



# Improving Vaccine Utilization and Preventive Health Maintenance Measures for Patients with Inflammatory Bowel Disease

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**INTRODUCTION:** Proactive health maintenance can help detect and/or prevent many complications of inflammatory bowel disease (IBD) and its treatments. Suboptimal adherence to vaccination and health maintenance guidelines underscores the need for enhanced provider and patient education in this area.

**METHODS:** In response to a request for proposal, Cedars-Sinai Medical Center (Project PREVENT), Icahn School of Medicine, and Westlakes/CME Outfitters piloted educational and/or systems-based interventions designed to improve vaccination utilization and focus on health maintenance among patients with IBD.

**RESULTS:** Project PREVENT reported that patient-centered messaging can improve preventive health awareness in IBD, although there was no difference in intent to obtain preventive health interventions by type of messaging (online interactive educational content versus static health maintenance reminders), and no difference in actual receipt of influenza vaccination.

The Icahn group reported suboptimal vaccination rates among patients with IBD, apparently due to lack of patient awareness about vaccine benefit, as well as practice-related factors. Marital status and age were associated with higher rates for certain vaccinations. Digital outreach and educational intervention helped increase rates for influenza and pneumococcal vaccination.

The Westlakes/CMEO quality improvement initiative resulted in increased vaccinations, mental health, cancer, and bone health screening rates as well as improvements in smoking cessation counseling. Clinicians with fewer patients with IBD may be more likely to follow preventive health guidelines.

**DISCUSSION:** Suboptimal vaccination rates among patients with IBD reflect the need for targeted education and intervention. Recommendations for future research include complementing digital outreach with in-office intervention, implementing risk-based patient outreach, and using advanced technologies to improve vaccination documentation.

**LAY SUMMARY:** Patient-centered messaging and education can help improve vaccination rates and adherence to preventive health measures among patients with inflammatory bowel disease, possibly lowering the risk of disease- or treatment-related complications.

**KEYWORDS:** Crohn's disease; education; health maintenance; preventive health; ulcerative colitis; vaccination

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## INTRODUCTION

Inflammatory bowel disease (IBD) is a group of chronic, relapsing inflammatory disorders of the gastrointestinal (GI) tract, the most common types being Crohn's disease (CD) and ulcerative colitis (UC). These disorders affect approximately 3 million adults<sup>1</sup> and 70,000 children<sup>2</sup> in the United States (US), for whom annual mean health care costs are more than 3-fold higher than for those without IBD (approximately \$23,000 vs \$7,000 per patient per year).<sup>3</sup> IBD can be associated with substantial patient morbidity, missed work and school, and diminished quality of life.<sup>4-10</sup> Disease management strategies often consist of biologics and small-molecule drugs with the intent to reduce symptoms and heal the mucosa. Whether due to the mechanism of immunosuppression from such medications, or to the inherent immune dysregulation of the disease process, patients with IBD are at an increased risk of certain infections and malignancies. As the range of approved therapeutic options for IBD continues to expand, patients and caregivers make collaborative treatment choices based upon evidence regarding disease prognosis, treatment effectiveness and safety, and response to therapy. Mitigation of risk is therefore an important factor in therapeutic decision-making for patients and providers.

Many infectious and neoplastic complications of IBD and its treatments are preventable or detectable early with delivery of proactive health maintenance measures.<sup>11</sup> To that end, various professional societies and government agencies have issued recommendations pertaining to vaccination and health maintenance in patients with IBD.

### American College of Gastroenterology (ACG)

The 2017 ACG Clinical Guideline for Preventive Care in IBD<sup>12</sup> recommends annual influenza vaccination for all patients. The guideline further specifies that all non-live vaccines can be administered regardless of immunosuppressive medication use, and generally advises avoidance of live vaccines in immunosuppressed patients, with a few exceptions. In terms of specific vaccines for individuals with IBD, the ACG 2017 guideline recommends pneumococcal vaccination for adult patients receiving immunosuppressive therapy, and administration of other vaccines (e.g., tetanus, diphtheria, and pertussis [Tdap], hepatitis A and B viruses [HAV and HBV], human papillomavirus [HPV], meningococcal vaccine) as outlined by the Advisory Committee on Immunization Practices. When possible, the guideline recommends administration of age-appropriate vaccinations before initiating

immunosuppressive therapy, such as during periods of disease remission or low immunosuppression.<sup>12</sup>

The ACG guideline also addresses other aspects of health maintenance including:

- Cervical cancer screening in immunosuppressed women with IBD
- Screening for depression and anxiety in patients with IBD
- Screening for melanoma and non-melanoma skin cancers
- Screening for osteoporosis
- Counseling smoking cessation

### American Gastroenterological Association (AGA)

The AGA has issued a set of quality and performance measures in IBD, which are designed to enhance physician accountability and establish financial incentives for delivering high-quality care.<sup>13</sup> These measures incorporate metrics for health maintenance including:

- Thiopurine methyltransferase (TPMT) testing prior to starting azathioprine or 6 mercaptopurine
- Postoperative monitoring for recurrence of CD at 6 to 12 months after surgical resection
- Measures for colorectal cancer screening and surveillance

### Crohn's & Colitis Foundation

Quality measures issued by the Crohn's & Colitis Foundation<sup>14</sup> focus on vaccine education and smoking cessation counseling for patients with CD, including:

- Whether a patient with IBD who is on immunosuppressive therapy has been educated about appropriate vaccinations, including (1) annual inactivated influenza, (2) pneumococcal vaccination with a 5-year booster, (3) non-live herpes zoster vaccine, and (4) general avoidance of live virus vaccines
- Whether a patient with CD and who is an active tobacco smoker has been recommended smoking cessation and offered treatment or provided suitable referral at least annually.

In addition, the Crohn's & Colitis Foundation Health Maintenance Checklist for adults<sup>14, 15</sup> addresses:

- Whether a patient with IBD who is on immunosuppressive therapy has been educated about appropriate vaccinations, including (1) annual inactivated influenza, (2) pneumococcal vaccination with a 5-year booster, (3) non-live herpes zoster vaccine, and (4) general avoidance of live virus vaccines
- Cancer prevention
- Dual x-ray absorptiometry scan
- Purified protein derivative or interferon-gamma release assay (IGRA)
- Smoking status
- Depression check

In addition to the above, new health maintenance quality measures for patients with IBD are forthcoming from the ACG and American Society for Gastrointestinal Endoscopy's GIQuIC Registry, available at <https://GIQuIC.org>.

### Centers for Disease Control and Prevention (CDC)

In addition to the recommendation that all individual 50 and older receive the inactive herpes zoster vaccine, recent guidance from the CDC recommends 2 doses of nonlive, recombinant zoster vaccine for prevention of shingles and related complications in adults aged 19 years or older who are or will be immunodeficient because of their disease or therapy.<sup>16</sup>

Patients with IBD are at an increased risk of developing respiratory syncytial virus (RSV) infection and hospitalization.<sup>17</sup> With the approval of 2 RSV vaccines in 2023, the CDC updated its guidance and recommended RSV vaccination for all adults aged 75 years and older and for consideration in those individuals aged 60-74 at increased risk due to chronic disease and immunosuppression.<sup>18</sup> Previously, the CDC limited its RSV vaccine recommendation to infants and young children (ages 8-19 months).<sup>19</sup>

In 2021, the US Food and Drug Administration (FDA) approved both a 15-valent and a 20-valent pneumococcal conjugate vaccine (PCV15 and PCV20, respectively) for use in adults aged 18 years or older. The CDC's Advisory Committee on Immunization Practices (ACIP) specifies use of either PCV20 alone or a sequential combination of PCV15 and a 23-valent pneumococcal polysaccharide vaccine (i.e., PCV15 followed by PPSV23) for all adults aged 65 or older and for adults aged 19-64 years with underlying medical conditions or other risk factors who have not received a PCV or whose vaccination history is

unknown. The ACIP also recommends either a single dose of PCV20 or one or more doses of PPSV23 for adults who have started their pneumococcal vaccine series with PCV13 but have not received all PPSV23 doses.<sup>20</sup> Other notable updates to CDC guidelines include those pertaining to coronavirus-2019 (COVID-19) vaccination, which ACIP recommends for everyone aged 6 months or older.<sup>21</sup>

### SUBOPTIMAL ADHERENCE TO VACCINATION AND PREVENTIVE HEALTH RECOMMENDATIONS

Despite the proliferation of vaccination and preventive health recommendations from numerous organizations, adherence to such guidance remains suboptimal.<sup>22-28</sup> The situation underscores the need for enhanced provider and patient education, as well as greater availability of resources, to improve adherence to appropriate vaccinations, increase awareness of IBD complications and comorbidities (e.g., skin cancer, depression), and facilitate patient-provider communication.

### Methods and Results

In 2018, the ACG, AGA, and the Crohn's & Colitis Foundation, in collaboration with Pfizer Independent Grants for Learning & Change (IGLC), partnered on an initiative to develop and implement educational and/or systems-based interventions to improve vaccination utilization and focus on health maintenance among patients with IBD. The partnering organizations issued a request for proposal (RFP) to US health care institutions; health care professional (HCP) societies and other organizations with a mission related to healthcare improvement; and government agency partners with the capacity to reach patients with IBD. Of 10 applications received, 3 institutions received funding through the RFP process: Cedars-Sinai Medical Center (Project PREVENT), Icahn School of Medicine, and Westlakes/CME Outfitters, LLC (CMEO). This white paper provides an overview of each of those group's initiatives, including project aims, results, and impact from each institution's perspective. Methods and results are presented together for each study to allow for better understanding of study aims and outcomes.

### Project PREVENT Summary

#### Aims

The Cedars-Sinai investigators identified a need for effective interventions to improve uptake of preventive health recommendations, with the ultimate goal

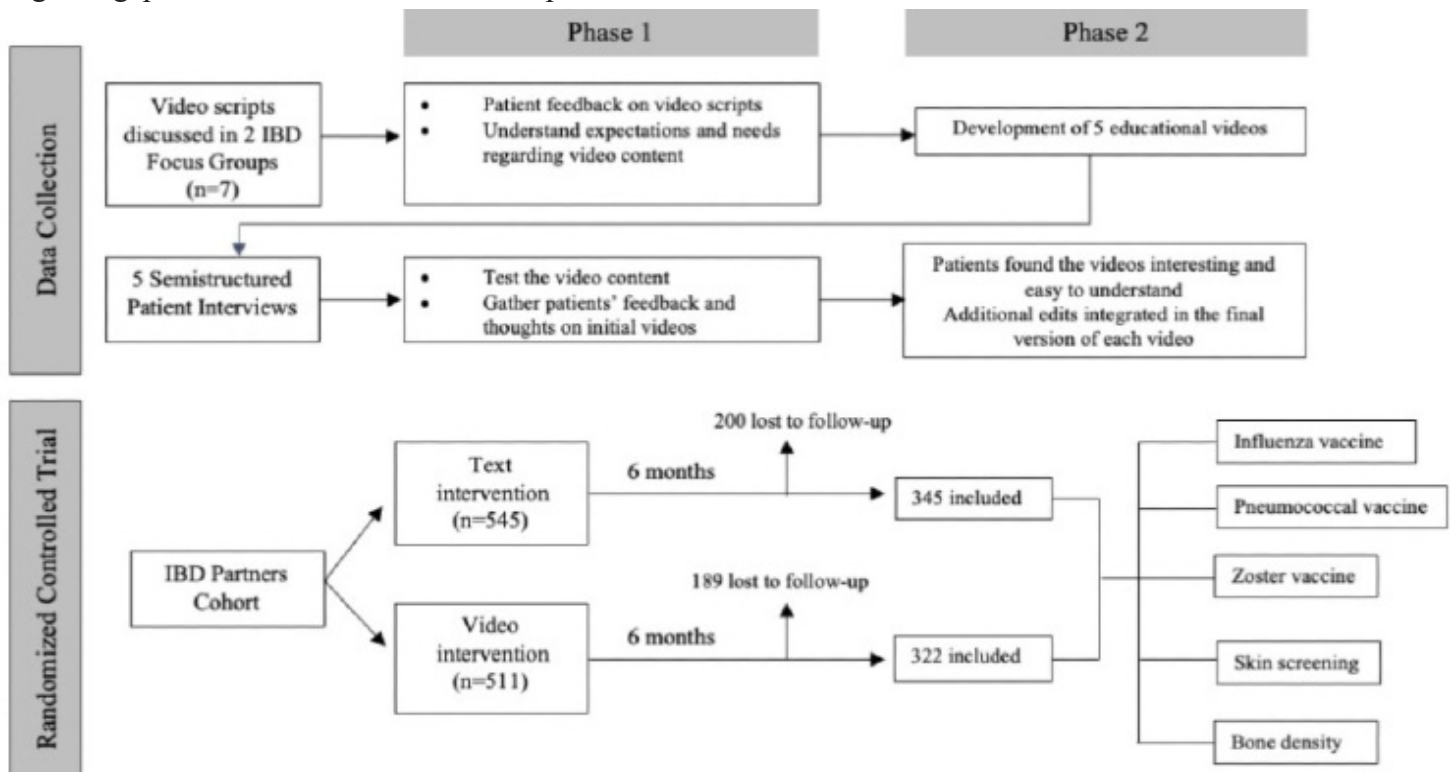
of reducing preventable complications and improve outcomes for patients with IBD.<sup>29</sup> They established the following key objectives for Project PREVENT.

- To understand patient knowledge, attitudes, and beliefs around uptake of vaccinations and malignancy screening through patient focus groups/qualitative interviews.
- To develop and pilot an interactive website that will provide customized recommendations for individual patients with IBD and direct them as relevant to five 60-90-second customized, animated videos (focusing on influenza, pneumococcal, and zoster vaccinations, bone health, and skin cancer screening), using information gleaned from focus groups/qualitative interviews.
- To conduct a randomized, controlled trial (RCT) assessing the effectiveness of the online interactive educational intervention versus standard static reminders to improve uptake of health maintenance recommendations in an online IBD cohort (IBD Partners).

### Methods

Content experts developed 5 video script prototypes summarizing preventive health recommendations for patients with IBD. Investigators then convened 2 in-person focus groups with a total of seven patients to gain insights into their thoughts and concerns regarding preventive health and their expectations for

the videos. An inductive thematic analysis informed development of the video prototypes. Afterward, investigators conducted 5 semi-structured interviews to gather additional patient feedback prior to finalizing the videos. They then enrolled consecutive adults from the internet-based IBD Partners cohort in a RCT comparing dynamic (video) to static (text) educational interventions (**Figure 1**). The RCT used block randomization stratified by influenza vaccine receipt in the prior year. All subjects were eligible for influenza and skin cancer interventions. Those on immunosuppressive therapy or age 65 or older were eligible for pneumococcal vaccination. Patients aged 50 years or older were eligible for shingles vaccination. Those with prior corticosteroid use or women aged 65 or older were eligible for bone health interventions. The primary outcome for this analysis was patient-reported receipt of the influenza vaccine within the 6-month influenza season during which the study was conducted (September 2019 to March 2020). Secondary outcomes included patient-reported intent to obtain and actual receipt of other preventive health interventions. Following study completion, an [interactive website](#) was developed and invitations were sent via e-mail blasts 10 times to GI physicians between September 2020 and December 2020 to direct patients to this patient-facing, freely accessible website to receive targeted, personalized preventive health recommendations.



**Figure 1.** Flow diagram of Project PREVENT focus groups and randomized controlled trial.<sup>29</sup> IBD, inflammatory bowel disease.

## Results

The RCT enrolled 1,056 patients with IBD who were randomized to receive either the dynamic video education (n=511) or static educational (text-only) messages (n=545). Demographic and disease characteristics were similar in the 2 groups (**Table 1**); similar proportions of patients received influenza vaccine in the prior year (55% of video group, 57% of text-only group). The proportion of patients who actually received the influenza vaccine did not differ by messaging type ( $P = 0.07$ ) (**Figure**

**2A**). There was no difference in intent to obtain the influenza vaccine by dynamic (75%) versus static (72%) intervention ( $P = 0.62$ ) (**Figure 2B**). Similarly, there was no difference between intervention groups in intent to obtain the pneumococcal or shingles vaccine, or bone health or skin cancer screening (**Figure 2C**). Overall, after receiving either educational intervention, 73% intended to receive the preventive influenza vaccination, a proportion that was significantly higher than the 57% of patients who had actually received the

Characteristic	Text Education	Video Education	P value
Total number of patients, n	545	511	N/A
Age (years), mean (SD)	51.2 (14.9)	50.3 (15.6)	0.34
Female gender, n (%)	378 (69)	382 (75)	0.05
<b>IBD diagnosis, n (%)</b>			
Crohn's disease	345 (63)	332 (64.5)	0.57
Ulcerative colitis	187 (34)	169 (33)	0.67
Indeterminate colitis	13 (2)	10 (2)	0.63
High school education or higher, n (%)	526 (97)	492 (96)	0.84
<b>Race, n (%)</b>			
White	483 (89)	454 (89)	
African-American	8 (1)	7 (1)	
Other	54 (10)	50 (10)	
Current smoking, n (%)	26 (5)	17 (3)	0.24
Body mass index (BMI), mean (SD)	25.9 (5.8)	25.8 (5.9)	0.83
Disease duration (years), mean (SD)	21.2 (13.5)	20.6 (13.0)	0.44
Ever GI surgery, n (%)	235 (43)	220 (43)	0.98
Ever GI hospitalization, n (%)	354 (65)	315 (62)	0.27
Number hospitalizations, mean (SD)	3.6 (2.8)	3.4 (2.5)	0.48
<b>Current medications, n (%)</b>			
Immunomodulator <sup>a</sup>	91 (17)	105 (21)	0.10
Corticosteroids	56 (10)	38 (7)	0.11
5-ASA	157 (29)	152 (30)	0.68
Anti-TNFf	161 (30)	150 (30)	0.99
Anti-integrin (vedolizumab)	57 (10)	40 (8)	0.16
Anti-IL-12/23 (ustekinumab)	42 (8)	37 (7)	0.82
JAKh inhibitor (tofacitinib)	4 (1)	4 (1)	0.92
Remission (sCDAI<150 or SCCAI≤2), n (%)	297 (62)	296 (67)	0.14
sCDAI, median (IQR)	100 (58-177)	107 (65-170)	0.49
SCCAI, median (IQR)	2 (1-4)	2 (1-3)	0.19

**Table 1.** Project PREVENT patient characteristics at time of enrollment (N=1056).<sup>29</sup>

<sup>a</sup> Immunomodulator defined as 5-mercaptopurine, azathioprine, or methotrexate

5-ASA, 5-aminosalicylic acid; GI, gastrointestinal; IBD, inflammatory bowel disease; IL, interleukin; JAK, Janus kinase; N/A, not applicable; SCCAI, simple clinical colitis activity index; SCDAI, short Crohn's disease activity index; TNF, tumor necrosis factor.

vaccine in the prior year ( $P < 0.001$ ). Prior receipt of the influenza vaccine was the factor most predictive of both intention to receive and actual receipt of the vaccine. Older age was also associated with a higher likelihood of intention to receive (age 36-75 years relative to 18-35 years;  $P = 0.006$ ) and actual receipt (age  $>75$  years relative to 18-35 years;  $P = 0.05$ ) of the influenza vaccine (Table 2).

### Impact

The RCT showed no difference in intent to obtain preventive health interventions by type of messaging, and no difference in actual receipt of the influenza vaccination in the subsequent influenza season, although the proportion of flu shot recipients was high in both groups, and numerically higher than in the previous year. However, after receiving either educational intervention, there was a reported increase in intent to receive the preventive influenza vaccination compared to the rate of patients who had actually received the vaccine in the prior year. Overall, the Project PREVENT results suggest that patient-centered messaging can improve preventive health awareness in IBD.

### Icahn School of Medicine project summary

#### Aims

The overall objective of this project was to develop and validate the use of patient-centered digital medicine technology to improve vaccination rates and preventive health compliance among patients with IBD. To meet that objective, the project had the following aims:

- Develop an English and Spanish digital toolkit that includes patient-centric digital reporting, online shared decision-making, and a digital wallet with ability to scan vaccination QR codes at the time of vaccine administration and integrate them with Apple Health.
- Conduct a prospective pre-post evaluation of

adoption and effectiveness of a digital toolkit in improving vaccination rates in 2 cohorts: (i) Proactive Cohort from Mount Sinai Crohn's and Colitis Registry (MSCCR) that has agreed to opt-in to digital care plans and participates in shared decision-making; (ii) Reactive Cohort of patients that walk-in to the IBD center.

- Expand the digital care plan to an external cohort of IBD patients to assess generalizability and to provide a sustainable solution at no cost to patients.

### Methods

Investigators queried an electronic health record (EHR)-derived clinical data repository to identify patients with confirmed IBD seen in the Icahn IBD center, matching this information with patients who had previously consented to enroll in a quality improvement (QI) initiative. The query involved extraction of patient demographics, medication data, and vaccination data from EHRs. Data was extracted from EHR-structured vaccination fields to calculate pre- and post-vaccination rates. The investigators used AppLab's Rx Universe Platform to deliver the digital toolkit through webApp and Secure Text communications.

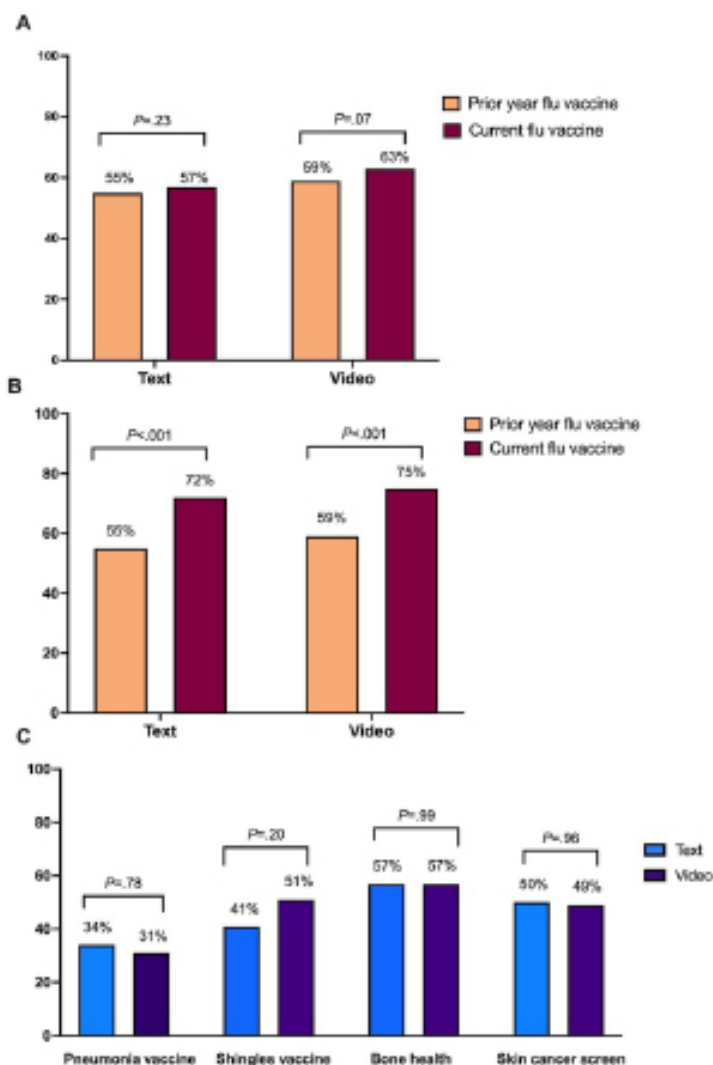
The project's primary outcome was percentage improvement in vaccination rates among eligible patients. Vaccination data available in the discrete computable form in the EHR was used to calculate the percentages. The investigators compared pre-intervention data from before March 2020 to post-intervention data in 2022.

### Results

The study cohort comprised 889 patients with a mean age of  $46 \pm 16.4$  years. Fifty-six percent of participants were female, 77% were White, and 50% were married; 510 (57%) patients were diagnosed with CD, and 530 (60%) were receiving biologic therapy. Regarding baseline vaccination rates, 352 (39.6%) of

Effect	Odds ratio (95% CI)	P value
Age (36-75 years vs 18-35 years)	0.86 (0.48-1.53)	0.61
Age ( $>75$ years vs 18-35 years)	3.00 (1.00-8.97)	0.049
Immunosuppression (yes vs no)	1.51 (0.97-2.34)	0.07
Prior influenza vaccination (yes vs no)	28.49 (18.45-44.00)	$<0.001$
Female (yes vs no)	1.44 (0.89-2.33)	0.14
Higher education (yes vs no)	0.78 (0.20-3.03)	0.71
Intervention (text vs video)	0.87 (0.57-1.33)	0.53

**Table 2.** Predictive model of factors associated with influenza vaccine receipt in Project PREVENT (N=667).<sup>29</sup> CI, confidence interval.



**Figure 2.** Primary and secondary Project PREVENT clinical trial outcomes. (A) No difference in actual influenza vaccine uptake between previous and current years. (B) Increased intent-to-receive flu vaccine after either educational intervention compared with actual receipt of flu vaccine in the prior year. (C) No difference in intent-to-receive other preventive health measures.<sup>29</sup>

IBD patients were documented in EHRs to have received an influenza vaccination in any of the past years, and 284 (31.9%) were documented to have received a pneumonia vaccination. Those numbers increased to 43.1% and 35.6%, respectively, when data were analyzed for subgroups of IBD patients on biologics and small-molecule therapies (n=531).

Among males (n=212) and females (n=270) between the ages of 9 and 45 years, only 5 males (2.4%) and 15 females (5.6%) were documented to have received HPV vaccines in discrete data fields.

Multivariate analysis using logistic regression showed that marital status was a significant predictor of receipt of pneumonia and influenza vaccinations (odds ratio 0.697).

Post-intervention, 398 (44.8%) of patients were documented in the EHR to have received an influenza vaccination at the end of 2022, and 327 (36.8%) were documented to have received a pneumonia vaccination. Those numbers increased to 48.0% and 40.5%, respectively, when data were analyzed for subgroups of patients with IBD on biologics and small molecules (n=531).

In the post-intervention period, among males between the ages of 9 and 45 years (n=212), 6 (2.8%) were documented to have received HPV vaccines. Among females in the same age group (n=270), 18 (6.7%) were documented to have received HPV vaccines in discrete data fields.

### Impact

The baseline vaccination rate among patients with IBD, as documented in EHRs in this project, were low. Marital status was significantly associated with greater rates of influenza and pneumococcal vaccinations in both univariate and multivariate analyses. The digital outreach and intervention helped in slightly increasing the post-intervention rate for influenza and pneumococcal vaccines.

Importantly, the digital outreach intervention was limited due to the unavailability of elective in-person visits during the COVID-19 pandemic, which coincided with most of the study period. Lack of office visits also prevented the IBD center staff from informing and educating patients in-person and addressing their concerns at the point of care.

### Westlakes/CMEO project summary

#### Aims

The Westlakes/CMEO project, “Streamlining Preventive Health for Patients with IBD Through Effective Care Models, Evidence-Based Guidelines, and Patient Engagement,” was offered as a QI activity under the Merit-based Incentive Payment System (MIPS) for learners. The project had the following objectives:

- Integrate recommended immunizations for patients with IBD into clinical practice.
- Implement guideline-based methods for preventive health maintenance among patients with IBD.
- Employ successful approaches to coordinated

patient-centered care for patients with IBD, including the establishment of an IBD medical home.

### Methods

The Westlakes/CMEO team launched a live and on-demand webcast on the CMEO website on March 28, 2019, focusing on the need for education on the importance of integrating digital coaching and tools to ensure provision of preventive care to patients with IBD. The webcast noted that delivery of appropriate vaccinations and necessary screenings for depression, cancer, and comorbid conditions is not consistent in the IBD population, and discussed the IBD Medical Home concept developed at the University of Pittsburgh<sup>30</sup> as a resource to help community GI providers apply team-based care in their own practices. The recorded webcast was later launched on YouTube (April 30, 2019) and myCME (May 7, 2019), and as an enduring resource on the CMEO Gastroenterology Digital Hub with full interviews with clinicians participating in the medical home model, a podcast (an audio-only version of the webcast), and a patient toolkit, which included a checklist of common preventive health-related questions to ask one's gastroenterologist or PCP, patient audio interviews, information about the patient digital health coaching program, and a list of online resources for additional IBD-related information.

Both the live and enduring activities targeted a national audience as well as a local audience affiliated with gastroenterology clinics associated with the Cleveland Clinic. Patient-reported outcomes were collected as part of the patient digital health coaching program. A total of 5,688 learners participated, including 1,992 live

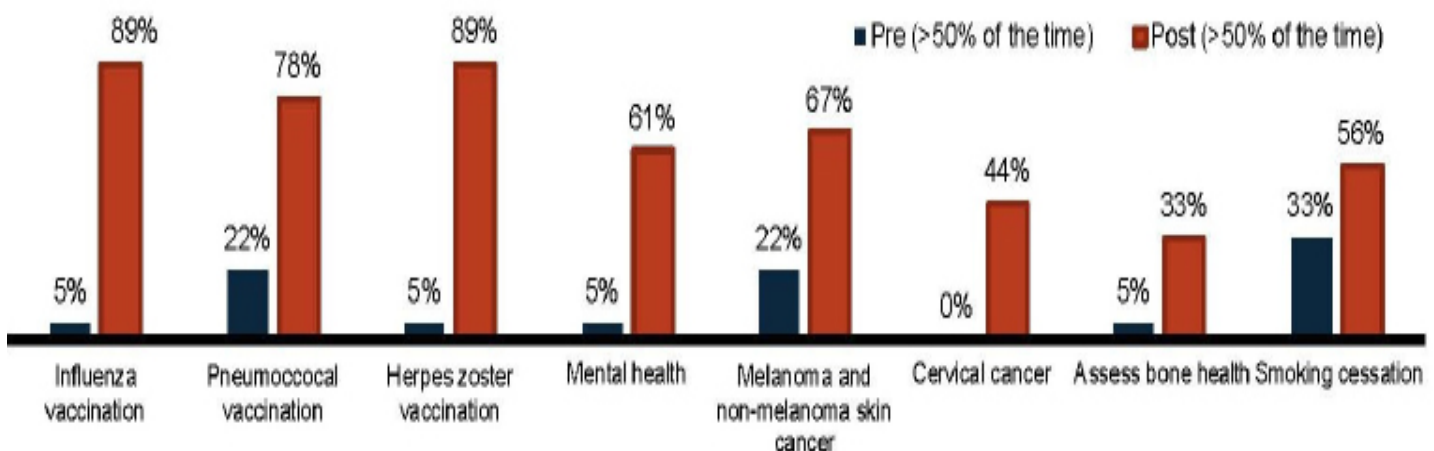
webcast participants; 2,801 learners completed the activities and received a certificate. Approximately two-thirds of the audience were physicians (63%), 16% were nurses, 14% were pharmacists, and 7% were physician's assistants or nurse practitioners. Nearly three-quarters of learners listed gastroenterology as their primary specialty, followed by 20% primary care, and the remaining 7% a combination of several other specialties.

As part of a preventive care QI initiative, Westlakes/CMEO evaluated vaccination and preventive health documentation in two cohorts, one consisting of community HCPs (n=250 patient charts) and the other consisting of HCPs in an academic center (n=2729 patient charts). Each group was exposed to the educational activity. Researchers gathered baseline data for the academic cohort in 2018 and post-education between January 1, 2020, and June 1, 2020. They also gathered baseline data pre- and post-education from the community cohort.

Additionally, CMEO partnered with Pack Health, an evidence-based patient engagement platform, in launching the patient digital health coaching program, which supported 100 patients diagnosed with IBD. Patients were matched with a dedicated Pack Health Advisor and engaged for 12 weeks via a series of phone calls, text messages, emails, and online lessons.

### Results

On the 250 patient charts received as part of the QI initiative, clinicians specifically noted that they did not realize the importance of screening for herpes zoster vaccination and for cancer. Notably, the participating



**Figure 3.** Improvements in IBD patient screening among participants in Westlakes/CMEO quality improvement initiative. N=25.

clinicians improved their screening for vaccinations, mental health, cancer, and bone health while also improving upon counseling patients for smoking cessation (**Figure 3**).

Focusing specifically on objective number 1, the educational activity resulted in a 59% improvement ( $P < 0.01$ ) in knowledge regarding pneumococcal vaccine schedules for patients with IBD, and a 19% net gain at follow-up. Greater than 50% adherence to recommended vaccinations in the 2017 ACG clinical guidelines improved by 11%. Nearly all (99%) learners expressed a commitment to discussing the importance of recommended vaccinations with their patients with IBD.

For the second objective, the Westlakes/CMEO team observed a 48% improvement ( $P < 0.01$ ) in knowledge about the ACG Clinical Guidelines for Preventive Care in IBD<sup>12</sup> immediately following education; the learner cohort retained that knowledge at follow-up, with a reduction of only 12% (from 48% to 36% gain) at 90 days following education. There was also a 17% improvement in learners' confidence (i.e., ratings of "confident" or "extremely confident") in their ability to implement guideline-based methods for preventive health maintenance. Ninety-six percent of learners expressed a commitment to implementing the guideline-based methods.

In terms of the third objective, the team reported a 56% improvement ( $P < 0.01$ ) in identifying the impact of the IBD medical home on patient quality of life, with a 42% net gain at follow-up. Learner confidence in employing successful approaches to coordinated, patient-centered care improved by 13%, and 99% of learners committed to integrating such care into their clinical practice for their patients with IBD.

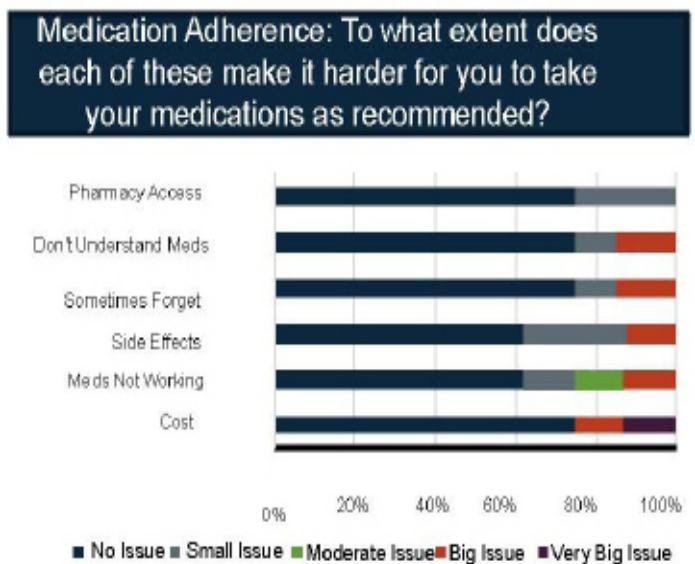
Of the 100 patients participating in the ongoing Pack Health coaching initiative, 90 were female with an average age of 47 years, and 10 were male with an average age of 42 years. Eight percent lived in rural areas, 82% were employed, and 6% were retired. Estimated average household income was \$60,170, based on learner zip code location and available US Census data. At the outset of the engagement, the top 3 participant-stated goals were to (1) achieve a healthy weight, (2) exercise more, and (3) develop healthier habits. Before beginning coaching, 21% reported visiting the emergency department in the previous 3-month period; 25% cited cost as a barrier to medication adherence (**Figure 4**); 33% reported limited

access to healthy foods, making it difficult for them to adhere to a healthy diet. The 12-week engagement consisted of 387 telephone calls (average 14 minutes per call), 927 text messages, 208 emails, and 236 online lessons completed, for a total of 1,818 touch points. Over the course of the engagement, adherence to infusion therapy increased from 54% to 89%, and health self-efficacy increased from 15% to 74%. As of this writing, the program is ongoing with the remaining patients currently engaged in coaching.

### Impact

As part of the QI initiative, clinicians improved their screening for vaccinations, mental health, cancer, and bone health while also improving in counseling patients for smoking cessation. For example, at baseline only 5% of clinicians were advising herpes zoster vaccination more than 50% of the time; at follow-up in 250 charts, this proportion increased to 89%. As a further reflection of the project's impact, 35 participating clinicians requested a MIPS certificate.

Furthermore, predictive modeling analysis suggested that, all else being equal, a clinician's IBD patient load — and not any other education or demographic element — predicts appropriate vaccine recommendation and understanding of the role of the IBD medical home. In a follow-up group of 60 learners, specialists with fewer self-reported patient loads were more likely to follow guidelines for preventive health, potentially due to their ability to spend more time with and pay



**Figure 4.** Medication adherence in Westlakes/CMEO quality improvement initiative: To what extent does each of these make it harder for you to take your medications as recommended?

more attention to these patients. Clinicians with higher patient loads, by contrast, may not feel as if they have as much time to address preventive health. A gap analysis suggested that gastroenterologists generally regard vaccination as the responsibility of primary care providers (PCPs), although screening rates were higher in the medical home model group than in controls. Future education should continue to reinforce the importance of vaccination and preventive health for those clinicians with higher load in order to demonstrate the value of installing these systems, such as an appropriate vaccine schedule and use of patient-centered medical homes, to their patients with IBD.

## DISCUSSION

The results of the 3 initiatives presented herein highlight the need for enhanced provider and patient education, as well as a need for greater availability of resources for disease prevention among patients with IBD. The suboptimal rate of vaccinations among patients with IBD in these different initiatives is consistent with the available literature and underscores the need for targeted awareness and intervention. These initiatives included large numbers of patients (1,056 in the PREVENT study and 889 in the Icahn School of Medicine project) and healthcare providers (5,688 learners of whom 2,801 completed the activities and received a certificate in the Westlakes/CMEO project).

Patient-reported reasons for not receiving an influenza vaccination include lack of awareness, concern for adverse effects (including transmission of influenza), skepticism of vaccine efficacy, and lack of recommendations from gastroenterologists or PCPs.<sup>28</sup> To that end, the Cedars-Sinai project results suggest that patient-centered messaging, whether by dynamic video education or via static text messages, can improve preventive health awareness in individuals with IBD. After receiving either educational intervention, 73% of patients intended to receive the preventive influenza vaccination, a proportion that was significantly higher than the 57% of patients who had actually received the vaccine in the prior year ( $P < 0.001$ ). Similarly, the Icahn project suggests that digital outreach and intervention can improve influenza and pneumococcal vaccination rates. In that study, the baseline vaccination rate among patients with IBD, as documented in EHRs, was far from optimal. The digital outreach and intervention, which included a toolkit allowing for digital reporting, online shared decision-making, and a digital wallet with ability to scan vaccination QR codes, helped increase the

post-intervention rate significantly for influenza and pneumococcal vaccines. Of note, marital status was significantly associated with greater rates of influenza and pneumococcal vaccinations in both univariate and multivariate analyses.

The Westlakes/CMEO project suggests that health provider education and coordinated patient-centered care (including establishment of an IBD medical home) can improve vaccination rates and patient adherence to preventive health measures. In this project, clinicians improved vaccination recommendation rates as well as their screening for cancer, mental health, and bone health issues while also improving in counseling patients for smoking cessation. For example, at baseline only 5% of clinicians were advising herpes zoster vaccination more than 50% of the time; at follow-up, this proportion increased to 89%. There is often poor communication between GI providers and PCPs regarding disease management strategies, duration of medication use (including properly weaning and tapering patients off medications), medication-related side effects, management of extra-intestinal manifestations of IBD, safe use of antibiotics during infections, and preventive health maintenance.<sup>31-33</sup> Projects such as those conducted as part of this initiative highlight the potential of increased education and communication between providers and patients, particularly in terms of facilitating shared decision-making and implementing vaccine administration and health prevention strategies.

It is important to note that these studies took place during the early stages of the COVID-19 pandemic and we hypothesize that this likely impacted on study results and specifically outcomes related to uptake of vaccine administration due limited patient education opportunities and decreased in-person contact and ability to offer in-office vaccines. Consequently, the actual impact of digital outreach and education efforts when access to in-person office visits is unencumbered, is likely higher than that observed in this study period. In addition, it is not known what impact anti-COVID-19 vaccine movements may have had on patient willingness to take other recommended vaccines evaluated in these studies.

The projects described herein indicate numerous potential avenues for further study. One recommendation for future studies is to adopt a multipronged approach combining digital outreach

with in-office intervention to improve vaccination rates. As part of in-office interventions, enhancing collaboration between GI provider and PCP offices will be of importance. Another recommendation is to use clinical databases and EHRs to better determine each patient's individual risk based on age, medication status, and comorbidities, with a link to a call to action (e.g., scheduling an appointment) or an opportunity to get further information via digital toolkits.

Finally, these studies highlight the importance of not only patient but also health care provider education related to health maintenance in patients with IBD. Optimizing provider education and using quality benchmarking efforts will be essential in pushing the needle to improve prevention measures.

## DISCLOSURES

### *Conflicts of Interest*

F.F.: Serves on Advisory Board for AbbVie, Avalo Therapeutics, BMS, Braintree Labs, Fresenius Kabi, GI Reviewers, GSK, IBD Educational Group, Iterative Health, Janssen, Pharmacosmos, Pfizer, Sandoz Immunology, and Viatrix; and is on the Data Safety Monitoring Board at Eli Lilly.

A.A.B.: Employee at AbbVie Inc. Contributions to this project are her own and not a reflection of AbbVie.

All other authors have no disclosures or potential conflicts of interest.

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### *Writing Assistance*

Peter D. Steinberg provided writing assistance in preparation of this manuscript.

### *Contributions to the Manuscript*

All authors contributed significantly to the project, "Improving Vaccine Utilization and Preventive Health Maintenance in IBD." Their roles encompassed the thorough review, development, and meticulous editing of the paper, ensuring the accuracy, relevance, and

integrity of the content. Each author brought unique insights and expertise to the project, contributing to a comprehensive and authoritative piece on an important aspect of IBD care.

### *Data, Analytic Methods, and Study Materials Availability Statement*

In the interest of supporting open scientific inquiry and fostering reproducibility, we will provide access to the data, analytic methods, and study materials associated with this research as listed below.

*Data Availability.* The dataset supporting the conclusions of this article will be made available by the authors, without undue reservation, to any qualified researcher. Data are available from the corresponding author upon reasonable request and with the execution of a data use agreement to ensure patient privacy and data integrity.

*Analytic Methods.* Full details of the analytic methods and computational code used in this study are included in the Supplementary Materials. Where proprietary constraints prevent the sharing of code, we will provide detailed algorithmic descriptions that enable replication.

*Study Materials.* Any original study materials, such as survey instruments, protocols, and software, will be made available upon request.

All additional files required to replicate the analysis reported in this paper are available from the corresponding author upon reasonable request.

## ABBREVIATIONS

ACG, American College of Gastroenterology; ACIP, Advisory Committee on Immunization Practices; AGA, American Gastroenterological Association; CD, Crohn's disease; CDC, Centers for Disease Control and Prevention; CME, CME Outfitters, LLC; EHR, electronic health record; FDA, Food and Drug Administration; GI, gastrointestinal; HAV, hepatitis A virus; HBV, hepatitis B virus; HCP, healthcare provider; HPV, human papilloma virus; IBD, inflammatory bowel disease; IGLC, Independent Grants for Learning & Change; JAK, Janus kinase; MIPS, Merit-based Incentive Payment System; MSCCR, Mount Sinai Crohn's and Colitis Registry; PCP: primary care provider; PCV: pneumococcal conjugate vaccine;

PPD: purified protein derivative; PPSV, pneumococcal polysaccharide vaccine; QI, quality improvement; RCT, randomized clinical trial; RFP, request for proposal; RSV: respiratory syncytial virus; Tdap, tetanus, diphtheria, and pertussis; TNF, tumor necrosis factor; TPMT, thiopurine methyltransferase; UC, ulcerative colitis.

## REFERENCES

- Inflammatory bowel disease: Prevalence. Centers for Disease Control and Prevention; 2022. <https://www.cdc.gov/ibd/data-and-statistics/prevalence.html>.
- Rosen MJ, Dhawan A, Saeed SA. Inflammatory bowel disease in children and adolescents. *JAMA Pediatr*. 2015;169(11):1053-1060.
- Park KT, Ehrlich OG, Allen JI, et al. The cost of inflammatory bowel disease: An initiative from the Crohn's & Colitis Foundation. *Inflamm Bowel Dis*. 2020;26(1):1-10.
- Kappelman MD, Rifas-Shiman SL, Porter CQ, et al. Direct health care costs of Crohn's disease and ulcerative colitis in US children and adults. *Gastroenterology*. 2008;135(6):1907-1913.
- Van Limbergen J, Russell R, Drummond HE, et al. Definition of phenotypic characteristics of childhood-onset inflammatory bowel disease. *Gastroenterology*. 2008;135(4):1114-1122.
- Vernier-Massouille G, Balde M, Salleron J, et al. Natural history of pediatric Crohn's disease: a population-based cohort study. *Gastroenterology*. 2008;135(4):1106-1113.
- Longobardi T, Jacobs P, Bernstein CN. Work losses related to inflammatory bowel disease in the United States: results from the National Health Interview Survey. *Am J Gastroenterol*. 2003;98(5):1064-1072.
- Ferguson A, Sedgwick DM, Drummond J. Morbidity of juvenile onset inflammatory bowel disease: effects on education and employment in early adult life. *Gut*. 1994;35(5):665-668.
- Cohen R. The quality of life in patients with Crohn's disease. *Aliment Pharmacol Ther*. 2002;16(9):1603-1609
- Casellas F, Arenas JI, Baudet JS, et al. Impairment of health-related quality of life in patients with inflammatory bowel disease: a Spanish multicenter study. *Inflamm Bowel Dis*. 2005;11(5):488-496.
- Kröner PT, Picco MF, Cangemi JR, Hayney MS, Farraye FA, Caldera F. The burden of vaccine-preventable diseases in patients with inflammatory bowel disease. *J Clin Gastroenterol*. 2022;56(9):798-804.
- Farraye FA, Melmed GY, Lichtenstein GR, Kane SV. ACG Clinical Guideline: Preventive care in inflammatory bowel disease. *Am J Gastroenterol*. 2017;112(2):241-258.
- Practice Resources: Quality & Performance Measures. American Gastroenterological Association; 2023. <https://gastro.org/practice-resources/quality-and-performance-measures/>.
- Syal G, Serrano M, Jain A, et al. Health maintenance consensus for adults with inflammatory bowel disease. *Inflamm Bowel Dis*. 2021;27(10):1552-1563.
- Caldera F, Bhat S, Govani S, Crohn's & Colitis Foundation Professional Education Sub-Committee. Health Maintenance Checklist; 2022. <https://www.crohnscolitisfoundation.org/science-and-professionals/education-resources/health-maintenance-checklists>
- Vaccines and preventable diseases: Shingrix recommendations. Centers for Disease Control and Prevention; 2023. [https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/recommendations.html#:~:text=CDC%20recommends%20Shingrix%20\(recombinant%20zoster,prior%20episode%20of%20herpes%20zoster](https://www.cdc.gov/vaccines/vpd/shingles/hcp/shingrix/recommendations.html#:~:text=CDC%20recommends%20Shingrix%20(recombinant%20zoster,prior%20episode%20of%20herpes%20zoster).
- Smith RA, Desai A, Hashash JG, Hayney MS, Farraye FA, Caldera F. Addressing the risks of respiratory syncytial virus for patients with inflammatory bowel disease in the era of novel vaccines. *Inflamm Bowel Dis*. 2023;29(11):1842-1845.
- Vaccines and Preventable Diseases: Healthcare providers: RSV vaccination for adults 60 years of age and over. Centers for Disease Control and Prevention; 2023. <https://www.cdc.gov/vaccines/vpd/rsv/hcp/older-adults.html#:~:text=CDC%20recommends%20that%20adults%2060,RSV%20vaccination%20will%20be%20beneficial>.
- Vaccines and Preventable Diseases: Respiratory syncytial virus (RSV) immunizations. Centers for Disease Control and Prevention; 2023. <https://www.cdc.gov/vaccines/vpd/rsv/index.html>.
- Kobayashi M, Pilishvili T, Farrar JL, et al. Pneumococcal vaccine for adults aged  $\geq 19$  years: recommendations of the Advisory Committee on Immunization Practices, United States, 2023. *MMWR Recomm Rep*. 2023;72(RR-3):1-39.
- Vaccines & Immunizations: Interim clinical considerations for use of COVID-19 vaccines in the United States. Centers for Disease Control and Prevention; 2023. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html>.
- Melmed G, Ippoliti AF, Papadakis KA, et al. Patients with inflammatory bowel disease are at risk for vaccine-preventable illnesses. *Am J Gastroenterol*. 2006;101(8):1834-1840.
- Wasan SK, Coukos JA, Farraye FA. Vaccinating the inflammatory bowel disease patient: deficiencies in

- gastroenterologists knowledge. *Inflamm Bowel Dis*. 2011;17(12):2536-2540.
24. Malhi G, Rumman A, Thanabalan R, et al. Vaccination in inflammatory bowel disease patients: attitudes, knowledge, and uptake. *J Crohns Colitis*. 2015;9(6):439-444.
  25. Jung YS, Park JH, Kim HJ, et al. Insufficient knowledge of Korean gastroenterologists regarding the vaccination of patients with inflammatory bowel disease. *Gut Liver*. 2014;8(3):242-247.
  26. Loubet P, Verger P, Abitbol V, Peyrin-Biroulet L, Launay O. Pneumococcal and influenza vaccine uptake in adults with inflammatory bowel disease in France: results from a web-based study. *Dig Liver Dis*. 2018;50(6):563-567.
  27. Wasan S, Calderwood A, Long M, Chen W, Sandler R, Farraye F. Immunization rates and vaccine beliefs in patients with inflammatory bowel diseases: an opportunity for improvement. *Am J Gastroenterol*. 2012;107:S667.
  28. Wasan SK, Calderwood AH, Long MD, Kappelman MD, Sandler RS, Farraye FA. Immunization rates and vaccine beliefs among patients with inflammatory bowel disease: an opportunity for improvement. *Inflamm Bowel Dis*. 2014;20(2):246-50.
  29. Long MD, van Deen WK, Weisbein L, et al. Web-based video education to improve uptake of influenza vaccination and other preventive health recommendations in adults with inflammatory bowel disease: randomized controlled trial of Project PREVENT. *J Med Internet Res*. 2023;25:e42921.
  30. Regueiro M, Click B, Holder D, Shrank W, McAnallen S, Szigethy E. Constructing an inflammatory bowel disease patient-centered medical home. *Clin Gastroenterol Hepatol*. 2017;15:1148-1153.
  31. Feuerstein JD, Sheppard V, Cheifetz AS, Ariyabuddhiphongs K. How to develop the medical neighborhood. *J Med Systems*. 2016;40:196.
  32. Torjesen I. Care of IBD patients compromised by poor communication between primary and secondary care. *BMJ*. 2012;12:344:e2675.
  33. Lai C, Sceats LA, Qiu W, Park KT, Morris AM, Kin C. Patient decision-making in severe inflammatory bowel disease: The need for improved communication of treatment options and preferences. *Colorectal Dis*. 2019;21(12):1406-1414.