Patient Reported Outcomes: the ICHOM Standard Set for inflammatory bowel disease in real life practice helps quantify deficits in current care

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AUTHOR CONTRIBUTIONS

Conception and design of study – DW, LM SPLT, AW

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ABSTRACT

Background

Patient reported outcome measures (PROMs) are key to documenting outcomes that matter most to patients and are increasingly important to commissioners of healthcare seeking value. We report the first series of the ICHOM Standard Set for Inflammatory Bowel Disease (IBD).

Methods

Patients treated for ulcerative colitis (UC) or Crohn's disease (CD) in our centre were offered enrolment into the web-based TrueColours-IBD programme. Through this programme, email prompts linking to validated questionnaires were sent for symptoms, quality of life, and ICHOM IBD outcomes.

Results

The first 1,299 consecutive patients enrolled (779 UC, 520 CD) were studied with median 270 days of follow up (IQR 116-504). 677 (52%) were female, mean age 42 years (sd 16), mean BMI 26 (sd 5.3). 483 (37%) were using advanced therapies at registration. Median adherence to fortnightly quality of life reporting and quarterly outcomes was 100% [IQR48-100%] and 100% [IQR75-100%], respectively. In the previous 12 months, prednisolone use was reported by 229 (29%) patients with UC vs. 81 (16%) with CD, $p<0.001$: 202 (16%) for <3 months and 108 (8%) for >3 months. 174 (13%) patients reported an IBD-related intervention and 80 (6%) reported an unplanned hospital admission. There were high rates of fatigue (50%) and mood disturbance (23%).

Conclusion

Outcomes reported by patients illustrate the scale of the therapeutic deficit in current care. Proof of principle is demonstrated that PROM data can be collected continuously with little burden on healthcare professionals. This may become a metric for quality improvement programmes, or to compare outcomes.

KEYWORDS: Inflammatory bowel disease; patient reported outcomes; ICHOM

INTRODUCTION

Ulcerative colitis (UC), Crohn's disease (CD) and inflammatory bowel disease unclassified (IBD-U) are inflammatory bowel diseases (IBD) that cause chronic symptoms that can reduce quality of life, social functioning, and occupational productivity.[1–4] Whilst clinicians caring for patients with IBD consider metrics such as stool frequency, rectal bleeding, biochemical, endoscopic and histologic parameters important for ascertaining disease control, these may not reflect what matters to patients.[5–7] There is also significant heterogeneity in real-world, clinician-reported quantification of symptom severity.[8] Clinical trial and provider outcome reports are shifting to include patient-reported outcome measures (PROM)[9], which are important for value-based healthcare where value is defined as outcomes that matter most to patients divided by the cost of that care.[10]

The International Consortium for Health Outcomes Measurement (ICHOM) has developed "Standard Sets" of outcomes for a diverse range of medical conditions to focus on value-based healthcare. These Standard Sets have been used to collect PROM data across multiple specialties including obstetric medicine, ophthalmology, oncology, and rheumatology.[11–14] A Standard Set for IBD was published in 2018 using the ICHOM evidence-based framework.[15] This incorporates both patient- and clinician-based outcome measures across domains including symptoms and quality of life, disease control, healthcare utilisation and disutility of care. Experience with the IBD Standard Set has not yet been published.

Evidence that digital data collection by patients is an effective approach to collecting such outcomes in practice is sparse. Our aims were to test the feasibility of collecting ICHOM data for IBD at scale; and to quantify the outcomes achieved in routine practice at an IBD Centre, as a metric for our quality improvement programme.

METHODS

Data Collection

TrueColours-IBD (TC-IBD) is a comprehensive web-based, real-time software programme which allows remote entry and monitoring of PROMs.[16] Participation in TC-IBD is offered to all patients with IBD being treated at the Oxford University Hospital Foundation Trust Hospitals (John Radcliffe Hospital and Horton Hospital), but was implemented in a staged fashion: patients with UC were enrolled first (from June 2018), followed by CD (from Jan 2019). Through email prompts, linked directly to validated questionnaires, patients can record a range of information relating to symptoms, quality of life and ICHOM outcomes. For symptoms (prompted daily or weekly), patients with UC or IBD-U complete the Simple Clinical Colitis Activity Index (SCCAI) and those with CD complete the Harvey-Bradshaw Index (HBI). The original clinician-reported version of the HBI was modified to a patient-facing version in order to exclude items that required physical examination, focusing on general well-being, abdominal pain, and stool frequency. Reliability of patient data collection for SCCAI using TC-IBD through item response theory has been reported [17], showing that only 4 items (rectal bleeding, diurnal stool frequency, nocturnal stool frequency and urgency) contribute to the total SCCAI, with negligible contributions from reporting of extraintestinal manifestations. Disease activity for SCCAI was classified as remission ≤2, mild 3-5, moderate 6-11, and severe ≥12, and for HBI remission ≤3, mild 4-6, moderate 7-11, and severe ≥12. For patient-reported disease control (prompted fortnightly), patients complete the IBD-Control-8.[18] All other ICHOM outcomes are asked at baseline (covering the previous 12 months) and entered with the assistance of a healthcare professional (HCP) and are then submitted 3 monthly by patients individually. Haemoglobin results within 3 months of the ICHOM being completed were entered into TC-IBD. To test the representativeness of the patient population enrolled, all patients in TC-IBD included in this study were audited by UK postcode and compared to all patients enrolled on the Oxford Infoflex IBD database. All patient responses are held on a secure Oxford Health server. Data exported for analysis and publication are de-identified. The current report relates to the patient-reported component of the Standard Set captured at the time of enrolment into the TC-IBD programme.

Commented [MOU1]: Considering all pts are invited to take part in TC, would it be worth to add what we are doing with the ones unable to complete the DA questionnaire?
Something like:
Patients unable to accurately answer symptom questionnaires due to prior surgical intervention (e.g. pouch or stoma in situ) are excluded from this but participate in all other questionnaires.

IBD Standard Set - Patient-Reported Questions

The IBD Standard Set of questions is the same for UC and CD. Integral to the IBD ICHOM Standard Set is quality of life as defined by the IBD-Control questionnaire.[14] This is a simple outcome tool designed to capture information regarding disease control and quality of life from the patient's perspective. The validated tool applies both to UC and to CD. The IBD-Control-8 score is a validated index using a subset of the full IBD-Control questionnaire, with scores ranging from 0 (worst) to 16 (best) (Table 1). A score of ≥13 identified patients with quiescent disease. An additional question from the full tool, "Over the past 2 weeks, have your bowel symptoms been getting worse, getting better or not changed" was also collected.[18]

The ICHOM Standard Set also includes baseline questions that capture 'case mix variables' including demographic characteristics such as height, weight, education level and smoking status. Disease-specific questions include disease duration, extent, extra-intestinal manifestations and comorbidities, which were entered with the assistance of a HCP at baseline. Questions regarding disutility of care target duration of oral prednisolone use over the preceding 12 months, complications relating to an intervention for IBD and its outcome, emergency department presentations, hospital admissions (excluding admissions for day case infusions) and total duration of hospitalisation. A history of a diagnosis of bowel cancer is also sought. Adherence to the longitudinal schedule of questionnaires was calculated for each patient and as an overall percentage. Reporting of admission data was cross referenced with Oxford hospitals admission data to estimate accuracy, acknowledging that information regarding admissions to other Trusts or health services would not be accessible.

Statistical Analysis

Continuous data are presented as summary statistics using mean (standard deviation, sd) for normally distributed variables and median (interquartile range, IQR) for non-parametric variables. Student's t-test or Wilcoxon rank-sum test were used for these data where appropriate. Categorical data are presented as number (percentage). Fisher's exact test or a chi-square test were used where appropriate. Adherence to the longitudinal schedule of questionnaires were calculated for each patient as the percentage of the expected number of returned questionnaires based on the duration of enrolment on the TC-IBD programme. Reproducibility of the validated scores (IBD-Control-8, SCCAI, and modified HBI) was

assessed by comparing the scores of patients a fortnight apart and during a 4-week period of self-reported ‘no change’ in disease control.

RESULTS

Patient population

Of the first 1,299 consecutive patients registered through the TC-IBD programme, 671 (52%) were female with a mean age at baseline response of 42 years (sd 16 years, range 16 – 85 years). Median BMI was 24.9 kg/m^2 (IQR 22.1 – 28.7) and 104 (8%) identified as current smokers. The group was skewed towards having completed higher education; demographic characteristics are summarised in Table 2. Median duration of follow up was 270 days (IQR 116-504 days) with a total of 453,068 person-days of follow up. Post code analysis showed 74% with an OX (local) postcode and 13% with a regional code (HP/RG/SN/MK). 13% came from further afield, consistent with the predominantly secondary care service of the Oxford IBD service. Comparison of the 1,299 patients with 3,355 patients on our Infoflex IBD database of all our patients showed no significant difference in post code proportions (p = 0.25). Patients with stomas or ileoanal pouches were excluded, owing to their lack of validated symptom indices.

IBD Characteristics

779 patients (60%) had UC and 520 (40%) patients had CD. Those with UC had a median disease duration of 6.4 years (IQR 1.8 – 13.9) vs. 10.8 years (IQR 4.8 – 20.0) for CD. HCP-assisted reporting of disease extent at baseline is shown in Table 2. Extra-intestinal manifestations of IBD were reported by 440 (34%) patients. These were less likely to be reported by patients with UC (231/779, 30%) than CD (209/520, 41%), p<0.001. Of those with UC, 58% were in clinical remission (SCCAI $\leq$2) compared to 66% with CD (HBI $\leq$3, Figure 1). Mean haemoglobin level was 135 g/L (sd: 14.4) with no difference between UC or CD. 169 (14%) patients were taking no medications at baseline (63 (8%) UC vs. 106 (22%) CD). Of the remaining 1,130 (86%), medication use is detailed in Table 3. Notably, 476 (37%) were using either biologic or small molecule therapy and 344 (26%) were taking an immunomodulator.

IBD-Control-8

Quality of life and the impact of patients' IBD are summarised in Table 4. Fatigue (50%), and anxiety and depression (23%) were common. Adherence to the schedule of reporting IBD Control-8 was good: patients completed a median 100% (IQR 48-100%) of the fortnightly

follow up questionnaires. Similarly, patients enrolled for at least 3 months completed a median of 100% (IQR 75-100%) of the expected number of quarterly follow up questionnaires. IBD-Control-8 scores and symptom scores were highly correlated, with Pearson's *r* being -0.68 ($p<0.001$) for UC and -0.70 ($p<0.0001$) for CD. Median IBD-Control-8 scores for those with UC in remission were 15 (IQR 13-16) vs. 8 (IQR 5-12) for those reporting active disease using SCCAI ($p<0.001$). Similarly for CD, median IBD-Control-8 scores for those reporting remission were 14 (IQR 12-16) vs. 7 (IQR 4-11) for active disease using the modified HBI ($p<0.001$). Reproducibility of the scores was good, with the mean difference two weeks apart in patients with self-reported disease stability being close to zero. Likewise, the intraclass correlation coefficient was high (Table 5).

Disutility of care

992/1,299 (76%) of patients reported no prednisolone use within the preceding 12 months. Prednisolone was used in 223 (29%) patients with UC and 84 (16%) patients with CD ($p<0.001$) with the statistically significant difference driven by a greater than expected number of UC patients using prednisolone. 202 (16%) reported use of prednisolone for less than 3 months, whilst 105 (8%) reported use for more than 3 months (Figure 2). 97 (7%) patients reported an IBD-related intervention (endoscopic, radiological, or surgical, 5% UC vs. 12% CD, $p<0.001$) and 82 (6%) reported having had an unplanned IBD-related hospital admission previously (4% UC vs. 10% CD, $p<0.001$). 291 (22%) patients reported a hospital attendance in the preceding year, of whom 183 (14%) reported requiring at least one hospital admission, exceeded by 224 (17%) who had at least one emergency department presentation in the same period. Of the 183 patients admitted, the median duration of admission was reported to be 5 days (IQR 3 - 7) for UC and 4 days (IQR 2 - 8) for CD. Following cross-referencing with hospital admission data for the John Radcliffe Hospital, 151/183 (83%) could be verified. 38 (3%) patients were admitted as an inpatient for a period longer than ten days. Patients from outside the Oxford area would have been admitted to the local hospital. Overall, 177 (14%) patients reported suffering from a complication of their IBD at some time in the preceding 12 months (Table 6).

DISCUSSION

Only by publishing internationally agreed patient-reported outcome measures will it be possible to compare individual hospitals or healthcare systems. This study, the first report using the ICHOM Standard Set for inflammatory bowel disease, demonstrates the feasibility of collecting ICHOM data directly from patients using a specific digital solution. It not only serves as a benchmark for outcomes in real-world practice at a major centre, but reveals the stark deficit in current care for patients with IBD. The ICHOM Standard set captures information spanning multiple domains that together provide a comprehensive picture of the disease experience from a patient perspective. The web-based TC-IBD platform is the vehicle by which the data are captured in real time, which also enables data to be captured longitudinally, so that trends can be identified and the impact of changes in practice (or treatment) can be measured. Integrating this process into routine clinical care enables a focus on the primary purpose of medicine – to improve the quality of life for our patients.

One stark reality of care for IBD is the much higher proportion (8%) of the overall cohort reporting steroid use for greater than 3 months in the past 12 months than expected, at a centre where much effort is spent on avoiding this outcome. Previous internal audit had indicated a figure close to 0%. From these data it is unclear whether this is being driven by the specialist physician, general practitioners, or the patients themselves; nor is it known whether this is better than, worse than, or the same for other hospitals with similar case-mix variables. It serves to benchmark practice and as a focus for measures to achieve steroid-free remission. Although it is better than the 58% of patients reporting steroid use for greater than 3 months over a 2 year period in the IBD2020 patient survey that covered over 7500 patients in 8 countries [19], there is much room for improvement. It highlights the need for further education, both for patients and clinicians, of the importance of reducing corticosteroid use. It also serves to quantify steroid-dependency despite the prevalent use of advanced or steroid-sparing therapies (39% using biologic/small molecule therapy and 30% taking an immunomodulator) at a major centre. The provision of digital self-monitoring tools for IBD provides an opportunity to explicitly track steroid use, with potential for alerts to reinforce strategies aimed at minimising steroid exposure.

Another reality is the impact that IBD has on psychosocial function and quality of life. The high prevalence of fatigue (50%) and anxiety or depression (23%) is similar to other studies showing a prevalence of fatigue in 41%, anxiety in 31%, and depression in 40% of large IBD cohorts using validated questionnaires.[20,21] The IBD2020 patient survey reported that over 50% of patients described significant fatigue and anxiety or depression.[19] Nevertheless, when these data are seen to apply to one's own cohort of patients, it serves as a reality check. That these data might be collected in any hospital, by applying the ICHOM Standard Set for patients to report themselves in routine practice, is a relevant message. Despite the impact of these highly prevalent manifestations of IBD, there exists a poor framework for their management. The move towards value-based health care, where value is defined as outcome divided by the cost of care[10], will need to address this deficit measured by individual patients communicating their unmet needs to clinicians via PRO collection, using web-based systems as a vehicle.

The unpredictability of IBD is a constant anxiety for many patients. Hospitalisation rates in our cohort were 14% in the preceding 12 months, which compares to a self-reported 28% hospitalisation rate in the IBD2020 report.[19] Admission was unplanned in 80 patients (6%), but 221 (18%) patients had at least one emergency department presentation during the same period. Given the impact of emergency department presentation on radiation exposure and steroid prescription [22–25], this is a transferrable metric on the overall quality of care for patients with IBD in a healthcare system. Data from the Qorus initiative in the USA reports similar figures with 14% corticosteroid use, 18% with emergency department presentations, and 14% hospitalisation rates. Importantly, however, use of a structured quality improvement program focussed on IBD care resulted in a meaningful decline in all of these metrics within 17 months of implementation.[26]

There are a number of limitations in our report. It may be questioned whether patients in Oxford are representative of a wider population, but 87% had a local or regional postcode, indicating the dominance of secondary care in our service. Selection bias remains possible due to patients not being recruited consecutively, but comparison of the patients in this study with those in our full database shows no difference from those enrolled into TC-IBD. Furthermore, disease characteristics and ICHOM data in the preceding 12 months at

baseline were entered with the assistance of a HCP, but subsequent outcomes are patient-reported, so there may be inaccuracies. This is compounded by potential concerns about the validity and reliability of patient-reported data relating to disease characteristics and disutility of care due to the wording of these items being generated de-novo. While the psychometric robustness of the items were not tested prior to data collection, supportive evidence for the performance of these items is indicated by the fact that hospital admissions and emergency department visits could be confirmed (for the John Radcliffe Hospital) in the large majority. The report also lacks data on clinician-reported aspects of the ICHOM Standard Set, since the TC-IBD system has yet to be integrated into the electronic patient record. In addition, the TC-IBD programme is currently Oxocentric, making translatability of our experience to other centres unclear. Other UK centres are in the process of starting the programme, which will shed light on whether digital solutions, such as TC-IBD, can reliably initiate the shift towards genuine patient engagement in the development of quality improvement initiatives.

This study demonstrates the feasibility of collecting longitudinal patient-reported outcome data using the ICHOM Standard Set for inflammatory bowel disease. The data quantify the deficit in current care for IBD by measuring outcomes agreed with and by patients, in contrast to disease outcomes which are the typical focus of clinician-driven encounters. It represents a step towards value-based delivery of IBD care. The approach has the potential to act as a metric for quality improvement programmes.

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CONFLICTS OF INTEREST

No authors report financial conflicts of interest. ST led the international group that developed the ICHOM Standard Set, of which KB was a member. None of the other authors have any conflict of interest in relation to publication of this work.

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FIGURE LEGENDS

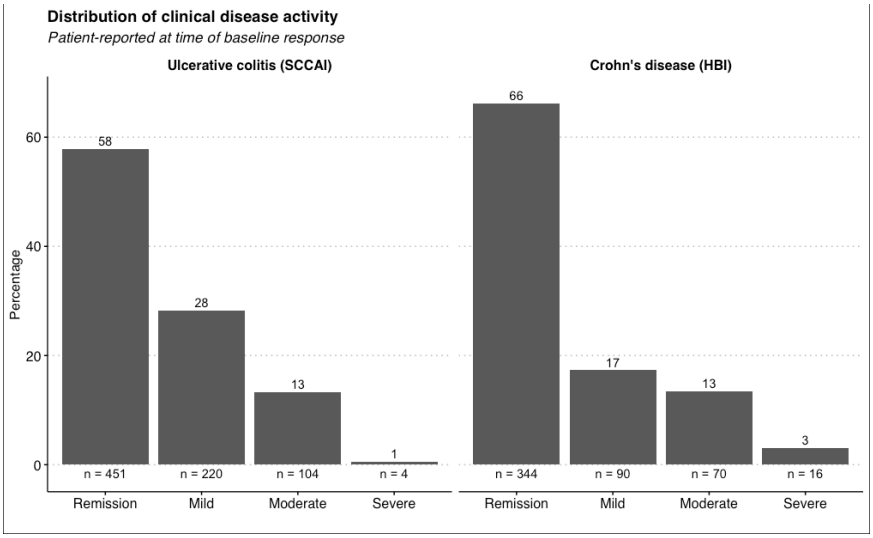

Figure 1: Self-reported disease activity by validated scores at the time of baseline response. Disease activity for SCCAI was classified as remission ≤2, mild 3-5, moderate 6-11, and severe ≥12. Disease activity for HBI was classified as remission ≤3, mild 4-6, moderate 7-11, and severe ≥12.

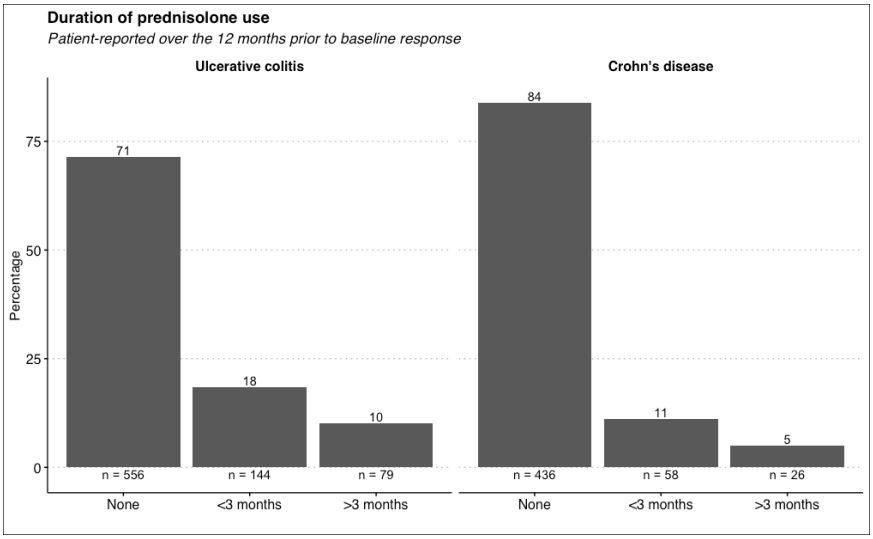

Figure 2: Patient-reported duration of prednisolone use for the 12 months prior to completing the baseline questionnaire

TABLES

Table 1: IBD Control-8

Do you believe that:

a. Your IBD has been well controlled in the past *two weeks*?
b. Your *current treatment* is useful in controlling your IBD?

In the past 2 weeks did you:

a. Miss any planned activities because of IBD?
b. Wake up at night because of symptoms of IBD?
c. Suffer from significant pain or discomfort?
d. Often feel lacking in energy (fatigue)?
e. Feel anxious or depressed because of your IBD?
f. Think you needed a change to your treatment?

Best possible score = 16, worst possible score = 0; each question has 3 categorical responses, scored as 0 for the least favourable and 2 for the most favourable.

Table 2: Demographics at enrolment

	IBD Diagnosis	
	Ulcerative Colitis (n=779, (60%))	Crohn's Disease (n=520, (40%))
Age, mean (sd)	43 (16)	41 (15)
Female, n (%)	413 (53)	258 (50)
Education Level		
Nil formal, n (%)	41 (5)	33 (6)
Primary, n (%)	12 (2)	7 (1)
Secondary, n (%)	271 (35)	204 (39)
Tertiary, n (%)	455 (58)	276 (53)
Smoking Status		
Never, n (%)	463 (59)	282 (54)
Former, n (%)	275 (35)	175 (34)
Current, n (%)	41 (5)	63 (12)
BMI, median (IQR)	25.0 (22.1-28.6)	24.6 (22.0-29.1)
Self-reported disease extent (Montreal)*, n (%)		
Proctitis (E1)	169 (22)	-
Left-sided (E2)	169 (22)	-
Extensive (E3)	216 (27)	-
Unsure	225 (29)	-

Ileal (L1)		-	225	(43)
Colonic (L2)		-	87	(17)
Ileal & Colonic (L3)		-	140	(27)
Upper GI (L4)		-	4	(1)
Other		-	64	(12)
Reported extra-intestinal manifestations	231	(30)	209	(40)
Previous infections				
HIV, n (%)	2	(0.3)	0	(0)
Hepatitis B, n (%)	1	(0.1)	1	(0.2)
Tuberculosis, n (%)	7	(0.9)	3	(0.6)

* Correlation with documented disease extent detailed under 'IBD Characteristics'

Table 3: Medications

	IBD Diagnosis	
Medication, n (%)	Ulcerative Colitis (n=779, (60%))	Crohn's Disease (n=520, (40%))
5-aminosalicylates, topical	158 (21)	0 (0)
5-aminosalicylates, oral	472 (63)	10 (2)
Prednisolone, topical	31 (4)	1 (0)
Prednisolone, oral	65 (9)	34 (7)
Budesonide (MMX or CIR)	27 (4)	17 (4)
Thiopurines	148 (20)	129 (26)
Methotrexate	24 (3)	35 (7)
Ciclosporin	3 (0)	0 (0)
Tacrolimus, topical	1 (0)	1 (0)
Tacrolimus, oral	1 (0)	0 (0)
Mycophenolate	5 (1)	1 (0)
Adalimumab	58 (8)	140 (29)
Golimumab	0 (0)	2 (0)
Infliximab	44 (6)	51 (10)
Ustekinumab	0 (0)	47 (10)
Vedolizumab	94 (12)	31 (6)
Tofacitinib	8 (1)	0 (0)
Mirikizumab	1 (0)	0 (0)

Medication information was captured by the TrueColours-IBD platform at the time of enrolment, which preceded release of tofacitinib in November 2018. Prior medication history was not recorded. MMX: modified matrix formulation; CIR: controlled ileal release.

Table 4: ICHOM Patient-Reported Outcomes

Metric	Ulcerative Colitis (n=779, (60%))	Crohn's Disease (n=520, (40%))

IBD Control-8, median (IQR)	13	(9-16)	13	(8-15)
Do you believe that: n (%)				
Your IBD has been well controlled in the past fortnight?	542	(70)	358	(69)
Your current treatment is useful in controlling your IBD?	557	(72)	314	(60)
In the past 2 weeks did you: n (%)				
Miss any planned activities because of IBD?	113	(15)	96	(18)
Wake up at night because of symptoms of IBD?	184	(24)	166	(32)
Suffer from significant pain or discomfort?	237	(30)	166	(32)
Often feel lacking in energy (fatigue)?	372	(48)	275	(53)
Feel anxious or depressed because of your IBD?	174	(22)	119	(23)
Think you needed a change to your treatment?	141	(18)	59	(11)
Over the past fortnight have your symptoms been: n (%)				
Better	152	(20)	61	(12)
Unchanged	505	(65)	369	(71)
Worse	122	(16)	90	(17)
Disutility of care				
Duration of prednisolone over the past 12 months, n (%)				
None	556	(71)	436	(84)
<3 months	144	(18)	58	(11)
>3 months	79	(10)	26	(5)
Healthcare utilisation – past 12 months, n (%)				
Admitted to hospital	103	(13)	80	(15)
Presented to emergency department	129	(17)	95	(18)
Colorectal cancer, n (%)	2	(0.3)	4	(0.8)

The IBD Control-8 questionnaire is one of the patient-reported outcome metrics collected by the ICHOM Standard Set for IBD

Table 5: Reproducibility of instrument scores

Instrument	Mean difference (sd)	Intraclass correlation (95% CI)
IBD Control-8	0.02 (1.9)	0.86 (0.84 – 0.87)
SCCAI (UC only)	0.002 (1.2)	0.85 (0.82 – 0.87)
Modified HBI (CD only)	-0.09 (2.0)	0.85 (0.81 – 0.88)

Table 6: Patient-reported complications

Reported Complication	IBD Diagnosis	
	UC n=779	CD n=520
Thiopurine pancreatitis	5	6
Other drug reaction/intolerance	35	29
Infection†	5	7
IBD progression	10	32
Post-operative complication	4	16
Other*	8	1

Total	67 (9%)	91 (18%)

† Pyelonephritis (1), shingles (2), gastroenteritis (1), pneumonia (1). * Depression, pregnancy, brain tumour, visual disturbance, bowel obstruction from capsule endoscopy, haematuria, rash.