

Accreditation of specialized asthma units for adults in Spain: an applicable experience for the management of difficult-to-control asthma

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Abstract: This paper, developed by consensus of staff physicians of accredited asthma units for the management of severe asthma, presents information on the process and requirements for already-existing asthma units to achieve official accreditation by the Spanish Society of Pneumology and Thoracic Surgery (SEPAR). Three levels of specialized asthma care have been established based on available resources, which include specialized units for highly complex asthma, specialized asthma units, and basic asthma units. Regardless of the level of accreditation obtained, the distinction of “excellence” could be granted when more requirements in the areas of provision of care, technical and human resources, training in asthma, and teaching and research activities were met at each level. The Spanish experience in the process of accreditation of specialized asthma units, particularly for the care of patients with difficult-to-control asthma, may be applicable to other health care settings.

Keywords: asthma unit, severe asthma, uncontrolled asthma, asthma treatment

Introduction

Asthma in adults is a heterogeneous disease usually characterized by chronic airway inflammation with hyperresponsiveness of airways to various stimuli. The prevalence estimates of asthma, in general, and the prevalence of severe asthma, in particular, are well known and sufficiently illustrative. According to the Global Asthma Report 2014,¹ asthma affects 334 million people with projections of 400 million in 2025. In addition, asthma still accounts for one of every 250 deaths worldwide, and almost all of these deaths are avoidable.² In Spain, prevalence rates of 5% and 10% have been estimated in adults and children, respectively, with more than three million people with asthma.^{3–5} In addition, there is a large geographical variability in asthma prevalence, with a trend toward stabilization following an increase in the prevalence of the disease observed in the past years.^{3,6} This complex disease affects patients of all ages. Although its diagnosis is usually easily established and most patients respond to therapy, approximately between 3% and 10% of adult asthma patients have disease that is difficult to control despite taking maximal doses of inhaled medications.⁷ Patients with therapy-resistant or difficult-to-control asthma require a rigorous and systematic approach to their diagnosis and treatment. Despite rigorous, optimized follow-up treatment, 75% of severe asthma patients did not achieve adequate symptom control and presented with impaired quality of life.⁸

Although much progress has been made in the understanding of difficult-to-control asthma, with consensus documents and clinical practice guidelines focused

on severe uncontrolled asthma with proposals for a stepwise diagnostic procedure and phenotype-targeted treatment,^{9,10} improvements in clinical practice are still limited. In addition, involvement of pulmonology services in the specialized approach for difficult-to-control asthma is insufficient. In a survey carried out in Spain, 47 (68.1%) of a total of 69 pulmonology services met criteria for an important level of health care activity in asthma, but only 29 (42%) had a monographic consultation for difficult-to-control asthma and 37 (53.6%) had implemented an education program. As for post-graduate education, only 31 (44.9%) provided their resident physicians with specific asthma training.¹¹

In 2015, the asthma area of the Spanish Society of Pneumology and Thoracic Surgery (SEPAR) addressed the task of establishing the necessary requirements for the provision of official accreditation standards of the different levels of care for asthma units already existing in hospitals of the Spanish National Healthcare System. Accreditation levels included basic units, specialized units, or specialized units of high complexity, with or without the distinctive of excellence, according to the fulfillment of a series of criteria established by the society.

The development and implementation of this nationwide strategic plan had several objectives, including improving the care and quality of life of asthma patients, particularly patients with severe difficult-to-control asthma in order to achieve a decrease and prevention of acute exacerbations, with a subsequent reduction in the number of visits to the emergency department, need of in-patient care, and inadequate use of asthma medications. All these actions have been complemented by the development and implementation of education and self-management strategies (where nursing plays a key and indispensable role) and follow-up of patients in monographic consultations for asthma and in the framework of multidisciplinary involvement of health care professionals.

In a recent scientific meeting of health care professionals of the different asthma units, which underwent specialized accreditation, it was agreed that a perspective article should be drafted to achieve greater dissemination of the details regarding the characteristics, service portfolio, and resources available in these units. The present document written and approved by all attendees of this event and members of units provides information and describes the initial global experience of asthma units accredited in Spain. It also aims to contribute to raising awareness among pulmonologists and other professionals about the problem of severe refractory asthma and the response offered by asthma units to improve

patient care and to minimize the complications and burden of this complex pathology. In this respect, we believe that the Spanish experience may be useful and potentially applicable to other settings, in particular with similar health care systems. However, workup details and assessment of outcomes were outside the scope of this report.

Difficult-to-control asthma

Significant progress and advances in the understanding of asthma and in the care of asthma patients with an increase in the number of medications and development of new protocolized therapeutic strategies have been associated with a substantial reduction in asthma-specific mortality and hospitalization rates for asthma. However, despite all these improvements and the development of clinical practice guidelines with specific recommendations for the control of asthma, it is well known that in clinical practice, adequate asthma control is achieved in only one-third of patients.^{12–14}

Uncontrolled severe asthma accounts for ~15% of all asthma patients but is associated with a higher morbidity and mortality as well as an important impact on health care costs and the consumption of resources.¹⁵ The AsmaCost study¹⁶ based on data of a prospective cohort of 627 patients throughout Spain with asthma diagnosed according to the guidelines of the Global Initiative for Asthma (GINA)¹⁷ and the adapted Spanish criteria (Guía Española de Manejo del Asma [GEMA])⁹ and followed up for 12 months revealed that the total societal cost for asthma was 1,726€ per patient annually (1,533€ to the National Health Service), with higher costs for patients older than 65 years and for those with a more severe disease (2,635€ for severe asthma). Based on these findings, the total annual cost of asthma in Spain was estimated to be 1,480 million euros. On the other hand, 70% of total costs were attributed to the poor control of the disease, which further reinforces the need to achieve clinical stability of the patients as it has been repeatedly emphasized in clinical practice guidelines.^{9,17}

From another perspective, poor asthma control is a determining factor of the high indirect costs related to absenteeism and reduced productivity. In a naturalistic and observational study (TENOR study) of 4,756 asthma patients recruited in 283 study sites from diverse geographical areas in the USA and followed up for 24 months, the mean annual costs for uncontrolled patients with difficult-to-treat asthma were more than double of those for controlled patients throughout the study.¹⁸ Different studies carried out in other countries have obtained similar results.^{19–21} Moreover, chronic comorbidities contribute to the burden and costs of persistent asthma,²² and poor adherence to asthma medication regimens, including

patients with difficult-to-control asthma, is a key problem contributing to poor disease control.²³ Adherence to asthma treatment in patients with uncontrolled difficult asthma is highly relevant, since treatments currently considered for step-up therapy (biologics, bronchial thermoplasty)^{9,17} are very expensive and, in many cases, are prescribed without adequate adherence to drug regimens in the lower steps.²⁴

A further interesting aspect concerns to deficiencies in the development and implementation of effective education programs for asthma patients, promotion of health, and social support. It has been demonstrated that education in self-management of asthma with symptom or peak flow monitoring, combined with regular medical visits and written action plans, is effective in improving health outcomes in adults with asthma.^{25,26} In a 1-year cluster randomized controlled multicenter study with the participation of 230 adults with mild-to-moderate persistent uncontrolled asthma, an asthma educational program based on a repeated short intervention, given in four face-to-face sessions at 3-month intervals was effective in improving asthma symptom control, future risk, and quality of life.²⁷ In this study, the education program included administration of a written personalized action plan and training on inhaler technique.²⁷ Other experiences reported similar results. In a controlled clinical trial in which a comprehensive asthma intervention program was evaluated in a population of Medicaid-insured asthmatic children, a significant improvement in health outcomes (emergency department visits, hospitalizations) and asthma health care costs was observed in the intervention group in the year after enrollment.²⁸ In a randomized patient selection study with crossover, a vigorous medical regimen and intensive educational program were able to decrease hospital use among a group of adult asthmatics who had previously required repeated readmissions for acute asthma exacerbations.²⁹ In a large teaching hospital (Glasgow Royal Infirmary) where asthma management was audited prospectively for 1 year, treatment of asthma patients in wards with a specialist interest in respiratory medicine was associated with a reduction in the rate of readmissions compared to patients admitted to general wards without this special interest (2% vs. 20%).³⁰

Given the complexity and multiple factors involved in the control of asthma, there is a need for establishing asthma units involved in the care of asthma patients, especially those patients with severe difficult-to-control disease. However, up to the present time, a few studies have demonstrated that assessment and management of patients in specific units for severe asthma are associated with substantial benefits in

terms of health (asthma control, quality of life) and reduction in economic burden. In a study of 346 patients with severe asthma referred to specialist centers across the UK and followed up for a median of 286 days, significant reductions in health-care use (primary care or emergency department visits), hospital admissions, and steroid dose were observed, which were accompanied by significant improvements in quality of life and asthma control.³¹ In a crossover study carried out in Spain, treatment of patients in asthma clinics was cost-effective and beneficial in asthma management in comparison with standard outpatient services.³² The National Asthma Program in Finland, probably one of the most outstanding health care networks for asthma patients, has shown that integration of different health care levels involved in the management of asthma (pneumologists, primary care physicians, and pharmacists) improves control of the disease and reduces the morbidity of asthma.³³

Specialized asthma units

The SEPAR has promoted the task of accrediting the levels of the different asthma units already existing in our country, with the following objectives: 1) to improve the level of care of asthma patients, ensuring a framework of quality of care; 2) to establish resources and facilitating their management; 3) to promote the development of training plans in asthma and to advance in the concept of “accreditation of knowledge”; 4) to favor collaboration with professionals from other clinical disciplines in a cooperative environment; and 5) to promote asthma research. Within the SEPAR training framework, a manual on severe asthma and difficult-to-control asthma has been published, which includes a chapter on the provision and organization of a severe asthma unit.³⁴

Briefly, three levels of specialized asthma care have accredited based on available resources: specialized unit for highly complex asthma, specialized asthma unit, and basic asthma unit. The characteristics of these three grades of accreditation are detailed in Table 1. Regardless of the level of accreditation obtained, the distinction of “excellence” could be granted when more requirements were met at each level. In order to obtain accreditation at each of the levels, there were indispensable requirements (IRs) that had to be met; also, there were two other criteria, which included evaluable criteria (EC) and recommended criteria (RC). The certification of each level was achieved if at least 80% of the EC corresponding to each category were fulfilled. The quality of each level was “excellent” if the result of the formula $(EC + RC) \times 100 / (\text{total number of EC} + \text{RC items at the level})$ was $\geq 80\%$.

Table I Criteria requested for accreditation of the different levels of asthma units by the Spanish Society of Pneumology and Thoracic Surgery (SEPAR)

Activities	Specialized unit for highly complex asthma	Specialized asthma unit	Basic asthma unit
Health care activity	Stable functioning organigram Availability of a physical space for consultations and complementary studies Provision of informatics systems, databases, documentation files, and action protocols Number of asthma patients attended annually between 500 and 1,000 Possibility of providing emergency care for patients with acute exacerbations without the need of hospital admission, >50/year Coordinated activity with other specialists (allergy, ear, nose, and throat, and pediatrics) is advisable Standardized education program	Stable functioning organigram Availability of a physical space for consultations and complementary studies Health care and education protocols Number of asthma patients attended annually between 250 and 500 Possibility of providing emergency care for patients with acute exacerbations without the need of hospital admission The presence of a database is advisable Coordinated activity with other specialists (allergy, ear, nose, and throat, and pediatrics) is advisable	Stable organigram Number of asthma patients attended annually between 100 and 250
Technical resources	Specific physical space Office and clinical material	Specific physical space Office and clinical material	Specific physical space Office and clinical material
Human resources	Multidisciplinary group of health care professionals specialized in asthma, with a specialist in pneumology as the head of the unit, and at least three staff physicians At least two nurses Other possible members of the unit: at least two scholars (recommendable) with optional one allergologist and a psychologist	A specialist in pneumology as the head of the unit, with at least two staff physicians At least one nurse At least one scholar (recommendable)	Activity developed by a specialist in pneumology
Accredited training in asthma	Teachers or attendees (participants) of accredited courses on asthma, at the level of the autonomous communities or given by SEPAR, or that some of the staff members had taken accredited international courses on asthma or a master in asthma Recommendable to have been a member of the Emerging Asthma Group (Grupo Emergente Asma [GEA]) of the SEPAR	Evaluable criteria (EC) that some of the staff members have been teachers or attendees (participants) of accredited courses on asthma at the autonomous community level or given by SEPAR EC that some of the staff members had taken accredited international courses on asthma or a master in asthma Recommendable that at least some member of the unit belongs to or has been taking part in the Emerging Asthma Group (GEA) of the SEPAR	Indispensable to have been taken part in accredited courses on asthma at the level of the autonomous communities or given by SEPAR, other accredited international courses on asthma or a master in asthma Recommendable to have been a member of the Emerging Asthma Group (GEA) of the SEPAR
Teaching activity	Pre-graduate and post-graduate teaching activity At least one of the staff members should have the academic degree of Doctorate in Medicine Study project or doctoral thesis related with asthma directed by the unit in the last 5 years	Pre-graduate and post-graduate teaching activity Recommendable that at least one the staff members has the academic degree of Doctorate in Medicine Recommendable to have the direction of a doctoral thesis on asthma in the last 5 years	Not requested at this level
Research activity	Minimal mandatory activity: at least five original articles published in journals with impact factor, recommendable at least two research projects financed by SEPAR, and at least participation in two projects in which the Integrated Research Program (IRP) of asthma of SEPAR would have been involved Participation in clinical trials of asthma It is recommendable the participation in research projects of the Biomedical Research Networking Centers (CIBER) and having obtained Fondo de Investigación en Salud (FIS) grants for some research project of the unit in the last 5 years	Minimal mandatory activity: at least two original articles published in journals with impact factor, recommendable at least one research project financed by SEPAR, and at least participation in one project in which the IRP of asthma of SEPAR would have been involved Recommendable to develop clinical trials of asthma	Recommendable that in the last 5 years, there has been an article published in a journal with impact factor and participation in a project financed by SEPAR or in projects in which the IRP of SEPAR would have been involved

(Continued)

Table 1 (Continued)

	Specialized unit for highly complex asthma	Specialized asthma unit	Basic asthma unit
Representative activity	Mandatory participation in asthma health promotion activities under the auspices of health care systems of the autonomous communities, the Spanish national health care system or international health care systems, or public or private bodies	Recommendable to belong or to have been a member of the Executive Committee of the Asthma Area of SEPAR or the Executive Committee of the IRP of asthma of SEPAR or a member of working groups of similar local (autonomous communities) or international societies	Not requested at this level

The integral care of the patient with severe asthma in a specialized multidisciplinary and high-quality setting presents many advantages, particularly related to the diagnosis of asthma, including identification of patients according to phenotypes, treatment of comorbidities, protocolized follow-up, optimization of the therapeutic arsenal, indication of specific treatments, and emphasis on health education for both patients and health care professionals. For instance, to have available a specialized nurse well trained in asthma education and use of inhaler devices will result in a better understanding of the disease, adherence to treatment, and control of the disease. In addition, there is a high prevalence of psychocomorbidity in asthma, and acting at this level can improve the quality of life of the patients, control of anxiety, low consumption of resources, etc. In this respect, psychological support may be recommendable. Likewise, the possibility of implementing complementary programs contributes to better control of the disease. This approach is associated with cost savings as a result of a better and rational use of the resources. In addition, accredited asthma units could help patients with asthma through identifying misdiagnosed cases of asthma and providing more appropriate treatment/referral. Misdiagnosis of non-asthmatic conditions as uncontrolled asthma has been reported to be as high as 12%–30%.^{35,36} The implementation of databases with relevant and updated clinical information is an essential tool for the independent analysis of the data of each unit or aggregated data from different units. This tool would also facilitate the development and participation in research projects.

This is effectively a proposal for the control and improvement of care provided to our patients, the results of which are pending to be collected and evaluated. We believe that diagnosis and treatment by highly specialized and experienced personnel in asthma will result in the achievement of a better control of disease. A recent study carried out in an asthma clinic of a university-affiliated hospital in Lugo in 2012 showed that all cost variables except drugs and diagnostic tests were significantly reduced in comparison with standard outpatient services, giving an annual saving per patient of €338.³²

Concluding remarks

The assessment and management of patients with severe difficult-to-control asthma in accredited asthma units aims to improve the quality of care and control of the disease. In addition, specialized asthma units can improve the cost-effectiveness of pharmaceutical expenditure, especially regarding the new and costly therapies. Health care professionals involved in the management of asthma should continue pursuing for unifying the quality of care of patients with asthma in a multidisciplinary collaborative setting.

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Disclosure

The authors report no conflicts of interest in this work.

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