

Concordance and discordance between patient-defined remission and remission based on
validated patient-reported outcome measures among patients with ulcerative colitis and
Crohns disease

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Abstract

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Background: Patients with Inflammatory Bowel Disease (IBD, which includes ulcerative colitis and Crohn's disease) experience periods of disease flares and remission. However, there may be differences in a patient's own definition of remission and remission based on validated patient reported outcome (PRO) measures. This secondary data analysis seeks to inform our understanding of the concordance and discordance between patient-defined remission and remission based on PROs and compare differences based on clinical and demographic factors in those with ulcerative colitis or Crohn's disease.

Methods: Data was obtained from the Crohn's and Colitis Foundation's IBD Qorus Learning Health System, which is a collaboration of patients and healthcare providers with the goal of continual quality improvement. Within IBD Qorus, patients, ages 18 and older, completed an online survey approximately one week before their clinic visit. Surveys included a variety of disease-related questions including patient-defined remission and PROs. Patients who completed surveys between September 2019 and February 2021 were included in the analysis. R and STATA 17 were used to assess sensitivity, specificity, concordance, and discordance. Logistic regression models were built to predict discordance, using generalized estimating equations.

Results: There were 2004 unique participants (806 ulcerative colitis and 1198 Crohn's disease) with 3257 eligible visits. For patients with ulcerative colitis, there was 22% discordance

between patient-defined remission and the PRO. For patients with Crohn's disease, there was 32% discordance between patient-defined remission and the PRO. Among ulcerative colitis patients in remission as defined by PROs, those who had a disease duration of less than 5 years had higher odds of discordance compared to those with disease duration of more than 15 years (OR: 1.97, 95% CI: 1.12, 3.49). Additionally, those who had lower health confidence scores of 0-6 (OR: 9.64, 95% CI: 4.64, 20.00) or scores of 7-9 (OR: 4.46, 95% CI: 2.33, 8.54) were more likely to report discordance compared to those with a health confidence score of 10. Likewise, patients with Crohn's disease who had a disease duration of less than 5 years (OR: 1.45, 95% CI: 0.99, 2.14) or a health confidence of 6 and lower (OR: 11.75, 95% CI: 7.37, 18.75) or 7-9 (OR: 3.57, 95% CI: 2.46, 5.17) had higher odds of discordance. Among patients with active disease as defined by PROs, those with a lower patient confidence had lower odds of discordance. Patients with ulcerative colitis who have patient confidence of 6 and lower (OR: 0.06, 95% CI: 0.03, 0.13) or health confidence of 7-9 (OR: 0.23 95% CI: 0.12, 0.43) had a lower odds of discordance compared to those with a health confidence score of 10. Crohn's disease patients with lower patient confidence of 6 and below (OR: 0.08, 95% CI: 0.04, 0.16) or 7-9 (OR: 0.28, 95% CI: 0.14, 0.55) had lower odds of discordance compared to those with a health confidence score of 10.

Conclusion: Discordance exists between patient-defined remission and PROs among patients with UC and CD. Patients with Crohn's disease had higher discordance than those with ulcerative colitis. When examining demographic and clinical predictors of discordance, health confidence was significant across both ulcerative colitis and Crohn's disease. Future research is needed to better understand the concept of health confidence and its relationship with accuracy of patient-reported remission.

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Introduction

Inflammatory Bowel Diseases (IBD) are characterized by inflammation of the gastrointestinal tract and include ulcerative colitis (UC) and Crohn's disease (CD). UC involves inflammation of the mucosa in the colon and rectum.¹ CD can involve any part of the gastrointestinal tract (from mouth to anus).² Both UC and CD have periods of disease flares (active disease) and remission. A variety of measurement approaches have been used to monitor and classify disease activity (i.e., having active disease or being in remission). However, most measures have focused on clinician-reported disease activity or biological assessments (e.g., C-reactive protein, fecal calprotectin, and endoscopy). With a shift to patient-centered care, there has been an increased focus on incorporating patient-reported outcomes (PROs) into IBD research and clinical practice, in part due to recommendations by the Food and Drug Administration.³

PRO measures for IBD, the PRO2 and PRO3, were derived from existing composite disease activity measures that included symptoms, clinical signs, endoscopic findings, and clinician-reported assessments. For UC, two items from the Mayo Score, rectal bleeding and stool frequency, comprised the new PRO measure (PRO2).⁴ Patients are considered in remission if they have no rectal bleeding and normal stool frequency. For CD, the Crohn's Disease Activity Index was modified to create a three-item PRO (PRO3) comprised of stool frequency, abdominal pain, and general wellbeing.⁵ For the PRO3, patients are considered in remission if they have 2 or fewer loose stools per day, no or mild abdominal pain, and feel generally well or slightly under par. Both the PRO2 and PRO3 are short and therefore easy for clinicians to integrate into busy clinical practice settings.⁶

Although the PRO2 and PRO3 measures are able to categorize patients into remission or active disease, patients may have different perceptions of remission. For instance, qualitative studies have reported that patients with IBD define remission as a decrease in abdominal pain and bowel movements, however, many do not anticipate complete resolution of symptoms.^{7, 8} In

fact, patients with CD report being in remission despite the continuation of symptoms, which is in contrast to accepted definitions of clinical remission that require patients to have no or few symptoms in the past 6 months.^{8, 9} Instead, patients often accept a new normal of increased symptoms which may lead to a delay in seeking effective treatments.⁸ Yet, not all patients have these views as some define remission as being steroid free and having no symptoms which is similar to clinical definitions.^{10, 11} Therefore, differences may exist between patient-defined remission and remission based on validated PROs.

Little is known regarding the concordance or discordance between patient-defined remission and remission based on validated PROs. Additionally, only a few studies have examined factors associated with discordance of other disease outcome measures. For instance, several patient factors including active disease, patients newly establishing care, and psychological factors were associated with patient-physician discordance of patients' health status (health status included abdominal pain, disease activity, physical functioning, psychological distress, and emotional well-being).¹² Identifying patients who consider themselves in remission despite having active disease based on PROs or alternatively which patients consider themselves as having active disease despite remission based on PROs may enable targeted interventions. For instance, additional education regarding short and long-term treat-to-target goals may be beneficial for subgroups of patients. Therefore, the purpose of this study is to determine the concordance and discordance between patient-report of remission and remission based on PROs and examine clinical and demographic predictors of discordance stratified by disease type.

Study Aims

This secondary data analysis had two aims. The first aim was to determine the sensitivity and specificity of patient-defined remission for detecting remission based on existing, validated PROs stratified by disease type. The second aim was to examine clinical and demographic predictors of discordance stratified by disease type. Discordance was examined

separately for those in remission based on PROs and those in active disease based on PROs. Clinical and demographic predictors included duration of IBD, current steroid use, current narcotic use, recent hospitalization, recent emergency room visit, patients' health confidence, age, and gender. Predictors were selected based on previous factors associated with patient-provider discordance^{12, 13} as well as factors commonly associated with higher levels of symptoms.^{14, 15}

Methods

Study Design

In this study, we examined the discordance between patient-defined remission and remission as defined by PROs in surveys collected within the Crohn's and Colitis Foundation's IBD Qorus Learning Health System between September 2019 and February 2021. Surveys contained measures of patient-defined remission, PROs, as well as clinical and demographic factors.

Study Setting

Retrospective data was obtained from the Crohn's and Colitis Foundation's IBD Qorus program. IBD Qorus is a learning health system which at the time of data collection was comprised of almost 30 academic and private gastroenterology practices. Learning health systems are collaborations of healthcare providers who share ideas and report quality metrics with the goal of continual quality improvement.^{16, 17} The goal of IBD Qorus is to improve the quality of care for IBD patients nationwide.¹⁸ Sites participating in IBD Qorus collected data from adult IBD patients prior to their gastroenterology clinic visit. Patients aged 18 and older complete surveys with each clinic visit; as a result, some patients have multiple clinic visits and therefore multiple surveys. IBD Qorus data is collected using both anonymous paper surveys (not included in current study) and electronic methods. Patients completing the electronic survey have an IBD diagnosis that is verified by the healthcare provider. Patients are emailed a link to an electronic survey approximately one week before their appointment and complete a variety of

disease-related questionnaires. Questions include the patient's number one concern related to IBD, patient-reported outcomes and symptoms, healthcare utilization, preventative health (vaccinations), and health confidence.

Study Subjects

Subjects in the current secondary data analysis were eligible if they completed the pre-visit survey between September 2019 and February 2021 and had complete data on self-reported remission and PROs. Patients could have multiple surveys during the timeframe. Patients with an ostomy were excluded.

Measures

The data collection instruments were included in IBD Qorus for quality improvement initiatives. Below we outline how the data was used in this secondary data analysis.

Patient-Defined Remission. To assess patient-defined remission, patients were asked the following question: *"Do you feel your disease is currently in remission (by remission we mean a complete absence of IBD related symptoms)?"* Response options were yes or no.

Patient-Reported Outcomes (PROs). The PRO2 was used for UC and asked patients about rectal bleeding (no blood in stool, blood less than 50% of time, blood 50% or more of time) and stool frequency (less stool than normal, normal number of stools, 1-2 stools more than normal, 3-4 stools more than normal, or 5 or more stools more than normal). For this study, patients were categorized as in remission if they reported no blood in the stool and a normal (or less than normal) number of stools.⁴ The PRO3 was used for CD and included three questions: loose stool, abdominal pain, and general well-being. Patients reported the average number of liquid or very loose stools over the past 7 days. Daily abdominal pain was reported as: none, mild, moderate, or severe. General well-being was reported over the past seven days as feeling: generally well, slightly below par, poor, very poor, or terrible. For this study, patients were categorized as in remission if they reported 2 or fewer loose stools, no or mild abdominal pain, and feeling generally well or slightly under par.⁵

Clinical. Clinical characteristics included type of IBD (UC or CD), duration of disease, disease extent, past surgeries, current use of steroids (yes/no), and current narcotic use (yes/no). Healthcare utilization was assessed with self-report of hospitalization or emergency department visit due to IBD in the past 6 months, which has high sensitivity and specificity with manual chart review.¹⁷ Patient confidence in disease management was assessed by asking *“How confident are you that you can control and manage most of your health problems related to IBD?”* Patients responded on a 0 to 10 scale with 0 indicating not confident at all and 10 indicating very confident.¹⁹

Demographics. Demographic characteristics included gender (male/female) and age (continuous variable in years) and were entered by the healthcare provider.

Data Analysis

Data analysis was performed using R and STATA 17. Demographic and clinical characteristics were reported based on disease type. Mean and standard deviations were reported for continuous variables. Percentages were reported for categorical variables. For patients who completed multiple surveys within the study period, we used the first completed survey for demographic and clinical characteristics. All analyses are stratified by disease type.

For the remaining analyses, all available data was utilized. To account for correlated data (i.e., patients with multiple surveys over time), models were built using Generalized Estimating Equations (GEE) with an exchangeable correlation. An exchangeable correlation structure was chosen which models that surveys within individuals are correlated equally regardless of the time interval. GEE models are robust to misspecification such that even if the working covariance model does not match the true underlying covariance, the regression coefficient estimates will still be correct. Sensitivity and specificity were calculated for patient-defined remission compared to PRO remission using a segment-level analysis to account for multiple observations per patient with STATA 17.²⁰ The PRO2 (UC) and PRO3 (CD) were dichotomized based on existing literature as described above.^{4, 5}

We built logistic multivariable regression models to determine clinical and demographic predictors of discordance using the R package, *geepack*.²¹ Multivariable analysis was conducted separately for each disease type (UC and CD) in which all variables were entered into the model. To examine discordance among patients who have inactive disease on PROs, patient-defined lack of remission (active disease) was the outcome variable (0=remission, 1=lack of remission). To examine discordance among patient who have active disease on PROs, patient-reported remission was the outcome variable (1=remission, 0=lack of remission). Significance was set at $p < 0.05$. A data-driven approach was used to determine cutoffs for health confidence. Based on histograms and logistic regression models, we determined three groups would fit the data the best: health confidence of 10, health confidence of 7-9, and health confidence of 6 or lower.

Results

After applying inclusion and exclusion criteria, there were 3257 eligible visits and 2004 unique participants (806 patients with UC and 1198 patients with CD). See Figure 1 for a flow diagram of inclusion and exclusion criteria.

Demographics and Clinical Characteristics

Demographic and clinical characteristics for patients with UC and CD are presented in Table 1.

Patients with UC. Patients with UC (n=806) were on average 44.1 years old (SD: 15.5) and predominantly female (57.8%). For disease duration, 31% had UC for less than 5 years, 23% for 5-10 years, 18% for 10-15 years, and 28% for 15+ years. Over half (52.6%) of participants had pancolitis. There were 1316 visits among patients with UC of which 54.6% (n=718) were in remission and 45.4% (n=598) had active disease based on the PRO2 (Table 2). During those visits, 50.8% (n=668) were patient-defined remission whereas 49.2% (n=648) were patient-defined active disease. Thirty-nine percent of patients had one visit, 24.5% had 2

visits, 15.5% had 3 visits, and 20.4% had four or more visits between September 2019 and February 2021.

Patients with CD. Patients with CD (n=1198) were on average 44.0 years old (SD: 15.6) and predominantly female (55.6%). For disease duration, 25% had CD for less than 5 years, 22% for 5-10 years, 17% for 10-15 years, and 36% for 15+ years. Almost half of participants (49.1%) had a non-stricturing and non-penetrating phenotype. There were 1,947 visits among patients with CD of which 63.4% (n=1234) were in remission and 36.6% (n=713) had active disease based on the PRO3. During those visits, 47.7% (n=929) were patient-defined remission whereas 52.3% (n=1018) were patient-defined active disease. Thirty-nine percent of patients had one visit, 25.8% had 2 visits, 16.9% had 3 visits, and 18.1% had four or more visits between September 2019 and February 2021.

Sensitivity, Specificity, and Discordance of Patient-Defined Remission

Patients with UC. For patients with UC, we examined the sensitivity, specificity, and discordance of patient-defined remission against the validated PRO2 adjusted for multiple tests per person (Table 3). Among 718 visits in which the PRO2 classified someone in remission, 553 times (77%) patients considered themselves in remission and 165 times (23%) patients considered themselves as having active disease (Adjusted Sens = 0.77). Among the 598 visits in which the PRO2 classified someone as having active disease, 483 times (80.8%) patients considered themselves in active disease and 115 times (19.2%) patients considered themselves in remission (Adjusted Spec = 0.79). Overall, there was 22% discordance between patient-defined remission and the PRO2.

Patients with CD. For patients with CD, we examined the sensitivity, specificity, and discordance of patient-defined remission against the validated PRO3 adjusted for multiple tests per person (Table 4). Among 1234 visits in which the PRO3 classified someone in remission, 781 times (63.3%) patients considered themselves in remission and 453 times (36.7%) patients considered themselves as having active disease (Adjusted Sens = 0.62). Among the 713 visits

in which the PRO3 classified someone as having active disease, 565 times (79.2%) patients considered themselves in active disease and 148 times (20.8%) patients considered themselves in remission (Adjusted Spec = 0.79). For patients with CD, there was 32% discordance between patient-defined remission and the PRO3.

Demographic and Clinical Predictors of Discordance Among Patients in Remission as Defined by PROs

Among patients in remission as defined by PROs, separate multivariable regression models were built based on disease type (UC and CD) to determine predictors of discordance (Table 5). Discordance is defined as patient-reported active disease despite remission based on PROs.

Patients with UC in Remission. Among patients with UC in remission based on the PRO2, those who have an IBD disease duration of less than 5 years had higher odds of discordance compared to those diagnosed for more than 15 years (OR: 1.97, 95% CI: 1.12, 3.49). Those with low patient confidence scores of 0-6 (OR: 9.64, 95% CI: 4.64, 20.00) or scores of 7-9 (OR: 4.46, 95% CI: 2.33, 8.54) were more likely to report discordance compared to those with a health confidence score of 10. There was no difference based on age, gender, current medications, emergency room, or hospitalizations.

Patients with CD in Remission. Among patients with CD in remission based on the PRO3, those who have an IBD disease duration of less than 5 years (OR: 1.45, 95% CI: 0.99, 2.14) had higher odds of discordance compared to those with a duration of greater than 15 years. Those with current prednisone use (OR: 3.41, 95% CI: 1.70, 6.84), current narcotic use (OR: 4.41, 95% CI: 1.54, 12.62) or emergency department visit (OR: 3.06, 95% CI: 1.30, 7.16) in the past 6 months had higher odds of discordance. Finally, those with health confidence of 6 and lower (OR: 11.75, 95% CI: 7.37, 18.75) or health confidence of 7-9 (OR: 3.57, 95% CI: 2.46, 5.17) were more likely to have discordance than those with a health confidence score of 10.

Demographic and Clinical Predictors of Discordance Among Patients in Active Disease as Defined by PROs

Among patients with active disease as defined by PROs, separate multivariable regression models were built based on disease type (UC and CD) to determine predictors of discordance (Table 6). Discordance is defined as patient-reported remission disease despite active disease based on PROs.

Patients with UC in Active Disease. Patients with UC who have patient confidence of 6 and lower (OR: 0.06, 95% CI: 0.03, 0.13) or patient confidence of 7-9 (OR: 0.23 95% CI: 0.12, 0.43) had a lower odds of discordance compared to those with a health confidence score of 10. Those with current prednisone use (OR: 0.49, 95% CI: 0.24, 0.98) had lower odds of discordance. There was no significant difference based on age, gender, disease duration, current medications, emergency room, or hospitalizations.

Patients with CD in Active Disease. Patients with CD who have significantly higher odds of discordance are 30-40 years old (OR: 2.62, 95% CI: 1.14, 6.00) or greater than 60 years old (OR: 2.67, 95% CI: 1.15, 6.21) compared to those less than 30 years old. Additionally, those with a diagnosis for 11-15 years (OR: 2.34, 95% CI: 1.06, 5.21) or more than 15 years (OR: 2.68, 95% CI: 1.38, 5.19) had a higher odds of discordance compared those with a diagnosis for less than 5 years. Those with current prednisone use (OR: 0.44, 95% CI: 0.18, 1.07), narcotic use (OR: 0.29, 95% CI: 0.08, 1.07), hospitalization (OR: 0.59, 95% CI: 0.18, 1.89) or emergency department visit (OR: 0.58, 95% CI: 0.21, 1.57) in the past 6 months had lower odds of discordance although these did not reach statistical significance. Finally, controlling for all other variables, patients with lower patient confidence of 6 and below (OR: 0.08, 95% CI: 0.04, 0.16) or health confidence of 7-9 (OR: 0.28, 95% CI: 0.14, 0.55) had lower odds of discordance compared to those with a health confidence score of 10.

Discussion

This study examined the sensitivity and specificity of patient-defined remission for validated PROs. In UC, patient-defined remission had a sensitivity of 0.77 and specificity of 0.79 for remission as measured by PROs. In CD, patient-defined remission had a sensitivity of 0.62 and specificity of 0.79 for remission as measured by PROs. This level of high specificity is similar to previously reported agreements in IBD Qorus between self-report and electronic health records for healthcare utilization (ED, hospitalizations, CT scans) and medication (steroids and narcotics).¹⁷ Patients with CD had a higher rate of discordance (32%) than patients with UC (22% discordance), which is also consistent with previous findings.²²⁻²⁴

Among patients who are in remission on PROs, 19% of UC patients and 21% of CD patients considered themselves in active disease. Patients with such discordance were more likely to have lower confidence in disease management. Confidence in disease management refers to patient's confidence in controlling and managing their health problems related to IBD. Others have conceptualized patient confidence as self-efficacy or the perception of an individual to manage their disease.^{25, 26} A previously reported cross-sectional study among 207 IBD patients found that lower-self efficacy was associated with more anxiety, productivity loss, and disability.²⁷ Patients who are in remission on PROs but yet consider themselves in active disease may need additional training to obtain the confidence and skills to manage their disease. Therefore, it could be that patient confidence or self-efficacy may serve as a modifiable factor that, when increased, can promote patients' self-management of their disease and improve accuracy of patient-reported remission.

Additionally, patients who had shorter disease duration (<5 years) were more likely to have discordance compared to those with a longer disease duration (>15 years). As IBD is a complex disease, considerations should be made for patient onboarding and education to help new patients learn about signs and symptoms of disease flares. A recent survey among 89 newly diagnosed patients (diagnosed <5 years) found that only 11% reported receiving

educational and psychological support and of those not receiving support almost half indicated that it would have been beneficial.²⁸ Another survey of 571 patients asked participants to report the amount of information they received within two months of their diagnosis with the majority reported little or no information about a variety of topics that patients indicated were very important.²⁹ It may be that limited access to disease information could lead newly diagnosed patients to have lower accuracy of patient-reported remission.

CD patients with current prednisone or narcotic use as well as those with recent emergency room visit were also more likely to have discordance. Discordance based on prednisone use highlights the complexity of disease activity definitions. If the patient's goal is steroid-free remission (i.e., being in remission without steroids), then it would be expected to have discrepancy between PRO remission and patient-defined remission. Those on narcotics were also more likely to have discordance. It could be that although these patients are in remission based on the PRO3, they may feel that the narcotics are masking abdominal pain symptoms or perceive their disease is not under control due to the need for narcotics. Rhudy and colleagues reported that IBD patients with chronic opioid use are more likely to discontinue biologic therapy.³⁰ Since symptoms of opioid withdrawal can overlap with symptoms of a disease flare, patients using opioids may also need targeted interventions aimed at promoting self-management of disease through identification of disease activity.

On the other hand, discordance may occur when patients have active disease based on PROs, but report being in remission. Patients with higher confidence were more likely to report discordance. It could be that patients with higher confidence are more comfortable managing their disease despite experiencing increased symptoms, although this hypothesis should be tested in future work. Among patients with CD, longer time since diagnosis and those 30-40 years old and >60 years (compared to <30 years old) were more likely to have discordance. It could be that as individuals have CD for longer periods of time, they may be more willing to tolerate a greater number of symptoms and still consider themselves in remission. A cross-

sectional survey of patient understanding of the terms “flare” and “remission” found the majority of patients have a symptom-focused understanding of disease flares and use self-management practices such as increasing sleep/rest, changing diet, and increasing medications.³¹

Furthermore, the authors noted that a subset of patients report persistent, mild symptoms during remission.³¹ This aligns with our study findings in which some patients had active disease based on PROs, yet reported remission. Therefore, additional research is needed on the complex interplay between patient-defined remission, PROs, endoscopic reports and intestinal inflammation and how that impacts self-management. Research is also needed to understand patient report of remission overtime and whether or not patients who have a longer disease duration are more likely to report they are remission.

Limitations

This analysis is a secondary data analysis and therefore is limited to the data that was already collected. Other factors such as health literacy, race/ethnicity, and socioeconomic status have the potential to influence patient’s self-report of remission but were not measured. Patient-defined remission asked participants if they were currently in remission. However, there was no timeframe so patients could be reporting for the past week, month, six months, or longer. Patients in IBD Qorus were recruited from specialty clinics and may have more severe disease compared to the general population of patients with IBD. For instance, the IBD Qorus sample had 50% of UC patients with pancolitis whereas other published literature reports around 34% of UC patients with pancolitis.³² Data were obtained from electronic surveys collected for quality improvement. Therefore, selection bias may have occurred in which highly motivated patients or those who are more engaged with care may have been more likely to complete the online survey. Electronic surveys were used since the IBD diagnosis is verified by the healthcare provider.

Conclusion

Discordance exists between patient-defined remission and PROs among patients with UC and CD, with higher levels of discordance for patients with CD. For those patients who had discordance between patient-defined remission and validated PROs, patient confidence was significantly associated with discordance across disease types. Therefore, additional research focused on patient confidence and accuracy of patient-reported remission is needed.

Figure 1. Flow diagram of inclusion and exclusion criteria.

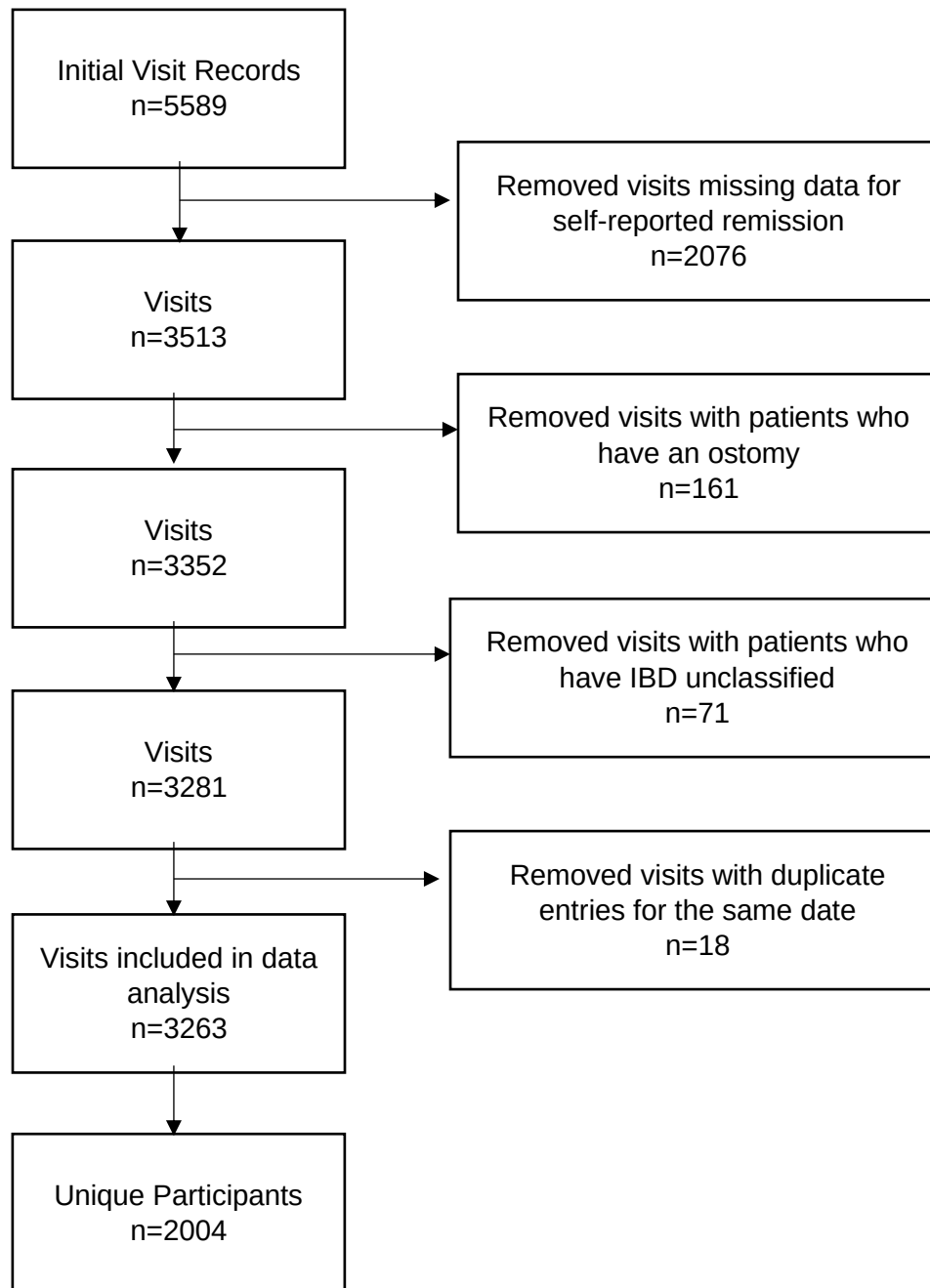


Table 1. Demographic and Clinical Characteristics of Patients with Ulcerative Colitis and Crohn's Disease from the IBD Qorus Collaborative.

	UC (n=806)	CD (n=1198)
Age – M (SD)	44.1 (15.5)	44.0 (15.6)
Gender – n (%)		
Female	466 (57.8%)	666 (55.6%)
Male	340 (42.2%)	526 (43.9%)
Other	0	1 (0.1%)
Duration of IBD – n (%)		
<5 years	246 (30.5%)	300 (25.0%)
5-10 years	189 (23.4%)	257 (21.7%)
11-15 years	144 (17.9%)	207 (17.3%)
>15 years	227 (28.2%)	434 (36.2%)
Current Medications – n (%)		
Current Steroid Use	87 (10.8%)	88 (7.3%)
Current Narcotic Use	22 (2.7%)	47 (3.9%)
IBD Care in the past 6 months – n (%)		
Hospitalization	50 (6.2%)	91 (7.5%)
Emergency Department	58 (7.2%)	102 (8.5%)
Patient Confidence – n (%)		
0-6	256 (31.8%)	376 (31.4%)
7-9	389 (48.3%)	587 (49.0%)
10 (highest health confidence)	161 (20.0%)	234 (19.5%)
Patient-defined Remission – n (%)		
Patient-defined Active Disease	368 (45.7%)	630 (52.6%)
Patient-defined Remission	438 (54.3%)	568 (47.4%)
Ulcerative Colitis Extent – n (%)		
Proctitis	100 (12.4%)	--
Left-sided	204 (25.3%)	--
Pan-colitis	424 (52.6%)	--
J-pouch	31 (3.9%)	--
Not sure	47 (5.8%)	--
Crohn's Disease Phenotype – n (%)		
Non-Stricturing and Non-Penetrating	--	588 (49.1%)
Stricturing and Non-Penetrating	--	306 (25.5%)
Penetrating and Non-Stricturing	--	142 (11.9%)
Penetrating and Stricturing	--	157 (13.%)
Crohn's Disease Location – n (%)		
Ileal	--	321 (26.8%)
Colonic	--	248 (20.7%)
Ileocolonic	--	567 (47.3%)
J-pouch	--	19 (1.6%)
Not sure	--	5 (0.4%)
Upper GI involvement	--	36 (3.0%)
Perianal involvement	--	183 (15.3%)

	UC (n=806)	CD (n=1198)
Number of Patient Visits – n (%)		
1 Visit	522 (39.7%)	763 (39.2%)
2 Visits	322 (24.4%)	502 (25.8%)
3 Visits	204 (15.5%)	330 (16.9%)
4+ Visits	268 (20.4%)	352 (18.1%)

UC = ulcerative colitis, CD = Crohn's disease

Note: -- indicates not applicable

Table 2. Patient-Reported Outcome Measures in Ulcerative Colitis and Crohn's Disease based on Patient Visits

	UC (n=1,316)	CD (n=1,947)
<i>Ulcerative Colitis - PRO2</i>		
Rectal Bleeding – n (%)		
No blood in stool	1005 (76.4%)	
Blood less than 50% of time	208 (15.8%)	
Blood 50% or more of time	103 (7.8%)	
Stool Frequency – n (%)		
Less stool than normal	84 (6.4%)	
Normal number of stools	718 (54.6%)	
1-2 stools more than normal	252 (19.1%)	
3-4 stools more than normal	144 (10.9%)	
5 or more stools more than normal	118 (9.0%)	
Patient Reported Outcome (PRO2) – n (%)		
Remission	718 (54.6%)	
Active	598 (45.4%)	
<i>Crohn's Disease - PRO3</i>		
Number of Soft Stools on Average – M (SD)		1.9 (2.5)
Abdominal Pain – n (%)		
None		1067 (54.9%)
Mild		590 (30.3%)
Moderate		251 (12.9%)
Severe		39 (2.0%)
General Well-being – n (%)		
Generally well		1099 (56.4%)
Slightly below par		534 (27.4%)
Poor		225 (11.6%)
Very poor		74 (3.8%)
Terrible		15 (0.8%)
Patient Reported Outcome (PRO3) – n (%)		
Remission		1234 (63.4%)
Active		713 (36.6%)

UC = ulcerative colitis, CD = Crohn's disease

Note: Data presented in this table is based on total patient visits.

Table 3: Epidemiological 2x2 Table for Sensitivity and Specificity of Patient-Defined Remission (test result) for Patient-Reported Outcome (true disease state) for Patients with Ulcerative Colitis

	PRO2 Remission (n=718)	PRO2 Active Disease (n=598)
Patient-defined Remission	553	115
Patient-defined Active Disease	165	483

Adjusted Sensitivity = 0.77, Adjusted Specificity = 0.79, Adjusted Concordance = 0.78, Adjusted Discordance: 0.22

Note: numbers are visit counts, sensitivity, specificity, concordance, and discordance are adjusted for multiple surveys using Generalized Estimating Equations (GEE)

Table 4: Epidemiological 2x2 Table for Sensitivity and Specificity of Patient-Defined Remission (test result) for Patient-Reported Outcome (true disease state) for Patients with Crohn's Disease

	PRO3 Remission (n=1234)	PRO3 Active Disease (n=713)
Patient-defined Remission	781	148
Patient-defined Active Disease	453	565

Adjusted Sensitivity = 0.62, Adjusted Specificity = 0.79, Adjusted Concordance = 0.68, Adjusted Discordance = 0.32

Note: numbers are visit counts, sensitivity, specificity, concordance, and discordance are adjusted for multiple surveys using Generalized Estimating Equations (GEE)

Table 5: Multivariable Logistic Regression Models for Patient-Defined Active Disease among Patients with Remission on PROs, Stratified by Disease Type

	UC (n=657)	CD (n=1226)
	OR (95% CI)	OR (95% CI)
Age (ref: <30 years)		
30-40 years	0.83 (0.45, 1.55)	1.00 (0.67, 1.50)
41-50 years	1.29 (0.65, 2.56)	1.21 (0.76, 1.93)
51-60 years	1.09 (0.52, 2.31)	1.07 (0.64, 1.78)
>60 years	0.89 (0.44, 1.80)	0.82 (0.49, 1.34)
Male gender (ref: female and other)	0.97 (0.63, 1.49)	1.09 (0.82, 1.46)
IBD duration (ref: >15 years)		
<5 years	1.97 (1.12, 3.49)	1.45 (0.99, 2.14)
5-10 years	0.87 (0.47, 1.63)	0.97 (0.63, 1.50)
11-15 years	0.82 (0.39, 1.71)	0.98 (0.66, 1.47)
Current prednisone use	1.39 (0.57, 3.39)	3.41 (1.70, 6.84)
Current narcotics use	0.98 (0.28, 3.38)	4.41 (1.54, 12.62)
Hospitalization in the past 6 months	3.56 (0.81, 15.72)	1.06 (0.45, 2.49)
Emergency Department in the past 6 months	0.98 (0.35, 2.77)	3.06 (1.30, 7.16)
Patient Confidence (ref: 10)		
6 and lower	9.64 (4.64, 20.00)	11.75 (7.37, 18.75)
9-7	4.46 (2.33, 8.54)	3.57 (2.46, 5.17)

PRO = patient-reported outcomes, UC = ulcerative colitis, CD = Crohn's disease, ref = reference group

Note: Odds Ratios are the odds of discordance. Discordance is defined as patient-reported active disease despite remission based on PROs.

Table 6: Multivariable Logistic Regression Models for Patient-Defined Remission among Patients with Active Disease on PROs, Stratified by Disease Type

	UC (n=658)	CD (n=707)
	OR (95% CI)	OR (95% CI)
Age (ref: <30 years old)		
30-40 years	1.05 (0.52, 2.12)	2.62 (1.14, 6.00)
41-50 years	1.02 (0.47, 2.19)	1.74 (0.72, 4.20)
51-60 years	0.84 (0.34, 2.07)	1.71 (0.72, 4.06)
>60 years	1.37 (0.64, 2.90)	2.67 (1.15, 6.21)
Male gender (ref: female and other)	1.07 (0.65, 2.90)	1.14 (0.72, 1.81)
IBD duration (ref: <5 years)		
5-10 years	1.30 (0.71, 2.40)	2.19 (1.01, 4.78)
11-15 years	1.65 (0.83, 3.28)	2.34 (1.06, 5.21)
>15 years	1.10 (0.55, 2.17)	2.68 (1.38, 5.19)
Current prednisone use	0.49 (0.24, 0.98)	0.44 (0.18, 1.07)
Current narcotics use	0.80 (0.18, 3.56)	0.29 (0.08, 1.07)
Hospitalization in the past 6 months	1.88 (0.62, 5.73)	0.59 (0.18, 1.89)
Emergency Department in the past 6 months	0.65 (0.21, 2.00)	0.58 (0.21, 1.57)
Patient Confidence (ref: 10)		
6 and lower	0.06 (0.03, 0.13)	0.08 (0.04, 0.16)
7-9	0.23 (0.12, 0.43)	0.28 (0.14, 0.55)

PRO = patient-reported outcomes, UC = ulcerative colitis, CD = Crohn's disease, ref = reference group

Note: Odds Ratios are the odds of discordance. Discordance is defined as patient-reported remission disease despite active disease based on PROs.

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