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Brief original

## Quality certification standard proposal “SpACE” for axial spondyloarthritis treatment units<sup>☆</sup>



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### ABSTRACT

**Background and objective:** Axial spondyloarthritis is an immune-mediated disease with a high cost, diagnostic delay and associated complications that makes it a particularly important condition. This work aims to establish a certification standard (SpACE Project) for monographic consultations in its diagnosis and treatment.

**Materials and methods:** Qualitative study of consensus, through the technique of the nominal group. First, a pragmatic review of the literature was carried out. Second, professionals involved throughout the care process (rheumatology, ophthalmology, gastroenterology, traumatology, family medicine, physical therapy, and nursing) were included.

**Results:** Thirty-seven possible standards were extracted from the pragmatic review of the literature. During the consensus phase only those standards with high feasibility and importance in the care process were prioritized. Finally, the group of 26 experts agreed on the inclusion of 14 standards.

**Discussion and conclusions:** SpACE is a consensus-based certification standard that seeks to improve health outcomes and more integrated care.

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## Propuesta de norma de certificación de calidad «SpACE» para unidades de tratamiento de pacientes con espondiloartritis axial

### RESUMEN

**Antecedentes y objetivo:** La espondiloartritis axial es una enfermedad inmunomediada con un elevado coste, retraso diagnóstico y complicaciones asociadas, lo que la convierte en una enfermedad con especial importancia. Este trabajo busca por consenso establecer un modelo de certificación (Proyecto SpACE) para consultas monográficas en su diagnóstico y tratamiento.

**Materiales y métodos:** Estudio cualitativo de consenso, a través de la técnica del grupo nominal. Primero, fue realizada una revisión pragmática de la literatura. Segundo, fueron incluidos profesionales involucrados a lo largo del proceso asistencial (reumatología, oftalmología, gastroenterología, traumatología, medicina de familia, fisioterapia y enfermería).

#### Palabras clave:

Espondiloartritis

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◇ The names of the SpACE group members are listed in Appendix A.

**Resultados:** Producto de la revisión pragmática de la literatura fueron extraídos 37 posibles estándares. Durante la fase de consenso solo aquellos estándares con una elevada factibilidad e importancia en el proceso asistencial fueron priorizados. Finalmente, el grupo de 26 expertos acordó la inclusión de 14 estándares.

**Discusión y conclusiones:** SpACE es una norma de certificación, fruto del consenso, que busca mejorar los resultados en salud y una atención más integrada.

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## Introduction

Axial spondyloarthritis (axSpA) is a chronic inflammatory disease that characteristically affects the sacroiliac and spine joints, causing pain and functional limitation. It is a chronic form of arthritis with an estimated incidence of 7 new cases per 100,000 population.<sup>1</sup>

AxSpA has its onset between the ages of 20 and 40, with an evolution in flare-ups of inflammation of the joints of the spine, or of other joints such as the shoulders, hips, knees or ankles. Patients with this condition have a high number of concomitant diseases, such as uveitis, psoriasis or inflammatory bowel disease, as well as comorbidities such as osteoporosis, obesity, hypertension, hypercholesterolemia, anxiety, depression, sleep disorders or fibromyalgia; all of which can impair their functional capacity and quality of life.<sup>2–6</sup> In most cases, the diagnosis of axSpA is delayed mainly due to its insidious onset, its low prevalence and the fact that it is not always recognised by the non-rheumatology physician.<sup>7</sup> This delay may prevent treatment in the early stages and may be responsible for aggravation of the disease, increased structural damage and loss of mobility.<sup>8</sup>

The estimated total annual cost per patient with axSpA is €20,328.00. Of this amount, 22.8% (€4,641.00) corresponds to direct costs (hospitalisations and pharmacological treatment), 43.5% (€8,845.00) corresponds to costs due to home modifications and informal carers and 33.6% (€6,843.00) to indirect costs.<sup>9</sup> Patients with axSpA often experience limitations in their social relationships, especially in the work environment, as they require more time off work. It has been estimated that work productivity losses due to axSpA are equivalent to €3,851/patient-year.<sup>10</sup>

As with other chronic immune-mediated inflammatory diseases, diagnosis and treatment involve different specialties and levels of care, and therefore the review of the care process and multidisciplinary treatment has been prioritised to ensure integrated, person-centred care.<sup>11</sup>

In recent years, quality certifications have spread due to their usefulness in reducing unnecessary variability, increasing diagnostic and therapeutic appropriateness, contributing to person-centred care and establishing the basis for making decisions based on the results.<sup>12</sup> In diseases such as axSpA, in which diagnostic uncertainty and comorbidities concur, certification can be a tool that contributes to achieving greater efficiency in the therapeutic effort of the different levels, moving towards comprehensive care. These tools are based on the idea that if the means (structure) and organisation (processes) are agreed as adequate and the objectives (results) are clearly set and monitored, the quality of care received by patients will be improved.<sup>13</sup>

This study was designed to establish the basis for a certification model to help reduce unnecessary clinical variability in specialised axSpA treatment units within rheumatology services.

## Material and methods

Qualitative study that sought to establish by consensus quality standards that could be used in a certification process applying the mixed methodology of self-assessment by the axSpA unit and

external assessment (audit), which was called the SpACE project. The study was conducted between July 2019 and January 2020.

Two face-to-face sessions and up to three rounds via virtual channels were conducted to establish a sufficient degree of consensus to identify relevant, acceptable and responsive quality standards.

### Participants

A total of 22 professionals from the specialties of rheumatology, ophthalmology, gastroenterology, traumatology, family medicine, physiotherapy and nursing and 4 experts in quality management and certification systems participated. The selection of participants was based on their specialised training and at least 10 years of previous experience in their field of expertise, taking into account that they have provided care to patients along the axial spondylitis care pathway. All agreed to participate in the study after being informed of the objectives and methodology.

### Procedure

First, a pragmatic review was carried out in the PubMed, Scopus, PEDro and Cochrane databases, using the terms: back pain, physical therapy, ankylosing spondyloarthritis, non radiographic axial spondyloarthritis, axial spondyloarthritis, quality of care, costs, service delivery and organisation. We proceeded in the same way with meta-search engines to search for information in grey literature (publications on websites, reports or recommendations produced by scientific societies). Finally, a meta-analysis search was performed on the websites of the following organisations and societies: Ministerio de Sanidad, Consumo y Bienestar Social, Sociedad Española de Reumatología, European League Against Rheumatism, American College of Rheumatology and National Institute for Health and Care Excellence. Papers potentially relevant to quality assessment or detailing its structure, functions and necessary resources were selected. We also searched for documentation of studies that described the resources use by this type of units in contrast with a non-monographic (standard) consultation.

Secondly, a qualitative consensus study was carried out among expert professionals. This involved two face-to-face sessions and a phase of individual work and discussion by electronic means.

In the first face-to-face session, the participants answered the following questions: how is correct care of the patient with axSpA achieved? are the necessary means available?, is health education carried out?, and what differentiates quality care? Their answers allowed a first draft of quality standards to be established, grouped into dimensions or areas to be explored.

For each quality standard, name, definition, purpose, standard threshold, numerator/denominator, source of information, method of assessment and bibliography were considered.

Through virtual channels, consensus was sought among the experts to identify those standards that met the requirements of being relevant and measurable from current information systems. In the last face-to-face session, participants reviewed the relevance, feasibility and degree of acceptance of the proposed standard for inclusion in the public health system. A priori con-

sensus was considered to be reached when an indicator was rated higher than 8.0 (scale of 0–10, with 10 representing high relevance and feasibility). Finally, the working group discussed the basis of the certification scheme, including: performance-based compliance levels, procedure for self-assessment through a platform (<http://www.space-cert.es>) and conditions for external assessment (including conditions for the setting up of an auditor panel).

The certification proposal was articulated in 4 levels (non-certified, certified, advanced certified and excellence certified). To establish this classification the experts considered the difficulties in practice in satisfying each indicator, so that the advanced and excellence certificates represented a higher level of achievement in the direction indicated by each indicator. To achieve the certificate level, it was required to meet the full set of standards at the “certified” level.

## Results

As a result of the literature review, 37 possible quality standards were obtained. During the initial session, the expert panel

reviewed this initial proposal to define quality standards. At the end of the meeting a total of 32 standards were established to be reviewed by the members of the expert panel. In the discussion phase, 14 standards were agreed upon, which were grouped into 4 dimensions (Table 1). These dimensions ranged from patient assessment to patient satisfaction and safety, multidisciplinary care and treatment outcomes.

The standards corresponded to structure ( $n=1$ ), care process ( $n=3$ ) and effectiveness, safety and patient experience outcomes ( $n=10$ ). Eleven standards (79% of the certification standards) had to be assessed by auditing a random selection of medical records; the remaining standards to be assessed by the existence or not of documentation or protocols to determine compliance with the criterion. For this phase of certification, it was recommended to apply batch sampling to determine whether the established quality standards were adequately and sufficiently met. The main advantage of this method is that it allows a small number of the total batch to be evaluated in order to accept or reject based on the result. For this process 3 h were considered necessary.

The self-assessment will be performed by a coordinator of the centre and will be the result of consensus among the

**Table 1**  
Standards for the certification of treatment units for patients with axial spondyloarthritis.

Standard	Dimension	Category	Level	Definition	Periodicity	Assessment method
Delay to care	Coordination	Outcomes	Certified	Care for patients with suspected inflammatory back pain indicative of a diagnosis of axSpA should not exceed 45 days	6 months	Referral for rheumatology consultation of patients with suspected axSpA in the previous 6 months will be analysed by the assessor.
Consultation with primary care	Coordination	Process	Advanced certified	There will be channels for consultation established between the 2 services to establish communications, either face-to-face or telematic to support the early diagnosis of the disease.	Annual	The assessor will analyse the evidence provided by the rheumatology service that demonstrates the existence of a stable consultancy system.
Assessment by a pain scale	Assessment and treatment	Outcomes	Certified	In the anamnesis of all patients with a suspected diagnosis of axSpA or already diagnosed and under follow-up, a scale will be applied to assess the degree of pain perceived by the patient.	Each consultation	The assessor shall analyse the existence of an assessment of the presence of pain through the application of objective measures such as BASDAI, EVA or ASDAS.
Assessment of functional capacity	Assessment and treatment	Outcomes	Advanced certified	In patients with suspected axSpA and in their follow-up by the rheumatologist, an adult functional capacity assessment scale will be applied in the anamnesis of all patients attending consultation.	6 months	The assessor will check for the presence of an assessment of functional ability using the BASFI scale.
Assessment of spinal mobility	Assessment and treatment	Outcomes	Certified	In patients with suspected axSpA and in their follow-up by the rheumatologist, assessment of spinal mobility should be recorded in the patient's history	6 months	The presence of an assessment of spinal mobility shall be analysed by the assessor.
Clinimetry and assessment of the patient	Assessment and treatment	Outcomes	Excellence certified	Proportion of patients with axSpA followed up in the clinic with a complete clinical evaluation, including questionnaires with the patient's perspective.	6 months	The assessor will analyse the medical history for evidence of spondylometry, assessment of pain, fatigue and mobility using scales, as well as peripheral joint counts in mixed forms and extra-articular manifestation
Assessment of remission or low activity	Assessment and treatment	Outcomes	Certified	Proportion of patients with axSpA achieving remission or low activity with therapeutic regimes	6 months	The presence of a remission or low activity phase (BASDAI < 4 and/or ASDAS-PCR < 2,1 or an alternative measure) in patients with a therapeutic plan of more than 6 months duration shall be analysed by the assessor

Table 1 (Continued)

Standard	Dimension	Category	Level	Definition	Periodicity	Assessment method
Assessment of extraarticular manifestations	Assessment and treatment	Outcomes	Certified	In patients with suspected axSpA and in the follow-up of those already diagnosed, the presence of extra-articular manifestations will be assessed	Each consultation	The assessor shall analyse whether the presence of extra-articular manifestations has been evaluated
Access to magnetic resonance	Coordination	Structure	Excellence certified	The rheumatology service will have direct access to request MRI tests to confirm/rule out the presence of sacroiliitis and spondylitis.	Six-monthly	The number of requests made before 30 days shall be analysed by the assessor taking into consideration the total of the specific agenda of sacroiliac MRI requests
Radiographic follow-up of axSpA	Assessment and treatment	Outcomes	Advanced certified	Patients with axSpA should have regular radiographic follow-up to assess structural damage based on disease activity and severity	Annual	The assessor shall analyse the radiographic follow-up, understood as the existence of compliance with the baseline radiographic protocol and its follow-up compliance
Multidisciplinary care	Coordination	Process	Certified	A multidisciplinary care protocol will exist in the rheumatology department	Annual	The assessor shall verify the existence of a multidisciplinary care protocol
Education in health plans	Person and patient safety-centred care	Outcome	Advanced certified	Proportion of diagnosed patients with axSpA who receive health education	Annual	The assessor shall analyse the presence of an assessment, preferably by the nurses, through a specific health education programme.
Patient satisfaction	Person and patient safety-centred care	Outcome	Excellence certified	Systematic collection of patient satisfaction with the process of care for axSpA by the rheumatology department	Annual	The assessor should verify the completion of patient satisfaction surveys (and 80% shall score $\geq 4$ on 5-step scales) by the rheumatology service to its users
Adverse event reporting system	Person and patient safety-centred care	Process	Excellence certified	Rheumatology professionals should actively participate in the reporting of safety incidents in the adverse event reporting system established in the centre, the SiNAPS programme, which allows preventive measures to be taken to avoid new incidents in the future due to the same causes.	Annual	The existence of the reporting system and its outcomes shall be analysed by the assessor.

staff of the rheumatology service. The application for quality certification is initiated by registering on the platform (<http://www.space-cert.es/>) designed ad hoc to capture all the necessary information, including the evidence justifying the self-assessment. The information included on the website corresponds only to the results of the self-assessment and not to patient data, in order to comply with legal regulations. The results of this self-assessment allow the service to apply an internal audit and implement improvement plans or corrective actions when advisable. Finally, the result of the self-assessment is externally contrasted during the external audit process, a review process that is also reflected in the platform.

## Discussion

A set of relevant, acceptable and sensitive quality standards is presented, agreed upon by rheumatology specialists with complementary profiles, which will lay the foundations for a future certification process for units caring for patients with axSpA. There is no history in the literature of proposals for standards for the certification of units that care for patients with axSpA. SpACE certification can contribute to homogenising clinical variability in the different axSpA services and achieve the implementation of the minimum necessary to care for people with this disease.<sup>10</sup>

The methodology used is similar to that used in other studies with similar objectives, although focused on other rheumatologic diseases, such as the case of psoriatic arthritis with the so-called QUANTUM project.<sup>14</sup>

The certification of care units has been linked to improvements in quality of care and prognosis of new onset by facilitating early diagnosis and treatment, optimising the use of resources (both human and material) for routine clinical practice in the medium and long term.<sup>15</sup> The provision of multidisciplinary care involving different professionals is linked to better clinical outcome. Other studies have shown an increase in quality of life and well-being with nursing consultations to assess inflammatory activity, and improved health education.<sup>16</sup>

This approach, in addition to reducing unnecessary variability, has other advantages. First, it can be expected to contribute to the provision of agreed minimum resource requirements and to the establishment of a greater number of specialised units in hospitals. Second, it should promote the identification of areas for improvement in services, or what corrective actions need to be implemented, to provide better value care.<sup>17</sup> Third, it stimulates improvements in outcomes by establishing benchmarking systems linked to the external recognition that comes with quality certification. Finally, having units recognised by third parties makes it easier for them to participate in national and international clinical

cal trials, as they have a proven structure and operating processes, allowing comparison of results.

### Limitations

This proposal has been developed within the framework of the Spanish health system. The proposed standards may not be generalised to other countries. The planned self-assessment and external evaluation require a pilot study to test the operability of the procedure and the application designed to facilitate this certification.

### Conclusions

In conclusion, SpACE is a proposal for a certification standard, the result of consensus, which seeks to ensure the necessary basic equipment and improve organisational processes, coordination between levels and health outcomes for patients diagnosed with axSpA.

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Novartis funded this research project. No Novartis employees were involved in the design, execution, data capture, interpretation of results and drawing of conclusions of this study. Responsibility for the study rests entirely with the authors.

### Conflict of interests

The authors have no conflict of interests to declare.

### Appendix A.

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