



GINA 2015: the latest iteration of a magnificent journey

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In the September issue of the ERJ, a new report summarises key updates to the GINA global strategy document <http://ow.ly/PKjhw>

The Global Initiative for Asthma (GINA) represents a remarkable source document that has changed the course of asthma in most countries. The first asthma guidelines have been published in Australasia, UK [1] and the USA [2]. Canadian and French recommendations proposed the concept of control [3, 4], and the National Asthma Education and Prevention Program Expert Panel Report initiated the concept of risk for asthma [5]. However, GINA is globally considered to be the prominent asthma recommendation building on existing knowledge and providing several updates or revisions since it was introduced in 1995 [2, 6, 7]. GINA 2015 represents a significant advance over the previous iteration, with a more practical approach and an increased appreciation of asthma as a public health problem [8]. Due to the expected impact of GINA 2015 it is mandatory to assess strengths and weaknesses although many of these cannot be ruled out due to the lack of information currently available.

Firstly and importantly, the GINA 2015 is not a guideline and should only be considered a strategy proposal based on an expert consensus. Key recommendations for diagnosis and management are considered and areas for research represent an interesting addition to the new iteration. Only recommendations for severe asthma use the GRADE approach [9]. The GINA evidence-based system may be sufficient for many recommendations but not for all, and a document as powerful as GINA should probably use the best system. In most guidelines, the evidence is drawn from randomised controlled trials only. Thus, recommendations do not apply for many patients due to the very strict inclusion criteria of these trials [10], for example excluding patients such as smokers, obese patients and those with multimorbidity. GINA should be commended for also considering real life and observational studies [11].

The new definition of asthma is closer to the mechanisms of the disease, but it is more complex than the previous one for a practising physician and may not differentiate asthma from chronic obstructive pulmonary disease (COPD) sufficiently. Interestingly, patient stratification is taken into account: "an overarching principle in the new GINA report is the importance of individualising patient management not only by using genomics or proteomics, but also with 'humanomics', taking into account the behavioural, social and cultural factors that shape outcomes for individual patients." However, no patient

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can be currently managed using genomics or proteomics, although this may be possible in future [12]. Moreover, all physicians treating asthmatics have always considered “humanomics” for each patient. GINA 2015, however, brings information on how to cope with individual patients and as such represents an important advance over previous GINA documents. Strategies to reduce the impact of impaired health literacy are very important and should be commended [13, 14].

Comorbidities are listed but, as previously, they do not properly consider rhinitis, the major one present in the vast majority of asthmatic patients. Moreover, there is confusion between rhinitis and rhinosinusitis, which represent two different diseases [15]. This is highly surprising, since most GINA members see regularly patients who complain from nasal and bronchial problems equally [16]. A proposed guideline for management of asthmatic patients should consider this issue adequately, or propose a link with an evidence-based reference document for the global assessment of the asthmatic patient with rhinitis: ARIA (Allergic Rhinitis and its Impact on Asthma), for example [17].

Although asthma patients of older age and those with asthma in pregnancy are considered, there is a major lack of information, representing an urgent research need to close the gaps [18, 19]. Interestingly, some insufficiently evidenced recommendations are proposed for asthma in older patients and the use of cardiac drugs. A GRADE-based recommendation (including the list of papers reviewed) [20] should be proposed urgently for the use of β_2 -agonists and β -blockers in patients with comorbid cardiac disease and asthma (and COPD).

The asthma–COPD overlap syndrome (ACOS) is rightly discussed in “a new chapter aimed at providing interim practical advice for primary care and non-respiratory specialists, and as a signal to regulators that evidence is needed about treatment for patients with features of both asthma and COPD,” along with “A syndromic approach to recognising asthma, COPD and ACOS in primary care,” but, as indicated, ACOS cannot yet be defined and the treatment unclear. There is an urgent need for future epidemiological [21] and mechanistic research components of ACOS, and treatment approaches [22]. However, in real life, most physicians in primary care use combination therapy in those they diagnose as having ACOS and make a diagnosis of asthma if the patient improves and COPD if there is no major change. It is, however, important to define the asthmatic and COPD components of ACOS, since inhaled corticosteroids are very effective in asthma to prevent exacerbations, whereas they are moderately effective in COPD but can induce pneumonia [23].

Preschool children often have wheezing but the diagnosis of asthma in this age group is difficult and the prognosis of the disease even more complex. GINA 2015 proposes a revised management of wheezing in this age group and indicates that there is insufficient evidence [24]. However, new data in cohorts in the general population are not sufficiently reviewed as novel data suggest that multimorbidity in preschool children has a significant clinical relevance for the prognosis of asthma [25].

The new GINA 2015 proposes a practical approach to management: “A list of common asthma phenotypes is provided, to prompt clinicians, including those in primary care, to recognise different clinical patterns among their patients, even if they lack access to complex investigations.” Importantly, pulmonary function tests are well described. However, as for other guides for disease management, there is a need for a larger use of GINA by physicians for individual patients [26]. Moreover, GINA 2015 cannot be used in many developing countries due to the lack of available/affordable recommended treatments in the proposal, as well as the definition of severe asthma restricted to developed countries [9, 27].

Control-based care is well defined and appraised. It makes an improvement over the previous iterations. “Assess [ment of asthma] includes not only symptom control ... but also risk factors, inhaler technique, adherence and patient preference, to ensure that treatment can be tailored to the individual. ‘Adjust treatment’ (up or down) includes not only medications but also non-pharmacological strategies and treatment of modifiable risk factors. ‘Review response’, including side-effects and patient satisfaction, is essential to avoid over- or under-treatment.” This practical approach closely follows the paper presented to the World Health Organization on severe asthma in 2010 [28] and may be used for other chronic diseases [29]. Comparing COPD and asthma, this common approach to the severity and control of chronic diseases suggests important areas for research: prevention of asthma, treatment of severe asthma, and treatment of all patients with COPD [30].

A strategy proposal may consider care pathways at the local level. GINA 2015 proposes “An explicit framework for tailoring treatment. The GINA report now draws a clear distinction between population-level (e.g. national guidelines, health maintenance organisations) and patient-level treatment decisions.” This chapter is important and follows what is currently done at the European Union level by the European Innovation Partnership on Active and Healthy Ageing [31]. However, more practical approaches should be proposed and the most successful national asthma plan was devised in 1995 and did not consider the GINA guidelines [32].

Expansion of the indication for low dose inhaled corticosteroids is very surprising since the evidence is clearly lacking and does not consider the possible side-effects of inhaled corticosteroids, which are likely to outweigh the benefits, in particular for children [33]. Moreover, compliance of patients is likely to be even worse than for other steps of GINA. This proposal is likely to be impossible to apply in real life.

Many other interesting proposals have been made including: 1) the term “flare-up” is now recommended for communication with patients; 2) an early rapid increase in inhaled corticosteroids is now recommended for many action plans; and 3) exacerbation severity classification has been streamlined into mild/moderate, severe and life-threatening.

GINA 2015 represents an excellent continuous update from previous iterations but modern medicine should be incorporated in the proposal. The next generation guidelines should incorporate integrated care pathways (suggested in GINA 2015 but not developed in practical terms), e-health and clinical decision support systems to propose a manageable and personalised medicine easily accessible to the patients, health and social care providers [34]. This is being done at the European Union level for rhinitis and the results of this initiative further deployed for asthma.

In summary, GINA 2015 is in line with previous GINA documents with new well-described changes. It is a remarkable educational tool but its applicability to patients in real life needs to be demonstrated. GINA 2015, as well as other guides for asthma, will be used by the Care Pathways action group of the European Innovation Partnership on Active and Healthy Ageing to propose integrated care pathways [30]. The current document may be very useful for new generation guidelines.

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