



## Editorial

 Highlights of the Spanish Asthma Guidelines (GEMA), Version 5.0<sup>☆,☆☆</sup>

## Novedades y otros aspectos destacados de la Guía Española para el Manejo del Asma (GEMA), versión 5.0



THE SPANISH ASTHMA GUIDELINES, better known by the acronym GEMA, have been in existence for more than 20 years. GEMA was the first SEPAR-led consensus to be produced in collaboration with other scientific societies. At present, given the number of participating scientific societies, it is probably the most important consensus documents currently implemented in any one disease in Spain, and has grown steadily to become the standard worldwide reference guideline on asthma in the Spanish language. It has been evaluated using objective methodological parameters (the AGREE tool), and these studies have positioned it among the best because of its quality, rigor, and presentation.<sup>1</sup>

Its objectives are to prevent asthma and to improve the clinical situation of affected individuals by giving the healthcare professionals who treat them further insight into this disease. To this end, a group of experts has drafted a set of preferably evidence-based recommendations that are clear, concise, and intelligible, and easily implemented by treating physicians. The reader, however, should not expect the guideline to provide an exposition of all the available knowledge on asthma. It is not an expert monograph, but is instead deliberately designed to be a brief, practical document.

Although GEMA is updated briefly on an annual basis, mainly to incorporate the most relevant literature citations, the text is revised in depth every 5 years by a new editorial team. Their task is to develop new guidelines and renew both structure and content. It has been 5 years since the appearance of GEMA 4.0, so in 2020 it was time to produce the new version, GEMA 5.0.

Because of its size, number of participants, design, and content, this new GEMA<sup>2</sup> has the very best prospects. A total of 108 asthma experts, accredited representatives of the above-mentioned 21 societies, scientific groups, associations, and foundations, have participated in drafting and reviewing this document. The sheer number of participants and societies involved in the consensus makes this new GEMA<sup>2</sup> the largest ever.

Changes include the reordering of sections and subsections. Particular care has been taken regarding the quality of the wording and the proper use of the Spanish language, given the guideline's wide international dissemination, particularly in Latin America.

The most important modifications, grouped by areas, include in the section of diagnosis-classification a cut-off point for FE<sub>NO</sub> that was reduced from 50 to 40 ppb. These revised values are in line with other expert recommendations,<sup>3</sup> and are more balanced and useful for clinical practice, while still retaining sufficient rigor. The new criteria for intermittent asthma are now more demanding: for example, the use of relief medication has been set at a maximum of only twice a month, in contrast to the previous limit of twice a week. Severity will be classified after appropriate treatment and on the basis of the amount of inhaled glucocorticoid needed to achieve and maintain disease control, while initial severity prior to treatment will no longer be taken into account. A new simple and practical diagnostic algorithm is provided for asthma in children.

Significant changes have been made in the therapeutic area. In the treatment of intermittent asthma, the problems resulting from the abuse of short-acting  $\beta_2$ -agonists (SABA) have been recognized, and options for the combination of on-demand inhaled glucocorticoid/formoterol or glucocorticoid/salbutamol have been incorporated, allowing the physician to choose one of these 3 options, depending on the patient's characteristics. In the case of mild persistent asthma, the first option is still inhaled glucocorticoids at low daily doses, although for patients with poor adherence to this option who do not improve after appropriate corrective educational intervention, on-demand administration of inhaled glucocorticoid/formoterol or glucocorticoid/salbutamol may be considered. In our view, the evidence provided on the effectiveness of this second option<sup>4,5</sup> is neither superior nor equal to the first, but it could be used in the scenario described. Therefore, the GEMA recommendation would fall somewhere between those of GINA<sup>6</sup> (in favor of on-demand glucocorticoid/formoterol) and the European Medicines Agency (against) in mild asthma. Another important modification has been the change in the concept and treatment of step 6 disease (severe uncontrolled asthma) in adults, now especially reserved for the use of biological drugs (omalizumab, mepolizumab, reslizumab, benralizumab, and dupilumab). A table is provided with the aerodynamic properties of the drug deposit provided by the different inhalers, while another novel addition is the recommendation of at least one minimal educational intervention with a short action plan in writing for all patients, based on the study sponsored by the SEPAR Asthma group (PROMETEO).<sup>7</sup> Some further therapeutic innovations have been introduced in the treatment of childhood asthma.

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<sup>☆☆</sup> The working paper referred to in this editorial can be accessed at: <https://www.gemasma.com>.

In the section on severe asthma, which is discussed in a separate section, phenotypes, which are now reserved only for severe asthma, have been simplified in 3 variants: allergic T2 asthma, eosinophilic T2 asthma, and non-T2 asthma, while the asthma phenotype associated with obesity has been set aside. A notable addition has been the inclusion of an algorithm for the treatment of severe uncontrolled asthma, based on the recent SEPAR consensus for severe asthma.<sup>8</sup> Furthermore, new biologics have been included in the treatment of severe asthma in children.

And finally, among a wide miscellany of other significant changes, we must highlight: the inclusion of care circuits, referrals between levels of care, and recent proposals from some working groups for patients after discharge for exacerbation<sup>9,10</sup>; the characteristics, activity, and resources of asthma units accredited by SEPAR or SEAI<sup>11</sup>; the inclusion of nasal polyposis (diagnosis and treatment) in the asthma-associated rhinitis section; a specific section on asthma and Covid-19, which includes, in particular, a table of possible drug interactions between drugs used to treat infection and asthma; new asthma prevalence data (in Spain and Argentina); and some basic considerations regarding telehealth and telemedicine applied to asthma.

As was the case in previous GEMA editions, this latest version takes a balanced attitude toward the most controversial aspects, avoiding extreme positions. Taking this middle ground is not in any way disingenuous: we believe it is the result of the deliberation, restraint, and independent thinking employed by the GEMA Executive Committee in the face of controversy.

We are confident that this new edition will earn the same recognition as its predecessors and achieve its objectives. In the meantime, we are already working on the GEMA 5.1 for 2021.

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