Validation of a Pharmacist Monitoring Tool for Patients with Inflammatory Bowel Disease

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BACKGROUND

- Monitoring specialty medications utilized for treating inflammatory bowel disease (IBD) is important due to their potential to cause adverse effects and need for dose adjustments to ensure optimal response
- Validated IBD physician assessment tools standardize assessment of disease state activity, but do not address medication-related concerns which lead to lower applicability of the tools for pharmacists
- In 2019, University of Wisconsin (UW) Health created a patient-reported outcome IBD monitoring tool, the gastro-intestinal metric (GIM) Score, in collaboration with payors, patients, physicians, and pharmacists to standardize assessments and identify suboptimal medication efficacy

Gastro-Intestinal Metric (GIM) Score

Assessment Question Category	
General well-being	
Abdominal pain	
Bowel frequency	Disease state progression
Blood in stool	
Resolution of symptom attempts	
Next dose awareness	
Work/school productivity	
Missed doses	Medication efficacy
Medication adverse effects	

- The GIM Score is currently being utilized by the specialty pharmacists during routine telephone follow-ups with patients taking IBD specialty medications

OBJECTIVES

1. Validate the GIM Score through comparison of pharmacist and physician assessments of patients' IBD control at the time of office visit
2. Develop a GIM Score cutoff for IBD disease activity stability

METHODS

Type: Prospective, single-center study
Time frame: September 1, 2024 to July 31, 2025
IRB: Minimal risk research approval
Study team: specialty pharmacists, student researchers, biostatistician
Inclusion criteria: Established with a UW Health gastroenterologist and an office visit scheduled during the study period; gastroenterologist is the prescriber of the patient's adalimumab (or adalimumab biosimilar), certolizumab, ustekinumab, risankizumab, tofacitinib, upadacitinib or ozanimod; adherent to IBD specialty medication (PDC>0.7); participant in UW Health Specialty Pharmacy Medication Management Program
Exclusion criteria: Pediatrics (<18 years old), pregnant, incarcerated

Study Design & Workflow

Patient Enrollment
- Completed by study team
- Recruited via mychart & phone
- Consented
- Flagged and episode created

Baseline GIM Score
- Conducted by specialty pharmacist on study team
- Administered via phone
- Within one week of scheduled office visit

Gastroenterologist Office Visit Assessment
- In-person or telemedicine
- Provider-administered IBD questionnaire
- Medication adjustments
- Labs, drug levels, procedures ordered

Follow-up GIM Score
- Conducted by specialty pharmacist on study team
- 8 weeks after baseline for stable patients
- 4 weeks after baseline for unknown stability

Research was completed in collaboration with ASHP Foundation

RESULTS

A total of 121 patients were included in the primary outcome and 104 patients in the secondary outcome analyses.

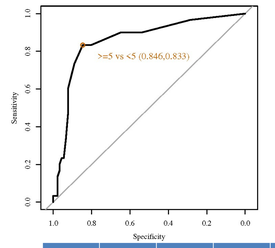
Table 1. Patient Demographic Information (n=152)

Variables	Value (%)
Age	
median (range) years	48 (19-82)
Sex	
Female	80 (52.6)
Male	71 (46.7)
Non-binary	1 (0.7)
Race	
White	140 (92.1)
African American	5 (3.3)
Asian	4 (2.6)
Unknown	2 (1.3)
Indian or Alaska Native	1 (0.7)
IBD diagnosis	
Crohn's disease	112 (73.7)
Ulcerative colitis	40 (26.3)
Severe disease	
J-pouch or ostomy	22 (14.5)

Primary Outcome
GIM Score is a **VALID** patient-reported outcome monitoring tool for IBD

Gastroenterologist Assessment Variables	Spearman Cor. Coef.	p-value
IBD patient questionnaire	0.472	<0.001
Provider visit assessment	0.262	0.004
IBD medication changes	0.231	0.011
Return to clinic timeframe	0.194	0.033
IBD medication monitoring level drawn	0.152	0.096
IBD lab monitoring (e.g. anemia, etc)	0.088	0.335
Fecal calprotectin drawn	0.081	0.376
Colonoscopy/endoscopy ordered	0.069	0.449
Oral steroid prescribed	0.069	0.449

RESULTS



Secondary Outcome
GIM Score Disease Activity
< 5 indicated patient is **stable**
≥ 5 indicated patient has an **unstable** disease state

Threshold	True Negative	True Positive	False Negative	False Positive	Sensitivity	Specificity	Youden	Logistic AIC	Logistic p-value
0	0	30	0	91	1.000	0.000	0	NA	NA
1	26	29	1	65	0.967	0.286	0.252	128.720	0.019
2	49	27	3	42	0.900	0.538	0.438	119.307	<0.001
3	59	27	3	32	0.900	0.648	0.548	109.391	<0.001
4	73	25	5	18	0.833	0.802	0.636	99.611	<0.001
5	**77**	**25**	**5**	**14**	**0.833**	**0.846**	**0.679**	**92.582**	**<0.001**
6	81	22	8	10	0.733	0.890	0.623	97.555	<0.001
8	84	18	12	7	0.600	0.923	0.523	105.988	<0.001
9	84	14	16	7	0.467	0.923	0.390	118.668	<0.001
10	85	10	20	6	0.333	0.934	0.267	127.422	<0.001
11	86	7	23	5	0.233	0.945	0.178	132.634	0.009
12	87	7	23	4	0.233	0.956	0.189	131.226	0.005
13	88	6	24	3	0.200	0.967	0.167	131.843	0.007
14	88	5	25	3	0.167	0.967	0.134	134.020	0.021
16	89	4	26	2	0.133	0.978	0.111	134.574	0.031
17	89	3	27	2	0.100	0.978	0.078	136.611	0.089
18	89	1	29	2	0.033	0.978	0.011	139.420	0.731
19	90	1	29	1	0.033	0.989	0.022	138.935	0.428
23	91	1	29	0	0.033	1.000	0.033	136.718	0.991
Inf	91	0	30	0	0.000	1.000	0	NA	NA

DISCUSSION

- The GIM Score has been fully integrated in the specialty pharmacist's patient assessment workflow to drive clinical decision making and standard gastroenterology clinic recommendations and follow-up
- Clinic access remains a barrier to timely office visits demonstrating the need for a monitoring tool that specialty pharmacists use to identify unstable patients and optimize medications in between visits
- Limitations of the study included a finite study timeframe due to grant requirements and limited access to IBD clinic visits restricting patient enrollment
- Future directions include the incorporation of the GIM Score results in gastroenterologist electronic health record flowsheets for easier review during clinic visits

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