**Validation of the IBD-Control Questionnaire across different sociodemographic and clinical subgroups: Secondary analysis of a nationwide electronic survey**

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**Abstract**

**Background** The IBD-Control Questionnaire is a simple, generic measure of patient-perceived disease control used increasingly in clinical practice and research. We aimed to address knowledge gaps in its psychometric performance, to ensure that it can be used with confidence in a variety of contexts.

**Methods** We analysed 7,341 responses to theIBD Registry COVID-19 survey, sent to 40,911 patients who completed an online self-assessment tool during the pandemic. Questions covered demographics, comorbidities, IBD sub-type, IBD-Control Questionnaire and symptom scores (CD-PRO2 or UC-PRO2). Psychometric properties of IBD-Control-8 were tested overall and within subgroups (CD, UC and IBD-U; male and female; ≤65 and > 65 years; number of co-morbidities; deprivation status).

**Results** Internal consistency was very strong overall (α: 0.84, ω: 0.89) and for each subgroup (α range: 0.81-0.85; ω: 0.86-0.90). Construct validity was demonstrated by moderate correlation of each item with global rating (VAS) (rs range: 0.47 to 0.65), strong correlation between IBD-Control-8 score and VAS (rs=0.74), moderate-to-strong with PRO2 scores (CD: rs = -0.718; UC: rs = -0.602) and significantly higher IBD-Control-8 scores for PRO2-remission versus -active, consistent across subgroups. Exploratory and Confirmatory Factor Analyses demonstrated a two-factor model (items loading onto ‘Health-related Quality of Life’ [HRQoL] or ‘Treatment’ domains). Extensive tests for factorial invariance confirmed consistency.

**Conclusions** IBD-Control-8 is a psychometrically robust scale which can be used across a range of populations. It offers a quick, reliable and valid method of assessing patient-perceived control. The construct of “control” includes traditional HRQoL and a novel domain relating to treatment perception.

**Keywords:** Inflammatory Bowel Disease; Patient Reported Outcome Measures

**Introduction**

The potential for patient-reported outcome measures (PROMs) to support patient-centred care, quality improvement and research for inflammatory bowel disease (IBD) is increasingly recognised.1,2 Condition-specific PROMs vary in their outcome coverage, ranging from very short instruments (e.g. eliciting information about two dominant symptoms)3,4 to multi-item questionnaires (measuring the broader construct of health-related quality of life [HRQoL] which encompasses physical, social and psychological impacts of disease).5–7 Multidomain instruments measuring HRQoL have been available for decades and continue to be developed, albeit there has been limited evidence of uptake beyond research settings.

The Inflammatory Bowel Disease Control Questionnaire (IBD-Control) was developed to measure “disease control from the patient perspective”.8 Its intended purpose was to provide a simple, intuitive screening tool for routine clinical practice. The guiding principal was to create a PROM that was generic enough to be relevant to any person living with IBD, irrespective of disease type, dominant symptoms, location, severity or behaviour. Hence, checklists of individual gastrointestinal symptoms were excluded in favour of broad, generic items. The conceptual model for “disease control” extended beyond the traditional notion of HRQoL to include patient perceptions about current treatment.8

The instrument’s main score is based on just eight questions (IBD-Control-8), of which five cover generic areas of HRQoL (pain or discomfort; symptoms disturbing sleep; fatigue; anxiety or depression; interference with normal activities) and three are relevant to the treatment domain. The PROM includes a visual analogue scale to elicit an overall self-rating of disease control. Originally developed in English, the IBD-Control has been independently translated into a number of other languages,9–12 with accumulating evidence of cross-cultural validity.9 Since its publication, it has achieved international endorsements13,14 and uptake in clinical practice,13 disease registries9,12,15 and varied research settings.16,2,17–19 This suggests that measurement of patient-perceived control using this simple, generic tool resonates with patients, clinicians and researchers.

The use of any PROM in such diverse contexts requires ongoing validation to ensure measurement properties are consistent. The initial validation paper8 did not include factor analyses exploring, and confirming, the structure of the IBD-Control scale to allow specific identification of the underlying constructs that it is measuring. Furthermore, it is critical to demonstrate that the scale structure is valid in different circumstances (e.g. during active illness compared to remission) and in different populations (e.g. across IBD subtypes, gender, age and deprivation groups and people with comorbidities) to ensure that it can be used with confidence by clinicians in a variety of contexts.

In the present study we aimed to expand the evidence base for the validity of the IBD-Control Questionnaire by applying factor analysis (exploratory and confirmatory), tests of factorial invariance and measures of construct validity across different socioeconomic and clinical subgroups. Analysis of data from an online survey undertaken by the UK IBD Registry provided a unique opportunity to investigate previously unreported properties of IBD-Control using a very large, nationwide sample.

**Materials and Methods**

**Data Source: The IBD Registry COVID-19 follow-up survey**

During the early phase of the COVID-19 pandemic, the UK IBD Registry and British Society of Gastroenterology developed and launched an online self-assessment tool to allow patients to determine risk level and support decisions about “shielding”.20 This tool used the Research Electronic Data Capture (REDCap®), a secure web-based application for building and managing online surveys.21 Of the patients who used the tool, 40,911 provided permission to be contacted for a follow-up survey which was hosted on the same platform. Invitations to participate in the follow-up survey were sent out in May 2021 via e-mail or SMS depending on preferences indicated when completing the tool. Reminders were sent by preferred contact method in mid-June 2021. The survey remained open to completion until the end of the study period (November 2021).

In addition to demographics (age, gender, ethnicity, place of residence), self-reported IBD diagnosis (CD, UC, IBD-U), selected comorbidities (in five categories: hypertension; respiratory or chest disease; angina, heart attack or stroke; heart failure; and heart valve disease) and current drug treatments, the survey included items relating to exposure to COVID-19; symptoms, testing and treatment for COVID-19; vaccination status; and a number of health-related outcomes. The PROMs included the IBD-Control Questionnaire8 and symptom-based scores.3,4 The electronic implementation of IBD-Control comprised the eight items required to generate the summary score (IBD-Control-8), the transitional question (same, better, worse) and the IBD-Control-VAS (Visual Analogue Scale). The IBD-Control-8 score ranges from 0 (worst) to 16 (best), whereas the VAS is scored 0 to 100 (0 = worst control).

Depending on self-reported diagnosis, patients were asked to complete a relevant two-symptom instrument, or “PRO2”. The CD-PRO2 is a subscore of the Crohn’s Disease Activity Index (CDAI) and asks about number of liquid stools per day and abdominal pain (0 = none, 1 = mild, 2 = moderate, 3 = severe) over each of the last seven days.4 The 7-day average scores are summed to calculate an unweighted score. The weighted CD-PRO2 score is calculated by multiplying the 7-day averages of the number of liquid stools and abdominal pain by 2 and 5 respectively, before summing. Disease remission is defined by a weighted CD-PRO2 score <8.4 The UC-PRO2 is derived from the Mayo score and determines the number of stools above baseline (0 = normal number of stools, 1 = 1-2 stools above normal, 2 = 3-4 stools more than normal, 3 = 5 or more stools above normal) and rectal bleeding (0 = none, 1 = visible blood with stool less than half the time, 2 = visible blood with stool half of the time or more, 3 = passing blood alone).3 The scores of both items were summed to calculate a 6-point scale UC-PRO-2 summary score. Disease remission was defined by a score for number of stools above baseline <2 and the absence of rectal bleeding.3

**Subpopulations (strata) of interest**

For the purpose of validating consistent performance properties within different sub-populations, we undertook analyses stratified by diagnosis (IBD sub-type), age (≤65 and >65 years), sex at birth, socioeconomic status (based on the Index of Multiple Deprivation, derived from area of residence and categorized into population quintiles) and the presence of other chronic conditions (number of co-morbidities).

**Statistical and psychometric analysis**

All analyses were performed within the IBD Registry’s Trusted Research Environment using de-identified data extracted from REDCap to R (Version 4.1.0, R Core Team 2021, R Foundation for statistical computing, Vienna, Austria) using the *redcapAPI* package. Descriptive statistics for continuous variables are summarized as median (interquartile range, IQR) or mean (standard deviation, SD), as appropriate. We conducted univariate analysis using independent sample t-tests or analysis of variance (ANOVA), Mann-Whitney U test or Kruskal Wallis test and Chi-square test or Fisher’s exact test for continuous parametric, continuous non-parametric and categorical data, respectively. Spearman’s rank correlation coefficient was used as a non-parametric measure of correlation.

Factor structure was ascertained through a two stage process. Data was split at random (50%,50%) into a exploratory and confirmatory data set. For exploratory factor analysis (EFA) the analysis was ran on the polychoric correlation matrix rather than the raw data (due to the data being 3-level ordinal). The Kaiser–Meyer–Olkin (KMO) statistic was used to test sampling adequacy (values above 0.7 are considered good). Bartlett’s test of sphericity was used to assess whether correlations between items were sufficiently large for exploratory factor analysis, (p<0.05 is indicative of sufficient correlations). The number of factors was established using a parallel analysis, before running the exploratory factor analysis using an Oblimin rotation (as it was assumed factors would correlate). Item loading above 0.5 and not cross loading above 0.4 on another factor were considered valid loadings.

Following this a confirmatory factor analysis (CFA) of the structure identified by the EFA was conducted. A diagonally least squares estimator was used due to the data being ordinal.22 Items were free to load onto their factors, and factors were free to correlate with each another. Model fit was assessed using a range of fit indices. Two incremental fit indices were computed, the Tucker-Lewis Index (TLI) and comparative fit index (CFI), whereby values of above 0.90 being deemed acceptable and values of 0.95 deemed good.23 # The absolute fit index, the root mean square error of approximation (RMSEA), was also produced where values of 0.05 and under are deemed good, values of 0.08 and under are deemed fair, values between 0.08 and .010 are deemed mediocre, and values over 0.10 are considered a poor fit.23,24 Finally, another absolute fit index, the standardised root mean square residual (SRMR) was calculated, values less than 0.08 are considered a good fit.23 Modification indices were inspected; errors were allowed to covary if modification indices were >10, loaded on the same factor and the correlated error terms made conceptual sense.

Internal consistency of PROM items was tested using Cronbach’s alpha and McDonald’s omega (the former being the most common method although it assumes tau equivalence with recent recommendations suggesting McDonald’s omega being a superior measure).25 This was conducted on the full data set, and in subgroups.

Finally, we tested measurement invariance of the scale to ensure that the factor structure and related properties were consistent across different groups. Firstly, we tested configural invariance (whether the factor structure holds across the two samples) by fitting the factor structure identified with a grouping variable. This model was assessed using the same fit indices described for the CFA. This configural model was then compared to the metric invariance model, which was the same structure but fixing factor loadings across groups (intercepts allowed to vary), this shows if each item contributes to the factor in a similar manner across the groups. The validity of the metric model was assessed using CFI differences (∆CFI) <0.01, RMSEA differences (∆RMSEA) <0.015 and SRMR differences (∆SRMR) <0.03, as the cut offs for showing metric invariance. The metric invariance model was then compared to the scalar invariance model in which factor loadings and intercepts are assumed to be equal across our groups, this allows us to ascertain if we can validly compare the means of factors across groups. The assessment for this was the same as for metric invariance except the SRMR cut off was more strict with ∆SRMR<0.015 to indicate scalar invariance. Finally, we also tested strict invariance in which residuals as well as slopes and intercepts were assumed to be constant, thus elucidating if the items residual variances (i.e. unique variance) is consistent across groups. This model was compared with the metric invariance model, and the same cut offs were used for this as in the previous model comparison.26

**Ethical Approval**

The study was approved by the UK Health Research Authority (IRAS ID 295681) and Research Ethics Committee (REC ID 21/NI/0064). Respondents to the survey provided electronic consent for participation.

**Results**

**Demographics of survey respondents**

Of 40,911 patients invited to complete the COVID-19 follow-up survey, 7,341 (17.9%) returned a response of whom 7,337 completed the IBD-Control-8 and IBD-Control-VAS (99.9% completion rate). Completion rate for CD-PRO2 was 91.2% of 3,808 respondents reporting a diagnosis of CD and that for UC-PRO2 was 96.8% of 3,298 respondents. Baseline patient characteristics of respondents are summarized in **Table 1**,overall and by diagnosis. Median age of all respondents was 48 years (range: 18-92), sixty three percent of participants were female and 52% reported a diagnosis of CD, 45% of UC and 3.1% of IBD-U. One fifth of participants (19%) indicated one additional comorbidity and 5.5% reported two or more. One in twenty (5.1%) were taking prednisolone and two thirds (67%) reported being treated with an advanced medical therapy at the time of the survey.

**Patient-reported outcome data**

**Figure 1** illustrates the distribution of responses to individual IBD-Control items, overall and stratified by self-reported diagnosis (see **Supplementary Tables S1** and **S2** for tabulated data). Overall, one in five respondents (19%) did not think their IBD was well-controlled over the last two weeks, with a further 6.3% being unsure. For those individual items covering traditional HRQoL domains, one in five (21%) reported missing planned activities because of IBD in the last two weeks, around one in three reported waking up at night because of IBD (32%), suffering significant pain or discomfort (35%) or feeling anxious or depressed because of their condition (31%). Just over half (55%) reported often feeling lacking in energy (fatigued). For treatment-related questions, one in five were either unsure (16%) or did not believe (4.2%) that their current treatment was useful in controlling their IBD. One in ten (11%) thought that they needed a change to treatment and a further one in five respondents (21%) were unsure. The proportions of total respondents indicating control was better, same or worse over the last two weeks were 5.9%, 78% and 16%, respectively.

The median overall IBD-Control-8 summary score derived from item responses was 12.0 (Range: 0-16) and that of the stand-alone IBD-Control-VAS was 80 (Range: 0-100). Median scores were comparable for CD and UC. Based on the published cut-off score for “quiescent” disease (IBD-Control-8 ≥13), 3,614 (49.3%) of the total cohort would be thus classified. Corresponding figures for CD and UC were 43% and 57%, respectively.

For patients with CD,the median weighted CD-PRO2 score was 6 (range: 0-72), with 58.6% categorized as remission over the last week (score of 7 or less). For those with UC, median score of UC-PRO2 was zero (range: 0-6) with 66.9% classified as remission over the last three days (i.e. rectal bleeding absent and number of stools was less than two above baseline per day). However, there were 449 patients (6.19%) who reported the “worst possible” response for each of their two PRO-2 symptom items – i.e. had the highest possible score on the relevant PRO-2 scale.

**Internal consistency of IBD-Control-8 items**

Measures of internal consistency for the IBD-Control-8 were very strong overall (α = 0.84, ω = 0.89; n=7,337 patients), consistent with originally reported findings (α=0.85, n=299 patients).8 Uniquely in the present study, we confirmed that consistency was maintained within sub-groups of patients categorised by diagnosis, sex at birth, age groups and deprivation status (**Table 2**: α and ω values consistently above 0.80; α ranging from 0.81 to 0.85; ω ranging from 0.86 to 0.90).

**Construct validity of individual IBD-Control-8 items versus visual analogue scale**

The IBD-Control-VAS score is a surrogate global measure of the construct of interest, providing a numerical rating of patient-perceived control using a “feeling thermometer” approach. If the eight questions within the IBD-Control-8 are each measuring an element of the same concept, their scored responses should correlate significantly with the IBD-Control-VAS. These hypothesized relationships were confirmed (**Figure 2**), with each item demonstrating significant, moderate-to-strong correlations with the VAS. As expected, the strongest correlation was observed for the most global question item (Q1a, rs = 0.647, p<0.001) as opposed to the remaining seven items (rs values ranging from 0.472 to 0.576, all p values <0.001). These analyses were consistent across sub-groups by sex, socioeconomic status, age group and comorbidity status.

**Figure 2** also confirms that responses to each question behave as a 3-item ordinal Likert scale, with median scores for patients recording “Not Sure” consistently lying intermediate between those responding “Yes” or “No”. The latter finding is consistent with the simple scoring system for IBD-Control-8 items (which assigns 1-point for “Not Sure” and either zero or two points for definitive replies). The assumption of ordinal scaling of the three response options justifies our approach to constructing correlation matrices for factor analyses.

**Construct validity of IBD-Control-8 summary score versus visual analogue scale**

As expected, there was a strong correlation overall between the IBD-Control-8 score and IBD-Control-VAS (rs=0.738, p<0.001; **Figure 3**) and this was consistent across diagnoses (CD: rs = 0.747, p<0.001; UC: rs = 0.714, p<0.001; IBD-U: rs = 0.745, p<0.001). This relationship also held for both sexes (Males: rs = 0.701, p<0.001; Females: rs = 0.750, p<0.001), across age groups (Age <65: rs = 0.745, p<0.001; Age ≥ 65: rs = 0.667, p<0.001), socioeconomic groups (Deprivation Quintile 4 and 5: rs = 0.759, p<0.001; Deprivation Quintile 1 and 2: rs = 0.714, p<0.001), and for patients categorized according to number of additional co-morbidities (None: rs = 0.733, p<0.001; One or more: rs = 0.748, p<0.001).

**Construct validity of IBD-Control-8 summary score versus PRO-2 symptom scores**

The IBD-Control-8 summary score demonstrated moderately strong correlation with the relevant PRO-2 score for each main form of IBD (CD: rs = -0.718, p<0.001; UC: rs = -0.602, p<0.001). The strength of these significant correlations was comparable by sex, socioeconomic groups, age groups and according to co-morbidity status (rs values ranging from -0.665 to -0.739 [p<0.001] for CD; -0.537 to -0.640 [p<0.001] for UC). Furthermore, known-group comparisons confirmed significantly higher IBD-Control-8 scores in cases categorized as in remission, as compared to active disease, based on the relevant PRO2 cut-offs (**Figure 4**). These findings remained statistically consistent in stratified analyses for each of the sociodemographic and clinical subgroups.

**Exploratory Factor Analysis**

The EFA data set had correlations between items that was sufficient for the EFA (Bartlett’s test of sphericity: p <0.001), and the Kaiser-Meyer-Olkin measure of sampling adequacy was good (KMO = 0.89).The parallel analysis suggested the data had a two factor structure. Exploratory factor analysis found that items in the IBD-Control-8 mapped into two factors as follows: items relating to Treatment - Q1a, Q1b, and Q3f; items relating to HRQoL - Q3a, Q3b, Q3c, Q3d and Q3e (**Figure 5**). Both factors had Eigenvalues >1 (i.e. above Kaiser’s rule cut off for valid factors). Factor loadings are summarized in **Table 3**. Of note, Q1a had a cross-loading of 0.42, this is a general item asking about patient-perceived control, such that its cross-loading is consistent with the conceptual model of ‘control’ encompassing two discrete factors. We left this item to load onto factor one in the CFA, since any impact on fit would be identified using modification indices.

**Confirmatory Factor Analysis**

CFA was conducted using the factor structure identified above. The initial CFA model showed a good fit of the data (CFI = 0.996, TLI = 0.995, RMSEA = 0.045 [90% CI: 0.039 - 0.052], SRMR = 0.038). Modification indices (MI) showed that covariance should be added between two pairs of residuals within the domain of treatment (MIs ≥ 10 between Q1b and Q3f and Q1a and Q3f). Model fit improved when covariance was added (CFI = 0.999, TLI = 0.998, RMSEA = 0.025 [90% CI: 0.018 - 0.032], SRMR = 0.023).

These data provide strong empirical evidence that the overall measurement construct encompasses questions mapping to two sub-domains, namely HRQoL and treatment.

**Measurement invariance**

The IBD-Control-8 scale showed configural invariance across all groups with good model fit in all cases, suggesting that the factor structure remains consistent across IBD-subtypes, sociodemographics and in those with or without comorbidities (**Table 4**). Likewise, **Table 5** shows that there was metric invariance, which confirms that the scale items contribute to the factors in a similar way across these population strata. In addition, evidence for scalar invariance across groups was strong (**Table 5**), suggesting mean scores can be validly compared between subgroups. Finally, there was also strong evidence for strict invariance meaning that even the residuals were largely consistent across groups (**Table 5**). The only measure that did not show substantive evidence for scalar invariance was the ∆CFI for gender being borderline (0.01), although both the SRMR and RMSEA values were well below the cut offs for gender. Taken together, these data indicate that the IBD-Control-8 is a scale that works extremely well across different diagnoses/comorbidities and sociodemographic groups.

**Discussion**

This is the largest validation study for the IBD-Control Questionnaire reported to date and provides important new insights into its psychometric properties. Factor analysis confirms that the IBD-Control-8 has a two factor structure (HRQoL and Treatment) which remains remarkably consistent across a range of clinical and sociodemographic groups. The scale was also found to have extremely good internal reliability. We found moderate correlations between IBD-Control-8 and symptom-based PRO scores, consistent with original work demonstrating construct validity versus clinician-reported symptom-based indices, multi-item HRQoL measures and global clinician ratings.8 Correlation with PRO-2 scores *per se* has not been reported previously, nor has consistency of construct validity when tested across different population strata. Very high correlation between IBD-Control-8 scores and PRO-2 scores was neither expected nor desirable, since the concept of patient-perceived disease control covers a much broader construct than a symptom-based index.

IBD-Control was created as a generic screening tool that would be relevant to patients with either form of IBD, unlike symptom-based activity scores which need to be tailored to either Crohn’s disease or ulcerative colitis. Given its generic nature, we were keen to confirm that measurement properties were similar between Crohn’s disease and ulcerative colitis, males and females, younger and older age groups, and between those with, or without, additional chronic conditions. Our new evidence for invariance in instrument performance extended also to deprivation status, suggesting that responses to IBD-Control-8 items were not influenced by socioeconomic factors (e.g. educational attainment or employment status). The simple item wording and use of three-point Likert response options were deliberate design choices for IBD-Control, seeking to minimise burden of completion, scoring and interpretation in routine settings.8 Taken together, our findings suggest the IBD-Control-8 is a psychometrically robust scale which can be used reliability across a range of contexts and offers a quick method of assessing patient-perceived control of IBD.

Our study is the first to use factor analysis to generate empirical validation of the original conceptual model of the questionnaire. The eight questions mapped as expected to a two-factor model comprising HRQoL and the novel domain of “Treatment”. Although typically characterised by researchers as a HRQoL instrument, IBD-Control is distinct from traditional questionnaires5 that focus only on physical, psychological and social impacts of disease. Our findings lend credibility to the notion that patient-perceived disease control is a measurable construct encompassing more than traditional HRQoL domains. Feelings about treatment efficacy and tolerability contribute to a patient’s sense of disease control.8

Despite the emergence of “treat-to-target”27 and a rightful emphasis on biochemical, endoscopic, histologic and radiologic measures of inflammatory activity, the case for patient-centred assessments remains strong.1 The lived experience of patients with IBD is not solely driven by extent or severity of inflammation, nor is holistic management confined to decisions about anti-inflammatory drug treatment. IBD-Control was not developed to satisfy the stringencies proposed by regulatory agencies to serve as an outcome measure for clinical trials underpinning anti-inflammatory drug labelling claims.28 Instead, it offers a simple summary score of patient-perceived health status and contains a validated set of screening questions to highlight concerns across physical, social, psychological and treatment domains to inform patient-centric consultations and help to quantify therapeutic deficit.13 Our data provide reassurance of the stability of measurement properties across different population strata, which is timely given the expanding routine use of IBD-Control within ‘apps’,29 patient portals, quality improvement initiatives13, registries15,9,12 and research.2,16–19

Our study has some limitations. First, the participants were patients who engaged with an online self-assessment tool20 and replied to an electronic survey. Case mix will not be representative of the general IBD population. The higher proportion of female respondents is typical of online health-related activity.30 Public awareness of factors relevant to “shielding” during the early pandemic may have encouraged those taking steroids or advanced therapies to use the tool, as reflected in high rates of use of these agents in the sample. By definition, online surveys will miss digitally-excluded patients who lack access to, or ability to use, the internet. We did not have access to information about phenotypic classification but do not believe there is a reason why specific subgroups should have been excluded or under-represented in this survey on the basis of disease characteristics. The impact of potential sources of selection bias is largely mitigated by very large numbers (20-fold greater than typical PROM validation studies) and by the broad geographical and sociodemographic coverage. Although an electronic survey is unlikely to have included currently-hospitalised cases, there were significant numbers of cases reporting “worst possible” symptoms on the relevant PRO-2 score.

Second, the survey relied on self-reported, as opposed to clinician-reported, IBD diagnosis. We cannot exclude the possibility that some respondents did not have IBD. However, numbers are likely to be small given that almost all provided details of their verifiable local IBD Service (99.6%). Third, a cross-sectional survey does not allow assessment of test-retest reliability or sensitivity to change in health status as repeated measures are needed. Evidence for such attributes for IBD-Control has been published previously.8,12,13

In conclusion, we have shown that the IBD-Control Questionnaire is feasible to collect electronically at a very large, national scale to capture a global measure of patient-perceived disease control. We have demonstrated for the first time that it has strong consistency and validity across sociodemographic and clinical subgroups and confirmed the expected two-factor representation of the instrument. The measurement of patient-perceived control may offer additional insights beyond traditional PROMs focused on selected symptoms3,4 or HRQoL alone.5 Further research is needed to determine whether routine measurement of self-reported disease control (alone or in combination with other PROMs or non-invasive biomarkers) can support improvements in care with respect to safety, treatment outcome, cost-effectiveness or patient experience. Growing uptake of IBD-Control by routine clinical services18, QI programs,13,16,19,31 international IBD registries9,12,15 and digital e-Health solutions29 offers future potential for diverse repositories of data to be linked for real-world outcomes research using this simple, generic but highly reliable and valid scale.

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**Conflict of interest**

F.T. and L.D. are employees of IBD Registry Ltd., a not-for-profit organisation owned by the British Society of Gastroenterology, the Royal College of Physicians and Crohn’s & Colitis UK.

**Data Availability**

Details of how to apply to use survey data held by the IBD Registry are available online: (<https://ibdregistry.org.uk/analysis-and-research/apply-to-use-our-data/>). For enquiries about data access, please e-mail: [analysis@ibdregistry.org.uk](mailto:analysis@ibdregistry.org.uk)

**Author contributions**

No additional writing assistance was used for this manuscript. K.B., P.C., G.G. and F.T. all contributed to design of the study. K.B., F.T., L.D., F.C., S.B. and N.K. contributed to design of the COVID-19 follow-up survey and its collection. G.G. and F.T. analyzed data, supervised by K.B. and P.C. K.B. drafted the manuscript. G.G. and P.C. critically revised the manuscript for important intellectual content. All authors have reviewed and approved the manuscript.

**Supplementary data**

Supplementary data are available at: [journal link]

**Table 1:** **Demographic and clinical characteristics of survey respondents and summary statistics for patient-reported outcome measures.** Overall population (n=7,337) and stratified by self-reported diagnosis

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Characteristic** | **Overall** | **Crohn's disease** | **Ulcerative colitis** | **IBD unclassified** |
| **Number of respondents** | 7,337 | 3,808 | 3,298 | 231 |
| **Age,** median (IQR) | 48 (36, 58) | 46 (35, 57) | 49 (38, 60) | 46 (34, 59) |
| **Sex** |  |  |  |  |
| Female | 4,608 (63%) | 2,465 (65%) | 1,989 (60%) | 154 (67%) |
| Male | 2,729 (37%) | 1,343 (35%) | 1,309 (40%) | 77 (33%) |
| **Deprivation Status (Quintile)** |  |  |  |  |
| 1 – least deprived area | 2,003 (27%) | 1,007 (27%) | 934 (29%) | 62 (27%) |
| 2 | 1,791 (25%) | 908 (24%) | 831 (25%) | 52 (23%) |
| 3 | 1,524 (21%) | 782 (21%) | 686 (21%) | 56 (24%) |
| 4 | 1,246 (17%) | 681 (18%) | 530 (16%) | 35 (15%) |
| 5 – most deprived area | 721 (9.9%) | 401 (11%) | 294 (9.0%) | 26 (11%) |
| **Place of residence** |  |  |  |  |
| England | 6,340 (87%) | 3,274 (87%) | 2,874 (88%) | 192 (83%) |
| Wales | 352 (4.8%) | 181 (4.8%) | 159 (4.9%) | 12 (5.2%) |
| Scotland | 502 (6.9%) | 264 (7.0%) | 214 (6.5%) | 25 (11%) |
| Northern Ireland | 94 (1.3%) | 63 (1.7%) | 29 (0.9%) | 2 (0.9%) |
| **Oral steroids (current)** |  |  |  |  |
| Yes | 407 (5.5%) | 185 (4.9%) | 212 (6.5%) | 10 (4.4%) |
| No | 6,869 (94%) | 3,591 (94%) | 3,061 (93%) | 217 (94%) |
| Unsure | 59 (0.8%) | 30 (0.8%) | 25 (0.8%) | 4 (1.7%) |
| **Advanced IBD therapies (current)** | 4,896 (67%) | 2,956 (78%) | 1,838 (56%) | 102 (46%) |
| **Number of comorbidities** |  |  |  |  |
| 0 | 5,510 (75%) | 5,510 (75%) | 2,920 (77%) | 2,437 (74%) |
| 1 | 1,425 (19%) | 1,425 (19%) | 713 (19%) | 652 (20%) |
| >1 | 402 (5.5%) | 402 (5.5%) | 175 (4.6%) | 209 (6.3%) |
| **Patient-reported symptoms** |  |  |  |  |
| CD-PRO2 weighted, *median (IQR)* | - | 6 (2, 12) | - | - |
| CD-PRO2 Remission, *n (%)* | - | 2,035 (59%) | - | - |
| UC-PRO2 score, *median (IQR)* | - | - | 0 (0, 1) | - |
| UC-PRO2 Remission, *n (%)* | - | - | 2,151 (67%) | - |
| **IBD-Control Questionnaire** |  |  |  |  |
| IBD-Control-8 score, *median (IQR)* | 12 (8, 16) | 12.0 (7.0, 15.0) | 14.0 (9.0, 16.0) | 12.0 (7.0, 15.5) |
| IBD-Control-8 Quiescent, *n (%)* | 3,614 (49%) | 1,637 (43%) | 1,872 (57%) | 105 (45%) |
| IBD-Control-VAS, *median (IQR)* | 80 (61, 94) | 80 (55, 90) | 85 (69, 95) | 78 (55, 90) |
| IBD-Control-VAS Quiescent, *n (%)* | 3,259 (44%) | 1,504 (39%) | 1,662 (50%) | 93 (40%) |

**Table 2: Internal consistency of the IBD-Control-8 scale, overall and by sub-groups**

|  |  |  |  |
| --- | --- | --- | --- |
| **Group** | **Cronbach’s alpha (α)** | **McDonald’s omega (ω) Total** | **McDonald’s omega (ω) Hierarchical** |
| **Overall** | 0.84 | 0.89 | 0.72 |
| **By diagnosis**  0.667 | | | |
| CD | 0.84 | 0.89 | 0.71 |
| UC | 0.84 | 0.89 | 0.72 |
| IBD-U | 0.85 | 0.90 | 0.69 |
| **By gender**  0.733 | | | |
| Male | 0.83 | 0.88 | 0.71 |
| Female | 0.84 | 0.89 | 0.72 |
| **By age group** | | | |
| ≥65 | 0.81 | 0.86 | 0.67 |
| <65 | 0.84 | 0.89 | 0.72 |
| **By deprivation index** | | | |
| 1 and 2 | 0.83 | 0.89 | 0.72 |
| 4 and 5 | 0.85 | 0.90 | 0.73 |
| **By number of comorbidities** | | | |
| No comorbidities | 0.84 | 0.89 | 0.72 |
| ≥1 comorbidity | 0.85 | 0.89 | 0.73 |

Table 3: Factor loadings for IBD-Control-8 question items.

|  |  |  |
| --- | --- | --- |
| **Question item** | **Factor 1** | **Factor 2** |
| Q1a. Your IBD has been well controlled in the past two weeks? | 0.42 | **0.54** |
| Q1b. Your current treatment is useful in controlling your IBD? | -0.07 | **1.02** |
| Q3a. Miss any planned activities because of IBD? | **0.77** | 0.07 |
| Q3b. Wake up at night because of symptoms of IBD? | **0.77** | 0.05 |
| Q3c. Suffer from significant pain or discomfort? | **0.85** | 0.02 |
| Q3d. Often feel lacking in energy (fatigued)? | **0.84** | -0.11 |
| Q3e. Feel anxious or depressed because of your IBD? | **0.72** | 0.05 |
| Q3f. Think you needed a change to your treatment? | 0.24 | **0.67** |

Data represent the regression coefficients. Bold values indicate which factor each items loads onto.

Table 4:Configural invariance model fit indices across different groups

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Grouped by:** | **RMSEA** | **CFI** | **TLI** | **SRMR** |
| Diagnosis | 0.038 | 0.99 | 0.99 | 0.033 |
| Gender | 0.038 | 0.99 | 0.99 | 0.032 |
| Age category | 0.039 | 0.99 | 0.99 | 0.032 |
| Comorbidities | 0.039 | 0.99 | 0.99 | 0.032 |
| Deprivation | 0.036 | 0.99 | 0.99 | 0.031 |
| RMSEA = Root mean square error of approximation; CFI = Comparative fit index; TLI = Tucker-Lewis index SRMR = Standardized Root Mean Square Residual; Comorbidities = number of comorbidities; Deprivation = Deprivation index category (Quintile). | | | | |

**Table 5:** **Metric, scalar and strict invariance across groups**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **Metric** | | | **Scalar** | | | **Strict** | | |
| **Grouped by:** | **∆RMSEA** | **∆CFI** | **∆SRMR** | **∆RMSEA** | **∆CFI** | **∆SRMR** | **∆RMSEA** | **∆CFI** | **∆SRMR** |
| Diagnosis | -0.001 | -0.001 | 0.001 | -0.001 | -0.001 | 0.002 | 0.01 | -0.008 | 0.009 |
| Gender | 0.004 | -0.003 | 0.004 | 0.001 | -0.002 | 0.003 | 0.011 | -0.010 | 0.011 |
| Age category | 0.002 | -0.002 | 0.003 | -0.002 | 0.000 | 0.001 | 0.003 | -0.003 | 0.007 |
| Comorbidities | -0.002 | 0.000 | 0.001 | -0.001 | 0.000 | 0.001 | 0.000 | -0.001 | 0.001 |
| Deprivation | 0.003 | -0.002 | 0.003 | -0.002 | 0.000 | 0.000 | 0.010 | -0.007 | 0.009 |

RMSEA = Root mean square error of approximation; CFI = Comparative fit index; SRMR = Standardized Root Mean Square Residual; Comorbidities = number of comorbidities; deprivation = Deprivation index category (Quintile).

**Figure 1: Distribution of responses to individual question items of the IBD-Control-8 among 7,337 survey respondents.** Overall (**Total**) and stratified by diagnosis (Crohn’s disease [**CD**], n=3,808; ulcerative colitis [**UC**], n=3,298; inflammatory bowel disease unclassified [**IBD-U**], n=231). “Negative” ratings indicate an answer of “No” for questions 1a and 1b, or “Yes” for Questions 3a to 3f, which are scored as zero in the summary score. Conversely, “Positive” ratings indicate an answer of “Yes” for questions 1a and 1b, or “No” for Questions 3a to 3f, which are scored as 2-points in the summary score. “Neutral” ratings indicate answers of “Not Sure” for all questions, which are allocated a score of 1-point.

Chart, box and whisker chart

Description automatically generated

**Figure 2:** **IBD-Control-VAS scores according to responses to each of the IBD-Control-8 items**. (A) IBD-Control 1a. Spearman’s R (Rs) = 0.647, p<0.001; (B) IBD-Control 1b. Rs= 0.487, p<0.001; (C) IBD-Control 3a. Rs= 0.472, p<0.001; (D) IBD-Control 3b. Rs= 0.527, p<0.001; (E) IBD-Control 3c. Rs= 0.553, p<0.001; (F) IBD-Control 3d. Rs= 0.455, p<0.001; (G) IBD-Control 3e. Rs= 0.475, p<0.001; (H) IBD-Control 3f. Rs= 0.576, p<0.001. Median IBD-Control-VAS scores were significantly different between the three response options for each of the eight items of IBD-Control (p<0.001, Kruskal-Wallis).

Chart

Description automatically generated

Figure 3: IBD-Control-VAS scores according to IBD-Control-8 score, overall and by diagnosis: (A) Overall. Spearman’s Rs= 0.738, p<0.001; Kruskal-Wallis: p<0.001 (B) Crohn’s disease. Rs= 0.747, p<0.001; Kruskal-Wallis: p<0.001 (C) Ulcerative colitis. Rs= 0.714, p<0.001; Kruskal-Wallis: p<0.001 (D) IBD-U. Rs= 0.745, p<0.001; Kruskal-Wallis: p<0.001. Boxplots show median (bold bar), interquartile range (shaded box) and range (error bars) of IBD-Control-VAS scores.

Chart, box and whisker chart

Description automatically generated

Figure 4: IBD-Control-8 scores according to remission status, defined using cut-offs for symptom-based scores (PRO2). (A) Overall, Wilcoxon: p<0.001; (B) Crohn’s disease. Wilcoxon: p<0.001; (C) Ulcerative colitis. Wilcoxon: p<0.001. These data provide evidence of known-groups construct validity.

**Diagram

Description automatically generated**

Figure 5: Exploratory factor analysis (EFA) confirming a two-factor representation for the measurement construct of IBD-Control-8. The eight items load to either a “Treatment” factor or to a second factor representing the traditional notion of Health-related Quality of Life (HRQoL). Values are factor loadings which represent standardized regression coefficients.

**Supplementary Table S1 Responses to individual items of the IBD-Control-8, overall and by self-reported diagnosis (as shown in Figure 1)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Question Item** | **Overall** | **Crohn's disease** | **Ulcerative colitis** | **IBD unclassified** |
|  | n=7,337 | n=3,808 | n=3,298 | n=231 |
| **1a. Your IBD has been well controlled in the past two weeks?** |  |  |  |  |
| No | 1,382 (19%) | 759 (20%) | 572 (17%) | 51 (22%) |
| Not sure | 459 (6.3%) | 277 (7.3%) | 162 (4.9%) | 20 (8.7%) |
| Yes | 5,496 (75%) | 2,772 (73%) | 2,564 (78%) | 160 (69%) |
| **1b. Your current treatment is useful in controlling your IBD?** |  |  |  |  |
| No | 307 (4.2%) | 165 (4.3%) | 136 (4.1%) | 6 (2.6%) |
| Not sure | 1,189 (16%) | 703 (18%) | 426 (13%) | 60 (26%) |
| Yes | 5,841 (80%) | 2,940 (77%) | 2,736 (83%) | 165 (71%) |
| **2. Have your bowel symptoms been getting worse, getting better or not changed?** |  |  |  |  |
| Better | 430 (5.9%) | 186 (4.9%) | 226 (6.9%) | 18 (7.8%) |
| No change | 5,700 (78%) | 2,967 (78%) | 2,555 (77%) | 178 (77%) |
| Worse | 1,207 (16%) | 655 (17%) | 517 (16%) | 35 (15%) |
| **3a. Miss any planned activities because of IBD?** |  |  |  |  |
| Yes | 1,527 (21%) | 921 (24%) | 551 (17%) | 55 (24%) |
| Not sure | 77 (1.0%) | 47 (1.2%) | 28 (0.8%) | 2 (0.9%) |
| No | 5,733 (78%) | 2,840 (75%) | 2,719 (82%) | 174 (75%) |
| **3b. Wake up at night because of symptoms of IBD?** |  |  |  |  |
| Yes | 2,314 (32%) | 1,458 (38%) | 778 (24%) | 78 (34%) |
| Not sure | 147 (2.0%) | 75 (2.0%) | 68 (2.1%) | 4 (1.7%) |
| No | 4,876 (66%) | 2,275 (60%) | 2,452 (74%) | 149 (65%) |
| **3c. Suffer from significant pain or discomfort?** |  |  |  |  |
| Yes | 2,567 (35%) | 1,495 (39%) | 974 (30%) | 98 (42%) |
| Not sure | 212 (2.9%) | 107 (2.8%) | 101 (3.1%) | 4 (1.7%) |
| No | 4,558 (62%) | 2,206 (58%) | 2,223 (67%) | 129 (56%) |
| **3d. Often feel lacking in energy (fatigued)?** |  |  |  |  |
| Yes | 4,041 (55%) | 2,313 (61%) | 1,606 (49%) | 122 (53%) |
| Not sure | 339 (4.6%) | 159 (4.2%) | 171 (5.2%) | 9 (3.9%) |
| No | 2,957 (40%) | 1,336 (35%) | 1,521 (46%) | 100 (43%) |
| **3e. Feel anxious or depressed because of your IBD?** |  |  |  |  |
| Yes | 2,239 (31%) | 1,273 (33%) | 891 (27%) | 75 (32%) |
| Not sure | 465 (6.3%) | 227 (6.0%) | 224 (6.8%) | 14 (6.1%) |
| No | 4,633 (63%) | 2,308 (61%) | 2,183 (66%) | 142 (61%) |
| **3f. Think you needed a change to your treatment?** |  |  |  |  |
| Yes | 779 (11%) | 442 (12%) | 297 (9.0%) | 40 (17%) |
| Not sure | 1,538 (21%) | 845 (22%) | 634 (19%) | 59 (26%) |
| No | 5,020 (68%) | 2,521 (66%) | 2,367 (72%) | 132 (57%) |

**Supplementary Table S2 Responses to individual items of the IBD-Control-8 stratified by population strata**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Question Item** | **Sex at birth** | | **Age Group** | | **Number of comorbidities** | | **Deprivation Status** | |
| **Males** | **Females** | **<65 yrs** | **≥65 yrs** | **None** | **≥1** | **Quintile 1**  Least deprived area | **Quintile 5**  Most deprived area |
|  | N=2,729 | N=4,608 | N=6,276 | N=1,065 | N=5,510 | N=1,827 | N=2,003 | N=721 |
| **1a. Your IBD has been well controlled in the past two weeks?** | | | | | | | | |
| No | 381 (14%) | 1,001 (22%) | 1,258 (20%) | 124 (12%) | 1,024 (19%) | 358 (20%) | 301 (15%) | 179 (25%) |
| Not sure | 141 (5.2%) | 318 (6.9%) | 394 (6.3%) | 65 (6.1%) | 322 (5.8%) | 137 (7.5%) | 104 (5.2%) | 63 (8.7%) |
| Yes | 2,207 (81%) | 3,289 (71%) | 4,622 (74%) | 874 (82%) | 4,164 (76%) | 1,332 (73%) | 1,598 (80%) | 479 (66%) |
| **1b. Your current treatment is useful in controlling your IBD?** | | | | | | | | |
| No | 83 (3.0%) | 224 (4.9%) | 291 (4.6%) | 16 (1.5%) | 242 (4.4%) | 65 (3.6%) | 63 (3.1%) | 48 (6.7%) |
| Not sure | 376 (14%) | 813 (18%) | 1,033 (16%) | 156 (15%) | 848 (15%) | 341 (19%) | 284 (14%) | 142 (20%) |
| Yes | 2,270 (83%) | 3,571 (77%) | 4,950 (79%) | 891 (84%) | 4,420 (80%) | 1,421 (78%) | 1,656 (83%) | 531 (74%) |
| **2. Have your bowel symptoms been getting worse, getting better or not changed?** | | | | | | | | |
| Better | 172 (6.3%) | 258 (5.6%) | 359 (5.7%) | 71 (6.7%) | 321 (5.8%) | 109 (6.0%) | 104 (5.2%) | 49 (6.8%) |
| No change | 2,242 (82%) | 3,458 (75%) | 4,823 (77%) | 878 (83%) | 4,306 (78%) | 1,394 (76%) | 1,623 (81%) | 509 (71%) |
| Worse | 315 (12%) | 892 (19%) | 1,092 (17%) | 115 (11%) | 883 (16%) | 324 (18%) | 276 (14%) | 163 (23%) |
| **3a. Miss any planned activities because of IBD?** | | | | | | | | |
| Yes | 404 (15%) | 1,123 (24%) | 1,416 (23%) | 111 (10%) | 1,124 (20%) | 403 (22%) | 329 (16%) | 223 (31%) |
| Not sure | 23 (0.8%) | 54 (1.2%) | 67 (1.1%) | 10 (0.9%) | 55 (1.0%) | 22 (1.2%) | 25 (1.2%) | 12 (1.7%) |
| No | 2,302 (84%) | 3,431 (74%) | 4,791 (76%) | 942 (89%) | 4,331 (79%) | 1,402 (77%) | 1,649 (82%) | 486 (67%) |
| **3b. Wake up at night because of symptoms of IBD?** | | | | | | | | |
| Yes | 670 (25%) | 1,644 (36%) | 2,084 (33%) | 230 (22%) | 1,658 (30%) | 656 (36%) | 510 (25%) | 323 (45%) |
| Not sure | 65 (2.4%) | 82 (1.8%) | 122 (1.9%) | 25 (2.4%) | 97 (1.8%) | 50 (2.7%) | 33 (1.6%) | 9 (1.2%) |
| No | 1,994 (73%) | 2,882 (63%) | 4,068 (65%) | 808 (76%) | 3,755 (68%) | 1,121 (61%) | 1,460 (73%) | 389 (54%) |
| **3c. Suffer from significant pain or discomfort?** | | | | | | | | |
| Yes | 691 (25%) | 1,876 (41%) | 2,314 (37%) | 253 (24%) | 1,815 (33%) | 752 (41%) | 566 (28%) | 334 (46%) |
| Not sure | 72 (2.6%) | 140 (3.0%) | 178 (2.8%) | 34 (3.2%) | 153 (2.8%) | 59 (3.2%) | 61 (3.0%) | 23 (3.2%) |
| No | 1,966 (72%) | 2,592 (56%) | 3,782 (60%) | 776 (73%) | 3,542 (64%) | 1,016 (56%) | 1,376 (69%) | 364 (50%) |
| **3d. Often feel lacking in energy (fatigued)?** | | | | | | | | |
| Yes | 1,170 (43%) | 2,871 (62%) | 3,617 (58%) | 424 (40%) | 2,929 (53%) | 1,112 (61%) | 946 (47%) | 491 (68%) |
| Not sure | 141 (5.2%) | 198 (4.3%) | 268 (4.3%) | 71 (6.7%) | 260 (4.7%) | 79 (4.3%) | 91 (4.5%) | 21 (2.9%) |
| No | 1,418 (52%) | 1,539 (33%) | 2,389 (38%) | 568 (53%) | 2,321 (42%) | 636 (35%) | 966 (48%) | 209 (29%) |
| **3e. Feel anxious or depressed because of your IBD?** | | | | | | | | |
| Yes | 665 (24%) | 1,574 (34%) | 2,025 (32%) | 214 (20%) | 1,627 (30%) | 612 (33%) | 493 (25%) | 301 (42%) |
| Not sure | 176 (6.4%) | 289 (6.3%) | 393 (6.3%) | 72 (6.8%) | 341 (6.2%) | 124 (6.8%) | 107 (5.3%) | 58 (8.0%) |
| No | 1,888 (69%) | 2,745 (60%) | 3,856 (61%) | 777 (73%) | 3,542 (64%) | 1,091 (60%) | 1,403 (70%) | 362 (50%) |
| **3f. Think you needed a change to your treatment?** | | | | | | | | |
| Yes | 229 (8.4%) | 550 (12%) | 715 (11%) | 64 (6.0%) | 573 (10%) | 206 (11%) | 193 (9.6%) | 104 (14%) |
| Not sure | 507 (19%) | 1,031 (22%) | 1,326 (21%) | 212 (20%) | 1,089 (20%) | 449 (25%) | 356 (18%) | 181 (25%) |
| No | 1,993 (73%) | 3,027 (66%) | 4,233 (67%) | 787 (74%) | 3,848 (70%) | 1,172 (64%) | 1,454 (73%) | 436 (60%) |

**References**

1. Bojic D, Bodger K, Travis S. Patient Reported Outcome Measures (PROMs) in Inflammatory Bowel Disease: New Data. J Crohns Colitis 2017;11(suppl\_2):S576–85.

2. Fletcher J, Cooper SC, Swift A. Patient-Reported Outcomes in Inflammatory Bowel Disease: A Measurement of Effect in Research and Clinical Care. Gastroenterol Insights 2021;12(2):225–37.

3. Jairath V, Khanna R, Zou GY, et al. Development of interim patient-reported outcome measures for the assessment of ulcerative colitis disease activity in clinical trials. Aliment Pharmacol Ther 2015;42(10):1200–10.

4. Khanna R, Zou G, D’Haens G, et al. A retrospective analysis: the development of patient reported outcome measures for the assessment of Crohn’s disease activity. Aliment Pharmacol Ther 2015;41(1):77–86.

5. Guyatt G, Mitchell A, Irvine EJ, et al. A new measure of health status for clinical trials in inflammatory bowel disease. Gastroenterology 1989;96(3):804–10.

6. Irvine EJ. Development and subsequent refinement of the inflammatory bowel disease questionnaire: a quality-of-life instrument for adult patients with inflammatory bowel disease. J Pediatr Gastroenterol Nutr 1999;28(4):S23-27.

7. Chen X-L, Zhong L-H, Wen Y, et al. Inflammatory bowel disease-specific health-related quality of life instruments: a systematic review of measurement properties. Health Qual Life Outcomes 2017;15(1):177.

8. Bodger K, Ormerod C, Shackcloth D, Harrison M, IBD Control Collaborative. Development and validation of a rapid, generic measure of disease control from the patient’s perspective: the IBD-control questionnaire. Gut 2014;63(7):1092–102.

9. de Jong ME, Taal E, Thomas PWA, et al. Cross-cultural translation and validation of the IBD-control questionnaire in The Netherlands: a patient-reported outcome measure in inflammatory bowel disease. Scand J Gastroenterol 2021;56(2):155–61.

10. Vicente Lidón R, García López S, Corsino Roche P, et al. Translation into Spanish and validation of a short questionnaire to measure the control of inflammatory bowel disease from the patient’s perspective: IBD-Control, EII-Control. Gastroenterol Hepatol 2022; 45(7):524-534.

11. Müller A, Bilger SS, Göldi A, et al. [The IBD-Control questionnaire: German translation and validation of the standardized questionnaire for Patient Reported Outcome Measurement in inflammatory bowel disease]. Z Gastroenterol 2022 Jun;60(6):911-926.

12. Deutscher D, Weil C, Chodic G, et al. Implementing electronic patient reported outcome measures in inflammatory bowel disease: Patient participation, score reliability and validity. Health Qual Life Outcomes 2023;21(1):2.

13. Wong D, Matini L, Kormilitzin A, et al. Patient Reported Outcomes: the ICHOM Standard Set for inflammatory bowel disease in real life practice helps quantify deficits in current care. J Crohns Colitis 2022; 16(12):1874-1881.

14. IBD Control (without VAS) | ECCO E-Guide [Internet]. [cited 2022 Apr 9];Available from: http://www.e-guide.ecco-ibd.eu/resources/calculator/ibd-control-without-vas

15. Data Submission Framework [Internet]. IBD Regist. [cited 2020 Mar 15];Available from: https://ibdregistry.org.uk/data-submission-framework/

16. Gonczi L, Kurti Z, Verdon C, et al. Perceived Quality of Care is Associated with Disease Activity, Quality of Life, Work Productivity, and Gender, but not Disease Phenotype: A Prospective Study in a High-volume IBD Centre. J Crohns Colitis 2019;13(9):1138–47.

17. Paulides E, Pasma A, Erler NS, van Eijk RLA, de Vries AC, van der Woude CJ. Impact of the Coronavirus Disease Pandemic on Health-Related Quality of Life of Patients with Inflammatory Bowel Disease. Dig Dis Sci 2022;67(7):2849-2856.

18. Ventress E, Young D, Rahmany S, et al. Transitioning from intRavenous to subcutAneous VEdolizumab in patients with infLammatory bowEl diSeaSe (TRAVELESS). J Crohns Colitis 2022 Jul 14;16(6):911-921.

19. van Linschoten RCA, van Leeuwen N, Nieboer D, et al. Value-based care pathway for inflammatory bowel disease: a protocol for the multicentre longitudinal non-randomised parallel cluster IBD Value study with baseline period. BMJ Open 2022;12(1):e050539.

20. Story of the COVID-19 IBD Risk Tool [Internet]. IBD Regist. [cited 2021 Oct 23];Available from: https://ibdregistry.org.uk/story-of-the-covid-19-ibd-risk-tool/

21. REDCap [Internet]. [cited 2023 Jan 24];Available from: https://www.project-redcap.org/

22. Mîndrilă D. Maximum Likelihood (ML) and Diagonally Weighted Least Squares (DWLS) Estimation Procedures: A Comparison of Estimation Bias with Ordinal and Multivariate Non-Normal Data. Int J Digit Soc 2010;1(1):60–6.

23. Hu L, Bentler PM. Cutoff criteria for fit indexes in covariance structure analysis: Conventional criteria versus new alternatives. Struct Equ Model Multidiscip J 1999;6(1):1–55.

24. MacCallum RC, Browne MW, Sugawara HM. Power analysis and determination of sample size for covariance structure modeling. Psychol Methods 1996;1:130–49.

25. Revelle W, Zinbarg RE. Coefficients Alpha, Beta, Omega, and the glb: Comments on Sijtsma. Psychometrika 2008;74(1):145.

26. Chen FF. Sensitivity of Goodness of Fit Indexes to Lack of Measurement Invariance. Struct Equ Model Multidiscip J 2007;14(3):464–504.

27. Colombel J-F, D’haens G, Lee W-J, Petersson J, Panaccione R. Outcomes and Strategies to Support a Treat-to-target Approach in Inflammatory Bowel Disease: A Systematic Review. J Crohns Colitis 2020;14(2):254–66.

28. Fehnel S, DeMuro C, McLeod L, Coon C, Gnanasakthy A. US FDA patient-reported outcome guidance: great expectations and unintended consequences. Expert Rev Pharmacoecon Outcomes Res 2013;13(4):441–6.

29. Walsh A, Travis S. What’s app? Electronic health technology in inflammatory bowel disease. Intest Res 2018;16(3):366–73.

30. Escoffery C. Gender Similarities and Differences for e-Health Behaviors Among U.S. Adults. Telemed J E-Health Off J Am Telemed Assoc 2018;24(5):335–43.

31. Inflammatory Bowel Disease | ICHOM – International Consortium for Health Outcomes Measurement [Internet]. [cited 2017 Mar 6];Available from: http://www.ichom.org/medical-conditions/inflammatory-bowel-disease/