



# The revised 2014 GINA strategy report: opportunities for change

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## Purpose of review

This document reviews a major revision of the Global Initiative for Asthma (GINA) Strategy for Asthma Management and Prevention that was published in 2014. The report aimed not only to update evidence-based recommendations for asthma diagnosis and management but also to innovate through a new format and layout to make its recommendations more clinically relevant and easier to implement.

## Recent findings

The GINA 2014 report includes a new definition of asthma that recognizes the heterogeneity of the disease and its phenotypes, and a new chapter about the asthma–chronic obstructive pulmonary disease (COPD) overlap syndrome. Among key messages, the report stresses that therapeutic decisions should be based not only on assessment of symptoms but also on risk factors for exacerbations, side effects of therapy and development of fixed airflow limitation. Asthma management includes not only medications but also nonpharmacological therapies and strategies, in a coordinated and personalized approach to individual patient care. On the basis of evidence about how to achieve behaviour change by health professionals, the recommendations are presented in a user-friendly format, with numerous tables, algorithms and flow-charts facilitating implementation. Background supporting material has been gathered online.

## Summary

The GINA 2014 report provides updated and more easily implementable recommendations on optimal asthma management.

## Keywords

asthma, Global Initiative for Asthma, guidelines, implementation

## INTRODUCTION

In the rapidly evolving field of asthma, a large amount of knowledge has been gathered in the last few years, making it difficult for clinicians to keep abreast of developments. The production of knowledge syntheses such as systematic reviews, meta-analyses and particularly clinical practice guidelines have been promoted as a means to make medical diagnosis and treatment more evidence-based. Not only have these means of gathering and analysing current evidence on specific key questions been increasingly used, but also the methods to produce guidelines have significantly evolved. For example, tools such as AGREE [1], suggesting how guideline development, reporting and evaluation can be optimized [1] and GRADE (Grades of Recommendation, Assessment, Development, and Evaluation) [2] providing a systematic assessment of the quality of evidence, and a summary of the relative importance of outcomes and risks of alternative management strategies, are currently used [3]. However,

guidelines are often poorly implemented. In order to improve outcomes, there is a need to produce and disseminate guidelines that are not only evidence-based but are also easy to implement in clinical practice, particularly primary care. The clinical decisions involved in management of a patient with a chronic condition such as asthma far outnumber the availability of systematic reviews; for example, during development of the recently published Australian asthma guidelines, 350 individual

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## KEY POINTS

- The 2014 Global Initiative for Asthma (GINA) Strategy report for Asthma Management and Prevention innovates through a new format and layout to make its evidence-based recommendations clinically relevant and easier to implement.
- GINA 2014 recommends that treatment should not be based only on symptoms but also on risk factors for exacerbations, side effects of therapy and development of fixed airflow limitation.
- Asthma management aims at a personalized approach to patient care, taking into account the characteristics of the disease, the patient environment/background and practical issues such as adherence and inhaler technique.
- The GINA 2014 report recommendations are presented in a user-friendly format, and the inclusion of many tables, algorithms and flow-charts in addition to supporting implementation tools should facilitate translation of its recommendations into care.

clinical questions were identified (<http://www.asthmahandbook.org.au/about/methodology>). There is therefore a need for evidence-based recommendations to be integrated into a global strategy for assessment and treatment of diseases, particularly for chronic conditions [4–7]. It is also important that such recommendations are framed in a user-friendly format that can be easily interpreted by clinicians.

The ‘Global Initiative for Asthma (GINA)’ was inaugurated in 1993 by the National Heart, Lung, and Blood Institute and the WHO, with the aim of communicating a strategy to help practitioners worldwide to improve asthma management [8]. Since 2002, the GINA Strategy Report for Asthma Management and Prevention ([www.ginasthma.org](http://www.ginasthma.org)) has been revised every year on the basis of a twice-yearly review of current and new evidence. This is conducted through the ongoing work of the GINA Scientific Committee, which includes leaders in asthma research and clinical practice. More recently, GINA has not only provided guidance on asthma evaluation and treatment, but it has also provided guidance on how to implement its recommendations [9].

Clinical practice guidelines are usually developed at a national or regional level, to allow for population characteristics, the healthcare system and availability of medications. The GINA report is not a ‘classical’ guideline, but instead it describes a global clinical approach to asthma care, a ‘strategy’, to help clinicians to understand how to implement diagnostic and therapeutic recommendations within a

comprehensive approach to asthma care that can be adapted to the needs of both low-resource and high-resource countries.

The GINA 2014 strategy report represented a major shift in both content and format, compared with previous years. An overview of what is new in the 2014 Report [10<sup>■</sup>] can be found in Table 1. In order to understand the rationale for these changes, this article describes the clinical, research and sociological context in which the report was developed, and how this is reflected in updated recommendations and a new format.

## THE CHANGING SPECTRUM OF CHRONIC AIRWAY DISEASE

A major transition is underway at present in our understanding of chronic airway disease. By contrast with previous concepts of ‘asthma’ and ‘chronic obstructive pulmonary disease’ (COPD) as separate diseases (a concept perpetuated by the inclusion criteria for many clinical trials [11]), chronic airway disease is now perceived as a spectrum of overlapping conditions. Asthma itself is accepted as being heterogeneous, a collection of diseases likely to have different underlying mechanisms, but with similar clinical features of variable respiratory symptoms and variable airflow limitation [12]. The various phenotypes/endotypes of chronic airway disorders (e.g. based on clinical features, inflammatory patterns or provoking factors) are increasingly well defined, thanks to the efforts on better defining clinical, physiological and inflammatory features. In GINA 2014, these emerging concepts are reflected in an updated definition of asthma, addition of a description of common clinical and inflammatory phenotypes, a change in the approach to diagnosis of wheezing children and in the inclusion of a new chapter about the asthma–COPD overlap syndrome (ACOS).

The GINA 2014 definition of asthma states: ‘Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation’. This definition, which is reminiscent of that proposed in a 1958 CIBA symposium [13], is simple for clinicians to remember and does not infer a specific pathophysiological process or molecular mechanism. Airway inflammation and hyperresponsiveness are common features of asthma but are not necessary or sufficient to make the diagnosis.

Consistent with this revised definition, there is an increased emphasis in diagnosis of asthma on

**Table 1.** Some key changes in the 2014 GINA report ([www.ginasthma.org](http://www.ginasthma.org)) [10<sup>\*\*\*</sup>]

(1) Presentation of a 'new' definition of asthma for clinical practice	Recognizes the heterogeneity of the disease and its many phenotypes
(2) Emphasis on confirming the diagnosis of asthma	Increased emphasis in documenting a history of characteristic symptom patterns, combined with obtaining evidence of variable airflow limitation. If already under treatment, progressive withdrawal procedures to allow diagnosis confirmation are explained
(3) Addition to aims of asthma management avoidance of both under and overtreatment	From pulmonary function tests and careful assessment of control criteria
(4) Provision of practical tools for assessment of the two domains of asthma control	Symptom control; risk factors for poor outcomes
(5) Discussion of a comprehensive approach to asthma management	Cycle of care: assess, adjust treatment and review response; medications: a new stepwise algorithm (see Box 3–5 in the GINA 2014 report [10 <sup>***</sup> ]); nonpharmacological interventions; treatment of modifiable risk factors and comorbidities; maximize the benefit of existing medications by checking inhaler technique and adherence before considering step up
(6) Discussion of a continuum of care for worsening asthma and exacerbations	Revised recommendations for written asthma action plans; new flow-charts for management of acute asthma in primary care and in acute care facilities
(7) Recognition of the value of noninvasive airway inflammation assessment to assess heterogeneity of asthma and personalize treatment approach for severe asthma	
(8) Addition of a new section on diagnosis of asthma, COPD and asthma–COPD overlap (ACOS)	Syndromic recognition in clinical practice, and appropriate initial treatment
(9) Revision of the approach to assessment and treatment of wheezing children	Emphasis on symptom patterns, e.g. occurrence of symptoms in between viral infections

COPD, chronic obstructive pulmonary disease.

documenting a history of characteristic symptom patterns, combined with obtaining evidence of variable airflow limitation from bronchodilator reversibility testing or other testing. Because of the potential for over/underdiagnosis of asthma, the GINA report stresses that evidence for the diagnosis should preferably be established before starting controller treatment, as it is often more difficult to confirm the diagnosis after treatment has been started. However, an algorithm of progressive treatment withdrawal to help confirm such a diagnosis is proposed.

A significant proportion of patients with symptoms of chronic airway disease have features of both asthma and COPD. The reported prevalence of ACOS varies from 15 to 55% of patients with airway obstruction [14,15]; importantly, these patients have worse outcomes than those with either condition alone [16]. The GINA 2014 report includes a novel chapter about ACOS; this was a joint project of GINA and the Global Initiative for Chronic Obstructive Lung Disease (GOLD, [www.goldcopd.org](http://www.goldcopd.org)). The chapter describes a syndromic approach for identifying ACOS in primary care and explains basic principles for initial treatment. Increasing awareness of ACOS should prompt regulatory bodies and manufacturers to include such patients in future studies.

## GOALS OF THERAPY INCLUDE RISK REDUCTION, NOT ONLY SYMPTOM CONTROL

In the goals of asthma management, not only is symptom control defined as a main target for therapy, but risk reduction is also stressed as an important goal of asthma care. In 2010, GINA adopted the recommendations of an ATS/ERS Task Force [17] in describing two domains of asthma control: current control of symptoms and future risk of adverse outcomes. This approach has been further expanded and emphasized in GINA 2014. Asthma symptom control (formerly 'current clinical control') is assessed over the previous 4 weeks: when symptoms are well controlled, the patient should not have symptoms or need for reliever more than twice/week, and no awakening or limitation of activity due to asthma. For assessment of future risk, a referenced table of risk factors has been provided; for exacerbations, this includes uncontrolled asthma symptoms, excessive short-acting beta<sub>2</sub>-agonist (SABA) use, inadequate inhaled corticosteroids (ICS; not prescribed, nonadherence or poor inhaler technique), low forced expiratory volume in one second, especially if less than 60% predicted, major psychological or socioeconomic problems, exposures (smoking; allergen exposure if sensitized), comorbidities

(obesity, rhinosinusitis, confirmed food allergy and so on), sputum or blood eosinophilia and pregnancy. Nonmodifiable risk factors include ever being intubated or ever in an ICU for asthma, or having one or more severe exacerbations in the previous 12 months. The GINA report also lists risk factors for the development of fixed airflow limitation and for side effects of medication. By contrast with the previous approach of numerically combining lung function with symptoms in the assessment of asthma control, the value of lung function is now primarily seen to lie in the assessment of future risk, wherein it is an important predictor of both exacerbations and accelerated decline in lung function.

Separate from the assessment of asthma control, the severity of asthma is assessed retrospectively from the level of treatment required to control symptoms and exacerbations [17]. Severity may however change over months or years, or under the influence of treatments. This approach is concordant with recently published guidelines for severe asthma [18<sup>\*\*\*</sup>].

### **INCREASING INTEREST IN PERSONALIZED TREATMENT**

In the past decade, interest in the concept of 'personalized' medicine has been expanding. This term is variously used for the concept of management based on molecular analysis, and for patient-centred individualized care. The updated approach to asthma management in all age groups in the GINA 2014 report is comprehensive but more practical than before; it acknowledges the fundamental role of ICS as the mainstay of asthma therapy (and expands the indications for ICS to patients with symptoms more than twice a month and/or an exacerbation in the last 12 months), but it also defines the role of added pharmacological and non-pharmacological interventions. Barriers to optimal asthma control are discussed, with a particular focus on common problems such as incorrect diagnosis, incorrect inhaler technique and poor adherence, which, if not considered, may lead to inappropriate increases in treatment [19].

In describing treatment options, the GINA report distinguishes between population-level decisions, which are often largely based on group mean data from meta-analyses, clinical trials and observational studies as well as cost and availability, and patient-level decisions, in which the clinician should also take into account any phenotypic characteristics that might predict treatment response (e.g. current smokers may need a higher dose of ICS than nonsmokers), the patient's preferences and concerns, and practical issues such as cost, inhaler technique and adherence.

Assessment and therapy can hence be targeted towards the needs of a given individual. This is particularly true for severe asthma, wherein an increasing number of biomarkers are being identified, particularly as predictors of treatment response [20<sup>¶</sup>]. With the development of new costly therapies for severe asthma, it is needed to better characterize asthma in order to select the best therapeutic approach. However, despite the increasing interest in assessing phenotypes and even endotypes, both related to either its characteristics or mechanisms, to date, only a few will result in changes in asthma management. The most obvious is however the assessment of corticosteroid needs and potential response in documenting airway eosinophilia with noninvasive measures such as induced sputum analysis. Inflammatory biomarkers from induced sputum analysis, fractionated concentration of exhaled nitric oxide measures and even blood eosinophils may not only help predict treatment responses but also can help differentiate asthma from other airway diseases such as ACOS and COPD. There are reminders that nonpharmacological interventions for asthma should not be neglected, and guided self-management education has been proven to be highly effective in improving asthma outcomes. It should however include self-monitoring of symptoms and/or peak expiratory flow, a written asthma action plan and regular medical review.

### **PERSISTING CARE GAPS IN ASTHMA MANAGEMENT**

Many care gaps still persist in asthma management [21]. Among those, the significant problem of over-diagnosis or underdiagnosis of asthma (contributed to by underuse of pulmonary function measurements in diagnosing respiratory symptoms), inadequate assessment of asthma control, failure to assess treatment adherence and patients' concerns, failure to provide self-management education, including a written action plan, incorrect inhaler technique [22] and poor prescribing, including delayed prescription of ICS are often cited [23–25]. In some countries, lack of access to care or essential medications such as ICS and SABA lead to poor control of the disease. There are striking examples that when these care gaps are addressed, asthma outcomes markedly improve [26].

### **EVIDENCE ABOUT HOW TO CHANGE BEHAVIOUR OF HEALTH PROFESSIONALS**

We now have strong evidence to base interventions aimed at inducing behaviour changes in caregivers in order to reduce the above care gaps, but these are insufficiently applied [27,28]. Didactic teaching and

textbook-style documents are known to be ineffective; a first step is to provide recommendations that are clinically relevant, clearly described and feasible for implementation into day-to-day practice, and this was a key focus during preparation of the GINA 2014 report. Behaviour change can also be facilitated by integrating recommendations into health-care systems, for example in using embedded recommendations in Electronic Medical Records [29], in order to reduce barriers to change.

## **SUPPORT FOR INTEGRATING IMPLEMENTATION WITH CLINICAL RECOMMENDATIONS**

Since the inception of guidelines production, it has been known that their recommendations are often not well integrated into care. Among barriers to implementation, many have been identified, such as insufficient knowledge of those to whom the guideline is addressed, their attitudes, skills, beliefs and values [30]. Furthermore, elements such as the cost and complexity of translating the recommendations in various cultural and socioeconomic contexts in addition to the lack of time or resources available are often mentioned.

Research on how to facilitate guidelines, standards and strategies in the last 2 decades has identified elements to help facilitate this translation in care [31,32]. Some important aspects deal with the production and communication of the recommendations. Indeed, as pointed out by Gagliardi *et al.* [33], the guideline/report format (e.g. simple, clear, user-friendly, with summaries in Tables, Figures and so on) and which content is presented (e.g. essential notions, means of individualizing recommendations and applying them into care and so on) are crucial [34,35]. Guideline developers should ideally include implementation experts from the first stages of the process, rather than thinking about how to implement the recommendations into clinical practice after the guideline has been completed.

To integrate new developments in the field of knowledge translation into its production, GINA formulated its recommendations on the basis of systematic reviews and meta-analyses, using reviews based on the GRADE tool where these were available, and incorporating clinical consensus about how recommendations could be implemented in clinical practice. With regard to its content, background material that was not essential for clinical practice (e.g. physiopathology, pharmacology, mechanisms) is provided in an online Appendix, accessible on the GINA website. With regard to its format and communicating the evidence, the new report integrates many tables and flow-charts illustrating current knowledge about the various issues involved in

asthma diagnosis and management. They include new flow-charts about management of asthma exacerbations in primary care and in acute care facilities, and practical advice about how to step down controller treatment. As well as hard copies of the full report and 'Pocket Guides' for primary care, the website is also being optimized to increase the availability of the document and resources.

Furthermore, the GINA Scientific Committee considered from the start, even before writing the document, how to make the report more easily implementable. The content and layout were structured to include algorithms, care paths and reminders of the various types of information needed to make appropriate decisions and to individualize care. Hopefully, the information conveyed will also help the practitioner and educators to apply 'shared decision-making' strategies to help improve patient understanding of suggestions and improve adherence.

Although GINA provides guidance on implementation, this should of course be done at the local level. In this regard, we previously published the proposed framework of a local/national implementation strategy [9]. We also developed an 'implementation tool box' including various documents and reminders that can be applied into care and adapted to local needs.

## **CONCLUSION**

The GINA 2014 report can thus be seen to reflect changes in our understanding of chronic airway disease and of the importance of both symptom control and risk reduction. The report reflects the increasing interest in personalized asthma care, awareness of persisting gaps in asthma care, evidence about how to achieve change in behaviour of health professionals and support for integrating implementation into clinical recommendations. As in the past, there will be an ongoing process of review and revision, to ensure that asthma outcomes continue to improve.

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## **Conflicts of interest**

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**(1) Personal benefits\***

It includes fees (for lectures, advisory committees, travel grants or consultancy services) either intermittent or regular, from which you benefit personally.

Company	Nature/Purpose of payment
AZ	Advisory boards and speakers bureau for all
GSK	
Merck	
BI	
Novartis	
Takeda	
Aerocrine	

**(2) Nonpersonal interests\* (All funds managed through nonpersonal UBC research accounts).**

Includes fees or grants paid and used for research, education, equipment, salaries and so on,

Company	<\$10 000	>\$10 000	Nature/Purpose of support
GSK		>10 000	Research
BI		>10 000	Research
Wyeth		>10 000	Research
Genentech		>10 000	Research
Canadian Institute for Health Research		>10 000	Research
Medimmune		>10 000	Research
Ono		>10 000	Research
Novartis		>10 000	Research
AllerGen NCE		>10 000	Research
Boston Scientific		>10 000	Research

Chair GINA Executive and member of Science Committee

H. Reddel

In the past 3 years, I have participated in advisory boards for AstraZeneca, Boehringer Ingelheim, GlaxoSmithKline and Novartis; have been a member of a data safety monitoring board for AstraZeneca, GlaxoSmithKline, Merck and Novartis; have provided consulting for AstraZeneca, Biota, Mundipharma and Novartis; have provided independent medical education at symposia funded by Aerocrine, AstraZeneca, GlaxoSmithKline and Novartis; and have received unrestricted research grants from AstraZeneca and GlaxoSmithKline. I am a member of the Guidelines Committee for the Australian Asthma Handbook, and a member of the Respiratory Expert Group for Therapeutic Guidelines. I am also the Chair of the GINA Science Committee.

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