

# Multicriteria Decision Analysis for Updating of Quality Indicators for Inflammatory Bowel Disease Comprehensive Care Units in Spain

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## Abstract

**Background and Aims:** Management of inflammatory bowel disease [IBD] is complex and IBD Comprehensive Care Units [ICCU] facilitate the delivery of quality care to IBD patients. The objective of this study was to update the existing set of quality indicators [QIs] for ICCUs, based on a nationwide quality certification programme carried out in Spain, from a multi-stakeholder perspective and using multicriteria decision analysis [MCDA] methodology.

**Methods:** An MCDA comprising three different phases was conducted. In phase 1, a systematic literature review was performed, and after validation by a scientific committee comprising 11 experts, a preliminary set of QIs was developed. In phase 2, a larger group of 49 experts determined the relevance and relative importance of each QI by prioritising and weighing the preliminary set. Finally in phase 3, the scientific committee reviewed the results and made a final selection via a deliberative process.

**Results:** The final set comprised 67 QIs, classified as Structure [23 QIs], Process [35 QIs] and Outcome [9 QIs], which were ranked according to their relative importance. Multidisciplinary management was the most important requirement in ICCUs, followed by continuity of care, standardisation of clinical care and, especially, the incorporation of patients' reported outcomes.

**Conclusions:** This updated set of QIs comprises a weighted and prioritised set of items that represent the essential minimum of criteria for ensuring appropriate quality of care in the management of IBD patients.

**Key Words:** Comprehensive care unit; inflammatory bowel disease; multicriteria decision analysis; patient reported outcome; quality indicators.

## 1. Introduction

Inflammatory bowel disease [IBD] comprises a group of disabling, chronic, intestinal, immune-mediated, inflammatory diseases.<sup>1</sup> Crohn's disease [CD] and ulcerative colitis [UC] are the most common IBD, and their incidence and prevalence are currently increasing.<sup>2,3</sup> Both have a major impact on patients' physical health status, social functioning, and quality of life, and may lead to permanent disability.<sup>4–8</sup>

Despite the existence of effective surgical and medical therapeutic approaches, the global management of IBD is

complex. Patients often need monitoring of disease activity, complications, and therapeutic responses that may require the participation of various health care specialists.<sup>9–12</sup>

International clinical practice guidelines acknowledge the importance of clinical IBD multidisciplinary teams as the key element in achieving optimal clinical care.<sup>13–15</sup> Multidisciplinary management of IBD patients may increase remission rates, reduce morbidity and surgery requirements, and help patients to achieve normal social functioning.<sup>16–18</sup> This multidisciplinary management is best provided at IBD

comprehensive care units [ICCU].<sup>18</sup> Therefore, the creation and certification of ICCUs may benefit IBD patients, as the quality of the health care provided has a direct impact on their quality of life.<sup>19–21</sup> It is important, therefore, to define the minimal structure, processes, and outcomes requirements to ensure the adequate functioning of the ICCU and to produce a set of quality indicators [QIs] that assess whether a given ICCU meets these minimal requirements.<sup>19,20</sup>

Several studies have been conducted at local, national, and international levels to define the development of a minimum set of quality indicators for the assessment and measurement of quality of care for IBD patients.<sup>19,20,22–36</sup> However, most of the proposals comprised general recommendations and were not suitable for ICCU certification.<sup>22</sup>

In 2014, the Spanish Working Group on Crohn's Disease and Ulcerative Colitis (Grupo Español de Trabajo sobre Enfermedad de Crohn y Colitis Ulcerosa [GETECCU])<sup>37</sup> conducted a Delphi study that aimed to define a set of QIs for certifying ICCUs, evaluating their quality, and identifying areas in need of improvement.<sup>23</sup> Since then, GETECCU has successfully certificated ICCUs all over the Spain, applying this set of QIs.<sup>38</sup> ICCUs voluntarily applied to participate in the certification process and were granted quality certifications by an independent auditor if they met the requirements.<sup>39</sup>

However since 2014, new advances and trends have emerged in IBD management. In addition to new clinical approaches, the incorporation of patients' reported outcomes [PROs] is a key aspect for determining value in health and must be taken into account for an optimal management of IBD.<sup>40</sup> Moreover, new methodologies have been developed to improve the item selection processes. For example, Multicriteria Decision Analyses [MCDA] allow not only the selection of key attributes but also the assessment of the relative importance of each item, providing a final set of weighted QIs.<sup>41,42</sup>

Taking these principles into account and considering the previous set of items proposed by GETECCU in 2014, this study aimed to produce a new updated set of minimum essential QIs which included patients' reported outcome measurements [PROMs] and patients' reported experience measurements [PREMs], from a multi-stakeholder perspective and using MCDA methodology.

## 2. Materials and Methods

### 2.1. MCDA methodology

The MCDA applied in this study was performed according to the recommendations of the International Society for Pharmacoeconomics and Outcomes Research [ISPOR], which establishes the appropriate steps and techniques for these analyses.<sup>41,42</sup> An MCDA can apply any one of three different methods: 1) value measurement models, in which the alternatives are prioritised by a weighted numerical score; 2) outranking methods, in which alternatives are compared by pairs and ranked; and 3) reference-level models, in which minimum levels are predefined, and it is decided whether the alternative attains the level.<sup>41,42</sup>

Due to the wide number of possible QIs that were expected to be found, for practical reasons the outranking method and the reference-level model methodology were discarded, and the value measurement model was considered the best approach for producing this MCDA. The MCDA was structured in three different phases. In phase 1, a draft set of QIs was selected and

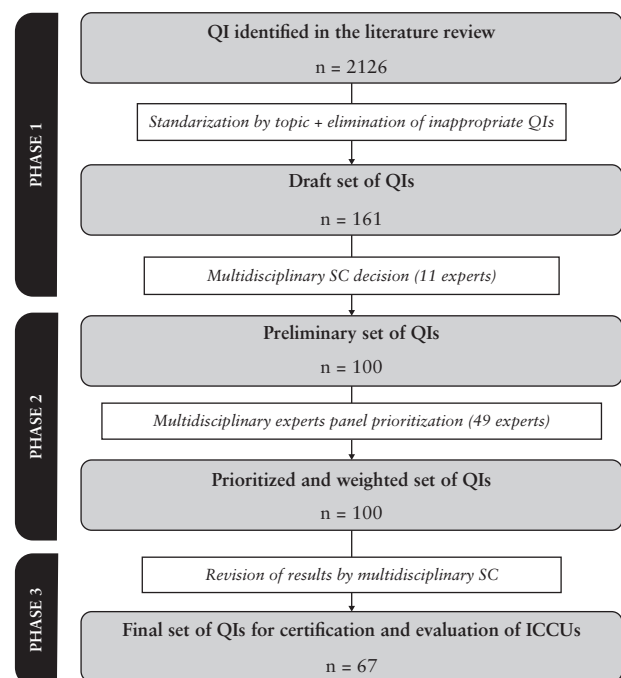
defined based on a literature review. In phase 2, QIs selected from the previous phase were weighted and prioritised based on their relevance in IBD management. Finally in phase 3, the results were discussed and the list of final QIs in IBD were selected by means of a deliberative process [Figure 1].

### 2.2. Participants

A scientific committee [SC] revised the entire MCDA process and actively participated in consensus phases 1, 2, and 3. The SC included five gastroenterologists, three IBD patients, two IBD nurses, one health care quality specialist, and one colorectal surgeon [Supplementary Table 1]. Additionally, a multidisciplinary panel of experts in IBD was selected. This panel was responsible for evaluating and prioritising the QIs according to their relevance, in order to establish a weighted score for every indicator.<sup>41,42</sup>

The project recruited a total of 49 participants, all potential stakeholders in the evaluation of ICCU quality [Supplementary Table 2]: 20 specialised IBD gastroenterologists [GETECCU affiliates]<sup>37</sup>; 15 IBD patients (eight members of Crohn and Ulcerative Colitis Association [ACCU]<sup>43</sup> and seven patients who were not affiliated to ACCU and were recruited by SC gastroenterologists); eight IBD nurses from the Nurse Working Group on Inflammatory Bowel Disease [GETEII]<sup>44</sup>; three health care quality specialists, members of the Spanish Society for Healthcare Quality [SECA]<sup>45</sup> with expertise in the area of study; and three coloproctology surgeons from the Spanish Association of Coloproctology [AACP].<sup>46</sup>

The entire MCDA process was performed with the assistance of three specialists in health economics and outcomes research, who were responsible for the correct application of the MCDA methodology and for providing methodological support throughout the evaluation process to ensure that the methodology was well understood and correctly followed.



**Figure 1.** Flowchart of the QI selection process. ICCU, inflammatory bowel disease comprehensive care unit; QI, quality indicator; SC, scientific committee.

## 2.3. MCDA development

### 2.3.1. Phase 1: definition and selection of QIs

The first phase of the study focused on identifying all potential QIs presented in the literature, to generate a first draft set of items. A structured bibliography review was performed following the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses [PRISMA].<sup>47</sup> A systematic search was conducted in MEDLINE, EMBASE, and the Cochrane Plus Library and also in databases of articles written in Spanish, the Índice Médico Español, and MEDES [Medicina en Español]. Additionally, manual searches were carried out in the websites of multiple scientific societies and health care institutions. Searches were performed up to January 2020. The search strategy used was based on the combination of different search terms: ‘inflammatory bowel diseases’, ‘patient care team’, ‘standards’, ‘quality indicators’, ‘practice guidelines’, or ‘standard of care’, among others. Details of the structured bibliographical review can be found in [Supplementary Tables 3 and 4](#).

The definition and implications of each indicator were recorded and, additionally, the number of times each individual QI was mentioned or considered in the articles assessed was also documented. To generate a more manageable set of items, the QIs included were then screened by the study’s SC. Based upon the information gathered, QIs with similar topics were unified as one single item. Furthermore, items with a low number of mentions during the bibliographical review were revised; most of them were considered of low relevance and consequently eliminated.

Based on these results, a questionnaire with the definition and implications of the draft set of QIs was designed. This questionnaire was revised by all the SC members who evaluated the suitability of each single indicator for inclusion as a QI for the ICCU certification. When a particular indicator was excluded, the SC members specified whether this was due to the indicator being unsuitable for an audit evaluation, irrelevant, or for other reasons. The SC revised and proposed changes for the definition for each QI, ensuring that the definitions were clear and comprehensible to all the stakeholders who participated in the subsequent phases of the study. Finally, the SC members were asked to provide any additional QI that might be considered of relevance and had not been included in the draft set of QIs.

Once all SC members had completed the questionnaire, results were presented and discussed in an online board meeting with all the SC members, who determined the final set of QIs. The items for which no unanimous agreement was reached were re-evaluated until a consensus was achieved by all the members of the SC. The set of QIs obtained after this process was assessed in phase 2.

### 2.3.2. Phase 2: weighting and prioritisation of the QIs

In the second phase of the study, the multidisciplinary panel of 49 participants prioritised the preliminary set of QIs. QIs were ranked by importance according to a weighted score. For this purpose, the preliminary set of QIs was categorised into three groups [structure, process, and outcomes], and subsequently classified in nine more subgroups of 10 to 12 items, which grouped items with related topics [Figure 2].

The experts had to distribute a total of 100 points between the QIs in each subgroup, considering that the more important indicators should receive higher scores. Afterwards,

experts also distributed another 100 points between the nine subgroups of QIs considered in the analysis. The final score of each individual QI was the result of multiplying the individual score in its subgroup by the global subgroup score. When this weighted score was obtained, the final score of every single QI was mathematically adjusted so that all QIs added up to a total score of 100 points.

The questionnaire was designed to avoid the possibility of under- or over-rating QIs. Panel participants were also instructed not to score a specific QI when they felt that they lacked the expertise to evaluate it. Mathematical corrections were applied to ensure that unscored QIs did not affect the final weight scores. The design of the questionnaire also allowed the experts to provide comments on the indicators, doubts regarding their comprehensibility, or suggestions for improvement, which were used to improve the definitions of the QIs: no questions about comprehensibility or interpretation were raised during the process. Finally, the team in charge of the methodology was available to the panellists throughout the process, to answer questions and record their comments.

Finally, a sensitivity analysis was performed assuming that the nine QI subgroups were equally important. According to all the panel evaluations, each QI was assigned an individual final score based on experts’ assessments.

### 2.3.3. Phase 3: deliberative process

In this last phase of the MCDA, the results of phase 2 were evaluated by the SC. The aim of the final phase 3 of the study was to examine the results of the MCDA through a deliberative process and to select the final set of QIs.

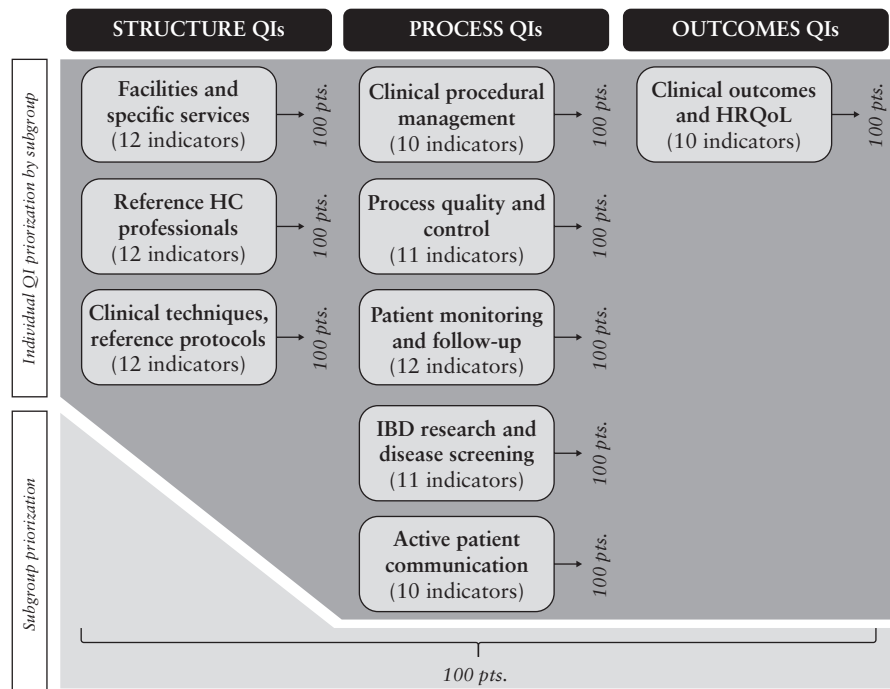
First, the SC set a score threshold in order to select the QIs that were most relevant. Three different mathematical assessments of the results were conducted: the change in ranked score distribution of individual QIs; change in ranked global satisfaction score according to individual QIs; and change in ranked total cumulative score according to individual QIs. Moreover, sensitivity analysis results were also taken into consideration. QIs of relevance obtained from this scenario were reconsidered if they had not been included in the original assessment. Finally, all discarded QIs were evaluated one by one by the SC. Those unanimously considered of clinical relevance by the SC were also included in the final set.

## 3. Results

### 3.1. Identification and selection of the first set of QIs

The systematic literature review identified a total of 216 publications of interest. After the elimination of duplicates and the exclusion of articles that did not meet the selection criteria, a total of 60 publications were considered adequate for data extraction [Supplementary Figure 1].

From the assessment of these 60 publications selected in the literature review, 2126 potential QIs related to IBD management were identified. Most of these initial QIs were repeated in more than one publication or considered the same topic. After eliminating duplicates, the number of QIs was reduced to 268. Additionally, QIs that did not appear in five or more publications were specifically revised at a first SC meeting and those considered irrelevant or un-evaluable were eliminated. This led to a final draft set of 161 QIs [139 quality items and 22 PROMs and PREMs].



**Figure 2.** Methodology followed for the prioritisation and weighting of the QIs used during phase 2. HC, health care; IBD, inflammatory bowel disease; QI, quality indicator; HRQoL: health-related quality of life.

This first preliminary set of QIs was integrated in a questionnaire which was administered to individual SC members for phase 1 evaluation. At a second meeting considering phase 1 evaluations, the SC selected a total of 100 QIs [36 structure, 53 process, and 11 outcome, of which two were clinical items and nine PROMs and PREMs] and were then assessed in phase 2.

### 3.2. Weighting and prioritisation of the criteria QIs

The preliminary set of 100 QIs was evaluated by the 49 members of the multidisciplinary panel. The responses of the panel allowed the categorisation of the QIs from the highest weighted score [2.06] to the lowest score [0.51], based on the preferences of the participants. The scores according to the panel's preferences and the sensitivity analysis are shown in [Supplementary Tables 5 and 6](#).

### 3.3. Deliberative process and selection of final QIs list

In this final phase, the phase 2 results were evaluated. Based on the analyses performed, the optimal threshold would be at a point between the first 45 and 64 QIs. Following this methodology, the SC finally decided to consider the first 50 QIs as the most relevant items [[Supplementary Figures 2–4](#)].

Sensitivity analysis was also considered. QIs that were within the set threshold of the first 50 items in this scenario, and had not been considered relevant in the original assessment, were included in the list of selected QIs. Ten additional QIs were considered relevant. To ensure that the use of this approach did not lead to the exclusion of relevant items, all excluded QIs were assessed individually, and those considered relevant by consensus of all the SC members were also included in the final set. Seven QIs were incorporated in this way.

Finally, 33 items were discarded [[Supplementary Table 7](#)], and a definitive set of 67 QIs was selected. Of this final set, 23 QIs were classified as 'structure', 35 as 'process', and nine as 'outcome' [[Supplementary Tables 8–10](#)]. Scores were then redistributed eliminating the unselected items, and were adjusted to ensure that all the QIs selected added up to 100 points.

### 3.4. Description of selected QIs

[Table 1](#) shows the selected QIs, ranked by relevance according to the participants' preferences. The panel ranked the QIs related to the multidisciplinary management of IBD as the most important. The presence of gastroenterologists, IBD nurses, experienced surgeons, endoscopists, and radiologists in the IBD multidisciplinary team was considered the most important structural aspect of an ICCU.

After multidisciplinary management, the next most important area was the continuity and standardisation of clinical care. Thus, process QIs referring to the availability of on-demand consultations [either in person or by phone] in case of flares between the scheduled visits, and the availability of specific IBD diagnosis and treatment protocols, were also scored highly. PROMs and PREMs were assigned a major role. Measurement of the disease status from the patient's perspective by using PROMs was considered an important outcome QI. Furthermore, many PREMs reflecting patients' evaluation of the health care received were regarded as relevant and were included as QIs.

## 4. Discussion

QIs can be defined as measurable, objective standards used to monitor and control the structure, process, and results of care. Their measurement provides a basis for the implementation of corrective measures and continuous quality



**Table 1.** Final list of QIs selected after the implementation of the MCDA methodology

Position	QI	Definition	Group	Inclusion criteria <sup>a</sup>	Weighted score
1	Two gastroenterologists specialised in IBD	The ICCU has at least two gastroenterologists specialised in IBD	Structure	Original assessment	2.723
2 <sup>b</sup>	Nurse specialised in IBD	The ICCU has at least one nurse specialised in IBD	Structure	Original assessment	2.391
3 <sup>b</sup>	Surgeon/surgery team specialised in IBD	The ICCU has at least one surgeon or a surgery team specialised in the surgical treatment of patients with IBD	Structure	Original assessment	2.296
4	Endoscopist specialised in IBD	The ICCU has at least one endoscopist with experience in the diagnosis and treatment of patients with IBD	Structure	Original assessment	1.883
5 <sup>b</sup>	Radiologist specialised in IBD	The ICCU at least one reference radiologist specialised in IBD	Structure	Original assessment	1.836
6 <sup>b</sup>	MRI technique access	The ICCU has access to MRI examinations	Structure	Original assessment	1.750
7 <sup>b</sup>	Specific draw lines for the treatment with cyclosporine or anti-TNF in a UC flare	In patients with a UC flare who do not respond to intravenous corticoids, treatment with cyclosporine or anti-TNF drugs is initiated after a maximum period of 7 days	Process	Original assessment	1.740
8 <sup>b</sup>	Outpatient nurse consulting room	The ICCU has an outpatient nurse consulting room	Structure	Original assessment	1.715
9 <sup>b</sup>	Updated clinical protocols	The ICCU keeps the clinical protocols updated or follows the national/international guidelines on IBD management	Structure	Original assessment	1.708
10	Nurse specialised in ostomies	The ICCU has the support of a nurse specialised in ostomies	Structure	Original assessment	1.697
11	Patients requiring care between visits	The ICCU has the infrastructure to attend to patients with symptoms requiring care between the programmed visits	Structure	Original assessment	1.677
12	Laparoscopic surgery access	The ICCU has access to laparoscopic surgery or TAMIS	Structure	Original assessment	1.662
13 <sup>b</sup>	Specific draw-lines for the immunosuppressor treatments in corticoid-dependent patients	In patients with IBD who have received two or more rounds of corticoids during the previous year, immunosuppressant treatment is initiated	Process	Original assessment	1.630
14 <sup>b</sup>	Extension of the illness in the diagnosis	When a patient is diagnosed with IBD, a complete study of the extension of the pathology is performed, including a colonoscopy and an evaluation of the involvement of the small intestine, if there is suspicion of CD	Process	Original assessment	1.576
15 <sup>b</sup>	Pharmacotherapeutic protocols	The ICCU has a standardised protocol for the use of medicines, specifying when to administer them and how to measure their efficacy, and listing the associated adverse events	Structure	Original assessment	1.566
16	Colonoscopy or radiology for guiding a therapeutic decision	In patients with symptoms despite the treatment for IBD, the activity of the disease is evaluated by analytical parameters and a colonoscopy or radiology to guide therapeutic decision	Process	Original assessment	1.562
17	Rheumatologist specialised in IBD	The ICCU has the support of a rheumatologist with experience in the management of IBD patients	Structure	Original assessment	1.554
18 <sup>b</sup>	Mortality rates of elective surgery	The mortality of elective surgery is under 2% for the past 5 years	Outcome	Original assessment	1.554

Table 1. Continued

Position	QI	Definition	Group	Inclusion criteria <sup>a</sup>	Weighted score
19 <sup>b</sup>	Morbidity rates of elective surgery	In patients with IBD treated by elective surgery, the rate of severe morbidity requiring re-treatment is under 10%	Outcome	Original assessment	1.534
20	Measurement of outcomes reported by the patients about the perception of their own general or specific health [PROM]	The ICCU reports information about PROMs annually in patients' medical records. Of the total number of patients seen, 80% reported good control of their disease based on their perception of their own general or specific health, following the methodology proposed by ICHOM <sup>28</sup>	Outcome	Original assessment	1.534
21	Specific draw-lines to the treatments use in refractory CD	Any treatment must be stopped when the refractory criteria are met	Process	Original assessment	1.524
22 <sup>b</sup>	CT technique access	The ICCU has access to CT examinations	Structure	Original assessment	1.519
23 <sup>b</sup>	Multidisciplinary IBD committee in the ICCU	Complex decisions, including the indication for surgery, are taken by a multidisciplinary committee of IBD comprising gastroenterologists, radiologists, surgeons and nurses	Process	Original assessment	1.509
24	Access to all pharmaceutical treatments	The ICCU offers patients access to all medicines approved for IBD if considered appropriate	Process	Original assessment	1.499
25	Decision making including the agreement of the patient	The ICCU selects the treatment which best fits the needs of the patients after obtaining their agreement	Process	Original assessment	1.491
26 <sup>b</sup>	Specialised outpatient consulting rooms	The ICCU has private rooms to receive outpatient visits, specialised in IBD	Structure	Original assessment	1.485
27 <sup>b</sup>	Anti-TB treatment in patients treated with biologic medicines	Before initiating a biologic therapy, IBD patients with any sign of latent TB have received an appropriate anti-TB treatment	Process	Original assessment	1.485
28 <sup>b</sup>	Abdominal echography diagnosis techniques	The ICCU has access to abdominal echography techniques	Structure	Original assessment	1.484
29	Contact with the ICCU in case of emergencies [PREM]	Each year the ICCU reports information on patients' perceptions about the service received. Of the total number of patients seen, 80% responded positively to the following question about PREM: 'In case of emergency, I have the opportunity to communicate with my IBD care team when I have symptoms of a flare or complications'	Outcome	Original assessment	1.484
30	Information about the pathology [PREM]	Each year the ICCU reports information on patients' perceptions about the service received. Of the total number of patients seen, 80% responded positively to the following question about PREM: 'My IBD care team has given to me sufficient information about my disease'	Outcome	Original assessment	1.458
31	Follow-up during the phases of the pathology [PREM]	Each year the ICCU reports information on patients' perceptions about the service received. Of the total number of patients seen, 80% responded positively to the following question about PREM: 'My IBD care team participates in all phases of my disease [emergencies, outpatient visits, hospitalisation, endoscopies, etc.]'	Outcome	Original assessment	1.456

Table 1. Continued

Position	QI	Definition	Group	Inclusion criteria <sup>a</sup>	Weighted score
32	Confidence in the IBD care team [PREM]	Each year the ICCU reports information on patients' perceptions about the service received. Of the total number of patients seen, 80% responded positively to the following question about PREM: 'I am convinced that my IBD care team is able to manage appropriately my disease'	Outcome	Original assessment	1.449
33 <sup>b</sup>	Gastroenterologist present during hospital stay	A gastroenterologist of the ICCU participates actively in the management of the hospitalised patients	Process	Original assessment	1.444
34	Adequate attention in medical visits [PREM]	Each year the ICCU reports information on patients' perceptions about the service received. Of the total number of patients seen, 80% responded positively to the following question about PREM: 'My physician pays attention to me during medical visits'	Outcome	Original assessment	1.438
35 <sup>b</sup>	Emergency services protocols for IBD patients	The ICCU has a protocol for the care of IBD patients who use the emergency service	Structure	Original assessment	1.434
36 <sup>b</sup>	Colorectal cancer screening programmes	All IBD patients in the ICCU with indication of colorectal cancer screening in accordance with international guidelines are evaluated by periodical colonoscopies	Process	Original assessment	1.417
37 <sup>b</sup>	Information on risks/benefits before a surgical procedure	The clinical history records that the patient has received appropriate prior information about the benefits and risks associated with a surgery	Process	Original assessment	1.414
38	Consideration of patients' opinions [PREM]	Each year the ICCU reports information on patients' perceptions about the service received. Of the total number of patients seen, 80% responded positively to the following question about PREM: 'My opinion and my personal and working situation have been taken into account in the decisions regarding the management of my disease'	Outcome	Original assessment	1.405
39 <sup>b</sup>	Facilities for administering intravenous medicines	The ICCU has facilities for the administration of intravenous medicines	Structure	Original assessment	1.402
40 <sup>b</sup>	ICCU located in the digestive system service	The ICCU is located in the digestive system service	Structure	Original assessment	1.394
41	Annual re-evaluation of patients	All patients are re-evaluated at least once a year, including those in remission	Process	Original assessment	1.389
42 <sup>b</sup>	Elective surgeries performed by specialists	Elective surgeries are performed by the surgeons in the ICCU staff	Process	Original assessment	1.386
43 <sup>b</sup>	ICCU located in a hospital with endoscopy unit	The ICCU is located in a hospital with an endoscopy unit in the digestive system service	Structure	Original assessment	1.384
44 <sup>b</sup>	Emergency consultation services	The ICCU can attend to outpatient consultations when there is suspicion of a severe flare or complication, at least during workdays	Process	Original assessment	1.384
45 <sup>b</sup>	Biologic medicines monitoring programmes	The ICCU has a programme to perform the clinical and laboratory monitoring of patients treated with biologic therapies	Process	Original assessment	1.372

Table 1. Continued

Position	QI	Definition	Group	Inclusion criteria <sup>a</sup>	Weighted score
46	Severe UC management protocol	The ICCU has specific protocols for the management of patients with severe UC	Structure	Original assessment	1.369
47	ICCU located in a hospital with surgery department	The ICCU is located in a hospital with a surgery department	Structure	Original assessment	1.359
48	Attenuated vaccines in patients treated with biologic therapies or immunosuppressants	Attenuated virus vaccines are avoided in patients treated with immunosuppressants or biologic therapies	Process	Original assessment	1.356
49 <sup>b</sup>	Information on risks/benefits before starting an immunomodulator or immunosuppressant treatment	The clinical history records that the patient has received appropriate information about the benefits and risks associated with an immunomodulator or immunosuppressant treatment prior to its initiation	Process	Original assessment	1.352
50 <sup>b</sup>	Information on risks/benefits before starting a biologic treatment	The clinical history records that the patient has received appropriate information about the benefits and risks associated with a biologic treatment prior to its initiation	Process	Original assessment	1.352
51 <sup>b</sup>	Phone consultation service at scheduled times	The ICCU has phone consulting lines available for patients at scheduled times, at least on workdays	Structure	Sensitivity analysis	1.346
52 <sup>b</sup>	Cards with the contact data of the ICCU	The patient has received information with the contact data of the ICCU, including the phone number and his/her attendance schedule	Process	Sensitivity analysis	1.346
53 <sup>b</sup>	TB test before starting a biologic treatment	Before starting a biologic treatment, patients with IBD have performed a test to detect TB, according to the current recommendations	Process	Sensitivity analysis	1.336
54 <sup>b</sup>	HBV vaccination	All patients with IBD have been vaccinated against HBV	Process	Clinical	1.327
55 <sup>b</sup>	Pre-ostomy interviews	Before a surgical intervention that might include an ostomy, the patient has been interviewed by a nurse specialised in ostomies	Process	Sensitivity analysis	1.308
56 <sup>b</sup>	Antiviral treatment in patients with a positive HBsAg test	All patients with a positive HBsAg test receive antiviral treatment while undergoing a biologic therapy	Process	Clinical	1.302
57 <sup>b</sup>	Monitoring of immunomodulator or immunosuppressant treatments	The ICCU has a program to perform the clinical and laboratory vigilance of patients treated with immunomodulator or immunosuppressant therapies	Process	Clinical	1.295
58 <sup>b</sup>	Priority visits	The ICCU has a circuit of priority visits for patients referred from the GP, emergency service, or other health care professionals due to a recent diagnosis or a severe flare of IBD	Process	Sensitivity analysis	1.291
59 <sup>b</sup>	Physician specialised in IBD assigned to each patient	Each patient is assigned a physician specialised in IBD, identifiable, and responsible for his/her clinical care	Process	Clinical	1.266
60 <sup>b</sup>	Specific draw-lines for the maintenance of thiopurines during the pregnancy	Patients with IBD treated with thiopurines maintain this treatment during pregnancy. If the patient prefers to finish the therapy, this must be documented	Process	Clinical	1.261
61 <sup>b</sup>	Registry of patients treated by the ICCU	The ICCU has a registry recording all patients treated by the unit	Process	Sensitivity analysis	1.259



Table 1. Continued

Position	QI	Definition	Group	Inclusion criteria <sup>a</sup>	Weighted score
62 <sup>b</sup>	Gastroenterologist with updated training	The gastroenterologists of the ICCU participate at least once a year in an IBD training activity	Process	Sensitivity analysis	1.213
63 <sup>b</sup>	HBV screening	In patients with IBD, screening HBV tests are performed at the onset patient's first visit to the UAI.	Process	Sensitivity analysis	1.213
64 <sup>b</sup>	Registry of patients receiving biologic therapies	The ICCU has a registry recording all patients treated with biologic therapies	Process	Sensitivity analysis	1.209
65 <sup>b</sup>	Scientific research projects	The ICCU performs or participates in scientific IBD research projects	Process	Sensitivity analysis	1.190
66 <sup>b</sup>	Antithrombotic treatment during hospital stays	Antithrombotic treatment is initiated in all hospitalised patients	Process	Clinical	1.172
67 <sup>b</sup>	CMV test in UC	In patients with UC and a severe corticoid-dependent flare, rectal biopsies are obtained in order to rule out CMV infection	Process	Clinical	1.144

CD, Crohn's disease; CMV, cytomegalovirus; CT, computerised tomography; GP, general practitioner; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; IBD, inflammatory bowel disease; ICCU, IBD comprehensive care units; ICHOM, International Consortium of Health Outcomes Measurement; MCDA, multicriteria decision analysis; MRI, magnetic resonance imaging; PREM, patient-reported experience measure; PROM, patient-reported outcome measurement; QI, quality indicators; TAMIS, trans-anal minimal invasive surgery; TB, tuberculosis; TNF, tumour necrosis factor; UC, ulcerative colitis. <sup>a</sup>The screening methods were: 1) original assessment, consisting in the selection of the first 50 indicators, the criterion considered most suitable by the scientific committee based on the statistical assessment of the results; 2) clinical: assessment of the indicators that were excluded in the original assessment but were then reincorporated due to their clinical relevance and based on the scientific committee's preferences; and 3) sensitivity analysis, consisting in the reincorporation of the indicators within the first 50 places in this scenario, and which were not under consideration in the original assessment..

<sup>b</sup>Indicator also considered in the previous set: Calvet X *et al.* *J Crohns Colitis* 2014;8:240–51.

improvement.<sup>48,49</sup> Therefore, QIs enable professionals and organisations to monitor and evaluate how health care systems respond to patients' needs.<sup>50</sup> They provide a quantitative basis for clinicians and organisations aiming to achieve improvements in care.<sup>51</sup>

QIs also make it possible to compare health care units of similar characteristics. They are crucial for the process of certification, which aims to harmonise and raise the quality of care delivered to patients.<sup>32</sup> QIs are thus essential to ensure optimal health care services in all clinical fields.<sup>31</sup>

In the GETECCU Delphi consensus report, an expert panel formed by patients, IBD nurses, surgeons, and gastroenterologists selected a set of 56 QIs [12 'structure', 20 'process,' and 24 'outcome'].<sup>23</sup> Based on the consensus results, a final set of 53 standardised QIs adapted for external auditing was established in 2016.<sup>52</sup> Using this standardised set of QIs, GETECCU has implemented a Certification of Inflammatory Bowel Disease Units [CUE] programme since 2017. The certification process was voluntary and was performed by external auditors. In cases where minimum compliance is not achieved, GETECCU offers help by designing an action plan specific for the applicant ICCU.<sup>39</sup>

Up to January 20 21, 53 ICCUs have been audited and 51 have been granted the quality accreditation. Healthcare professionals have expressed high levels of satisfaction with the certification programme, recording average satisfaction scores of 8.5 out of 10.<sup>39</sup> The new set of QIs obtained using an MCDA approach can be regarded as a major improvement, with a view to development for the CUE programme. The MCDA methodology aids the decision-making process, providing clarity on the items that are relevant and the importance attached to each one, and thus increasing the consistency, transparency, and legitimacy of the processes.<sup>41,42</sup> The results of this MCDA present QIs ranged by importance,

giving additional value to the items that were considered essential. This process serves as a starting point for identifying the most relevant items and for prioritising the QIs that should be achieved first to ensure high-level quality of care. The current review also identified certain QIs that have been rendered obsolete by advances in IBD management, and thus serves as part of a periodical updating process.<sup>53</sup> A third and final reason for updating the QIs was to encourage patients to participate in their own health care management and evaluation.

The study highlights five key essential aspects for evaluating ICCUs: 1) the multidisciplinary and specialised management of IBD patients; 2) the continuity of care, comprising both the care on demand and the participation of the ICCU team in all the phases of IBD management; 3) the standardisation of clinical care; 4) the evaluation of clinical outcomes using PROMs; and 5) the assessment of quality of care using PREMs.

The updated set of QIs includes 46 items that were previously recorded in the original GETECCU Delphi consensus,<sup>23</sup> and thus adds 21 new QIs selected during this MCDA study: eight 'structure', six 'process', and seven referring to the use of PROMs and PREMs to measure the ICCU's quality of care.

Participants were instructed to waive the evaluation of a given QI if they felt unprepared, and the scoring system was adapted to ensure that these missing responses did not affect the final scores. The rates of non-scored QIs were low for most variables. As expected, non-clinicians felt unprepared to rate the importance of the clinical QI score. For example, most patients did not score the outcome indicators concerning mortality and morbidity.

Many of the QIs in the present study have also appeared in earlier publications.<sup>19,20,22–36</sup> Among these proposals, the recent consensus conducted by the European Crohn's and Colitis Organisation [ECCO] supported the construction of a list of criteria summarising current standards of care in IBD

in Europe.<sup>19,22</sup> The final list comprised 111 QIs [31 'structure', 42 'process', 38 'outcome']. However, the ECCO concluded that the list of QIs was not intended as a basis for certification or accreditation as it was recognised that few centres would meet all the criteria.<sup>19,22</sup> The ECCO's proposal of QIs was not published when the literature review was performed, and so the ECCO criteria were not available at the time of beginning the MCDA process. However, the SC checked the new QIs for relevant missing indicators. The ECCO criteria were very similar to those previously published by GETECCU,<sup>23</sup> and no new QIs referring to key aspects of care were identified.

Outside Europe, in Canada, several studies have published QI sets assessing various measures, such as the EPIC group study in 2014,<sup>36</sup> with a total of 11 QIs for the correct management of IBD, and the more recent study conducted by the PACE group in 2019, which proposed a total of 45 QIs [nine 'structure', 30 'process', and six 'outcome'].<sup>29</sup> Despite the differences in scope and geographical jurisdiction, all the studies present a number of similarities. Most of them were conducted following the Delphi methodology or a similar methodology like the RAND/UCLA approach.<sup>29</sup> To the best of our knowledge, the present study is the first MCDA conducted for the development of a set of QIs for ICCU certification.

Although previous projects have also included multidisciplinary experts' panels, in the present study, efforts were made to include panellists from five different Spanish societies, including gastroenterologists [GETECCU], patients' associations [ACCU], nurses' societies [GETEII], experts in health care quality assurance [SECA], and coloproctology surgeons [AACP]. As a result, multiple points of view were recorded, filling possible gaps in knowledge between groups and enhancing their respective strengths.

Another strong point of the study is the inclusion of the evaluation of patient-centred outcomes, for instance considering PROs to promote patient empowerment. Several studies have considered patient-centred outcomes in IBD management. The ICHOM project in IBD, based on an international working group, selected a minimum set of 12 standards of patient-centred outcome measures for used in different health care settings.<sup>28</sup> Another example is the IQCARO Project, in which a 10-indicator checklist was generated entirely from the perspective of IBD patients. The items selected covered important aspects including professionalism, patients' autonomy, information, and accessibility and continuity of care from the patients' perspective.<sup>31</sup> Other studies have determined patients' satisfaction by administering the 'Quality of Care Through Patients' Eyes' [QUOTE-IBD] survey,<sup>54,55</sup> which has been used frequently in recent decades.<sup>20,56,57</sup>

This study is not without limitations. The first is that it was performed from the perspective of a public national health care system [the Spanish National Health System], and so the QIs included here may not be automatically applicable to other health care models. However, the QIs defined in the present study focus on several key aspects of care and, with some adaptation, are probably generalisable to most clinical care settings.

Another possible limitation of the study is the distribution and number of experts and areas of expertise involved in the process. The multidisciplinary panel included gastroenterologists, IBD patients, IBD nurses, quality health care specialists and coloproctology surgeons, in order to represent the wide range of staff members an ICCU may have. The distribution of experts was thought to be representative of the relative

weight of each group in defining the QIs. In this sense the ratio of gastroenterologists to other professionals or patients was slightly lower, and the rate of patients' representatives slightly higher, than in the previous set of QIs created in 2014.<sup>23</sup> In addition, among the patients included in the multidisciplinary panel, eight were members of the ACCU patients' association or were selected by the SC gastroenterologist. This approach carries a risk of a bias towards higher-educated patients with a higher than average interest in IBD. However, the SC considered that an adequate evaluation of a set of QIs referred to IBD units would require a thorough knowledge of the disease and the health care system. As in the case of gastroenterologists, nurses, surgeons, and the other specialists, an 'expert patient' profile was selected for the panel. Therefore, we believe that choosing patients with a thorough knowledge of the disease was a strength rather than a limitation of the study.

In addition, other experts involved in the ICCU such as nutritionists, rheumatologists, radiologists, pharmacists, psychiatrists, psychologists, or ostomy specialists were not represented in the study, as they were not considered to be involved in the unit's core activities. This might be another limitation of the study and the inclusion of these practitioners should be considered in future projects.

Finally, the ideal number of QIs is not well established. This number should maintain a balance between a wide array of data captured and the practicality of the set of QIs to be used.

In conclusion, the 67 QIs proposed here, created from a multi-stakeholder perspective and applying the MCDA methodology, constitute a weighted and prioritised set of items that represent the essential minimum criteria to ensure quality of care for IBD patient management. Furthermore, the emphasis on patient-centred outcome measures is a key aspect of the present study and offers a new approach to the evaluation of ICCU quality and performance.

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## Conflict of Interest

XC reports grants from AbbVie, Kern, and Janssen; reports consultancy fees/honoraria from AbbVie, Janssen, Pfizer, and Takeda; reports support for travel to meetings from AbbVie, Takeda, Janssen, and Ferring; reports payment for lectures including service on speaker bureaus from Abbott, Janssen, Pfizer, and Takeda; and reports payment for development of educational presentations from Abbott, Janssen, and Pfizer. JP reports grants from AbbVie and Pfizer; reports consultancy fees/honoraria from AbbVie, Arena, Athos, Boehringer-Ingelheim, Celgene, Galapagos, Genentech/Roche, GlaxoSmithKline, Janssen, Mirum, Morphic, Nestlé, Origo, Pandion, Pfizer, Progenity, Protagonist, Takeda, Theravance, and Wasserman; reports support for travel to meetings from AbbVie and Takeda; reports payment for lectures including service on speaker bureaus from Abbott, Janssen, Pfizer, and Takeda; and reports payment for development of educational presentations from Abbott, Janssen, Pfizer, and Roche. JG-E, AC-G and MAC are employees of PORIB, a consultant company, focused on economic evaluation of health interventions and health outcomes research, which has received financial

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XC: concept and design, acquisition of data, analysis and interpretation of data, drafting of the article, and final approval of the version. JP: concept and design, acquisition of data, analysis and interpretation of data, drafting of the article, and final approval of the version. JGE: concept and design, acquisition of data, analysis and interpretation of data, methodological support, drafting of the article, and final approval of the version. ACG: concept and design, acquisition of data, analysis and interpretation of data, methodological support, drafting of the article, and final approval of the version. EB: concept and design, revising it critically for important intellectual content, and final approval of the version. LM: concept and design, revising it critically for important intellectual content, and final approval of the version. FP: concept and design, revising it critically for important intellectual content, and final approval of the version. ENC: concept and design, revising it critically for important intellectual content, and final approval of the version. AG: concept and design, revising it critically for important intellectual content, and final approval of the version. PN: concept and design, revising it critically for important intellectual content, and final approval of the version. RS: concept and design, revising it critically for important intellectual content, and final approval of the version. MAC: concept and design, acquisition of data, analysis and interpretation of data, methodological support, drafting of the article, and final approval of the version. MBA: concept and design, acquisition of data, analysis and interpretation of data, drafting of the article, and final approval of the version.

## Supplementary Data

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

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