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Kaplan, Alan; van Boven, Job F.M.; Ryan, Dermot; Tsiligianni, Ioanna; Bosnic-Anticevich, Sinthia

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GINA 2020: Potential Impacts, Opportunities, and Challenges for Primary Care



Alan Kaplan, MD, CCFP(EM), FCFP^a, Job F.M. van Boven, MSc, PharmD, PhD^b, Dermot Ryan, FRCGP, MB, BCh, BAO^c, Ioanna Tsiligianni, MD, MPH, PhD^d, and Sinthia Bosnic-Anticevich, BPharm (Hons), PhD^e, on behalf of the REG Adherence Working Group Toronto, ON, Canada; Groningen, the Netherlands; Edinburgh, UK; Crete, Greece; and Sydney, NSW, Australia

In 2019, it was reported that changes to asthma management reported in the Global Initiative for Asthma (GINA) “... might be considered the most fundamental changes in asthma management in 30 years.” These changes refer to the recommendation that the treatment of asthma in adolescents and adults would no longer include short-acting β_2 -agonist (SABA) only, but that people with asthma should receive either symptom-driven inhaled corticosteroids (ICS)-containing treatment (mild asthma) or daily ICS-containing treatment. The fundamental reason for this shift was driven by concerns about the risks and consequences associated with SABA-only treatment, the need to improve the day-to-day management of asthma symptoms to prevent exacerbations and emergent evidence. These recommendations have subsequently been reinforced and characterized in GINA 2020, and it is reasonable to say that they are significant, not only in terms of an asthma management framework but also as a management approach in practice. This opinion article specifically focuses on opportunities and challenges associated with the implementation of GINA 2020 in primary care practice that need to be recognized and addressed if the shift in asthma treatment paradigm is to be successfully implemented into day-to-day practice. © 2021 Published by Elsevier Inc. on behalf of the American Academy of Allergy, Asthma & Immunology (J Allergy Clin Immunol Pract 2021;9:1516-9)

Key words: GINA 2020; Asthma management; Primary care; Translation; Implementation

In 2019, the Global Initiative for Asthma (GINA) for the first time since its establishment in 1993 redefined the framework within which we manage asthma. That is, with the then newly

emerging evidence,^{1,2} the recommendation that adolescents and adults with asthma should no longer be treated with short-acting β_2 -agonists (SABAs) alone (even in mild disease), but rather that they receive symptom-driven or daily inhaled corticosteroids (ICS), was released. This recommendation was reinforced and characterized in GINA 2020.³

At the time of these new recommendations, it is reasonable to say that the medical community, in particular that in primary care, recognized the need for change. There had been substantial evidence both in research and practice that asthma management in practice was suboptimal⁴⁻⁶ and the perceptions and behaviors of patients with regard to their medicines were potentially putting them at risk,⁷⁻⁹ even those patients with mild asthma.¹⁰ The causes behind these behaviors are multifactorial; however, many are associated with the lifelong relationship that people with asthma develop with their medication, including short-acting reliever therapies (SABAs). First, at the time of diagnosis, many people with asthma commence treatment with SABAs, thereby often recognizing them as their go-to asthma treatment, providing immediate and effective relief of their symptoms.⁸ Secondly, although it is established that even in mild asthma, low-dose regular ICS reduces symptoms, exacerbations, and improves quality of life,^{3,11} people with asthma are often not adherent to regular ICS (either alone or in combination with long-acting β_2 -agonist [LABA]) often leading to SABA monotherapy,¹² SABA over-reliance and overuse,¹³⁻¹⁵ and consequently serious future risk of asthma exacerbations^{8,16} even in people with mild asthma.^{10,17} But of course, the issue of overuse of SABA medications is far more reaching than among those individuals with mild asthma, with a recent European study indicating that up to 30% of people with asthma (across the spectrum of asthma severity) overuse their

^aDepartment of Family and Community Medicine, University of Toronto, Toronto, ON, Canada

^bDepartment of Clinical Pharmacy & Pharmacology, Groningen Research Institute for Asthma and COPD (GRIAC), University Medical Center Groningen, University of Groningen, Groningen, the Netherlands

^cUsher Institute of Population, University of Edinburgh, Edinburgh, United Kingdom

^dDepartment of Social Medicine, Faculty of Medicine, University of Crete, Crete, Greece

^eQuality Use of Respiratory Medicines Group, Woolcock Institute of Medical Research, University of Sydney, Sydney, NSW, Australia

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Corresponding author: Sinthia Bosnic-Anticevich, BPharm (Hons), PhD, Woolcock Institute of Medical Research, University of Sydney, 431 Glebe Point Road, Glebe, NSW 2037, Australia. E-mail: Sinthia.bosnic-anticevich@sydney.edu.au. 2213-2198

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Abbreviations used

GINA- Global Initiative for Asthma

ICS- Inhaled corticosteroids

LABA- Long-acting β_2 -agonist

SABA- Short-acting β_2 -agonist

SABA medications.¹³ Therefore, when the findings of 2 large randomized controlled trials showed that in mild asthma ICS/LABA prn (cf SABA prn) has similar clinical benefits to regular ICS + SABA prn in terms of exacerbations (along with significantly reduced daily dose of ICS),^{1,2} there was excitement among the asthma community around the implications of these new findings. It is, in fact, these 2 studies that led to the new asthma management recommendations in GINA, that is, that adolescents and adults with asthma should no longer be treated with SABA alone (even in mild disease), but rather that they receive symptom-driven or daily ICS.

A paradigm change like this brings opportunities and challenges as well as successes and concerns, both for people with mild asthma treated in primary care, where most people with mild asthma are managed, and those individuals who have become “reliant” on the use of SABA medications. Here, we provide our view on the implementation of GINA 2020, with a particular focus on changes for step 1 and step 2 therapy, beyond clinical outcomes. We highlight the opportunities and challenges we expect to arise in the management of asthma in primary care. These are summarized as a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis (Figure 1). SWOT is a strategic planning framework/technique commonly used by individuals and organisations as part of project planning.

OPPORTUNITIES AND CHALLENGES OF IMPLEMENTING GINA 2020 FOR MILD ASTHMA IN PRIMARY CARE

Strengths and opportunities

This paradigm shift has the potential to:

- (1) address the issue of SABA overuse and the relationship that patients develop with SABA as their initial asthma treatment is halted;
- (2) change the content of busy primary care consultations through removal of the need to stress and coach the patient on regular daily adherence of ICS and increasing the time spent on other core aspects of asthma management such as diagnosis confirmation, asthma self-management plan creation and education, and so on;¹⁸
- (3) alleviate the fears of patients relating to the regular use of corticosteroids and harnesses patient motivation to use medication when needed (ie, at minimum dose) rather than regularly in mild asthma;¹⁹
- (4) may play into patient preference for symptom-driven treatment²⁰; and
- (5) encourage a more personalized, real-world, and clinically titrated use of ICS to treat the underlying eosinophilic inflammation, resulting in an overall lower total dose of inhaled steroids over time and by preventing exacerbations, lowers the need for oral steroids and all its attendant risks.

Weaknesses and threats

Despite the potential opportunities, this shift in paradigm needs to be implemented into a health care environment in which health care practices and patient expectations are engrained. In many ways it necessitates a markedly different approach to the delivery of care. The challenges associated with this include:

- (1) The need for a confirmatory asthma diagnosis before treatment commencement. Although the paradigm shifting studies were conducted in patients in whom an asthma diagnosis has been confirmed, this often does not reflect real-life practice.²¹ The reality is that SABA medication is often initiated before an asthma diagnosis is confirmed and many patients do not have/do not recall or deny a diagnosis of asthma, especially when purchasing SABA medication over the counter, in the community pharmacy.¹⁴ If the pharmacological recommendations of GINA 2020 are to be followed without a confirmed asthma diagnosis, the use of ICS in a patient without a firm diagnosis of asthma may lead to ineffective, costly, or even harmful effects, whereas a delay in treatment initiation until a confirmatory asthma diagnosis is made (which often only occurs over time, particularly when the patient is asymptomatic at presentation) may place the patient at risk.
- (2) The risk of delayed initiation of regular preventer medication. One of the trials underpinning GINA 2020 indicated that the regular use of low-dose ICS slightly outperformed ICS/LABA prn in step 2 therapy in terms of lung function (by approximately 40 mL) and asthma control in terms of well-controlled asthma weeks.¹ It has been known for many years that delayed institution of ICS leads to irreversible loss of lung function^{22,23}; hence commencing regular ICS therapy earlier leads to better outcomes. With this new approach, long-term, regular ICS or ICS/LABA may be prevented due to new patient expectations of a prn approach to preventer medication.
- (3) The missed opportunity of failing to commence treatment on a sufficiently high dose of ICS or ICS/LABA medication. For individuals with a long history of symptoms before diagnosis, it is preferable to start with a higher dose of regular ICS treatment. This may be compromised with this new approach, especially if a diagnosis is delayed.
- (4) The need to re-educate patients, educators, clinicians, and pharmacists on many fundamental aspects of asthma management. This includes the fact that the GINA 2020 changes only apply to one particular ICS strength, in one specific combination of ICS/LABA (which contains a rapid onset of action LABA) and that these recommendations cannot be transferred to other ICS/LABA combinations. Further, the role of different treatments, inhaler technique (as most SABAs are delivered via a pressurized Metered Dose Inhaler; however, ICS/LABA is primarily dispensed in a dry powder inhaler), and adherence support requires reiteration. The new paradigm also has implications for monitoring asthma symptom control and future risk. For example, SABA pharmacy refill frequency has traditionally been used as a quick screening tool to monitor asthma control, and this will no longer be possible in the same way and therefore may require a modified approach to assessing asthma control in the community. Finally, while the use of ICS/LABA (which contains a rapid onset of action LABA) before exercise and as-needed for symptom relief has been shown to be

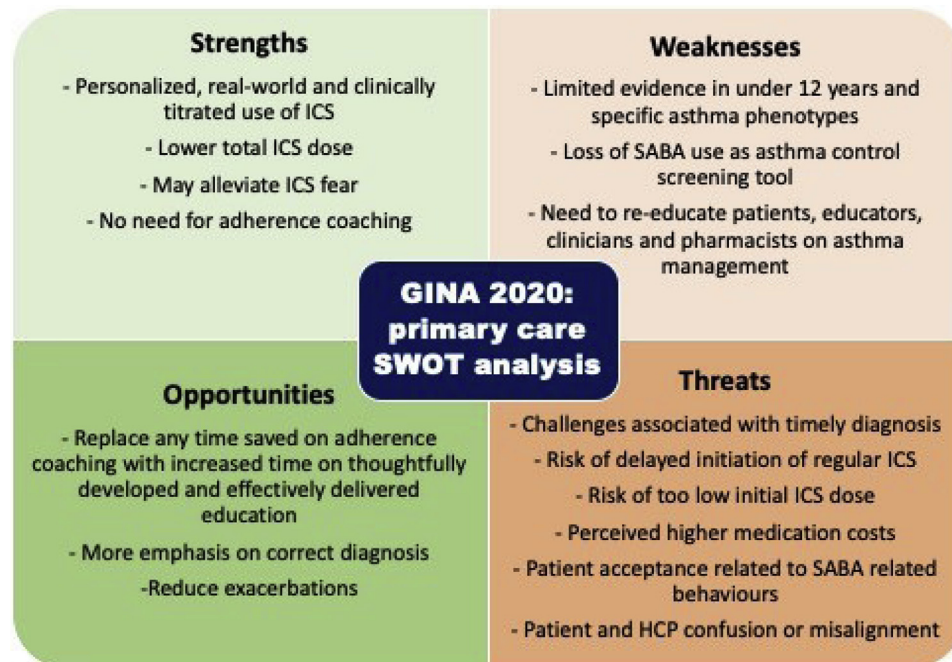


FIGURE 1. Primary care SWOT analysis of GINA 2020. *GINA*, Global Initiative for Asthma; *HCP*, health care provider; *ICS*, inhaled corticosteroids; *SABA*, short-acting β_2 -agonist; *SWOT*, Strengths, Weaknesses, Opportunities, Threats.

non-inferior to regular maintenance ICS with as-needed SABA for preventing exercise-induced bronchoconstriction, and superior to as-needed SABA alone,²⁴ there is a need for education to reiterate the need for asthma symptom monitoring in these patients as exercise-induced symptoms are 'frequently' a marker of poor asthma control,²⁵ taking particular note of those patients who only report exercise-induced symptoms.

- (5) The issue of medication access as a result of costs or medication supply policies. The itemized cost of a SABA is much less than an ICS/formoterol on a dose per dose cost, and we can only hypothesize that this will have implications on patients' ability/priority to purchase their asthma medication, as has been shown to be the case up until now.^{24,25} This consideration is best balanced with overall health care cost savings that may arise by reducing exacerbations, presenteeism, absenteeism, and long-term oral corticosteroid side effects, although formal cost-effectiveness analyses are lacking. Further to cost, there may be policies (such as those in the United States) that limit the ability of pharmacies to distribute more medication to individuals where only limited supply of drug each month or every 90 days is allowed. This may therefore require a change in health care policy relating to supply to individuals.

Beyond this, while GINA 2020 does not recommend as-needed ICS/LABA in children, there still remain significant gaps in our understanding of the role of ICS/LABA in children. Although there is some evidence for the efficacy of ICS/LABA (administered in the maintenance and reliever therapy regimen) in children aged 4 to 11 years²⁶ and the addition of ICS/SABA (prn) to regular ICS²⁷ in children/adolescents (aged 5-18 years), unanswered questions remain. These have been identified²⁸ and including questions relating to treatment response to endotypic variations of

asthma,²⁹ especially in younger children where asthma flare-ups are commonly triggered by respiratory infections.²⁸ Further, the practical implications of an ICS/LABA prn only based treatment for young children, for whom the decision to medicate is determined by others, for example, for young children or while outside of the home, at school or sport, is further complicated. Research shows that parents often lack knowledge and information³⁰ and providers rarely discuss action plans with caregivers and children,³¹ and this has the potential to become particularly problematic with ICS/LABA prn-only treatment.

CONCLUSIONS

Although GINA 2020 offers promising novel opportunities and potential benefits for more personalized and pragmatic asthma treatment, it presents significant challenges and, of course, raises more questions. Once again, the changes in GINA 2020 highlight the need for good medical practice, but perhaps in different ways. The need for a firm, timely diagnosis not only remains but also becomes critical, and with that we need to consider ways in which this can be done effectively, efficiently, and accurately. Do we currently have the tools in spirometry, bronchial provocation testing, and biomarkers to achieve this? There continues to be a need to assess patients and their needs; to perform regular thorough structured reviews incorporating trigger modification (including smoking cessation), inhaler technique, management of comorbidities, (self) monitoring accompanied by personal asthma action plans, and perhaps more than ever, thoughtfully delivered education. But in this uncertain future, most recently complicated by the COVID 19 pandemic, how is this care delivery to look? What is clear is that we must find ways to use the best possible technologies, biomarkers, and strategies to more accurately and precisely evaluate our patients

in primary care if our shift in paradigm is ultimately to lead to improved rather than confused asthma management practices and outcomes for patients, society, and health care providers alike.

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