ICHOM

International Consortium for
Health Outcomes Measurement

INFLAMMATORY
BOWEL DISEASE
DATA COLLECTION
REFERENCE GUIDE

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Measuring
results
that matter

Planned
Activities

Inflammatory Bowel Disease

ICHOM

INFLAMMATORY BOWEL DISEASE

We are thrilled that you are interested in measuring outcomes for your patients with inflammatory bowel disease according to ICHOM standards. It is our hope that this Reference Guide will facilitate the process of implementing our Standard Set and ensure the collection of comparable data for global benchmarking and learning.

Introducing ICHOM and the Reference Guide

ICHOM brings together patient representatives, clinician leaders, and registry leaders from all over the world to develop Standard Sets: comprehensive yet parsimonious sets of outcomes and case-mix variables that we recommend to track for specific medical conditions.

Each Standard Set focuses on patient-centered results, and provides an internationally-agreed upon method for measuring each of these outcomes. We do this because we believe that standardized outcomes measurement will open new possibilities to compare performance globally, allow clinicians to learn from each other, and rapidly improve the care we provide our patients.

Our Standard Sets include baseline conditions and risk factors to enable meaningful case-mix adjustment globally, ensuring that comparisons of outcomes will take into account the differences in patient populations across not just providers, but also countries and regions. We also include high-level treatment variables to allow stratification of outcomes by major treatment types. A comprehensive data dictionary, as well as scoring guides for patient-reported outcomes, is included in the appendix.

Working Group Members for Inflammatory Bowel Disease

The following individuals dedicated both time and expertise to develop the ICHOM Standard Set for Inflammatory Bowel Disease in partnership with ICHOM, under the leadership of Professor Simon Travis, Professor of Clinical Gastroenterology at the University of Oxford.

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Supporting Organizations

The Inflammatory Bowel Disease Standard Set is made possible only through the support of the following sponsor*:

Thank you.

Treatment Approaches Covered for Inflammatory Bowel Disease

For Inflammatory Bowel Disease, the following treatment approaches (or interventions) are covered by our Standard Set:

Treatment Approaches	Medical | Surgical | Supportive
Conditions Covered	An adult (>16) with a diagnosis of Inflammatory Bowel Disease (IBD) including Crohn's disease, ulcerative colitis and indeterminate colitis (or IBD unclassified)

ICHOM Standard Set for Inflammatory Bowel Disease
Case-Mix Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Demographics				
All patients	Year of birth	N/A	Baseline	Patient-reported
	Male or female			
	Education level	Highest level of schooling completed using the International Standard Classification of Education		
	Smoking status	(of cigarettes, cigars or tobacco)	Baseline and annual follow-up	
	Patient height	To calculate BMI	Baseline	
	Patient weight			
Baseline clinical factors				
All patients	Comorbidities including autoimmune conditions	N/A	Baseline and annual follow-up	Patient-reported
	Previous infection	HIV, HBV or TB		
Baseline condition factors				
All patients	Diagnosis	Crohn's disease, ulcerative colitis, indeterminate IBD or colitis unclassified	Baseline	Clinician-reported
	Date of diagnosis	N/A		
	Disease phenotype	Tracked via Montreal Classification		
	Presence of extra-intestinal manifestations	Eye, skin, joint, hepatobiliary or other	Baseline and annual follow-up	

Treatment Variables

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Treatment factors				
Surgical patients	Type of IBD-related surgery	Including method of surgical procedure, date of surgery and type of colectomy	Baseline and annual follow-up	Clinician-reported
Medical patients	Current medication			
Patients diagnosed with colorectal cancer	Participation in a colorectal cancer surveillance programme	N/A		

Outcomes

Patient Population	Measure	Supporting Information	Timing	Suggested Data Sources
Symptoms, function and quality of life				
All patients	Change in bowel symptoms	Tracked via the IBD-Control	Baseline and 6 monthly	Patient-reported
	Missing planned activities			
	Night symptoms			
	Pain or discomfort			
	Energy and fatigue			
	Anxiety or depressed			
	Overall control over IBD			
	Weight			
All patients with Crohn's Disease	Fistulae symptoms	N/A		
Disutility of care				
All patients	Steroid use	Use of prednisolone within the previous 12 months	Baseline and annual follow-up	Clinician-reported
	Occurrence and impact of complication from an IBD intervention	Including whether a complication occurred and the outcome of the complication		
Healthcare utilization				
All patients	Time spent in hospital	Including all IBD-cause admissions requiring an overnight stay and emergency department visits	Baseline and annual follow-up	Clinician-reported
Survival and disease control				
All patients	Presence of anaemia	Using WHO definitions	Baseline and 6 monthly	Clinician-reported
	Disease activity and remission	Tracked via the Manitoba Index and additional clinician report		Patient and Clinician-reported
	Colorectal cancer	Diagnosis of colorectal cancer and preceding colorectal dysplasia	Baseline and annual follow-up	Clinician-reported
	Overall survival	Date of death		
	Cause of death	Death attributable to IBD or to an intervention for IBD		

Measurement Timeline and Sample Questionnaires

The following timeline illustrates when Standard Set variables should be collected from patients, clinicians, and administrative sources. Links to the sample questionnaires may be found in the legend below.

| Baseline (e.g. diagnosis or start of treatment) | 6 months | 1 year | 18 months | Continue on a 6 monthly and annual basis |

□ Patient-Reported Form Baseline, 6 months, and Annually **(link)**

● Clinical Form Baseline and Annually **(link)**

□ Clinical Form 6 months **(link)**
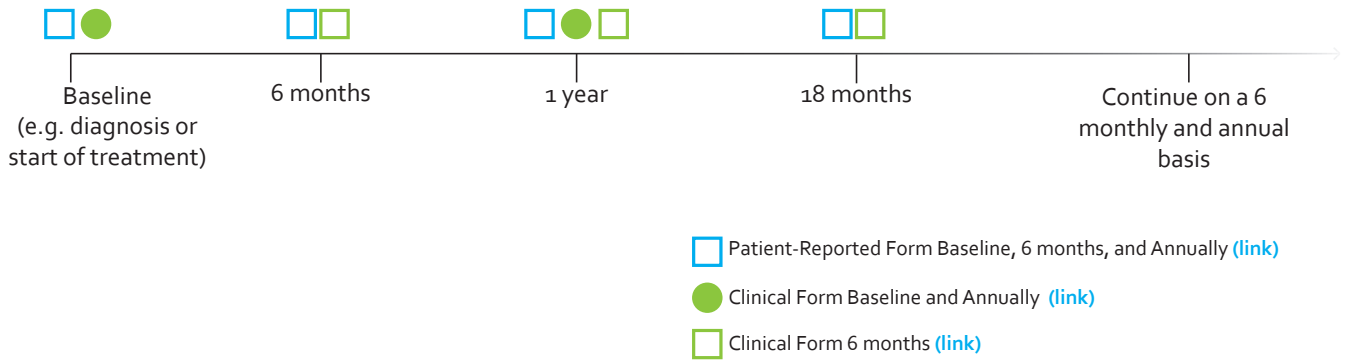
Collecting Patient-Reported Outcome Measures

Survey Used	Licensing Information	Scoring Guide
IBD-Control PROM	IBD-Control is made available to the IBD community without license or fees, but the authors retain copyright and request that the original paper is cited in any published output.For more details, see: Bodger et al. 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.	(Please note, only some questions of the IBD-Control questionnaire are asked, therefore a total score is not applicable or requested within this guide)

The Growing ICHOM Community

By implementing the ICHOM Standard Sets, you become part of an expanding, international community of innovative health care providers dedicated to improving value for patients. To learn more about how ICHOM can assist your organization in implementing outcome measurement, contact us at **implement@ichom.org**, or visit **http://www.ichom.org/measure**.

Appendix

Introduction to the Data Dictionary

This data dictionary is designed to help you measure the ICHOM Inflammatory Bowel Disease Standard Set as consistently as possible with the Working Group recommendation. ICHOM is actively preparing for benchmarking efforts based on this data, and all data submitted for comparisons will need to be transformed into the following data structure if not already structured as such. **We are happy to provide an Excel version of this data dictionary for technical use.**

Please timestamp all variables. Some Standard Set variables are collected at multiple timepoints, and we will ask you to submit these variables in a concatenated VARIABLEID_TIMESTAMP form for future analyses. For example, VARIABLEID_BASE (baseline); VARIABLEID_6MO (6 month follow-up); VARIABLEID_1YR (1 year follow-up), etc.

Case-Mix Variables

Variable ID:	N/A
Variable:	Patient ID
Definition:	Indicate the patient's medical record number
Supporting Definition:	This number will not be shared with ICHOM. In the case patient-level data is submitted to ICHOM for benchmarking or research purposes, a separate ICHOM Patient Identifier will be created and cross-linking between the ICHOM Patient Identifier and the medical record number will only be known at the treating institution
Inclusion Criteria:	All patients
Timing:	On all forms
Reporting Source:	Administrative or clinical
Type:	Numerical
Response Options:	According to institution

Demographics

Variable ID:	AGE
Variable:	Year of birth
Definition:	In what year were you born?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Numerical
Response Options:	YYYY
Variable ID:	SEX
Variable:	Patient sex
Definition:	Please indicate your sex at birth:
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Male
	1 = Female

Variable ID:	LEVEDC
Variable:	Level of education
Definition:	What is the highest level of schooling you have completed?
Supporting Definition:	The level of schooling is defined in each country as per ISCED [International Standard Classification]
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient reported
Type:	Single answer
Response Options:	0=None
	1=Primary (Primary education typically lasts until age 10 to 12)
	2=Secondary (Secondary education typically lasts until age 16 to 18, e.g. High school)
	3=Tertiary (Tertiary education includes what is commonly understood as academic education but also includes advanced vocational or professional education e.g. Bachelor's or equivalent level, Master's or equivalent level, and doctoral or equivalent level, respectively)
Variable ID:	SMOKE
Variable:	Smoking status
Definition:	Smoking status (of cigarettes, cigars or tobacco)
Supporting Definition:	Smoking status (of cigarettes, cigars or tobacco)
Inclusion Criteria:	All patients
Timing:	Baseline
	Annually
Reporting Source:	Patient reported
Type:	Single answer
Response Options:	0=Never smoked (those who have smoked less than 100 tobacco products in their lifetime)
	1=Ex-smoker (someone who has previously smoked daily or occasionally, but has not smoked for over 6 months)
	2=Current smoker (someone who smokes any tobacco product either daily or occasionally)

Baseline clinical factors

Variable ID:	HEIGHT
Variable:	Body Height
Definition:	How tall are you?
Supporting Definition:	For calculating BMI
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value of height in metric or imperial system
Variable ID:	HEIGTHUNIT
Variable:	Body Height Units
Definition:	Height units
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = centimeters
	2 = inches
Variable ID:	WEIGHT
Variable:	Body Weight
Definition:	How much do you weigh?
Supporting Definition:	For calculating BMI

Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value of weight in metric or imperial system
Variable ID:	WEIGHTUNIT
Variable:	Body Weight Units
Definition:	Weight units
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Kilograms
	2 = Pounds
Variable ID:	COMORB
Variable:	Comorbidities
Definition:	Have you been told by your doctor or care provider that you have any of the following? Tick all that apply.
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Multiple answers
Response Options:	0=The patient has no other diseases
	1=Heart disease (for example angina, heart attack or heart failure)
	2=High blood pressure (sometimes referred to as 'hypertension')
	3=Lung disease (for example asthma, chronic bronchitis or emphysema)
	4=Leg pain when walking due to poor circulation
	5=Diabetes (Type I or Type II)
	6=Kidney disease
	7=Disease of the nervous system (for example Parkinson's disease or multiple sclerosis)
	8=Liver disease
	9=Cancer (within the last 5 years)
	10=Depression
	10=High cholesterol (sometimes referred to as hyperlipidemia)
	11=Problems caused by stroke
	12=Osteoarthritis, or degenerative arthritis
	13=Back pain
	14=Rheumatoid arthritis
	15=Ankylosing spondylitis
	16=Primary sclerosing cholangitis
Variable ID:	PREVINFECTHBV
Variable:	Previous HBV infection
Definition:	Have you been previously diagnosed with or treated for Hepatitis B virus?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No
	1 = Yes
Variable ID:	PREVINFECTHIV
Variable:	Previous HIV infection
Definition:	Have you previously been diagnosed with or treated for human immunodeficiency virus (HIV)?

Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No
	1 = Yes

Variable ID:	PREVINFECTTB
Variable:	Previous TB infection
Definition:	Have you previously been diagnosed with or treated for tuberculosis (TB)?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = No
	1 = Yes

Baseline condition factors

Variable ID:	DIAG
Variable:	Diagnosis
Definition:	Indicate the diagnosis
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0 = Crohn's disease
	1 = Ulcerative colitis
	2 = Indeterminate IBD or colitis unclassified

Variable ID:	DATEOFDIAG
Variable:	Date of diagnosis
Definition:	Indicate the date of diagnosis
Supporting Definition:	MM/YYYY
Inclusion Criteria:	All patients
Timing:	Baseline
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	MM/YYYY

Variable ID:	DISAGEONSET
Variable:	Age of onset
Definition:	Tracked via Montreal Classification
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=A1 - Age of onset 16 yr or younger
	1=A2 - Age of onset 17--40 yr
	2=A3 - Age of onset over 40

Variable ID:	DISLOCALBEHAV
Variable:	Age of onset
Definition:	Tracked via Montreal Classification
Supporting Definition:	N/A
Inclusion Criteria:	CD only
Timing:	Baseline and annually
Reporting Source:	Clinician reported

Type:	Multiple answers
Response Options:	0=L1 CD Localisation - terminal ileum
	1=L2 CD Localisation - Colon
	3=L3 CD Localisation - Ileocolon
	4=L4 CD Localisation - Upper gastrointestinal
	5=B1 Behaviour - Nonstricturing, nonpenetrating
	6=B2 Behaviour - Stricturing
	7=B3 Behaviour - Penetrating
	8=P - Perianal disease

Variable ID:	DISEXTSEV
Variable:	Age of onset
Definition:	Tracked via Montreal Classification
Supporting Definition:	N/A
Inclusion Criteria:	UC + IBDU
Timing:	Baseline and annually
Reporting Source:	Clinician reported
Type:	Multiple answers
Response Options:	0=S0 Disease Severity - Remission, no symptoms
	1=S1 Disease Severity - Mild UC, passage of four or fewer stools/day (with or without blood), absence of any systemic illness, and normal inflammatory markers (ESR)
	2=S2 Disease Severity - Moderate UC, passage of more than four stools per day but with minimal signs of systemic toxicity
	3=S3 Disease Severity - Severe UC, passage of at least six bloody stools daily, pulse rate of at least 90 beats per minute, temperature of at least 37.5°C, haemoglobin or less than 10.5g/100mL, and ESR of at least 30 mm/h
	4=UC extent - E1 Ulcerative proctitis, Involvement limited to the rectum (that is, proximal extent of inflammation is distal to the rectosigmoid junction)
	5=UC extent - E2 Left-sided UC (distal UC), Involvement limited to a proportion of the colorectal distal to the splenic flexure
	6 = UC extent - E3 Extensive UC (pancolitis), Involvement extends proximal to the splenic flexure

Variable ID:	PRESEIM
Variable:	Presence of extra-intestinal manifestations
Definition:	Eye, skin, joint, hepatobiliary or other
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Reporting Source:	Clinician reported
Type:	Multiple answers
Response Options:	0=None
	1=Skin
	2=Joint
	3=Hepatobiliary
	4=Eye
	5=Other

Treatment Variables
Treatment factors

Variable ID:	IBDSURG
Variable:	IBD-related surgeries
Definition:	Indicate if the patient has had any IBD-related surgeries
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and annually
Reporting Source:	Clinician reported
Type:	Multiple answers
Response Options:	0=No IBD-related surgery
	1=Small bowel resection
	2=Strictureplasty
	3=Segmental colectomy (with or without stoma)
	4=Total colectomy and ileostomy (this operation usually is for acute UC)
	5=Creation of ileorectal anastomosis
	6=Total proctocolectomy and ileostomy
	7=Ileocecal resection
	7=Other

Variable ID:	SURGMETH
Variable:	Method of IBD-related surgery
Definition:	If the patient has received IBD-related surgery indicate the method of surgical procedure
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Text
Response Options:	0=single-port laparoscopic surgery
	1=multiport laparoscopic surgery
	2=conventional open surgery

Variable ID:	SURGDATE
Variable:	Date of IBD-related surgery
Definition:	Please indicate the date of surgery
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	DD/MM/YYYY

Variable ID:	COLECT
Variable:	Colectomy
Definition:	Indicate whether the patient currently has a stoma in situ
Supporting Definition:	N/A
Inclusion Criteria:	All patients who have had colectomy surgery
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=Patient has not had a colectomy
	1=No stoma in situ
	2=Yes, stoma in situ

Variable ID:	DX
Variable:	Current medication
Definition:	What type of medication does the patient currently take (regardless of when started)
Supporting Definition:	N/A

Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Multiple answers
Response Options:	0=no IBD medication currently taken
	1=steroids
	2=biologics – Anti-TNF Agents (e.g. Adalimumab (Humira®), Certolizumab pegol (Cimzia®) Golimumab (Simponi®), Infliximab (Remicade®), Infliximab-dyyb (Inflectra®))
	3=biologics - Integrin receptor antagonists (e.g. Natalizumab (Tysabri®), Vedolizumab (Entyvio™))
	4=biologics - interleukin-antagonists (e.g. ustekinumab (Stelara®))
	5=mesalamine (or mesalazine)
	6=thiopurines (e.g. azathioprine, 6-mercaptopurine) or methotrexate
	7=other immunomodulators (e.g. mycophenylate, cyclosporine, tacrolimus)
	8=others (including probiotics, cellular therapy, nutritional, symptom control)

Variable ID:	COLOPROG
Variable:	Colorectal cancer surveillance programme
Definition:	Was the patient in a colorectal cancer surveillance programme prior to their diagnosis of colorectal cancer?
Supporting Definition:	N/A
Inclusion Criteria:	All patients who have been diagnosed with colorectal cancer
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=Yes
	1=No (programme is available)
	2=No (no surveillance programme available)
	3=Unknown

Outcomes
Symptoms, function and quality of life

Variable ID:	IBDCON1
Variable:	Question 1a of the IBD-Control
Definition:	Do you believe your IBD has been well controlled in the past two weeks?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure

Variable ID:	IBDCON2
Variable:	Question 1b of the IBD-Control
Definition:	Do you believe your current treatment is useful in controlling your IBD?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure
	3=Please tick if not currently taking any treatment

Variable ID:	IBDCON3
Variable:	Question 2 of the IBD-Control
Definition:	Over the past 2 weeks, have your bowel symptoms been getting worse, getting better or not changed?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Better
	1=No change
	2=Worse

Variable ID:	IBDCON4
Variable:	Question 3a of the IBD-Control
Definition:	In the past 2 weeks, did you miss any planned activities because of IBD? (e.g. attending school/college, going to work or a social event)
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure

Variable ID: IBDCON5

Variable:	Question 3b of the IBD-Control
Definition:	In the past 2 weeks, did you wake up at night because of symptoms of IBD?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure

Variable ID:	IBDCON6
Variable:	Question 3c of the IBD-Control
Definition:	In the past 2 weeks, did you suffer from significant pain or discomfort?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure

Variable ID:	IBDCON7
Variable:	Question 3d of the IBD-Control
Definition:	In the past 2 weeks, did you often feel lacking in energy (or fatigued) (by 'often' we mean more than half of the time)
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure

Variable ID:	IBDCON8
Variable:	Question 3e of the IBD-Control
Definition:	In the past 2 weeks, did you feel anxious or depressed because of your IBD?
Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure

Variable ID:	IBDCON9
Variable:	Question 3f of the IBD-Control
Definition:	In the past 2 weeks, did you think you needed a change to your treatment?

Supporting Definition:	For all IBD-Control items please note the response option number does not correlate with the scoring guide for the IBD-Control tool and is for coding only.
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Not sure
Variable ID:	FISTSYMPT
Variable:	Symptoms from fistula
Definition:	Do you experience symptoms from any of the following fistula?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Multiple answers
Response Options:	1=No fistula
	2=Perianal fistula
	3=Rectovaginal fistula
	4=Enterocutaneous fistula
	5=Other fistula
Variable ID:	WEIGHT
Variable:	Body Weight
Definition:	How much do you weigh?
Supporting Definition:	For calculating BMI
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Numerical
Response Options:	Numerical value of weight in metric or imperial system
Variable ID:	WEIGHTUNIT
Variable:	Body Weight Units
Definition:	Weight units
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Kilograms
	2 = Pounds
Variable ID:	WEIGHTUNIT
Variable:	Body Weight Units
Definition:	Weight units
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and 6-monthly
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	1 = Kilograms
	2 = Pounds

Disutility of care

Variable ID:	STERUSE
Variable:	Steroid use
Definition:	Please indicate whether prednisolone has been used in the last 12 months

Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No use of prednisolone in the last 12 months
	1=Use of prednisolone in the last 12 months of less than 3 months total duration
	2=Use of prednisolone in the last 12 months for more than 3 months total duration

Variable ID:	COMPOCCUR
Variable:	Occurrence of a complication
Definition:	Indicate whether the patient experienced a (unexpected or expected) complication whist during IBD intervention or 3 months following intervention
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No complication occurred
	1= Yes, complication occurred

Variable ID:	COMPOUT
Variable:	Outcome of the complication
Definition:	If yes , a complication occurred, please indicate the outcome
Supporting Definition:	N/A
Inclusion Criteria:	All patients who've had a complication
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No further intervention required
	1=Surgical intervention required
	2=Radiological intervention required
	3=Endoscopic intervention required
	4=Medical intervention required

Variable ID:	COMPHOSP
Variable:	Outcome of the complication - hospitalization
Definition:	Did the complication leading to prolonged hospitalization
Supporting Definition:	(i.e. longer than reasonably expected)
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Unknown

Variable ID:	COMPHOSPDAY
Variable:	Outcome of the complication - hospitalization
Definition:	If the complication lead to prolonged hospitalization, indicate the total number of days the patient was hospitalized for
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	N/A

Variable ID:	COMPADM
Variable:	Outcome of the complication - unplanned admission
Definition:	Did the complication lead to an unplanned admission
Supporting Definition:	N/A

Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=Yes
	1=No
	2=Unknown

Variable ID:	COMPADMDAY
Variable:	Outcome of the complication - unplanned admission
Definition:	If the complication lead to an unplanned admission, indicate the total length of stay for all unplanned admissions due to complication within 1 year
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	

Healthcare utilization

Variable ID:	HOSPADMALL
Variable:	All IBD-related admission to hospitals
Definition:	How many times has the patient been admitted (requiring at least an overnight stay) to a hospital/acute care facility in the last 12 months (IBD-related)?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	N/A

Variable ID:	HOSPADMPLA
Variable:	All IBD-related planned admissions to hospitals
Definition:	How many times has the patient been admitted (requiring at least an overnight stay) to a hospital/acute care facility in the last 12 months (IBD-related) for a planned admission?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	N/A

Variable ID:	HOSPADMUNP
Variable:	All IBD-related unplanned admissions to hospitals
Definition:	How many times has the patient been admitted (requiring at least an overnight stay) to a hospital/acute care facility in the last 12 months (IBD-related) for a unplanned admission?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	N/A

Variable ID:	TOTLENST
Variable:	Total length of all admissions and readmissions
Definition:	Total length of all, (all-cause) admissions and readmissions within 1 year
Supporting Definition:	In days
Inclusion Criteria:	All patients

Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	N/A
Variable ID:	TOTEDVIS
Variable:	Total number of emergency room visits
Definition:	Total number of emergency room or emergency department visits within 1 year
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	N/A

Survival and Disease Control

Variable ID:	ANAEMIA
Variable:	Presence of anaemia
Definition:	Indicate if there is evidence of anaemia?
Supporting Definition:	Anaemia is defined by the WHO as a haemoglobin (at sea level) of <12.0 g/dl in non-pregnant women, <11.0g/dl in pregnant women and <13.5 g/dl in men
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No
	1=Yes
	2=Unknown
Variable ID:	DISACTCR1
Variable:	Disease activity - clinical remission
Definition:	Is the patient clinically in remission?
Supporting Definition:	This could be determined using any recognised assessment or questionnaire.
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No
	1=Yes
	2=Unknown
Variable ID:	DISACTCR2
Variable:	Disease activity - biological remission
Definition:	Is the patient in biological remission?
Supporting Definition:	This could be determined using any approach, (e.g. endoscopically, radiological, histologically).
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No
	1=Yes
	2=Unknown
Variable ID:	DISACTCR3
Variable:	Disease activity -method of determining biological remission
Definition:	If the patient is in biological remission, how was this determined?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported

Type:	Multiple answers
Response Options:	0= Endoscopically (e.g. endoscopy, colonoscopy)
	1= Radiologically (e.g. fluoroscopy, CT, MRI)
	2= Biochemistry (e.g. CRP, faecal calprotectin)
	3= Histologically (tissue analysis)
Variable ID:	DISACTPR
Variable:	Disease activity
Definition:	In the last 6 months, my disease has been
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Patient-reported
Type:	Single answer
Response Options:	0=Constantly active giving me symptoms every day
	1=Often active, giving me symptoms most days
	2=Sometimes active, giving me symptoms on some days (for instance 1–2 days/week)
	3=Occasionally active, giving me symptoms 1–2 days/month;
	4=Rarely active, giving me symptoms on a few days in the past 6 months
	5=I was well in the past 6 months, what I consider a remission or absence of symptoms
Variable ID:	COLOCA
Variable:	Colorectal cancer
Definition:	Has colorectal cancer been diagnosed?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No
	1=Yes
	2=Unknown
Variable ID:	COLODYS
Variable:	Colorectal dysplasia
Definition:	If colorectal cancer has been diagnosed, had colorectal dysplasia previously been diagnosed?
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No
	1=Yes
	2=Unknown
Variable ID:	DATEDEATH
Variable:	Date of death
Definition:	Indicate the date of death
Supporting Definition:	N/A
Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Numerical
Response Options:	DD/MM/YYYY
Variable ID:	DCOD
Variable:	Cause of death attributable to IBD
Definition:	Indicate if death was attributed to IBD
Supporting Definition:	N/A

Inclusion Criteria:	All patients
Timing:	Baseline and follow-up
Reporting Source:	Clinician reported
Type:	Single answer
Response Options:	0=No
	1=Yes
	2=Unknown

Variable ID:	INDCOD
Variable:	Cause of death attributable to IBD-related intervention

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Reference Guide Revisions

Reference Guide Version	Location within Reference Guide	Content Change
1.0.1	Contact Information	Removed inactive email address: ichomteam@ichom.org

www.ichom.org