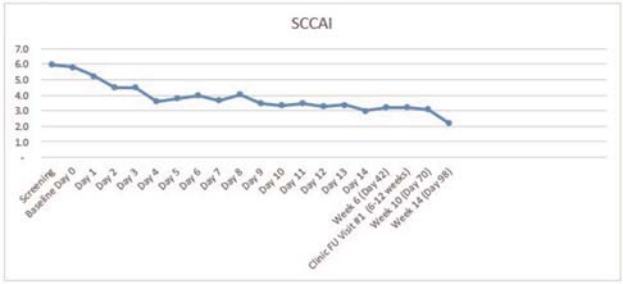
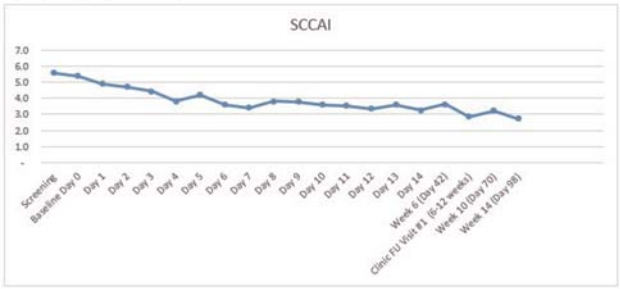
Figure 1: Simple Clinical Colitis Activity Index (SCCAI) after Tofacitinib Initiation in Cohort (Panel A) and in Sub-Group Without Concomitant Corticosteroid Use (Panel B) through Week 14

A (n=65) Cohort



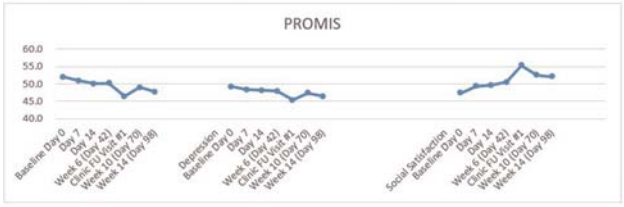
B (n=27) Sub-group without Any Corticosteroid Use



[668] **Figure 1.**

METHODS: An initial 65 patients initiating tofacitinib were recruited from 13 academic and community gastroenterology practices. Demographic information, disease and medication histories were obtained. Patients completed PRO surveys on days 1–14, and at week 6, 10 and 14. Outcome data included the simple clinical colitis activity index (SCCAI), and PRO measurement information system (PROMIS) measures of depression, anxiety and social satisfaction. A score of < 4 with a decrease by >1.5 points is considered response. PROMIS measures are calibrated using a T score (mean of the US population equal to 50, standard deviation (SD) of 10). A higher PROMIS score equates to more of the measure (higher scores worse for depression, anxiety and better for social satisfaction).
RESULTS: A total of 62/65 (95%) completed electronic PRO data through week 6. Mean age was 38.4 (SD 14.9), 61.5% were male, mean disease duration was 9.6 years and 58.5% were on concomitant steroids at baseline. Mean disease activity at baseline (n = 65) was active (SCCAI of 5.6 (SD 3.2)), with reductions in mean disease activity to SCCAI 3.1 on day 14, 2.7 on week 14 (Figure 1). At the time of first in-person clinical visit (week 2–6), only 18.2% remained on steroids. Among patients initiating tofacitinib without concomitant corticosteroid use (n = 27), early reductions in SCCAI were seen (mean SCCAI 5.4 at baseline, reduced to SCCAI 3.8 by day 4). Improvements in all PROMIS measures (anxiety, depression, social satisfaction) were seen through week 14 (Figure 2). A total of 54.2% met criteria for response at day 14, with 52.2% at week 6.
CONCLUSION: Real time electronic PRO data capture provided the ability to assess cessation of steroids and time to response to tofacitinib via important PRO outcomes. Tofacitinib was associated with a rapid response in this ongoing prospective multi-center real-world cohort, independent of steroid use. Continued enrollment and long-term data, planned through week 30, will enhance our understanding of UC.

Figure 2: Patient Reported Outcome Measurement Information System (PROMIS) Measures on Anxiety, Depression and Social Satisfaction after Tofacitinib Initiation through Week 14



PROMIS measures calibrated to T score of 50 in general population, lower scores consistent with improvements in depression, anxiety, while higher scores show improvement in social satisfaction (L-> R, Anxiety, Depression, Social Satisfaction)

[668] **Figure 2.**

S0669

Project PREVENT: A Randomized Controlled Trial of Preventive Interventions in Patients With Inflammatory Bowel Disease

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INTRODUCTION: Patients with inflammatory bowel disease (IBD) are at increased risk of infections, bone fractures and skin cancers. Preventive efforts may reduce the risk of these complications. Using an iterative patient-centered approach, we developed dynamic preventive health videos and tested the impact of these videos, compared to static text-based interventions, on preventive health uptake in patients with IBD.
METHODS: Consecutive adults with IBD enrolled in the IBD Partners cohort were enrolled in a randomized controlled trial of dynamic (video) vs. static (text) educational interventions. We used block randomization stratified by prior year influenza vaccine receipt. All subjects were eligible for influenza vaccine and skin cancer interventions. Those on immunosuppression or age $\geq$ 65 years were eligible for the pneumococcal vaccine intervention. Patients $\geq$50 years of age were eligible for the shingles vaccine intervention. Those with prior corticosteroid use or women $\geq$65 years of age were eligible for bone health interventions. The primary outcome for this analysis was post-intervention intent to obtain influenza vaccine. Secondary outcomes included intent to obtain other preventive health interventions.
RESULTS: A total of 1056 patients with IBD were included; 545 were randomized to static interventions and 511 to dynamic interventions. Demographic and disease characteristics were similar in the two groups and similar proportions of patients received influenza vaccine in the prior year (57%). The majority of patients were in remission (Table 1). There was no difference in intent to receive influenza vaccine after receipt of static *vs.* dynamic intervention (72% *vs.* 75%, $P = 0.62$). There was also no difference in intent to receive pneumococcal or shingles vaccines, bone health or skin cancer screening by intervention. Overall, 57% had received a vaccine prior to the intervention, while 73%

[669] **Table 1.**

Table 1: Characteristics of IBD Partners Patients in Project PREVENT

Characteristic	Static Intervention (n=545)	Dynamic Intervention (n=511)	P value
Age (years)	51.2 (14.9)	50.3 (15.6)	0.34
Gender (% female)	69%	75%	0.05
IBD subtype			
Crohn's disease	63%	65%	0.57
Ulcerative colitis	34%	33%	0.67
IBD-U	2%	2%	0.63
Education (% >high school)	97%	96%	0.84
Race (%)			0.99
Caucasian	89%	89%	
African American	1%	1%	
Other	10%	10%	
Current smoking (% yes)	5%	3%	0.24
BMI	25.9 (5.8)	25.8 (5.9)	0.83
Disease duration (years)	21.2 (13.5)	20.6 (13.0)	
Ever GI surgery (% yes)	43%	43%	0.98
Ever GI hospitalization (% yes)	65%	62%	0.27
Number hospitalizations	3.6 (2.8)	3.4 (2.5)	
Current medications (%)			
Anti-TNF	30%	30%	0.99
Vedolizumab	10%	8%	0.16
Ustekinumab	8%	7%	0.82
Tofacitinib	1%	1%	0.92
Immunomodulator*	17%	21%	0.10
Corticosteroids	10%	7%	0.11
5-ASA[&]	29%	30%	0.68
Remission (% yes)	62%	67%	0.14

Categorical, or mean (SD) as appropriate

[669] **Table 2.**

Table 2: Post Intervention Changes in Intent to Receive Influenza Vaccine among IBD Patients in Project PREVENT

Characteristics	All patients (n=683)		P value	Static intervention (n=376)		P value	Dynamic intervention (n=307)		P value
	n, %			n, %			n,%		
Prior flu vaccine (pre-intervention)	388	57%	<0.001	208	55%	<0.001	180	59%	<0.001
Intent to obtain flu vaccine (post-intervention)	502	73%		271	72%		231	75%	

reported they intended to get a vaccine after the intervention ($P < 0.0001$). Results were similar when stratified by static (55% pre vs. 72% post, $P < 0.0001$) or dynamic intervention (59% pre vs. 75% post, $P < 0.0001$) (Table 2).
CONCLUSION: This randomized controlled trial of dynamic (video) vs. static (text) interventions showed no difference in intention to undergo preventive health recommendations by type of messaging. Further studies measuring receipt of preventive health services are ongoing. Patient-centered educational messaging can improve preventive health awareness in IBD.

S0670

Patient Characteristics, Treatments, and Health Outcomes Over 6 Months in Patients With Inflammatory Bowel Disease Treated in Community Practice Using a Specialized Pharmacy Team

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INTRODUCTION: The treatment of inflammatory bowel disease (IBD) is complex and often times requires the long-term use of biologic/small molecule therapy. The prior authorization process for biologic/small molecule therapy is complicated and may result in delayed delivery of necessary therapy. This registry assesses the impact of patient demographics on health outcomes, the medication approval process and compliance in patients with IBD in community GI practices that use a dedicated pharmacy team with expertise in the prior authorization process.
METHODS: This IRB-approved, ongoing, observational registry captures long-term health outcomes, patient management and pharmacy support data every 6 months for up to 10 years. Patients are ≥10 yo, have IBD and are already receiving or newly starting subcutaneous biologic therapy or tofacitinib. A dedicated pharmacy team is responsible for processing all prior authorizations. Pharmacy data is collected from the pharmacy team and clinical data is collected from the community site every 6 months.
RESULTS: There were 164 patients enrolled in the registry between March 2018-November 2019. Two-thirds of patients had Crohn's disease (CD) and one-third had ulcerative colitis (UC). The table reports baseline demographics, IBD therapies previously taken as well as those used at the time of registry entry. Of note, steroids were more commonly used to manage patients with UC vs CD ($P = 0.014$), a higher percentage of Hispanic patients had UC ($P = 0.012$) and more CD patients had previous IBD-related surgeries ($P = 0.00001$). At the time of registry entry, 95.2% of biologic/small molecule prescriptions were accepted with the first prior authorization request and nearly two-thirds of patients started treatment ≤20 days from prescription. After 6 months, 83.6% of patients were considered stable compared to baseline, 6.2% had improved and 10.3% had worsened. During that same time, 3.5% of patients were hospitalized (80% IBD-related). IBD medications remained the same for 88.5% of patients but were changed for some due to inadequate response (5.1%), intolerance (3.2%) or other reasons (3.2%).
CONCLUSION: Patients with IBD who are managed at community sites with the support of a specialized pharmacy team can receive biologic/small molecule therapy in an expedited manner. Comparisons of regional differences and longer-term health outcomes will be performed as additional patients are enrolled and the registry progresses.

[670] **Table 1. Baseline Characteristics, Previous and Current IBD Medications**

	Crohn's disease (n=108)	Ulcerative colitis (n=59)	Total (n=164)***
Mean Age (years) (min-max)	40.6 (18-83)	43.9 (20-87)	41.8 (18-87)
Female	58.3%	50.8%	54.9%
Race			
White	84.8%	94.5%	88%
Black	10.5%	3.6%	8.2%
Other	4.8%	1.8%	3.8%
Hispanic	4.8%	17.2%	8.8%
BMI (mean; min-max)	26.6 (15.6-46.2)	26.8 (16.5-48.7)	26.7 (15.6-48.7)
Past surgery related to IBD	61.2%	12.1%	42.8%
Hospitalized in previous year	6.7%	1.8%	5.0%
Drug Classes Used in Prior Year*			
6-MP	3.7%	3.4%	3.7%
Azathioprine	6.5%	5.1%	6.1%
Budesonide	3.7%	5.1%	4.3%
Methotrexate	13.1%	5.1%	9.8%
Steroid, Oral	24.3%	44.1%	31.3%
Steroid, IV	0.9%	3.4%	1.2%
Meds Previously Failed**			
Adalimumab	22.5%	17.5%	20.4%
Certolimumab pegol (Approved for CD)	8.8%	1.8%	5.7%
Golimumab (Approved for UC)	2.0%	17.5%	7.0%
Infliximab	38.2%	33.3%	35.7%
Ustekinumab	2.9%	5.3%	3.8%
Vedolizumab	14.7%	15.8%	15.3%
Current Concomitant Therapy			
6-MP	2.0%	0	1.3%
Azathioprine	6.9%	1.7%	5.1%
Budesonide	4.9%	1.7%	3.8%
Mesalamine	8.8%	36.2%	19.0%
Methotrexate	7.8%	1.7%	5.7%
Steroid, Oral	0	15.5%	9.5%
Steroid, IV	1.0%	0	0.6%
IBD Current Therapy			
Adalimumab	48.1%	37.3%	44.5%
Certolizumab pegol (Approved for CD)	0.9%	0	0.6%
Golimumab (Approved for UC)	0	33.9%	12.2%
Tofactinib (Approved for UC)	0	23.7%	8.5%
Ustekinumab	50.9%	5.1%	34.1%
*Patient may or may not still be on med at baseline.			
**Patients may have failed more than 1; no patients previously failed tofactinib.			
***3 patients had diagnoses of Crohn's disease and ulcerative colitis.			

S0671

The Association of Frailty With Mortality and Relapse Frequency in Inflammatory Bowel Disease

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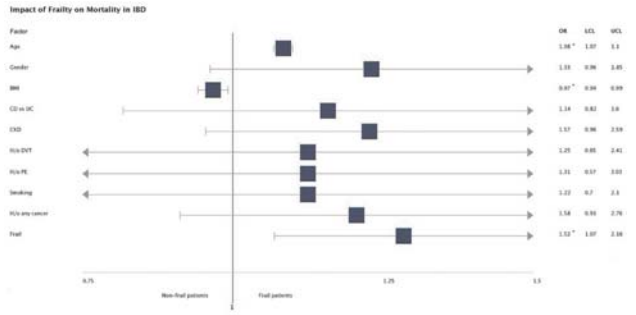
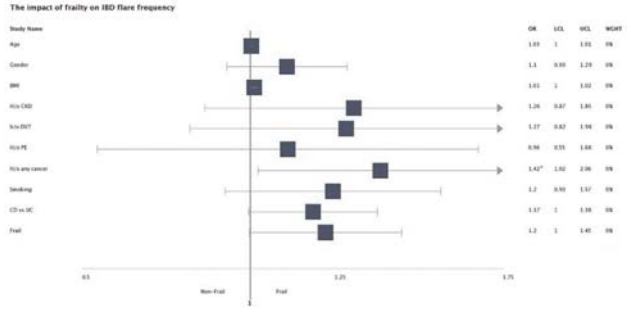
INTRODUCTION: Frailty represents a state of diminished physiologic reserve. While the influence of frailty on gut immune response, inflame-aging and microbiome composition is subject to ongoing investigation, limited data exists on clinical outcomes in frail inflammatory bowel disease (IBD) patients. We tested the hypothesis that a modified frailty index will predict mortality and propensity for more frequent flares of inflammatory bowel disease.
METHODs: An observational analysis of a retrospectively collected data from a single center in patients with Ulcerative Colitis and Crohn's disease was performed. Study period was 2008–2019. A 7 factor IBD frailty index was modified from the Canadian Study of Health and Aging Frailty Index. For each patient a frailty score and a frailty index were calculated. A frailty index of >0.27 was used to define a frailty. Multivariate logistic regression analyses were conducted to assess the probability of mortality and >5 IBD flares in frail and non-frail patients, while controlling for potential comorbid confounders. The calibration of logistic models was tested via Hosmer-Lemeshow test; predictive capacity was assessed via a c-statistic obtained from receiver operating curves.
RESULTS: A total of 2978 patients were included; 53.5% with Ulcerative colitis, 0.5% with indeterminate colitis and the rest with Crohn's. The prevalence of frailty was 32% in this population of patients with IBD. Frail patients with IBD were more frequently older, female, had a higher mean BMI and were more often smokers ($P < 0.001$ for all via two-tailed t-tests and chi-square analysis). The prevalence of mortality in frail patients was statistically higher than the mortality prevalence in the non-frail (11.42% vs 3.75%, $P < 0.01$). Similarly, a higher proportion of frail patients experienced >5 IBD flares than non-frail patients (35.6% vs 27.5%, $P < 0.001$) through the study period. On regression analysis (Figure 1), frailty was associated with highest odds for mortality in patients with IBD (odds ratio 1.52, confidence interval 1.07–2.16, $P = 0.01$). Frail status did not predict the odds of having >5 IBD relapses as compared to non-frail patients (odds ratio 1.20, confidence interval 0.99–1.45, $P = 0.05$).
CONCLUSION: This study provides the first evidence of an association between frailty and mortality in patients with inflammatory bowel disease. Potential areas of further investigation include phenotypic assessments of frailty, rather than an index approach utilized herein, in patients with IBD.



[671] **Figure 1.** The Impact of Frailty on IBD Mortality.



[671] **Figure 2.** The Impact of Frailty on IBD Flare Frequency.