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CONSENSUS/GUIDELINES

Delphi consensus statement: Quality indicators for Inflammatory Bowel Disease Comprehensive Care Units☆

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Abstract

Background and aims: While it is commonly accepted that Inflammatory bowel disease (IBD) Comprehensive Care Units (ICCUs) facilitate the delivery of quality care to Crohn's disease and ulcerative colitis patients, it remains unclear how an ICCU should be defined or evaluated. The aim of the present study was to develop a comprehensive set of Quality Indicators (QIs) of structure, process, and outcomes for defining and evaluating an ICCU.
Methods: A Delphi consensus-based approach with a standardized three-step process was used to identify a core set of QIs. The process included an exhaustive search using complementary approaches to identify potential QIs, and two Delphi voting rounds to select the QIs defining the core requirements for an ICCU.
Results: The consensus selected a core set of 56 QIs (12 structure, 20 process and 24 outcome). Structure and process QIs highlighted the need for multidisciplinary management and continuity of care. The minimal IBD team should include an IBD nurse, gastroenterologists, radiologists, surgeons, endoscopists and stoma management specialists. ICCUs should be able to provide both outpatient and inpatient care and admission should not break the continuity of care. Outcome QIs focused on the adequate prophylaxis of disease complication and drug adverse events, the need to monitor appropriateness of treatment and the need to reinforce patient autonomy by providing adequate information and facilitating the patients' participation in their own care.
Conclusions: The present Delphi consensus identified a set of core QIs that may be useful for evaluating and certifying ICCUs.

1. Introduction

Crohn's disease (CD) and ulcerative colitis (UC) have a substantial impact on patients' physical health, social functioning and quality of life[1,2]. Optimal care for these patients attains remission, avoids disease and treatment-related complications and allows patients with inflammatory bowel disease (IBD) to achieve normal social functioning and quality of life[3]. This care requires the coordinated action of a number of health care professionals who are members of functional IBD Comprehensive Care Units (ICCUs).

Although the available guidelines provide support for the management of IBD[4–12], they do not cover all factors that need to be integrated to provide the best care. Aspects like a multidisciplinary approach, or the processes and structure that are required for optimal patient care, are often not considered but may be as important as the availability and proper use of effective medicines. Furthermore, it has been shown that expert management can decrease morbidity, surgery requirement, and even mortality in patients with IBD[13–16]. While it is commonly accepted that ICCUs facilitate the provision of quality care to CD and UC patients, it remains unclear how an ICCU should be defined. Specifically, the minimal requirements that a unit should fulfill to be categorized as an ICCU, the basic tasks and procedures that an ICCU should perform or how to measure its functioning, have not been established. A systematically developed set of structure, process and outcome Quality Indicators (QIs) is fundamental for certifying ICCUs, evaluating their quality, and identifying areas for improvement.

Most previous attempts to define characteristics of ICCUs[10–12,16–30] have evaluated individual aspects of care, specifically the delivery of on demand therapy or multidisciplinary care. Only a few have provided a defined set of QIs or characteristics that may help to categorize and evaluate a unit of this kind. To be useful, QIs should comply with the following minimal series of requirements: a) all stakeholders should be involved in their definition, b) they should be measurable for future evaluation, c) QI requirements should be reasonably achievable by currently active ICCUs and d) the best methodology available should be used to select the most important QI. A major limitation of currently published QIs is the lack of a clear methodology for systematically detecting, evaluating and selecting variables.

The current best options for selecting QIs are probably the methods using Delphi consensus agreements. The Delphi process is particularly suitable when views of different fields (in this case nurses, patients and physicians) have to be integrated[31]. The Delphi panel approaches combine a systematic review of the literature for the best available scientific data with an iterative process to obtain the collective judgment of experts in order to determine the appropriateness of processes of care in medicine. This approach is now widely used to develop QI across all areas of medicine[32–34]. This method of selecting QIs is reliable and has been shown to have content, construct, and predictive validities[35].

Few studies in gastroenterology have developed explicit QIs using Delphi consensus[36,37], and, to our knowledge, this approach has only recently been used in the area of IBD[38]. The aim of the present study was to develop a comprehensive set of structure, process, and outcome QIs for defining and evaluating an ICCU, based on expert consensus using a Delphi consensus method.

2. Materials and methods

We used a Delphi consensus-based approach with a standardized three-step process to identify a set of QIs, as described below (Fig. 1). The method uses a formal group process, in which an expert panel discusses and iteratively rates the appropriateness of candidate QIs using a two-round web-based survey[31,39].

2.1. Development of Quality Indicators

An exhaustive search applying three different and complementary approaches was used to identify potential QIs:

a) Literature search. An extensive search was performed in EMBASE, MEDLINE, the Indice Médico Español, MEDES-MED, and The Cochrane Plus Library using multiple search strategies (annex 1). In addition, a generic search in Google and multiple searches in government and non-governmental institutions for "grey literature" were performed. QIs obtained from the documents retrieved in the literature search were collected and added to the initial comprehensive list of potential QIs.

b) Existing clinical guidelines[4–12] were reviewed to establish an ordered set of candidate QIs for subsequent evaluation.

c) Discussion groups: Three separate discussion groups were created comprising patients, nurses, and medical doctors respectively. The groups had from eight to ten participants and were designed to represent the respective

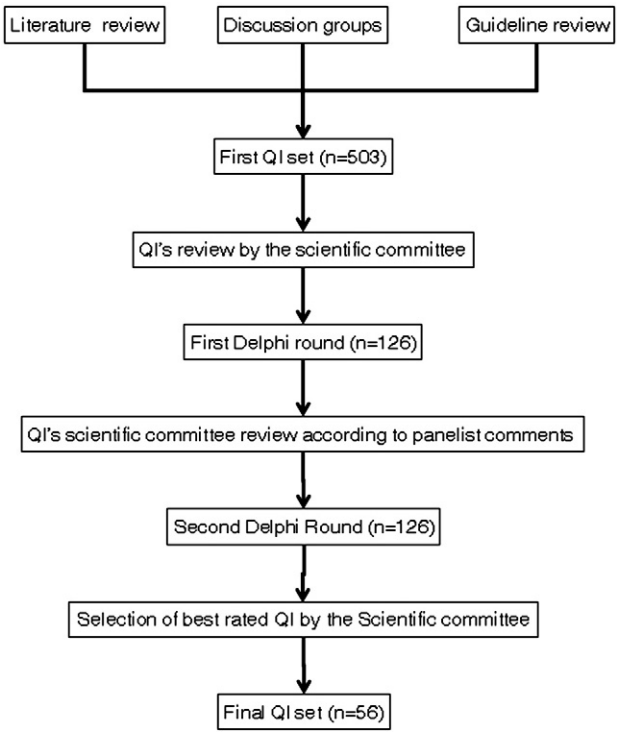

Figure 1 Flow-chart of the Quality Indicators (QI) selection process.

populations — for example, regarding the proportion of CD or UC, or sex distribution for patients. IBD-dedicated nurses and doctors were recruited to represent different hospital levels and geographical areas of Spain. If the proposed structure, process and outcome QIs did not appear spontaneously in conversation the trained investigator mentioned it explicitly. The discussions were recorded and transcribed, and the content was further analyzed in order to identify possible QI using the NUDIST Vivo 8 program.

The QIs were initially categorized according to the process of care (prophylaxis, diagnosis, treatment, etc.) that they covered. For each candidate QIs, the population to which it applied and the process of care that it measured were defined. Specifically, candidate QIs are designed using "if and then" statements, where "if" describes the eligible patient population and "then" defines the process of care that should be performed. For example: "If a patient has been diagnosed of IBD, then s/he should be tested for markers of hepatitis B virus and inoculated with vaccine when indicated".

The scientific committee (SC) included five medical doctors with IBD expertise, one nurse, and one patients' representative. All were designated by and acted in representation of their respective national societies. The SC included also two support methodologists. During the preparation of the QIs, six members of the SC – one patient, one nurse, and four gastroenterologists – evaluated the initial set of QIs for five major characteristics: straightforward identification in medical records (i.e., availability, ease of data retrieval, and cost), the number of indicators developed (with regard to an optimal number), evidence in the literature, structure versus process indicators, and linkage to outcomes (i.e., the need to demonstrate that adherence to indicators is associated with better outcomes)[36]. Redundant

QIs and those not fulfilling these characteristics were eliminated to keep the number of QIs to be voted on by the participants within reasonable limits.

2.2. Selection of expert panel members

The expert panel members were selected by the SC and included patient representatives (n = 4), nurses (n = 7), surgeons (n = 2) and physicians (n = 18). Most members of the SC also participated in the voting process. The predominance of gastroenterologists and nurses was justified by the need that participants should have previous knowledge and extensive experience of the structure and functioning of ICCUs. In this regard, nurse and physician panelists were selected because they were well-known experts in IBD and all of them had published studies in the area of IBD in peer-reviewed journals. All participants had also preferential dedication to IBD and lead or work in either dedicated IBD clinics or ICCUs. In addition, many of the panel members were selected due to their responsibilities in management or their expertise in Delphi consensus. Medical and nurse panelists represented hospitals that differed markedly in size, complexity, and geographical location within Spain.

2.3. Expert panel ratings

Overview: As stated below, a Delphi method was used to rate the appropriateness of each candidate QI. In the first round, the experts rated each proposed QI individually without interaction with other members. Ratings were based on the review of an evidence report distributed to the panel in advance. These ratings were analyzed in order to assess their relative relevance, removing the less significant QI and adding new ones following the panelists' suggestions. In the second round the panelists were allowed to vote, without suggesting modifications or adding comments. Each of the indicators was then re-rated in an iterative process. Reaching agreement was not required during the panel rating process. Voting was anonymous and the votes of all panelists had the same weight in the analysis. In addition, according to their field of expertise, nurse and patient participants were allowed to waive a question when they considered that they were unable to provide an informed answer.

2.4. Rating system

Before the first round of ratings, the panel was provided with an e-mailed report summarizing the literature review, the topics considered in the discussion groups, and the list of candidate QIs. Using the best available data contained in the report, the panelists rated the relevance of each candidate QI using a standard nine-point scale where 1 indicates "extremely irrelevant" and 9 indicates "extremely relevant". They were also tasked with identifying additional QIs not included on the original list, or modifying existing QIs that were deemed to be imperfect. The mean of the panel ratings and a measure of dispersion for each indicator were determined. Agreement was evaluated using the coefficient of variation (CV) from very high (CV < 25%), high (25%–50%) or low (>50%–75%) to very low (>75%).

Table 1 Scoring of core structure Quality Indicators.

Quality indicators	Number of panelists answering	Overall score	Physicians' score	Nurses' score	Patients' score
Hospital characteristics					
1. The ICCU should have a dedicated outpatient clinic with nurse care.	31	8	7.7	8.7	8.3
2. The ICCU should have outpatient facilities where drugs can be administered intravenously.	31	8.4	8.5	8.4	8.0
3. The ICCU should be integrated in a hospital with an Emergency Department.	31	8.2	8.2	8.3	8
4. The ICCU should be integrated in a Digestive Disease Department that has hospitalization facilities.	31	8.6	8.7	8.6	8.5
5. The ICCU should be integrated in a hospital with an Endoscopy Unit.	31	8.4	8.5	8.4	8
Specific ICCU facilities					
6. There should be outpatient specialized clinics for IBD patients.	31	8	8.1	7.4	8.8
7. The ICCU should have a telephone service for patient consultation.	31	8.1	7.9	8.7	8.3
Registers					
8. The ICCU should have a registry of all the IBD patients.	31	8.3	8.3	8.6	7.5
9. The ICCU should have a registry of IBD patients receiving biological drugs.	31	8.1	8.2	7.6	8.5
Personnel					
10. The ICCU should have at least one IBD specialized nurse.	31	8	7.7	8.6	8.5
Personnel: Referral professionals					
11. The ICCU should include a surgeon or surgical team with experience in the surgical treatment of IBD patients.	31	8.5	8.6	8.4	8.5
12. The ICCU should include a reference radiologist with experience in digestive diseases.	31	7.8	7.9	8	7.3

Table 2 Scoring of core process Quality Indicators.

Quality Indicators	Number of panelists answering	Overall score	Physicians' score	Nurses' score	Patients' score
Quality and organization					
13. The ICCU should offer the possibility of urgent outpatient consultation when there is a presumption of flare or complication. On demand care should be available at least from Monday to Friday.	31	8.4	8.2	8.6	8.8
14. The ICCU should have a preferential visit circuit for patients sent by their GP, the emergency ward or other health care professionals for a recent diagnosis or a severe flare of IBD.	31	7.9	7.9	7.5	8.8
15. Each IBD patient should be assigned an identifiable IBD specialist in charge of his/her clinical care.	31	7.1	6.7	7.1	9
Diagnostic tests					
16. The ICCU should have access to CT.	31	8.5	8.5	8.4	8.8
17. The ICCU should have access to MRI.	31	8.5	8.4	8.4	8.8
18. The ICCU should have access to abdominal ultrasound.	31	8.3	8.2	8.3	8.8
Patient care					
19. The ICCU should have access to therapeutic endoscopic dilation of bowel strictures.	31	8.1	8.1	8.3	8.3
20. The ICCU should have a clinical and laboratory monitoring program for patients under immunosuppressive treatment.	31	8.7	8.7	8.7	8.8
Patient care					
21. The ICCU should have a clinical and analytical monitoring program for patients under biological treatments.	31	8.7	8.7	8.7	8.8
22. The patient should receive a card with the contact data of the IBD unit, including the telephone number and opening hours.	31	8.2	8	8.4	8.5
23. The ICCU should have a colorectal cancer surveillance program in IBD patients, in line with international guidelines.	27	7.9	7.7	8.3	–
24. Complex care decisions, including surgery indication, should be discussed in IBD committees including a gastroenterologist, a radiologist and a surgeon.	29	8.2	8.2	8	9
Surgery					
25. Elective surgery should be performed exclusively by surgeons from the ICCU.	30	7.9	8.2	6.8	8
26. Before surgery that may result in a temporary or permanent stoma, the IBD patient should have an appointment with a nurse specialized in stoma care.	31	8.1	8	8.1	8.3
Admission					
27. The ICCU gastroenterologist should actively participate in the management of the hospitalized IBD patient.	31	8.4	8.5	8.1	8.8
Guidelines					
28. The ICCU should maintain their own updated protocols or adhere to international guidelines on the management of IBD.	27	8.3	8.5	8	8.8
29. The ICCU should have protocols for the use of drugs.	30	8.1	8	7.9	9
30. The ICCU should have a specific protocol for IBD patients admitted to the Emergency Department; emergency department staff should have full access to this protocol.	30	7.3	7.3	6.9	9
Continuing education and research					
31. Gastroenterologists in the ICCU should participate in at least one educational activity about IBD per year.	24	8	8	7.8	–
32. The ICCU should carry out and/or participate in research projects on IBD.	29	8	8	8.1	8.3

The SC predefined a cut-off value of 7.5 for structure, process and outcome items to be included as QIs. To explore the potential different perspectives of physicians, patients and nurses, a predefined separate subgroup analysis of responses was performed in addition to the general Delphi analysis. QIs not meeting criteria for selection in the whole group but rated 9 over 9 by any of the groups – physicians, nurses or patients – were assessed individually and included in the final set of indicators.

Table 3 Scoring of core outcome Quality Indicators.

Quality Indicators	Number of panelists answering	Overall score	Physicians' score	Nurses' score	Patients' score
Diagnosis and follow-up					
33. When a patient is diagnosed with IBD, s/he should undergo a thorough study of the extension of disease, including colonoscopy and a small bowel assessment if there is a suspicion of CD.	31	8.1	8.3	8.1	6.8
34. Before starting treatment with a biologic drug, IBD patients should be tested for tuberculosis using either two consecutive tuberculin tests or an immunologic test and a chest X-ray.	27	8.9	8.9	9	–
35. IBD patients should be tested for hepatitis B and C at diagnosis.	27	8	8	8	–
36. All IBD patients should be vaccinated against Hepatitis B.	28	7.9	8	7.8	–
37. In patients with UC and a severe flare, rectal biopsies should be taken to rule out Cytomegalovirus infection.	25	8.6	8.5	9	–
Treatment					
38. Before starting treatment with a biologic drug, IBD patients with any sign of tuberculosis (on chest X-rays, or on tuberculin or immunologic tests) should receive adequate antituberculous therapy.	30	8.8	8.8	9	8
39. All HBsAg-positive IBD patients should receive antiviral drugs while being treated with an anti-TNF drug.	20	8.7	8.7	–	–
Treatment					
40. Attenuated virus vaccines must be avoided in patients receiving immunosuppressive or anti-TNF drugs.	26	8.7	8.7	8.7	–
41. IBD patients with suspected septic complications should receive early appropriate antibiotic treatment.	25	8.6	8.7	8.6	–
42. In all IBD patients who had required two or more courses of steroids in the last year, treatment with an immunosuppressive drug should have been considered.	25	8.6	8.6	8.8	
43. In patients with severe flare of UC not responding to intravenous steroids, treatment with either cyclosporine or an anti-TNF drug should be initiated within 7 days.	20	8.6	8.6		
44. Patients with steroid-refractory CD should receive an anti-TNF agent.	24	8.1	8	8.3	–
45. No IBD patients should receive a steroid dose over 20 mg a day for more than 6 months.	20	8.1	8.1	–	–
46. Antithrombotic therapy should be indicated in all IBD patients while hospitalized.	24	8	8.3	7.3	–
47. IBD patients should maintain thiopurine treatment during pregnancy. Refusal of treatment should be documented.	25	8.2	8.3	7.6	–
Treatment					
48. It should be documented in the clinical records that patient received adequate information regarding benefits and risks before being started on immunosuppressive therapy.	28	8	8	8	8,3
49. It should be documented in the clinical records that patients received adequate information regarding benefits and risks before starting biologic therapy.	28	8.1	8	8.2	8.3
50. Patients receiving immunosuppressive drugs should be monitored with a blood count at least every four months.	29	8.1	7.9	8.8	8.3
	26	8.1	7.8	8.7	–

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Table 3 (*continued*)

Quality Indicators	Number of panelists answering	Overall score	Physicians' score	Nurses' score	Patients' score
51. Patients receiving anti-TNF drugs should be monitored with a blood count at least every four months.					
Surgery					
52. In IBD patients undergoing elective surgery, rates of severe morbidity requiring ICU admission should be lower than 5%.	20	8.2	8.2	–	–
53. Mortality of elective surgery should be less than 2%.	20		8.2	–	–
54. Ileo-anal pouches should only be made by surgeons performing at least 10 of these operations a year.	20	–	8	–	–
55. It should be documented in the clinical records that the patient has received adequate information regarding benefits and risks before surgery.	23	8	8	8	–
Surgery					
56. Rates of temporary ileostomy after elective ileocecal resection should be lower than 20%.	22	8	8	–	–

As many QIs scored above this cut-off point, the value was increased post-hoc to keep the number of QIs within reasonable limits. These were named "core QI", always selecting the higher ratings. The remaining QIs with scores above the pre-established 7.5 cut-off are provided in a table.

3. Results

3.1. Selection of QI and Delphi rounds

After the literature review and synthesis, discussions groups and the review of the guidelines, 503 potential QIs were identified (Fig. 1). To reduce this set to a manageable size, two members of the SC and one supporting methodologist reviewed the QIs and eliminated duplicated or clearly inadequate items. In addition, the health professionals of the SC and the members of the physician discussion group evaluated the remaining set of items for their relevance from 1 to 9 on a Likert scale. QIs that did not reach a minimal score of 5 were eliminated. A final set of 126 QIs, comprising 40 structure, 44 process and 42 outcome QIs, were included in the first Delphi round.

After receiving the panelists' votes and the comments, the SC modified the wording of many QIs, introducing substantial changes in some cases. The second Delphi round also included 126 QIs — again, 40 structure, 44 process and 42 outcome.

3.2. Analysis and selection of the final set of QIs

After the second Delphi round, 83 QIs scored over 7.5 out of 9 and reached good or very good agreement between the panelists. As the number of QIs above the predefined cut-off point of 7.5 was high, the SC decided to establish a core set of 56 QIs (12 structure, 20 process and 24 outcome). Core QIs were selected including the highest rated QIs and the QIs voted 9/9 by any of the major participant groups (physicians, nurses or patients).

3.3. Description of selected QIs

Core QIs are shown in Tables 1 to 3 and additional selected QIs in Table 4. The two main principles underlying the structure and process QIs were the need for multidisciplinary management and the continuity of care. Regarding multidisciplinary management, physicians, nurses and patients perceived the role of the IBD nurse as an essential part of IBD patient care. Core QIs include the need for a nurse and time and space for specific nurse outpatient consultations. In addition to nurses and gastroenterologists, the minimal IBD team should include radiologists, surgeons and endoscopists. Another component considered essential was support from a nurse specialized in stoma management. The QIs also underline the need to provide care in a hospital environment equipped with an Emergency Department, inpatient facilities and an essential set of radiological and endoscopic examinations.

All stakeholders also agreed on the importance of the continuity of care and on demand care: that is, ICCUs should be able to provide both outpatient and inpatient care. Outpatient care should include the possibility of drug infusion, monitoring of patients under immunosuppressive and biologic drugs, and availability of on demand outpatient consultation, including over-the-phone consultation. Admission should not break the continuity of care: the same team should provide outpatient care, prescribe, administer and monitor the treatment, and provide inpatient care. Regarding the process QIs, patients were especially concerned about two specific points: having a protocol for their management when admitted to the Emergency Department and being assigned to a named, specific IBD specialist responsible for their care.

Outcome QIs can be divided in three main groups. The first group refers to the adequate prophylaxis of disease complications and drug adverse events — for example, tuberculosis screening and prophylaxis in patients taking biologics, or the need to prevent CD recurrence after surgery. The second group relates to the need of monitoring the appropriateness of treatment — for example, the indication of biologics in steroid-refractory IBD. Finally,

the third group comprises a large number of QIs highlighting the need to reinforce patient autonomy by providing adequate information, allowing patients to take their own informed decisions and facilitating their participation in their own care.

4. Discussion

In any field of medicine, Quality Indicators are needed to monitor patient management. Our study provides a comprehensive set of QIs for defining and evaluating ICCUs obtained

Table 4 Selected additional Quality Indicators.

Quality Indicators	Number of panelists answering	Overall score	Physicians' score	Nurses' score	Patients' score
Structure Quality Indicators					
57. The ICCU should have the infrastructure to allow on demand attention to the patients who develop symptoms between scheduled visits.	31	8.6	8.5	8.7	8.8
58. The ICCU should have the infrastructure to allow patients to consult professionals about their disease or its treatment between scheduled visits.	31	7.8	7.6	8.7	7.5
Structure: Hospital characteristics					
59. The ICCU should be integrated in a hospital with a Department of Surgery.	31	8.5	8.6	8.4	8.5
60. The ICCU should be integrated in a hospital with a Radiology Department.	31	8.1	8	8.1	8.3
Structure: Specific ICCU facilities					
61. The ICCU should have examination rooms for appointments with physicians.	31	8.7	8.7	8.9	8.8
62. The ICCU should have a telephone hotline for patient consultations during specified hours at least on working days.	31	7.7	7.7	7.7	8
63. The IBD should have examination rooms for appointments with nurses.	31	7.5	**7**	8.7	8.3
Structure: Registers					
64. The ICCU should have a registry of the IBD patients receiving immunosuppressive therapy.	31	7.8	7.9	7.6	7.8
Structure: Personnel					
65. The ICCU should have at least two IBD specialized gastroenterologists.	30	7.6	7.6	7.5	8.3
Structure: Personnel organization					
66. The ICCU should have an identifiable person in charge.	30	7.8	7.8	7.6	8
Structure: Personnel: Reference professionals					
67. The ICCU should receive support from a nurse specialized in stomas.	31	7.7	7.7	7.9	8
68. The ICCU should receive support from endoscopists with training in endoscopic therapy in IBD patients.	31	7.7	7.6	7.7	8.3
Process Quality Indicators					
Process: Diagnostic test					
69. The ICCU should have access to endoanal ultrasonography.	30	7.8	7.5	8.1	8.7
Process: Guidelines					
70. Protocols should be revised at least once each 4 years.	26	7.6	7.6	**7.3**	–
Process: Continuing education					
71. Nurses in the ICCU should participate in at least one educational activity on IBD per year.	27	7.6	7.6	7.6	–
72. Surgeons in the ICCU should participate in at least one educational activity on IBD per year.	24	7.5	7.4	7.8	–
Process: Research and committees					
73. The ICCU should offer patients who do not respond to approved treatments the possibility of participating in clinical trials, whether in the same ICCU or in another ICCU with research infrastructure.	30	7.7	7.7	7.4	8.7
74. All patient deaths should be discussed by mortality committees.	26	7.5	7.6	6.3	–

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Table 4 (*continued*)

Quality Indicators	Number of panelists answering	Overall score	Physicians' score	Nurses' score	Patients' score
Outcome Quality Indicators					
Outcome: Diagnosis and follow-up					
75. *Clostridium difficile* infection should be evaluated in every flare that presents as diarrhea.	24	7.6	7.9	6.5	–
76. In patients with a severe flare of colonic CD, rectal biopsies to rule out *Cytomegalovirus* infection should be taken.	25	7.8	7.6	8.8	–
77. In patients with symptoms despite IBD treatment, activity should be evaluated by colonoscopy or radiology to guide therapeutic decisions.	26	7.7	7.5	8.2	–
78. Patients should undergo surveillance for colorectal cancer unless the procedures are contraindicated or if the patient refuses.	25	7.8	7.8	8.4	7
Outcome: Treatment					
79. All IBD patients with any sign of tuberculosis should receive adequate antituberculous therapy.	27	7.8	7.7	8.6	–
80. IBD patients under anti-TNF or immunosuppressive treatment should be vaccinated against the flu.	20	7.8	8	8.5	5
Outcome: Treatment					
81. IBD patients under triple immunosuppression (anti-TNF or cyclosporine plus immunosuppressive drugs plus steroids) should receive prophylaxis for *Pneumocystis* sp. infection.	25	7.8	7.7	8.6	–
82. Patients with CD should receive treatment to prevent recurrence after surgery.	24	7.8	7.8	7.8	–
83. IBD patients should not have received steroids — even at doses lower than 20 mg for more than 9 months during the last year.	24	7.7	7.7	–	–

following a standardized process, allowing the identification of the QIs considered most relevant by major stakeholders involved in the management of IBD, including health care professionals and patients.

Three main aspects emerge as the basic requirements for ICCUs from our study: i) continuity of care, with special emphasis on the availability of on demand facilities, ii) the central role of the specialist nurse – that is, a dedicated nurse with special dedication and experience in IBD management – and iii) the need for a multidisciplinary approach including the participation of dedicated IBD specialists, endoscopists, surgeons, radiologists and specialists in stoma management. The level of consensus on these topics was very high for the majority of QIs. Many of the outcome QIs refer to a safer use of available drugs, prevention of disease complications, and the need for adequate information and involvement of patients in their own care. Finally, it is interesting that both health care professionals and patients perceived research as essential component of care in an ICCU.

QI ratings were quite similar between patients, nurses, and medical doctors. Only two points that were not considered as very important by nurses and physicians were regarded as a priority by patients: having a protocol for their management when admitted to the Emergency Department and having a named, specific IBD specialist in charge of their care. The first QI probably reflects the perception that non-specialized urgent care is often sub-optimal in these difficult-to-treat patients, and the second highlights the importance of the personal relationship for adequate patient care. Being managed by a team – even if the management is optimal – causes insecurity in patients.

A few previous studies aimed at establishing QIs in some aspects of IBD care have been published. Cassinotti et al. used the UK IBD inpatient case audit tool, a set of QIs developed from an audit in Oxford hospitals to compare inpatient care at two European hospitals[17]. Van der Eijk et al.[23] developed a set of QIs to audit ICCUs in eight countries across Europe, although the method for selecting the QIs was not described. Finally, in 2009 the IBD Standards group published the first set of UK national QIs for IBD patient care that includes many structure and process QIs[26]. These QIs have been used in three consecutive audits of UK ICCUs[27–29].

The set of QIs established in the current study reproduce some of the recommendations made by the IBD Standards group in the UK Service QI[26], but there are some notable differences as well. Specifically, stakeholders in the present consensus did not feel a number of previously proposed QIs to be essential, in particular the availability of a psychologist, a dietitian or a dedicated pharmacist or reference rheumatologist, ophthalmologist, dermatologist or obstetrician, and the availability of joint gastroenterologist and surgeon consultations. On the other hand, the role of the nurse and the need for a multidisciplinary approach, though not strictly requiring a joint patient visit, were identified as most relevant.

A major strength of the present study is the fact that the Delphi system-based rating allowed the classification of the QIs according to relevance. This makes it possible to increase or reduce the number of QIs, retaining the most important ones at all times. In addition, the QIs include not only structure and process QIs, but also objective outcome QIs designed to evaluate ICCU performance. Although QIs for IBD care will probably change little from country to country, a limitation of the present study is that the QIs were developed in the context of the eminently public Spanish Healthcare System. As the setup of ICCUs may be different in various countries, the findings of this study may not be generalizable to other health care systems due to differences in education, job profiles, and other factors; for example, IBD nurses may not be available. Nevertheless, most of the indicators are likely to be of help for devising quality measurements even in health systems that differ markedly from the Spanish one. In this regard, it is interesting that many of the QIs selected in the present study were considered as helpful aspects of IBD patient care in a recent review by Kane[40]. Furthermore, the consensus selected many (though not all) of the eight recently reported IBD measurements of the PQRS – the performance measurements program for the Centres for Medicare[41] – as key QIs. It should be also noted that very recently, Melmed et al.[38] reported a set of QIs for IBD management obtained using a Delphi method. This group developed 10 QIs and 10 outcome measurements for evaluating IBD management. Although with a different wording, most of the standards were also included in the more comprehensive list reported in the present study. The fact that two similar studies in different settings reported similar QIs supports the reliability of both sets of results.

A second limitation of the study may have been the selection of the panelists. The panel attempted to represent a wide range of ICCUs of different size and complexity around Spain. The panelists were selected both by its scientific background and clinical expertise in IBD and because they worked or managed ICCUs. Gastroenterologists purposely predominate because they are responsible for leading and managing the ICCUs. Although we tried to include a wide representation of all stakeholders – patients, nurses, gastroenterologists and surgeons – it could have been interesting to include also other important specialties, namely radiologists, general practitioners, psychologists, stoma therapists or rheumatologists. This point should be taken into account for future developments.

The QIs have many uses and can be applied in different ways, either using self-evaluation or may be for determining the needs for improvement of the different units or for the accreditation of IBD units by scientific societies or administrations.

QI requirements could also favor further developments or changes in the management of IBD patients; for example, the results of the study might mean that not all hospitals can care for IBD patients on their own, and a trade-off may appear in less populated areas between geographical proximity and availability of specific resources. In consequence, two or more units may, for example, need to associate to create a surgical team that complies with QI requirements.

Finally, QIs, like any another tool for treatment or management of patients, are neither intrinsically useful nor valuable. Their usefulness and applicability must be demonstrated, and their costs and their effectiveness in improving quality of care must be established.

In conclusion, the present study identifies a set of key QIs for evaluating and certifying ICCUs. Stakeholders participating in the process rated the following characteristics of ICCU as the most important: multidisciplinarity, continuity of care at the different out and inpatient facilities, availability of on demand assistance, and the strengthening of the safety of the various therapeutic options.

Authorship statement

Xavier Calvet: conception and design, acquisition of data, analysis and interpretation of data, drafting of the article and final approval of the version.

Julián Panes: conception and design, acquisition of data, analysis and interpretation of data, drafting of the article and final approval of the version.

Noelia Alfaro: conception and design, acquisition of data, analysis and interpretation of data, drafting of the article and final approval of the version.

Pablo Lázaro: conception and design, acquisition of data, analysis and interpretation of data, drafting of the article and final approval of the version.

Joaquín Hinojosa: conception and design, revising it critically for important intellectual content and final approval of the version to be published.

Beatriz Sicilia: conception and design, revising it critically for important intellectual content and final approval of the version to be published.

Marta Gallego: conception and design, revising it critically for important intellectual content and final approval of the version to be published.

Ildefonso Pérez: conception and design, revising it critically for important intellectual content and final approval of the version to be published.

Fernando Gomollón: conception and design, revising it critically for important intellectual content and final approval of the version to be published.

Conflict of interest

The consensus did not make specific treatment recommendations. The authors did not disclose any conflicts of interest related to the QI content, the elaboration or the writing of the present article.

Xavier Calvet has served as a speaker, consultant and advisory member and has received research funding from MSD and Abbvie.

Julia Panés, Board Membership: Pfizer; Consulting fees: Pfizer, Abbvie, MSD, UCB, Novartis. Grants: Abbvie, MSD. Payment for lectures: Abbvie, MSD, Ferring,

Joaquin Hinojosa did not disclose any conflicts of interest.

Beatriz Sicilia did not disclose any conflicts of interest.

Marta Gallego did not disclose any conflicts of interest.

Ildefonso Pérez did not disclose any conflicts of interest.

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