	72.8
Primary care physician (% yes)	858	89.6
Education level		
Less than 12th grade	10	1.1
High school graduate	67	7.3
Some college	169	18.4
College graduate	382	41.7
Graduate school	289	31.5
Current smoker	40	4.2
Current medications (% yes)		
Antibiotics*	49	5.1
5-ASA,*** oral	542	56.8
5-ASA, rectal	91	9.5
Biologic ^	337	35.2
Thiopurine%	248	26.0
Methotrexate	33	3.5
Calcineurin inhibitor#	3	0.3
Corticosteroid, oral	101	10.6
Corticosteroid, rectal	43	4.5
Budesonide (oral)	40	4.2
Clinical trial medication	4	0.4
Any chronic immunosuppression~ (% yes)	514	53.7

ciprofloxacin or metronidazole,

^{** 5-}aminosalicylic acid,

 $^{\ ^{\}wedge}$ defined as infliximab, adalimumab, certolizumab pegol or natalizumab,

^{%6-}mercaptopurine or azathioprine,

[#]cyclosporine or tacrolimus,

chronic immunosuppression defined as current use of biologic or immunomodulator (thiopurine, methotrexate, calcineurin inhibitor)

Table 2

Individual vaccines patient were told to avoid, by use of chronic immunosuppression*

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Vaccine	Chronic immunosuppression* (n=514)		No chronic immunosuppression (n=444)		p value
	n	%	n	%	
Hepatitis (% yes)	8	1.6	2	0.5	0.09
Influenza mist (% yes)	98	19.1	20	4.5	< 0.01
Influenza injection (% yes)	13	2.5	7	1.6	0.30
Pneumonia** (% yes)	8	1.6	2	0.5	0.09
Herpes Zoster (% yes)	30	5.8	4	0.9	< 0.01
Varicella (% yes)	23	4.5	3	0.7	< 0.01
MMR*** (% yes)	18	3.5	2	0.5	< 0.01

^{*} chronic immunosuppression defined as current use of biologic or immunomodulator (thiopurine, calcineurin inhibitor, methotrexate)

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^{**} Self-reported receipt of pneumonia vaccine (no data on whether 23-valent or 13-valent vaccine administered)

^{***} Measles, mumps, rubella

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	Not at all concerned	A little concerned	Somewhat Concerned	Concerned	Very Concerned
Side effects of vaccines					
Vaccines might worsen my IBD					
Vaccines may not work for me due to my IBD					

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 \underline{Yes} <u>No</u> Don't Know (Q4120) Hepatitis B 0 0 0 (Q4160) Hepatitis A 0 0 0 (Q4240) Varicella (chicken pox) 0 0 0 (Q4320) Pneumococcal (pneumonia) 0 0 0 (Q4360) Influenza (regular flu or swine flu) 0 0 \circ (Q4400) Meningococcal (meningitis) 0 0 0 (Q4200) HPV (cervical cancer and genital warts) 0 0 0 (Q4280) Zoster (Shingles) 0 0 0 (Q11060) Tetanus 0 0 0

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