



## Quality standards for celiac disease comprehensive care units: A Spanish multidisciplinary consensus integrating professional expertise and patient perspectives

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## Abstract

Celiac disease (CD) is markedly underdiagnosed, with significant diagnostic delays, while long-term follow-up is often inconsistent or incomplete. Current CD care, marked by heterogeneity and limited standardization, fails to address these challenges. The Spanish Society for Celiac Disease aimed to define quality standards to support the design, implementation, and evaluation of comprehensive care units for CD. A structured consensus process was conducted using the Delphi methodology, with collaboration from the Spanish Association of Gastroenterology, the Spanish Society of Digestive Pathology, and the Spanish Society of Pediatric Gastroenterology, Hepatology and Nutrition, and patients and caregivers nominated by Spain's three main celiac associations. This process defined 18 structural, 16 process, and 5 scientific-educational standards, providing guidance on human resources, infrastructure, diagnostic and therapeutic procedures, research, and continuous professional development. All but one standard reached a very high consensus, with a mean coefficient of variation of 9.1%. These standards provide a framework for centers of excellence in CD care, promoting multidisciplinary management and patient-centered outcomes. By integrating institutional expertise and patient perspectives, they ensure relevance, feasibility, and alignment with current clinical challenges, serving as a potential model for other healthcare systems and as a foundation for future accreditation processes.

**Key Words:** Celiac disease; Comprehensive care units; Delphi consensus; Multidisciplinary management; Patient-centered care; Quality standards

**Core Tip:** The Spanish Society for Celiac Disease, with major gastroenterology societies and patient representatives, establishes the first standardized quality standards for comprehensive care units for celiac disease in Spain. Through a multidisciplinary Delphi process, 18 structural, 16 process, and 5 scientific-educational standards were defined, achieving very high agreement (mean coefficient of variation: 9.1%). This consensus addresses variability in clinical practice and organizational models, ensuring equitable access to expertise, patient education, and structured follow-up. As an evidence-based and patient-centered approach, it promotes the harmonization of clinical care and continuous quality improvement, providing a robust model adaptable to international healthcare systems.

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## INTRODUCTION

Celiac disease (CD) is a chronic immune-mediated systemic disorder triggered by gluten ingestion in genetically susceptible individuals. It is characterized by the presence of specific antibodies, HLA-DQ2/8 genetics, and varying degrees of small-intestinal enteropathy. Despite advances in diagnosis and management, there remains a need for a comprehensive and multidisciplinary approach to the care of patients with CD[1]. Clinical practice often spans heterogeneous healthcare settings where access to standardized protocols and appropriate resources is limited, further exacerbating underrecognition and inconsistency in follow-up[2,3].

Globally, the seroprevalence of CD is estimated at approximately 1.4%, with a biopsy-confirmed prevalence of about 0.7%[4]. However, CD remains markedly underdiagnosed, with screening studies suggesting that up to 75%-90% of cases may remain unrecognized[5,6]. The wide clinical and biological heterogeneity of the disease contributes to this problem. CD can affect individuals of all ages and presents with highly variable clinical patterns, which may range from a broad spectrum of gastrointestinal and extra-intestinal symptoms to asymptomatic or subclinical presentations[7,8].

Furthermore, patients with a confirmed CD diagnosis warrant structured follow-up. Despite self-reported adherence to a gluten-free diet (GFD), inadvertent gluten exposure remains common and may explain persistent or recurrent symptoms. Such adverse symptoms represent a major contributor to disease burden and impaired quality of life[9]. Symptoms may also arise from comorbid functional gastrointestinal disorders and other non-CD causes that further compromise patient well-being. Therefore, comprehensive follow-up should extend beyond assessment of dietary compliance to include regular evaluation of symptom patterns, nutritional status, and psychosocial impact, enabling timely and targeted interventions. Moreover, inadvertent transgressions can also contribute to persistent villous atrophy and increased risk of long-term complications, even in patients who remain clinically asymptomatic[10]. Nutritional follow-up is also essential in CD, as patients are at risk of nutrient deficiencies resulting from intestinal malabsorption and from imbalanced dietary patterns due to the GFD, which may adversely affect overall health[11]. Consequently, ensuring strict adherence while maintaining a balanced nutritional status presents a significant challenge that patients cannot navigate alone. In this context, the role of the specialized dietitian extends beyond simple advice; it constitutes a fundamental clinical requirement to optimize health outcomes and preserve quality of life.

Current CD care, marked by this variability and lack of standardization, does not adequately address these challenges [12]. In 2017, the Spanish Ombudsman published a report based on a survey of 12059 patients in Spain, highlighting concerns regarding diagnostic delays, insufficient information at diagnosis, lack of access to professional dietary counselling, and inconsistent follow-up practices[13]. Similar shortcomings have also been reported in other countries[14-17]. When considered alongside current literature and clinical guidelines[18-26], these findings underscore the persistent need to improve healthcare management in this setting (Table 1).

The Spanish Society for Celiac Disease [Sociedad Española de Enfermedad Celiaca (SEEC)] aims to improve the quality of life of individuals affected by CD. In this context, the objective of this study was to develop, through a structured and multidisciplinary Delphi consensus process, a set of agreed-upon structural, process, and scientific-educational quality standards to guide the design, implementation, and evaluation of a Comprehensive Care Unit for patients with CD (CCU-CD).

## METHODOLOGY

### Methodological framework

A classical Delphi methodology was conducted between January 2025 and June 2025 to develop expert-based quality standards for CCU-CD. The Delphi approach was chosen due to the limited evidence regarding the optimal structural, procedural, and educational requirements that CCU-CD should fulfil. The development process was coordinated by the SEEC and included representation from the Spanish Association of Gastroenterology (AEG), the Spanish Society of Digestive Pathology (SEPD), and the Spanish Society of Pediatric Gastroenterology, Hepatology and Nutrition (SEGHNP).

### Scientific committee

A scientific committee was established to implement the predefined study objectives, generate the initial list of statements, and, with the support of a dedicated methodologist, supervise each Delphi round, and address methodological issues. The committee was also responsible for drafting the initial version of the standards. It comprised six

**Table 1 Patient-identified concerns in celiac disease care and their clinical justification for quality standards**

| Patient concern                                                                                                                                                            | Clinical justification for quality standards                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 Insufficient knowledge, low clinical suspicion, and poor awareness of diagnostic guidelines among physicians                                                             | CD has very heterogeneous presentation patterns, leading to delayed or missed diagnoses and long-term complications. Specialized units can standardize diagnostic pathways and improve early detection                                                                                                                                            |
| 2 Difficulties in ensuring timely referral to specialized settings                                                                                                         | Excessive delays between symptom onset and diagnosis are common, resulting in prolonged patient morbidity and dissatisfaction                                                                                                                                                                                                                     |
| 3 Lack of clearly defined criteria for recommending duodenal biopsy in patients with strong clinical suspicion but negative anti-tissue transglutaminase type 2 antibodies | Clinical practice regarding seronegative CD shows wide variability, which can lead to both underdiagnosis and overdiagnosis                                                                                                                                                                                                                       |
| 4 Lack of clinical indicators for non-celiac gluten/wheat sensitivity                                                                                                      | Structured protocols are needed to distinguish non-celiac gluten/wheat sensitivity from CD and other conditions that may mimic gluten-related disorders                                                                                                                                                                                           |
| 5 Doubts regarding the appropriateness of advanced diagnostic procedures in uncertain cases                                                                                | Novel and clear evidence-based algorithms are necessary to avoid unnecessary or insufficient advanced testing                                                                                                                                                                                                                                     |
| 6 Limited knowledge and training among clinicians who recommend a GFD                                                                                                      | Insufficient clinician training often results in suboptimal dietary advice and poor adherence. There is a clear need for accurate and evidence-based dietary education as part of multidisciplinary support                                                                                                                                       |
| 7 Lack of policies for the general inclusion of dietitians in healthcare systems and, more specifically, in CD care                                                        | Delayed or absent patient access to dietitians in both primary and secondary care reduces the effectiveness of nutritional interventions and worsens patient outcomes                                                                                                                                                                             |
| 8 Limited resources for adequate psychological support, especially for children and adolescents recently diagnosed with CD                                                 | Unaddressed psychological needs may lead to maladaptive coping strategies, reduced dietary adherence, and persistent negative emotions, especially in the first year following diagnosis                                                                                                                                                          |
| 9 Uncertainty about adherence to international guidelines for investigating non-responsive CD                                                                              | Overall, non-adherence to evidence-based recommendations results in reduced rates of mucosal healing, impaired quality of life, and increased healthcare utilization due to unresolved or worsening disease. Regular, guideline-driven follow-up and multidisciplinary care are essential to optimize outcomes in this complex patient population |
| 10 Lack of consensus regarding which patients can be monitored in primary care, which require specialist follow-up, and when shared management is appropriate              | Specialist-led care (gastroenterology or pediatrics) is associated with higher rates of dietitian involvement and better dietary adherence compared with primary care alone. However, primary care follow-up can be suitable if there is access to structured dietary counselling and clear protocols for monitoring complications and adherence  |

CD: Celiac disease; GFD: Gluten-free diet.

experts (three women and three men). Five were specialists with extensive clinical and or research experience in CD, including an adult gastroenterologist, a pediatric gastroenterologist, a clinical immunologist, a biomedical researcher, and a dietitian-nutritionist. One was a general adult gastroenterologist.

Each committee member contributed to the drafting of standards within their respective area of expertise, ensuring balanced coverage of all relevant aspects of CD diagnosis, management, and follow-up. The initial document containing the statements was based on a combination of expert clinical experience, consultation with patient associations, and a narrative review of the published literature. Although a systematic review was not performed, relevant evidence was identified through targeted searches of key publications and existing guidelines to inform the development of the statements. Consequently, these statements do not carry formal ratings of the quality of evidence or strength of recommendations. Individual contributions were subsequently consolidated into a unified draft, which was jointly reviewed, discussed, and refined during iterative meetings of the committee.

The standards were organized into three main domains: Structural standards (human resources, infrastructure, and organizational support), process standards (implementation of diagnostic, therapeutic, and follow-up procedures), and scientific and educational standards (research, continuous education, and innovation).

Prior to distribution, the survey was pilot-tested with two members of the scientific committee with relevant clinical and research expertise in CD to assess clarity, comprehensibility, and completion time. Minor wording adjustments were made based on their feedback.

### Panel of experts

A multidisciplinary panel of experts (11 women and eight men) was convened to achieve expert consensus and to refine and validate the standards. Eligibility was based on recognized expertise in CD, clinical experience, academic contributions, or involvement in patient advocacy groups. All participants were based in Spain and represented multiple health care centers and professional backgrounds relevant to CD care. Accordingly, the panel included pediatric and adult gastroenterologists, including one with a broader and generalist perspective to ensure the applicability of the standards across diverse clinical settings, a pathologist, a psychologist, and a dietitian-nutritionist, as well as researchers in nutrition, gluten, immunology, and genetics. The perspectives of patients and caregivers were also integrated in the expert panel, with representatives nominated by the Federation of Celiac Associations of Spain (FACE), the Association of

Celiacs of Catalonia, and the Association of Celiacs and Gluten-Sensitive Individuals from Madrid, ensuring that the proposed standards incorporated patient-centered outcomes and addressed practical aspects of care delivery.

### **Delphi consensus process**

The multidisciplinary panel of experts was invited to participate in a Delphi process, which included two rounds and was conducted anonymously through electronic voting to minimize potential bias.

**Round 1:** Experts were asked to rate each statement using a 10-point Likert scale (1 = strongly disagree, 10 = strongly agree). The initial questionnaire included 39 items. Participants could provide qualitative comments for any item, and comments were mandatory when the rating was < 7. Experts could also suggest modifications to existing statements or propose new ones.

**Between-round revision:** All numerical scores and qualitative comments were independently reviewed by the scientific committee. Items were revised as needed for clarity, structure, and alignment with expert input. The committee also considered whether items should be merged or modified to better reflect emerging consensus, while ensuring the original intent was retained. Suggestions for additional statements were considered for inclusion.

**Round 2:** Experts re-rated the revised items prepared by the scientific committee in response to feedback from Round 1. Items that reached a very high degree of agreement [coefficient of variation (CV) < 25%] and had not received any suggestions for modification in the first round were not sent for re-evaluation. In this round, participants could suggest further wording modifications but were not allowed to introduce new items.

**Anonymity and data collection:** All responses were collected anonymously using Google forms. Each round remained open for 14 days, with two reminders sent in each period to maximize participation.

**Consensus definition and statistical analysis:** For each item, the mean score and CV were calculated. A minimum mean score of 7 was required for an item to be considered acceptable. The degree of agreement was determined using the CV, with lower CV values indicating higher consensus.

Quantitative data were analyzed using standard descriptive statistics. Qualitative comments provided by the experts were reviewed by the scientific committee and used to improve statement clarity and content between rounds when appropriate.

### **Finalization of the standards framework**

Following completion of the Delphi process, the scientific committee finalized the framework of standards. The final document was shared with panel members for minor editorial clarifications, without modification of the consensus-based content. No substantial content changes were made during this step.

### **Ethical considerations**

This study involved only expert opinion and no personal or patient data. Therefore, formal ethical approval was not required.

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## **MAIN RESULTS**

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All invited experts participated in all rounds, responding to every question, resulting in a 100% response rate per round and per item. Patient representatives contributed equally to all aspects of deliberation, ensuring that the perspectives of patients and caregivers were fully incorporated into the consensus development.

A total of 18 structural standards, 16 process standards, and 5 scientific and educational standards were defined to guide the development of CCU-CD. Structural standards encompassed aspects such as multidisciplinary staffing, access to specialized laboratories and imaging, endoscopy and pathology facilities, as well as the integration of nutritional, psychological, and inpatient care resources. Process standards addressed coordination of laboratory, endoscopic, and histological procedures, implementation of evidence-based clinical protocols, structured nutritional and vaccination follow-up, and mechanisms to ensure patient safety and support. Scientific and educational standards emphasized creation of patient registries and biobanks, promotion of research initiatives, continuous professional education, and organization of multidisciplinary training programs.

All standards achieved “very high” level of agreement, except for the second structural standard attaining a “high” level of consensus, according to predefined thresholds (very high: CV < 25%; high: CV < 50%). The mean CV across all items was  $9.1 \pm 0.9$ , with all but 14 standards showing a CV below 10%, denoting strong overall consensus and consistency among respondents.

Tables 2, 3, and 4 present the list and definitions of the structural, process, and scientific and educational activity quality standards, together with the corresponding mean score, CV, and level of agreement obtained in the second Delphi round.

**Table 2 Structural quality standards for establishing a Comprehensive Care Unit for patients with Celiac Disease**

| Position        | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Mean | CV (%) | Agreement |
|-----------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------|-----------|
| 1 <sup>1</sup>  | The CCU-CD should be located in a center that has access to professionals from various disciplines with proven experience in the diagnostic process of CD, including pediatric and adult gastroenterologists, clinical laboratory specialists, immunologists, geneticists, pathologists, and dietitian-nutritionists. These professionals may belong to the same center or to an affiliated or reference center that ensures standardized reporting in accordance with national and international protocols and guidelines                                                                                                                                                                                                                                                                                                                               | 9.86 | 3.64   | Very high |
| 2               | The CCU-CD should have access to hematology, biochemistry, and/or immunology laboratories equipped with specific profiles for performing complete blood counts, macronutrient analyses (proteins, lipid profile, glucose), and micronutrient assessments (vitamins and minerals), as well as updated and validated CD-specific serological tests, including total IgA, anti-tTG2 IgA and IgG, and anti-EMA IgA and IgG. Testing should also include measurement of GIP in urine and/or stool, as well as any other assays that contribute to the differential diagnosis of CD or the identification of associated clinical conditions ( <i>e.g.</i> , fecal calprotectin, fecal occult blood, or fecal pancreatic elastase). These determinations may be carried out in the institution's own laboratories or in collaborating or reference laboratories | 9.64 | 6.83   | Very high |
| 3               | The CCU-CD should have access to a microbiology laboratory capable of detecting microbial agents (viruses, bacteria, fungi, and parasites) that may cause villous atrophy, as well as for testing for infections caused by HIV, mycobacteria, and <i>Cryptosporidium</i>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | 9.55 | 8.99   | Very high |
| 4               | The CCU-CD should have access to testing for serological markers characteristic of other immune-mediated diseases ( <i>e.g.</i> , autoimmune atrophic gastritis) and/or causes of non-celiac enteropathy ( <i>e.g.</i> , autoimmune enteropathy). These assessments may be performed within the center or through a collaborating or reference laboratory                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 9.64 | 6.03   | Very high |
| 5               | The CCU-CD should have access to a laboratory capable of performing full HLA-DQ genotyping to determine genetic susceptibility to CD and to stratify risk according to the genetic profile (DQ2.5, DQ8, DQ2.2, and DQ7.5)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 9.86 | 3.56   | Very high |
| 6               | The CCU-CD should be located in a center with a digestive endoscopy unit equipped to obtain biopsy samples for histological examination, as well as to conduct follow-up evaluations and identify CD-related complications. These units should also offer capsule endoscopy and enteroscopy when clinically indicated                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 9.68 | 5.87   | Very high |
| 7               | The CCU-CD should be located in a center with a pathology department staffed by technicians and pathologists experienced in processing, recognizing, and grading histological lesions consistent with CD, and in performing differential diagnoses with other forms of enteropathy. The team should also be skilled in identifying other morphological abnormalities that may explain persistent symptoms in cases of non-responsive CD, such as microscopic colitis                                                                                                                                                                                                                                                                                                                                                                                     | 9.32 | 12.12  | Very high |
| 8               | The CCU-CD should have the capacity to obtain the intraepithelial lymphogram by flow cytometry for its patients, either at its own center or by referring samples to an experienced center. These centers should have received expert guidance during the initial implementation of the technique to ensure accurate and reliable interpretation of results, thereby supporting appropriate diagnostic assessment and patient follow-up                                                                                                                                                                                                                                                                                                                                                                                                                  | 9.50 | 7.79   | Very high |
| 9               | The CCU-CD should have access to a radiology department equipped with appropriate imaging modalities for the detection of potential complications or diseases associated with CD: Ultrasound, computed tomography, and magnetic resonance imaging. In cases with suspected type II refractory CD, positron emission tomography scanning should also be available, either within the center or through an affiliated or reference institution                                                                                                                                                                                                                                                                                                                                                                                                             | 9.14 | 14.45  | Very high |
| 10              | The CCU-CD should include at least one consultation room where a specialist, either a pediatric gastroenterologist or an adult gastroenterologist, can provide personalized, expert care for the diagnosis and follow-up of patients with CD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 9.77 | 4.39   | Very high |
| 11              | The CCU-CD should have qualified professionals (preferably dietitians or dietitian-nutritionists) experienced in providing dietary and nutritional counseling for patients with CD as well as GFD. These professionals should work in close collaboration with the physicians responsible for patient care and provide support both at the time of diagnosis and during follow-up. Dietary counseling should be individualized, taking into account patient age, family environment, and cultural preferences                                                                                                                                                                                                                                                                                                                                            | 8.86 | 22.37  | Very high |
| 12              | The CCU-CD should have specific tools to evaluate adherence to the GFD, particularly in non-responsive patients. These tools should include validated dietary questionnaires (administered by qualified personnel, preferably dietitians or dietitian-nutritionists) and the measurement of GIP in urine and/or stool                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 9.59 | 8.30   | Very high |
| 13 <sup>1</sup> | The CCU-CD should have the support of an endocrinology and nutrition unit to assist in the specialized management of adult patients with complex nutritional deficiencies resulting from malabsorption, debilitating complications requiring enteral or parenteral nutritional support ( <i>e.g.</i> , jejunoileitis or lymphoma), and other forms of malnutrition (such as overweight or obesity) or associated endocrinopathies ( <i>e.g.</i> , type 1 diabetes, thyroid disease)                                                                                                                                                                                                                                                                                                                                                                      | 9.57 | 7.06   | Very high |
| 14              | The CCU-CD should collaborate with psychiatrists and/or clinical psychologists to support the management of psychiatric comorbidities or any other condition affecting the psychological and emotional well-being of patients (both children and adults), within a holistic and comprehensive model of care                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 9.18 | 13.29  | Very high |
| 15              | The CCU-CD should be led by a pediatric or adult gastroenterologist with specific dedication and experience in the different dimensions of CD (clinical care, teaching, and research). This leadership role may be shared by more than one professional                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9.32 | 14.20  | Very high |
| 16              | The CCU-CD should have validated tools to assess health-related quality of life in both pediatric and adult patients, using age-appropriate questionnaires. These assessments should be performed regularly by profes-                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 8.95 | 13.99  | Very high |

|                 |                                                                                                                                                                                               |      |       |           |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|-------|-----------|
|                 | sionals trained in their interpretation to ensure continuous patient monitoring                                                                                                               |      |       |           |
| 17              | The center hosting the CCU-CD should include a day hospital facility where intravenous treatments can be administered safely, such as parenteral iron or, in the future, biological therapies | 9.14 | 14.45 | Very high |
| 18 <sup>1</sup> | The CCU-CD should have access to inpatient facilities to ensure continuity of care in cases requiring hospitalization due to CD-related complications                                         | 9.71 | 7.38  | Very high |

<sup>1</sup>Not assessed in round 2 because they achieved a high degree of consensus (CV < 25%) and received no suggestions for modification during round 1.

CV: Coefficient of variation; CCU-CD: Comprehensive Care Unit for patients with Celiac Disease; CD: Celiac disease; HIV: Human immunodeficiency virus; tTG2: Tissue transglutaminase type 2; EMA: Endomysial antibodies; GIP: Gluten immunogenic peptides; GFD: Gluten-free diet.

## DISCUSSION

This consensus defined a set of structural, process, and scientific-educational quality standards to guide the organization of CCU-CD and ensure consistent, effective care. To our knowledge, this represents the first initiative to define and formalize quality-of-care standards for CD. Developed through a multidisciplinary Delphi process, these standards provide an operational framework that complements existing clinical practice guidelines and supports the delivery of high-quality, equitable, and patient-centered care for individuals with CD.

Led by the SEEC, this initiative brought together gastroenterologists, immunologists, dietitian-nutritionists, psychiatrists, pathologists, and researchers from multiple institutions across Spain, integrating clinical, nutritional, psychological, and scientific perspectives. The SEEC worked in close collaboration with the AEG, SEPD, and SEGHN, while also incorporating patient and caregiver input through nominations from the FACE, the Association of Celiacs of Catalonia, and the Association of Celiacs and Gluten-Sensitive Individuals. This inclusive approach ensured that the standards reflect both professional consensus and patient-centered priorities, thus achieving a framework that reflects clinical reality and the unmet needs of those affected, in line with current follow-up practices and clinical guidelines[23, 27].

Consistent with the multidisciplinary vision of the SEEC, these standards extend beyond diagnostic criteria to encompass nutritional education, psychological care, structured clinical follow-up, and research promotion, thereby addressing the multifaceted needs of patients and the evolving challenges in CD management. The high level of agreement achieved across nearly all standards underscores the shared recognition among experts of the essential components of optimal care and highlights the importance of clearly defined standards in achieving high-quality, equitable care in CD. However, this should be interpreted with caution. Many of the proposed elements, such as multidisciplinary care, access to appropriate diagnostic resources, and structured nutritional support, are widely recognized as essential components of CD management. In this regard, the value of this consensus does not lie in identifying novel requirements, but in formalizing and integrating these elements into a coherent and operational framework that supports implementation and evaluation in clinical practice.

Recent international guidelines, such as those from the European Society for the Study of Coeliac Disease and the American College of Gastroenterology, highlight the need for evidence-based frameworks to standardize the diagnosis, management, and follow-up of CD[24,28]. Nevertheless, considerable variability persists in clinical practice and care organization across regions, resulting in unequal access to multidisciplinary support, patient education, and long-term monitoring[1,12,18,20,21,23]. In this context, and given the need to strengthen epidemiological surveillance and facilitate early diagnosis to reduce complications and improve quality of life[3], the present consensus moves beyond clinical recommendations by translating these high-level principles into a concrete, operational framework that defines the structural and process requirements for CCU-CD.

Furthermore, the standards emphasize critical phases of care that are often neglected, such as the transition from pediatric to adult care[2,29]. The inclusion of specific transition protocols (Table 5) aims to mitigate the high risk of follow-up loss during adolescence, ensuring a continuum of care that preserves long-term health outcomes. Similarly, the requirement for specialized dietitians (standard 11, Table 3) is positioned not as an optional support, but as a fundamental clinical requirement, given that professional nutritional counseling is the cornerstone of treatment adherence and metabolic health in CD.

Comparable initiatives have been developed in other chronic and immune-mediated conditions, such as inflammatory bowel disease[30,31], uveitis[32], and rheumatoid arthritis[33], where structured models of specialized, multidisciplinary care have proven effective in improving diagnostic accuracy, treatment adherence, and patient-reported outcomes. These programs demonstrate that clearly defined structural and process standards are critical for ensuring equity and quality across healthcare systems. However, no standardized framework has yet been developed specifically for CD, despite its high prevalence, systemic nature, and the complexity of its management, which often requires coordination across multiple specialties and care levels. By aligning with successful approaches implemented in other chronic diseases, the standards proposed here provide a contextualized and scalable model for integrated CD care. While developed in the Spanish context, this framework may serve as a reference for other healthcare systems, although local adaptation will be necessary to account for differences in resources, organization, and infrastructure.

Moreover, this framework can serve as a foundation for quality assessment, benchmarking, and accreditation of CCU-CD, contributing to the harmonization of clinical practice and to continuous improvement in patient outcomes. As a next step, the SEEC plans to develop a "Self-Assessment Checklist" based on these standards, enabling hospitals to benchmark their current performance. Periodic review and adaptation of these standards will be essential to incorporate advances in diagnostic tools, therapeutic strategies, and patient-reported outcomes, thereby ensuring that the framework remains

**Table 3 Process quality standards for establishing a Comprehensive Care Unit for patients with Celiac Disease**

| Position | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Mean  | CV (%) | Agreement |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|--------|-----------|
| 1        | The diagnostic process for CD should ideally begin after confirming that the patient is consuming gluten. If the patient has previously followed a GFD, the exact dates should be documented in the clinical record whenever possible, and alternative diagnostic approaches should be considered if gluten exposure is deemed insufficient or interrupted                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 9.77  | 4.39   | Very high |
| 2        | Following CD diagnosis, each patient should be assigned either a pediatric or adult gastroenterologist, as appropriate, for disease follow-up. Once clinical and serological response to the GFD has been confirmed, long-term follow-up may be conducted by a pediatrician or primary care physician under a consensus-based protocol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 8.59  | 27.28  | Very high |
| 3        | The medical record should include detailed documentation of the diagnostic criteria used to establish the CD diagnosis in both children and adults, as well as appropriate ICD coding for statistical and epidemiological purposes                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 10.00 | 0.00   | Very high |
| 4        | The laboratory providing serological results to the CCU-CD must adhere to current diagnostic guideline recommendations for measuring anti-tTG2 and anti-EMA of IgA and IgG classes (the latter for IgA-deficient patients). A validated method must also be available to confirm IgA deficiency. Assay kits used should be clearly stated in reports, along with their sensitivity and specificity. Reports should also specify the diagnostic cut-offs required for positive results and for no-biopsy approach in children and adolescents, according to ESPGHAN recommendations. A note should clarify that quantitative results are method-dependent and may not be directly interchangeable with those obtained by other analytical systems. Internal quality control must be performed daily, and participation in external quality programs is mandatory | 9.86  | 3.56   | Very high |
| 5        | The CCU-CD should provide patients with a means of communication for reporting relevant clinical changes. Depending on available resources, this may include telephone contact, institutional email, or specific digital platforms                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 9.50  | 8.44   | Very high |
| 6        | The CCU-CD must base its procedures on national and international guidelines and apply protocols supported by the best available scientific evidence to ensure excellence in diagnosis, treatment, and follow-up. These protocols should incorporate the elements described in Table 5 and undergo regular review and updating                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9.36  | 12.99  | Very high |
| 7        | Laboratories performing HLA genetic testing must provide standardized reports meeting the minimum requirements recommended by the SEEC to ensure accurate interpretation. To ensure compliance, it is advisable that the reports be endorsed by the SEEC                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 9.82  | 4.02   | Very high |
| 8        | The CCU-CD should establish, in collaboration with the endoscopy and pathology departments, a Standard Operating Procedure defining the number and type of samples, as well as the collection and transport procedures for duodenal biopsies, both for histological study and intraepithelial lymphogram analysis by flow cytometry                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 9.73  | 5.66   | Very high |
| 9        | Laboratories performing immunophenotyping of duodenal lymphocyte populations (intraepithelial lymphograms) should use standardized flow cytometry methods with regular quality control and, preferably, staff experienced in intestinal mucosa. Reports should meet the minimum requirements suggested by the SEEC to ensure accurate interpretation                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 9.82  | 5.10   | Very high |
| 10       | The pathology department should provide standardized reports that supply pediatric and adult gastroenterologists with all necessary information for clinical interpretation. Reports should include a validated classification of histological lesions and a detailed description of findings to guide diagnosis and follow-up                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9.86  | 3.56   | Very high |
| 11       | Duodenal biopsy interpretation should be carried out by pathologists experienced in recognizing characteristic lesions. Double reading by two pathologists is recommended for all cases and mandatory in those with diagnostic uncertainty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 9.77  | 4.39   | Very high |
| 12       | The CCU-CD should offer newly diagnosed and follow-up CD patients access to dietary and nutritional counseling by qualified professionals (preferably dietitians or dietitian-nutritionists). Follow-up should be intensified in non-responsive cases or when symptoms persist                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 9.50  | 7.08   | Very high |
| 13       | The CCU-CD should conduct regular nutritional follow-up to identify and correct nutritional deficiencies and monitor nutritional status over time. These data should be systematically recorded in the medical history                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 9.32  | 14.58  | Very high |
| 14       | The CCU-CD should provide updated information on vaccination recommendations for CD patients, both at diagnosis and during follow-up, in accordance with regional public health guidelines                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | 9.32  | 9.59   | High      |
| 15       | The CCU-CD should implement a clinical monitoring program focused on safety for patients receiving immunosuppressive or, in the future, biological therapies                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 9.45  | 11.18  | Very high |
| 16       | The CCU-CD should inform patients about the existence of patient associations, which represent valuable complementary resources for psychosocial support and education on CD-related aspects                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | 9.69  | 6.68   | Very high |

CV: Coefficient of variation; CCU-CD: Comprehensive Care Unit for patients with Celiac Disease; CD: Celiac disease; tTG2: Tissue transglutaminase type 2; EMA: Endomysial antibodies; ICD: International Classification of Disease; GFD: Gluten-free diet; SEEC: Spanish Society for Celiac Disease.

relevant and responsive to evolving clinical challenges and improving the lives of patients with CD.

**Table 4 Scientific and educational activity quality standards for establishing a Comprehensive Care Unit for patients with Celiac Disease**

| Position | Definition                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Mean | CV (%) | Agreement |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|--------|-----------|
| 1        | The CCU-CD should, ideally, establish a registry of all actively followed patients within the specialized consultation setting, in full compliance with current data protection legislation. The registry should clearly identify cases of seronegative CD, CD with low-risk or non-compatible HLA genetics, non-responsive CD, and potential CD. Preferably, cases should be entered into a unified national registry provided by the SEEC. This registry may be used for both clinical and research purposes and, when possible, should be complemented by the collection of biological samples according to predefined Standard Operating Procedures | 9.05 | 17.22  | Very high |
| 2        | The CCU-CD should, ideally, have access to a biobank experienced in sample handling or, alternatively, establish its own sample collection to support research activities. The unit should also have the necessary infrastructure to ensure proper long-term storage of samples                                                                                                                                                                                                                                                                                                                                                                         | 9.27 | 14.19  | Very high |
| 3        | Members of the CCU-CD should actively participate in or promote research studies related to CD                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | 9.86 | 3.56   | Very high |
| 4        | At least one member of the CCU-CD should participate annually in a training or continuing education activity on CD, such as congresses, courses, workshops, or specialized seminars. Continuing education should cover both clinical and research aspects                                                                                                                                                                                                                                                                                                                                                                                               | 9.64 | 8.19   | Very high |
| 5        | All professionals involved in the diagnostic process of CD, including clinical and laboratory staff, should promote joint meetings ( <i>e.g.</i> , clinical case sessions) to share and reinforce up-to-date knowledge on CD within the multidisciplinary team                                                                                                                                                                                                                                                                                                                                                                                          | 9.77 | 4.39   | Very high |

CV: Coefficient of variation; CCU-CD: Comprehensive Care Unit for patients with Celiac Disease; CD: Celiac disease; ; SEEC: Spanish Society for Celiac Disease.

**Table 5 Essential elements to be included in clinical protocols supporting Comprehensive Care Unit for patients with Celiac Disease procedures**

| Phase                   | Essential elements                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Diagnosis               | <p>Coordinated and consensual approach with primary care and other specialized units, clearly defining referral criteria as well as symptoms and signs that should raise clinical suspicion of CD</p> <p>Management of biopsies deemed inadequate for histopathological assessment. Measures to be taken should be included (<i>e.g.</i>, preparing additional tissue sections, repeating the biopsy, or applying supplementary histopathological techniques)</p> <p>Procedures for accurate differential diagnosis of seronegative enteropathies, applicable to both lymphocytic duodenosis (Marsh 1) and villous atrophy (Marsh 3a)</p> <p>Diagnosis in individuals already on a GFD. The protocol should address cases in which the patient cannot tolerate or declines the gluten challenge, acknowledging that this may preclude a definitive diagnosis of CD</p>                                                                                                                                                                                            |
| Treatment and follow-up | <p>Follow-up protocol, defining the responsibilities of different levels of care: Specify which patients should continue follow-up in the hospital setting, which in primary care, and when shared care is appropriate</p> <p>Assessment of TSH levels for early detection of autoimmune thyroid disease</p> <p>Early detection of metabolic bone disease, including evaluation of calcium-phosphate metabolism and bone densitometry</p> <p>Indications and conditions for intravenous iron replacement in patients with CD and iron deficiency</p> <p>Transition from pediatric to adult care, specifying timing, process, and participants. A standardized transfer report should be completed by pediatric gastroenterologists, including all relevant clinical information for the adult gastroenterologist (diagnostic details, nutritional deficiencies at diagnosis, response to the GFD, adherence, and unresolved issues)</p> <p>Differential diagnosis of non-responsive CD in accordance with current clinical practice guideline recommendations</p> |

CD: Celiac disease; GFD: Gluten-free diet; TSH: Thyroid-stimulating hormone.

## CONCLUSION

This study establishes the first multidisciplinary Delphi consensus defining 39 quality standards to support the organization, development, and potential accreditation of CCU-CD. By promoting equitable access to expertise, structured follow-up, and patient education, these standards provide a scalable model for patient-centered care. The methodological rigor underpinning the consensus supports the effective implementation of these standards in clinical practice, improving patient outcomes and reducing unwarranted variability across healthcare settings.

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## FOOTNOTES

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