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Developing a Standard Set of Patient-Centred Outcomes for Inflammatory Bowel Disease—an International, Cross-disciplinary Consensus

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Abbreviations: AFA, Association François Aupetit; BMI, Body Mass Index; CCFA, Crohn's & Colitis Foundation of America; CCUK, Crohn's & Colitis UK; IBDQ, Inflammatory Bowel Disease Questionnaire; IBD-U, inflammatory bowel disease-undetermined; ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification; ICHOM, International Consortium for Health Outcomes Measures; MIBDI, the Manitoba IBD Index; PRO, patient-reported outcome; PROM, patient-reported outcome measure; SCQ, Self-reported Comorbidity Questionnaire

Abstract

Background and Aims: Success in delivering value-based healthcare involves measuring outcomes that matter most to patients. Our aim was to develop a minimum Standard Set of patient-centred outcome measures for inflammatory bowel disease [IBD], for use in different healthcare settings.

Methods: An international working group [*n* = 25] representing patients, patient associations, gastroenterologists, surgeons, specialist nurses, IBD registries and patient-reported outcome measure [PROM] methodologists participated in a series of teleconferences incorporating a modified Delphi process. Systematic review of existing literature, registry data, patient focus groups and open review periods were used to reach consensus on a minimum set of standard outcome measures and risk adjustment variables. Similar methodology has been used in 21 other disease areas [www.ichom.org].

Results: A minimum Standard Set of outcomes was developed for patients [aged ≥16] with IBD. Outcome domains included survival and disease control [survival, disease activity/remission, colorectal cancer, anaemia], disutility of care [treatment-related complications], healthcare utilization [IBD-related admissions, emergency room visits] and patient-reported outcomes [including quality of life, nutritional status and impact of fistulae] measured at baseline and at 6 or 12 month intervals. A single PROM [IBD-Control questionnaire] was recommended in the Standard Set and minimum risk adjustment data collected at baseline and annually were included: demographics, basic clinical information and treatment factors.

Conclusions: A Standard Set of outcome measures for IBD has been developed based on evidence, patient input and specialist consensus. It provides an international template for meaningful, comparable and easy-to-interpret measures as a step towards achieving value-based healthcare in IBD.

Key Words: Inflammatory bowel disease; patient reported outcomes; quality improvement

1. Introduction

A paradigm change is happening in healthcare. Many healthcare organizations are embracing value-based healthcare,[1–4] an approach that aims to achieve the best possible health outcomes for the lowest cost.[5,6] According to the framework presented by Porter *et al*.,[7] the key to determining "value" is measuring outcomes that matter most to patients. When providers are asked to report outcomes, performance improves,[1] even when those outcomes are not patient-defined. Outcome measurement [in contrast to more familiar measures of the care-delivery process[5,6]] has the potential to direct resources towards strategies with the highest value, which is particularly relevant for chronic diseases that are major drivers of healthcare costs.[8] For complex conditions such as inflammatory bowel disease [IBD], the potential gain from a value-driven healthcare strategy could be even greater than conditions with defined interventions, such as cataract surgery.[9]

Crohn's disease [CD] and ulcerative colitis [UC], collectively known as IBD, disproportionately affect young adults in their educationally and economically productive years, leading to reduced quality of life, social functioning and productivity,[10–13] often requiring lifelong drug treatment or major surgery.[14,15] This accounts for high costs to the healthcare system and society,[10,16,17] with annual direct healthcare costs in Europe alone estimated at 4.6–5.6 billion Euros, and a global rise in burden, particularly in East Asia.[12,18–20] Despite the potential impact on the individual, no patient-reported outcome measures [PROMs] are used in routine practice, so patient-reported outcomes [PROs], other than disease-related symptoms, are rarely captured. Furthermore, there remains widespread variation in clinical practice and quality of care provided to patients with IBD.[21–23] With the exception of collaborations such as the ImproveCareNow network,[24–26] current IBD registries track different outcomes or similar outcomes with different definitions, making meaningful comparisons between populations difficult.[27] Similarly, no 'core outcome sets' are currently available for IBD clinical trials to date, limiting the ability for direct comparison or combining of results.[28]

To align outcome measurement in IBD as a step towards value-driven care, the Oxford Academic Health Science Network collaborated with International Consortium for Health Outcomes Measurement [ICHOM] to form an IBD Working Group of clinical and outcome specialists, patients and their associations [Crohn's & Colitis Foundation of America, CCFA; Crohn's & Colitis UK, CCUK; and Association François Aupetit, AFA] from 12 countries. ICHOM is a non-profit organization founded in 2012 by Michael Porter of Harvard Business School, the Boston Consulting Group and the Karolinska Institutet [www.ichom.org], that aims to drive quality improvement and reduce variation in standards between healthcare providers through outcome measurement. This has resulted [as of 2017] in 21 Standard Sets of outcomes for different medical conditions that are being implemented in practice.[29–35] The advantage of this collective effort is that all use standardized methodology; consequently, each condition becomes part of a wider whole for introducing outcome measurement into routine practice, facilitating implementation when different disease areas can learn from others.

Our goal was to develop a minimum Standard Set of patient-centred outcomes for IBD to provide a common language for outcomes that can be tracked systematically.

2. Materials and Methods

2.1. Context and overview

The Standard Set for patients with IBD [age ≥16 years] aims to provide a template with meaningful, comparable and easy-to-interpret

measures that can be implemented in any healthcare setting to track and compare outcomes. It represents a 'minimum' standard to cover the cycle of care for both CD and UC and tracks health status [Figure 1[5]], while not precluding collection of additional measures.

Selection principles for outcomes were:

[i] feasible to capture in routine clinical practice;
[ii] the end results of care, not the process of care;
[iii]important to patients with IBD; and
[iv]responsive to change.

Four domains [Survival and Disease Control; Symptoms, Function, and Quality of Life; Disutility of Care; and Healthcare Utilization] were pre-specified, but not the number of measures. For PROMs, considerations included domain coverage and psychometric properties.[36,37] In the selection of the PROM tool, we aimed to capture health status and impact on quality of life beyond specific disease-related symptoms, using a validated instrument applicable to both CD and UC. Time points for data collection were determined by considering these principles and the burden of data capture on the patient or provider.

Case-mix variables for risk adjustment were selected by: [i] the relevance [strength of causal linkage between the characteristic and the outcome]; [ii] independency; [iii] practicality; and [iv] comparability at a global level.

2.2. The Project Team and Working Group

The Project Team comprised a Chair [ST], an ICHOM Project Leader [CR], and a Research Fellow [AK] responsible for co-ordinating a series of teleconferences and the consensus process. Material for discussion at each call was jointly prepared by the Project Leader and the Research Fellow, who reviewed available registry data and evidence from scientific literature. The Project Team invited patient associations to recommend patients or representatives and identified internationally recognized specialists. In accordance with standard ICHOM criteria, final selection of Working Group members considered [i] expertise, as evidenced by publications on patient outcomes, invitation to speak at international conferences, or national-level leader status, [ii] representation of different geographical areas and areas of expertise, [iii] availability in terms of being able to participate in discussions during teleconferences, and [iv] having no conflict of interest that could compromise the neutrality of the Standard Set. The resulting Working Group [n = 25, see author list] represented seven specialties or interest groups [patients, gastroenterologists, surgeons, specialist nurses, IBD registries, PROM methodology specialists and representatives of large patient organizations] from 12 countries [Australia, Belgium, Brazil, Canada, China, France, Germany, India, Netherlands, South Korea, UK and USA].

2.3. Consensus Process

A *systematic literature review* to identify IBD-related outcomes, relevant definitions and measurement tools of electronic databases [Medline, EMBASE, PsychInfo, Cumulative Index to Nursing and Allied Health Literature, Allied and Complementary Medicine, University of Oxford PROM bibliography database to 2005, and the Cochrane Library] was undertaken. The search strategy was deliberately chosen to capture all studies that reported on any clinical or patient-reported outcomes [including instruments used to measure them] for IBD, without restricting the search to specific domains or a specific time frame, although it was limited to randomized controlled trials, reviews, and meta-analyses published in English [see Supplementary Material 1, which can be found at *Journal of Crohn's and Colitis* Online]. This was supplemented by manual searching of references from key journals that included published IBD guidelines and reviews of IBD-related outcomes. The group convened eight teleconferences and seven online surveys incorporating a modified two-round Delphi process[38] to reach consensus based on evidence and specialist opinion between October 2015 and July 2016. Before each teleconference, the Project Team circulated an agenda, list of key proposals and relevant evidence from the literature for review [where relevant outcomes and metrics were organized into summary tables using a defined hierarchy]. These were then used to generate the discussions, with all participants at each call contributing to key decisions.

Each teleconference was followed by minutes and an online survey for feedback and voting [from all Working Group members

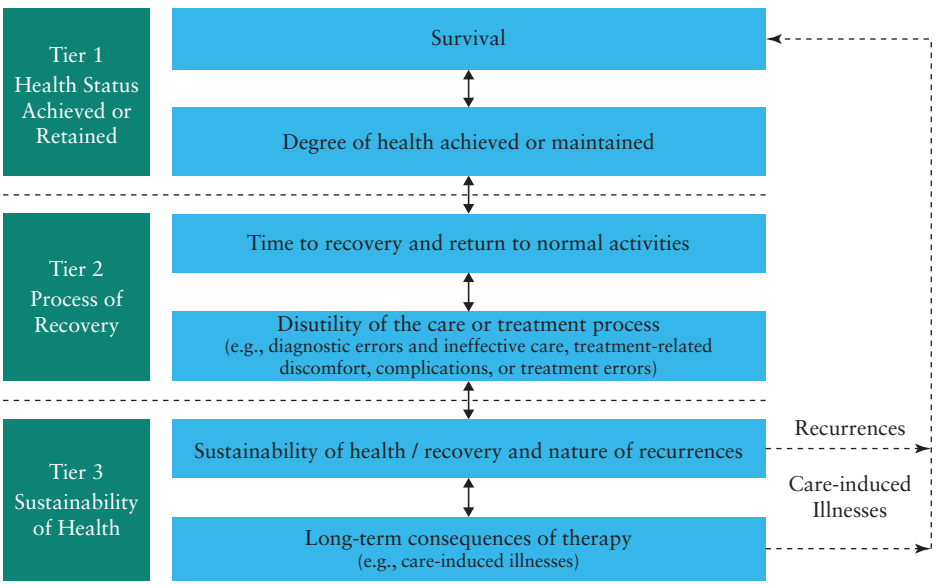

Figure 1. Michael Porter's hierarchy of outcome measures.

including non-participants of the call]. "Key decision areas" included: [i] the scope to be covered by the Standard Set [Calls 1 and 2, 1 survey]; [ii] items to be included in the Standard outcome set, including definition, response options, data source, and timing of collection [Calls 2–5, 3 surveys]; and [iii] case-mix factors required for risk adjustment, including definition, response options, data source, and timing of collection [Calls 5–8, 3 surveys]. "Consensus" was predefined as >70% of the voting Working Group members rating the item as very important [score of 7–9 on a 9-point Likert scale] in either voting round. The Project Team was excluded from voting, giving a maximum of 22 possible votes for each item. Results as percentage agreement were then made available to all Working Group members. Any items where consensus was not reached but ranked 7–9 by at least 50–70% of respondents were further discussed, followed by a second survey. Items ranked 7–9 by <50% of respondents were excluded from further surveys. Similarly, any newly introduced items, change in definition or timing of collection were subject to further surveys to reach consensus. All voted items were reviewed at the subsequent teleconference, whether voted in or out as per pre-defined consensus definition, to provide an additional opportunity for any of the Working Group members to challenge or confirm their inclusion.

A "patient focus group", including six IBD patients and two "1:1 patient interviews" were conducted[39] by CR after the Working Group launch, to obtain patients' perspectives on outcomes that matter most to them, using a structured interview and open-ended questions. Participants, nominated by CCUK and Crohn's & Colitis Australia, discussed which outcomes were of greatest importance to them. The focus groups represented a mix of patients with CD or UC who had received a variety of surgical and/or medical treatments with different healthcare utilization experiences. Additional 1:1 interviews were undertaken for one man and one pregnant woman. Representatives of patient associations and other Working Group members shared their experience with other patient focus groups[22,40–42] during teleconferences to confirm that the most important patient-reported outcome domains and patient concerns were represented in the Standard Set.

The resulting Standard Set was approved unanimously by the Working Group before being subject to "patient validation surveys" and a period of "open review" by interested clinicians before finalization. The patient validation surveys involved circulation of the Standard Set to a geographically and culturally diverse group of patients, with the aid of multiple patient organizations, including CCUK and Crohn's & Colitis Australia, as well as local patient groups invited by Working Group members from Brazil, India and China [PK, RB, ZhR]. The survey was translated into French, Hindi, Brazilian Portuguese, and simplified Chinese. It was completed by 318 patients representing a diverse age group and diverse geographical locations, with 83% indicating that they felt that the current Standard Set captured the most important outcomes that matter or have mattered to them [see Supplementary Material 2, which can be found at *Journal of Crohn's and Colitis* Online]. A web-based draft version of the Standard Set was made available to interested clinicians, ICHOM website registrants and other stakeholders for comment on the Standard Set before finalization.

3. Results

3.1. Scope: Patients with Inflammatory Bowel Disease

The agreed focus [75%, *n* = 16/20] was all patients [age ≥16 years] with IBD defined by the International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] diagnosis codes K50 [CD], K51 [UC] and K52.3 [IBD-Undetermined [IBD-U]]. Children [age <16 years] were excluded because PROMs derived for adults were potentially inapplicable and the Montreal classification of IBD[43] uses this threshold, recognizing that transitional care for young people with IBD can begin as early as age 14.[44–46] Other non-infective causes of colitis in ICD-10 code K52 were excluded.

3.2. Systematic Review of IBD-related Outcomes and Measures

Using a defined hierarchy,[5] outcomes and metrics were selected from 565 papers and abstracts for the Working Group, which was further informed by registry databases and input from patient focus groups. In the four domains, 239 preliminary outcome measures were identified, from which 14 measures and their instruments were selected [see Supplementary Material 3 and 4, which can be found at *Journal of Crohn's and Colitis* Online].

3.3. The Standard Set: Outcome Domains and Measures [Table 1]

3.3.1. Survival and Disease Control

Four measures were selected [Figure 2]. Although death attributable to IBD is infrequent, it is of overriding relevance to patients, highlighted by patient focus groups. Capturing overall survival allows the ultimate impact of care to be assessed. Recognizing the limitations of death registries and reporting in many countries, the Working Group voted [82%, *n* = 14/17] to include both "overall and IBD-specific survival". The Working Group recommends tracking survival each year.

Control of "disease activity and remission" is one of the major goals of treatment. Defining remission, however, is not straightforward, and no agreed tool currently exists to capture disease activity, which in itself can be defined in many ways. There is often discrepancy between the patient's symptoms and their state of biological remission, so the Working Group considered these separately. The consensus [100%, *n* = 17/17] was to use the Manitoba IBD index [MIBDI][47] [Table 2] for both UC and CD at baseline and 6-monthly intervals. The MIBDI is a single-item, patient-defined disease activity measure reported on a 6-point Likert scale allowing a 6-month recall period. It has been validated against the Harvey–Bradshaw Index, the Powell–Tuck Index, and the Inflammatory Bowel Disease Questionnaire [IBDQ].[48] The Working Group decided [88%, *n* = 16/18; 94%, *n* = 17/18] that the clinician should separately report clinical remission and biological remission, and document how biological remission was determined [biochemical, endoscopic, imaging].

"Colorectal cancer", although infrequently complicating IBD,[49] was important to patient focus groups. The Working Group agreed [94%, *n* = 16/17], since treatment may alter this outcome. Annual tracking of a definitive diagnosis was recommended, and for affected patients, reporting whether colorectal dysplasia had previously been diagnosed, and whether they had been participating in colorectal cancer surveillance. Surveillance details were considered to be beyond the scope of minimum standards.

"Anaemia", defined by the World Health Organization [WHO],[50] was recommended [71%, *n* = 12/17] as an independent marker of disease activity and potentially modifiable outcome, tracked at baseline and at 6-monthly intervals.

3.3.2. Healthcare Utilization

Two measures were selected [Figure 2]. Unplanned admissions or Emergency Department visits concern patients with IBD, since

Figure 2. ICHOM Standard Set for Inflammatory Bowel Disease. [1]IBD-Control Questionnaire [Q1–3]. [2]The Manitoba IBD Index.

they can imply suboptimal disease control, non-specialist care, or increased use of ionizing radiation [CT scans].[22] To achieve a practical measure, the Working Group recommended [71%, *n* = 12/17] recording "the total number of emergency room visits every 12 months" and "all IBD-related admissions requiring at least an overnight stay", defined as planned or unplanned, and recording the total length of stay in days over a 12-month period.

3.3.3. Disutility of Care

Two measures were selected [Figure 2]. "Complications resulting from IBD-related treatment" are a central concern for patients that informs their choices about management. Attribution to disease or therapy is contentious, and determining severity is difficult. The Working Group recommended [76%, *n* = 14/18] documenting a complication that occurred during or within 3 months of any treatment [medical, endoscopic, radiological, or surgical], separately recording the outcome [further intervention, unplanned admission, or prolonged hospitalization].

Steroid dependency is a cause of morbidity in IBD, is a concern to patients and may reflect quality of care.[51,52] The Working Group recommended [82%, *n* = 14/17] documenting any systemic "steroid use" within the previous 12 months and whether the duration exceeded 3 months.

3.3.4. Symptoms, Function, and Quality of Life [Patient-Reported Outcomes[35]]

One tool was selected to cover five measures that matter to patients ["change in bowel symptoms", "pain & discomfort", "normal activities", "energy & fatigue", and "depression & anxiety"] [Figure 2]. The tool recommended [100%, *n* = 20/20] was the IBD-Control Questionnaire,[42] applied every 6 months. All IBD-specific PROMs were examined by specialists within the Working Group [RF, WvD] for their conceptual and measurement designs, domain coverage and psychometric properties using ISOQOL criteria [Table 3].[36] Although the best established PROM in IBD is the Inflammatory Bowel Disease Questionnaire [IBDQ],[48] it has failed to embed itself in clinical practice because of its length and need for a licence. The IBD-Control questionnaire[42] captures disease control from the patient's perspective using generic language and measuring themes with which all patients with IBD can identify. It can be administered in less than a minute and has shown strong validity against the EQ-5D,[53] the UK-IBDQ,[54] the Harvey–Bradshaw Index[55] / Simple Clinical Colitis Activity Index,[56] and the Physician Global Assessment. For the purpose of the Standard Set, the Working Group selected Questions 1, 2 and 3 of the IBD Control Questionnaire to be included [Table 4], which adequately covered the five measures of interest.

"Nutritional status" and impact of "fistulae" [for patients with CD] were considered separately. No simple, responsive measure for either could be identified. The Working Group recommended [100%, *n* = 19/19] recording "height and weight" at baseline as a surrogate marker for nutritional status, from which the Body Mass Index [BMI] can be calculated, then the change in weight at 6-monthly intervals. For fistulae, a single question on presence or absence of a

Table 1. ICHOM Standard Set for Inflammatory Bowel Disease.

Patient population	Measure	Supporting information	Timing	Suggested data sources
Symptoms, function, and quality of life				
All patients	Change in bowel symptoms Missing planned activities Night symptoms Pain or discomfort Energy and fatigue Feel anxious or depressed Overall control over IBD	Tracked via the IBD–Control	Baseline and 6-monthly	Patient-reported
	Weight	N/A		
All patients with Crohn's Disease	Fistula symptoms			
Disutility of care				
All patients	Steroid use	Use of any systemic steroids 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-related 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 IBD 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		

Table 2. The Manitoba IBD Index.[47]

In the last 6 months, my disease has been
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

fistula [none, perianal, rectovaginal, enterocutaneous, or other] was added, to be completed at baseline and at 6-monthly intervals.

3.4. Case-mix Variables for Risk Adjustment

The Working Group defined a minimum set of patients' baseline characteristics [Table 5] to enable comparisons of outcomes between centres, regions or countries to be placed in context. Selection had to be practical to capture in routine care, balancing the burden with the need for accurate comparisons. The categories of case-mix variables included: "demographics" [year and sex at birth, education level, smoking status], baseline "clinical factors" [Self-reported Comorbidity Questionnaire, SCQ,[57] with specific inclusion of autoimmune conditions and previous infections with Human Immunodeficiency Virus, hepatitis B virus, or tuberculosis], baseline "condition factors" [diagnosis, date of diagnosis, disease phenotype using Montreal Classification,[43] and presence of extra-intestinal manifestations categorized as eye, skin, joint, hepatobiliary or other], and "treatment factors" [current medication: no IBD drugs, steroids, biologics, immunomodulators, other; type of IBD-related surgery]. Demographics and baseline clinical factors will be patient-reported, while baseline condition and treatment factors will be clinician-reported at baseline, and tracked annually as appropriate for smoking status, disease location/behaviour and treatment.

4. Discussion

A "minimum" set of standardized outcome measures represents a common language that can be used across healthcare jurisdictions as a step towards value-driven care in IBD. Value-driven care relies on reporting and systematic tracking of patient-centred outcomes, allowing providers to compare meaningful outcomes for patients and to adopt strategies that achieve the best "value" for participating stakeholders. This work represents a first step. The performance characteristics of the measures need evaluating in real-world practice. If adopted and implemented, such an approach has the potential to reduce variations in practice and improve standards of care on a global scale.

Existing studies show wide variations in the quality and delivery of care in IBD and suggest significant potential for improvement. National audit in the UK in 2006 led to the development of a set of IBD Standards that defined key performance indicators and recommendations for quality, patient-centred care.[23] In the USA, a collaborative of paediatric IBD centres formed the ImproveCareNow network to develop an outcomes registry using a shared, prospective database between nearly 50 centres. Over

Table 3. Domain coverage and psychometric properties of IBD-specific PROMs.

	Domain coverage by IBD-specific PROMs								
Outcome domains*	**IBDQ**	**SIBDQ**	**IBDQ-9**	**UK-IBDQ**	**CUCQ-32**	**CUCQ-8**	**IBD-control**	**RFIPC**	**IBD-DI**
Overall change in symptom status	Partially	No	Partially	No	No	No	Yes	No	No
Abdominal pain / discomfort	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Bowel habit	Yes	No	Yes	Yes	Yes	No	Indirectly	No	Yes
Rectal bleeding	Yes	No	No	Yes	Yes	No	Indirectly	No	Yes
Tenesmus	Yes	Yes	No	Yes	Yes	No	Indirectly	No	No
Night-time bowel movement / leakage	Indirectly	No	No	No	Yes	Yes	Yes	No	Indirectly
Faecal incontinence	Yes	No	No	Yes	Yes	No	Indirectly	Yes	No
Perianal fistula / discharge / pain	No	No	No	No	No	No	Indirectly	No	No
Unintentional weight change	Yes	Yes	No	No	No	No	No	No	No
Health-related QoL	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Fatigue and energy	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Emotional health	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Limitations to usual ADL	No	No	No	Yes	Yes	No	Indirectly	No	Yes
Work/education productivity	Yes	No	No	Yes	Yes	No	Yes	Partially	Yes
	Psychometric properties by IBD-specific PROMs								
Psychometric properties	**IBDQ**	**SIBDQ**	**IBDQ-9**	**UK-IBDQ**	**CUCQ-32**	**CUCQ-8**	**IBD control**	**RFIPC**	**IBD-DI**
Test–retest reliability [= reproducibility]	High	High	High	High	High	High	High	High	Med
Reliability – internal consistency	Med	Med	Med	Med	High	High	High	High	High
Content validity	High	High	High	High	High	High	High	High	High
Construct validity	Med	Med	Med	Med	High	High	High	High	High
Responsiveness [ability to detect change]	Med	Low	Low	Med	Unknown	Unknown	High	Low	Unknown

*Outcomes preliminarily selected by Working Group for inclusion within the Symptoms, Function, and Quality of Life domain.

Table 4. The IBD Control Questionnaire[42] [Questions 1–3].

1. Do you believe that:	
a. Your IBD has been well controlled in the past 2 weeks?	Yes/No/Not sure
b. Your current treatment is useful in controlling your IBD?	
2. Over the past 2 weeks, have your bowel symptoms been getting worse, getting better or not changed?	Better/No change/Worse
3. In the past 2 weeks, did you:	
a. Miss any planned activities because of IBD? [e.g. attending school/college, going to work or a social event].	Yes/No/Not sure
b. Wake up at night because of symptoms of IBD?	Yes/No/Not sure
c. Suffer from significant pain or discomfort?	Yes/No/Not sure
d. Often feel lacking in energy [fatigued] [by "often" we mean more than half of the time].	Yes/No/Not sure
e. Feel anxious or depressed because of your IBD?	Yes/No/Not sure
f. Think you needed a change to your treatment?	Yes/No/Not sure

the years, remission rates within the participating centres have increased from 55% to 75%, using the physician's global assessment.[24] This highlights what can be achieved when the provision of care is driven by outcomes.

The Standard Set presented here is the first coordinated international, multidisciplinary effort to reach a precisely defined core set of outcomes for all adult patients with IBD. The development process has followed reporting guidelines for core outcome sets.[58] This is an advantage, because IBD becomes just one of many [21 diseases as of 2017, www.ichom.org] diseases subject to the same process. The final Standard Set [Figure 2] tracks 14 outcome measures that encompass the full cycle of care for both CD and UC, as well as health status beyond completion of care. The selection process was guided by careful consideration of the hierarchy of outcome measures and pre-specified domains. Each of the selected outcome measures was subject to voting on definition, response options and data source in a formal consensus process. Practicality in terms of burden on the patient and/or the provider, and feasibility in a broad range of healthcare settings were additional considerations.

Importantly, the Standard Set emphasizes outcomes that matter most to patients. The US Food and Drugs Administration has advocated routine inclusion of PROs as co-primary endpoints in clinical trials.[59] Although improving quality of life is a common secondary endpoint in clinical trials, it has been the primary endpoint in only one trial in IBD[60] and is rarely captured in routine practice. While the IBDQ has been widely used in trials, it has failed to embed itself in routine practice because of its length, and pragmatic reasons of cost and administrative burden. A shorter version,[61] and other more recent variations of the IBDQ such as the UK version of the IBDQ[54] and Crohn's and Ulcerative Colitis Questionnaire[62] have similarly failed to gain popularity. The IBD-Control Questionnaire,[42] unanimously recommended by the Working Group, is a PROM tool developed with the primary aim of supporting patient-centred care in practice. It captures the patient's perspective on disease control using

Table 5. ICHOM Standard Set for Inflammatory Bowel Disease: case-mix and treatment variables.

Patient population	Measure	Supporting ionformation	Timing	Suggested data sources
Demographics				
All patients	Year of birth Male or female	N/A	Baseline	Patient-reported
	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 Patient weight	To calculate BMI	Baseline	
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 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	N/A		
Patients diagnosed with colorectal cancer	Participation in a colo-rectal cancer surveillance programme			

a simple set of generic items applicable to all patients with IBD. It is freely available without a licence and takes less than 60 s to complete, which gives it great potential in routine practice. Strong psychometric properties have led to its selection for the UK IBD registry, although it is yet to be validated in other languages apart from Spanish. The Standard Set of outcomes defined here are designed for clinical practice and would only be adaptable to clinical trials once performance characteristics are defined by prospective measurement.

Parallel efforts to define PROMs in IBD have been driven by the CCFA within the USA, and the 10 most highly rated process and outcome measures were published in 2013.[22] The current Working Group took advantage of this work by including key patient, association and clinical specialist representatives involved in the CCFA process. Similarly, the National Institutes of Health Patient-Reported Outcomes Measurement Information System metrics were developed for gastrointestinal symptoms in 2014.[63] The development process and selected measures of both these initiatives reassuringly have much in common with ICHOM, but challenges remain with standardization of these measures. Strengths of the ICHOM Standard Set include international representation of patients and clinicians' perspectives [including low-income countries], precise definitions of outcome measures and data sources for implementation, as well as recommended timelines for data collection. A minimum set of baseline characteristics [case-mix variables] has been determined to allow meaningful comparisons between populations via risk adjustment. The IBD Standard Set was further subject to patient validation surveys in several languages for global implementation and open review for comment by interested clinicians before finalization. Standard Sets remain open to modification by international agreement.

Nevertheless, the Standard Set has limitations. The patient numbers involved in focus groups and face-to-face interviews were few: however, unlike evidence-based science, the methodology of qualitative research and quality improvement depends not on numbers but on the extent to which concepts reflect the opinions of representative groups. There is no standard for determining an adequate group size,[64] and work in other fields has considered groups of 5–10 patients to be optimal.[39,65] Symptom domains of importance and concerns identified by our focus groups reflected those of earlier work by patient associations and others.[23,40,41,66–68] Patient representatives on the Working Group [MD, JM, HT, AW] present for the discussions and final decisions represented large patient organizations [CCFA, CCUK, and AFA]. More patients, groups and a wider validation survey might have been involved, but a balance had to be struck between resources and delivery within a 12 month time frame.

Despite the Working Group's best efforts to develop consensus definitions that were unambiguous, cultural characteristics and infrastructural differences will inevitably influence local data. For some measures, this meant that a broad definition had to be adopted. For example, although readmission and unexpected admission were identified as important outcomes for the domain Healthcare Utilization, the Working Group recognized the variation in thresholds for admission that exists between healthcare providers. It therefore chose to measure total length of stay and separately to track ED visits. The Standard Set also includes outcome measures that rely on pre-existing registry or administrative data. This is relevant for the Survival domain. Inaccurate or inconsistent information with respect to cause of death is well recognized. However, death is a central concern to patients, so could not reasonably be excluded as an outcome. The Working Group chose to include "unknown" as a response option for cause of death. Furthermore, not all outcome measures had practical definitions or validated tools available. This was the case for nutrition. Existing tools such as the Malnutrition Universal Screening Tool[69] act as a screening tool for referral [process

measure] rather than monitoring. Tools requiring anthropometrics or incorporating biochemical measures were considered impractical. The Working Group chose to measure height and weight at baseline for BMI calculation and then change in weight as a surrogate marker of nutritional status and an outcome of care, because this is a universally available, objective measure in low-income countries where access to more costly assessments may be difficult. We used a modified two-round Delphi process to reach consensus on each of the selected outcome measures, and case-mix variables including "how" and "when" these should be captured. The level of consensus deemed necessary in the Delphi process remains ambiguous in the literature, and there are no agreed norms for size of consensus, with practice varying from basic majority to more stringent proportions. The level of agreement used in our work was pragmatic, based on other successfully conducted international consensus processes for outcomes, including those used by ICHOM in other published Standard Sets. Notably, the Core Outcome Measures in Effectiveness Trials initiative used this cut-off.[70] The minimum denominator for all votes was 17, representing 77–81% of the Working Group members [excluding the Project Team]. It should be noted that while numbers formally participating in any given vote varied, all Working Group members were subsequently prompted for feedback and had the opportunity to confirm or challenge the results. The final Standard Set was approved unanimously by the Working Group.

This international, multidisciplinary IBD Working Group has developed a minimum set of patient-centred outcomes, tools and PROMs for collection in patients with IBD. Data collection needs to be piloted and a standardized collection platform developed before data quality and outcomes can be compared in different settings. ICHOM is committed to facilitating broad adoption of this set and has made the full recommendations freely available on its website [www.ichom.org/medical-conditions/inflammatory-bowel-disease], along with a reference guide to assist with technical aspects of implementation. The near-term goal will be to implement the set and to use this as a proof of concept towards broader adoption or endorsement by payors and governments. A steering committee will oversee revisions to the Standard Set to reflect changes in data collection capacity, to clarify outcome or baseline characteristics definitions as needed and respond to improvements in outcome measurement tools. In this way, the international IBD community can move towards the ultimate goal of acquiring internationally comparable data on patient-centred outcomes and improve the value of care.

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Andrew H Kim [AK] declares no conflicts of interest.

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Author Contributions

AK: study design, literature review, acquisition of data, analysis and interpretation of data, material support, drafting of manuscript, preparation of figures and tables, critical revision of the manuscript for important intellectual content, and approval of final work. CR: study design, material and technical support, acquisition of data, analysis and interpretation of data, preparation of figures and tables, critical revision of the manuscript for important intellectual content, and approval of final work. ST: study concept and design, obtained funding, study supervision, acquisition of data, analysis and interpretation of data, critical revision of the manuscript for important intellectual content, and approval of final work. MD, JG, JM, HT: acquisition of data, interpretation of data. BF, RB, WB, KB, AD, RD, RF, PH, PK, MoC, ZhR, CS, WvD, JvdW, AW, SkY, BS, SV: acquisition of data, analysis and interpretation of data, critical revision of the manuscript for important intellectual content, and approval of final work.

Supplementary Data

Supplementary data are available at *ECCO-JC* online.

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