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Allergic Rhinitis (J Maspero, Section Editor)

The Explosion of OTC Management of Allergic Rhinitis: Costs and Risks

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Abstract

Purpose of the Review To review self-medication and the increasing use of over-the-counter (OTC) medications in the treatment of allergic rhinitis in the last years.
Recent Findings Thanks to recent research and the use of mHealth tools, the preferences of patients, the role of primary care physicians, pharmacists, and specialists in the management of this prevalent condition have been known.
Summary Successful self-management of AR requires that patients be fully informed about the available treatment options, the proper use of nasal spray devices, the need for therapy based on prevention, and avoidance of allergens. The use of OTC medications facilitates access to treatment and lowers health costs, but requires education of patients, and advice from the pharmacist, the primary care physician and, occasionally, the specialist to ensure its effectiveness and avoid under-diagnosis, multimorbidities, sub-treatment, and adverse events.

Introduction

Allergic rhinitis (AR), sometimes considered a trivial or annoying medical condition, is increasingly recognized by health professionals (HCP) as clinically important because of its established relationship with asthma, the

adverse impact on quality of life (QOL), and other comorbid conditions [1]. AR is the most common allergic disease and is highly prevalent, affecting up to 60 million people in the USA and 20.5% of Argentine population [2]. Poorly controlled symptoms, which include loss of sleep, learning deficiencies, decreased cognitive functioning, and decreased long-term productivity, contribute to the reduction of health-related quality of life in patients with AR [3, 4]. Patients with AR complain of having difficulty with falling asleep at night, waking up at night, and lacking of a good night's sleep. [5] Patients also complain of fatigue, irritability, depression and dysthymia during the allergy season [6]. In addition to pointing out the negative effects of AR on health, AR patients state that the disease causes limitations in social activities and outdoor activities, and that their health prevents them from having a good job performance [5]. It is estimated that the work productivity of a patient with AR can decrease by 20% on the days when the symptoms worsen, and 22% of the patients surveyed in the National Allergy Survey that Assesses the Limitations (NASAL) expressed concern that their health prevents them from doing well at work. Only 11% of patients without AR expressed a similar concern [5]. In Latin America, participants from the AILA study consistently reported at least a 30 percentage point difference in their work productivity depending upon whether their allergies were mild or severe [7]. In addition to the decrease in productivity at work, an estimated 3.5 million lost workdays and 2 million school days lost per year are attributed to AR [8]. AR imposes a substantial burden of disease for some people, with the symptoms of AR exerting a negative burden on daily functioning and quality of life. In fact, AR is associated with a greater deterioration in labor productivity than other common chronic conditions, such as diabetes and hypertension [9]. AR affects sexual lives of the patients as well [10].

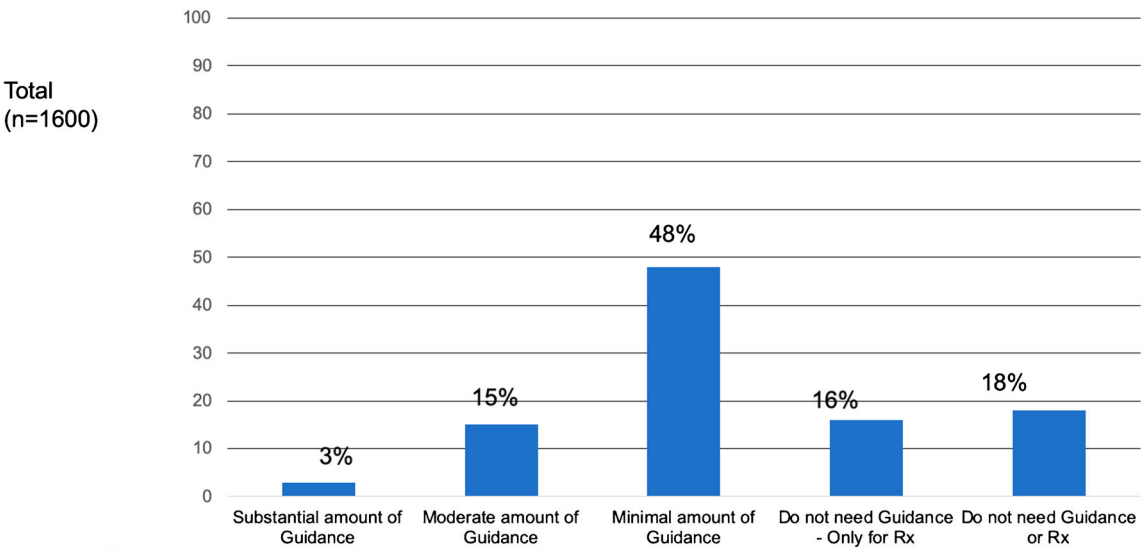
Management of Allergic Rhinitis

Given the effects of AR symptoms and concomitant diseases on the physical and emotional health of AR patients, and the high direct and indirect costs of the disease, adequate management of symptoms is of greatest importance [11]. Treatment includes allergen prevention, pharmacotherapy, and allergen immunotherapy [3]. A number of classes of pharmacological agents have been shown to be effective in the treatment of AR and are available without prescription (OTC) or on prescription (Rx) [3, 11]. Second generation oral antihistamines, intranasal antihistamines, intranasal corticosteroids (INS), and leukotriene antagonists have shown their efficacy and safety and can be administered alone or in combination [11].

Despite the widespread recognition of the clinical importance of AR, its management often begins outside the scope of medical care, with patients starting therapy with over-the-counter medications [12].

The Current Allergic Rhinitis Experience Survey (CARES) consumer arm was designed to assess the awareness, attitudes, and behaviors of consumers with AR to provide information on how to better manage AR in these patients, control their symptoms, and limit the negative effects of AR on health, physical and emotional quality of life, and labor productivity. The survey evaluated the perception of AR patients about their diagnosis, treatment preferences, and interactions with health professionals (HCP) and aimed to determine the degree to which people with AR self-manage their disease [13]. The vast majority of patients with AR included in the survey (74%) were taking only OTC medications. Respondents indicated that they primarily self-administered their AR with OTC and Rx medications (after obtaining an Rx from their HCP). The immense majority of patients with AR (82%) stated that they did not need a minimum guidance or needed no guidance from HCP to manage AR, while

only 3% said they required a substantial amount of guidance (Fig. 1). The results were similar for patients with AR who managed allergies with OTC medications only and those who were managed with Rx medications; the results were also similar for AR patients with or without a diagnosis of AR by a health professional (Fig. 1). Overall, 60% of the respondents stated that they felt very comfortable without the HCP guidance on the administration of AR, and the majority of AR patients stated that they were very comfortable without the HCP guidance on various aspects of the management of AR (Fig. 2). When comparing AR patients on OTC medication with those on INS, 64% and 49% of them, respectively, perceive that they can fully manage AR on its own. In practice, 80% of respondents said they self-managed their allergies, and 60% said they self-administered completely. AR patients who administer their own AR medication report greater satisfaction, since 78% of AR patients receiving OTC medications and 74% of AR patients receiving INS who self-manage their AR reported being completely satisfied (AR patients who took INS considered that they could self-manage their AR after obtaining an Rx without more information about their HCP). Only 29% of OTC users and 39% of INS users who do not self-manage their AR reported that they were completely satisfied [13]. The authors concluded that in the survey of 1600 patients with AR, the vast majority of responding consumers had taken or were taking an OTC medication to manage their AR. Patients with AR indicated that they are able to self-



OTC only (*n* = 1020)	3%	12%	50%	12%	23%
Rx ± OTC (*n* = 580)	5%	24%	42%	25%	4%
INS user (*n* = 451)	5%	23%	42%	26%	4%
Dx'd with nasal allergies (*n* = 1183)	4%	17%	47%	17%	15%
Not Dx'd (*n* = 417)	2%	12%	51%	11%	24%

Fig. 1. Perceived health care practitioner (HCP) guidance in the management of allergic rhinitis (AR). The vast majority of patients (82%) with AR indicated minimal to no guidance is required to manage allergies, and only 3% indicated that substantial guidance is needed [6].

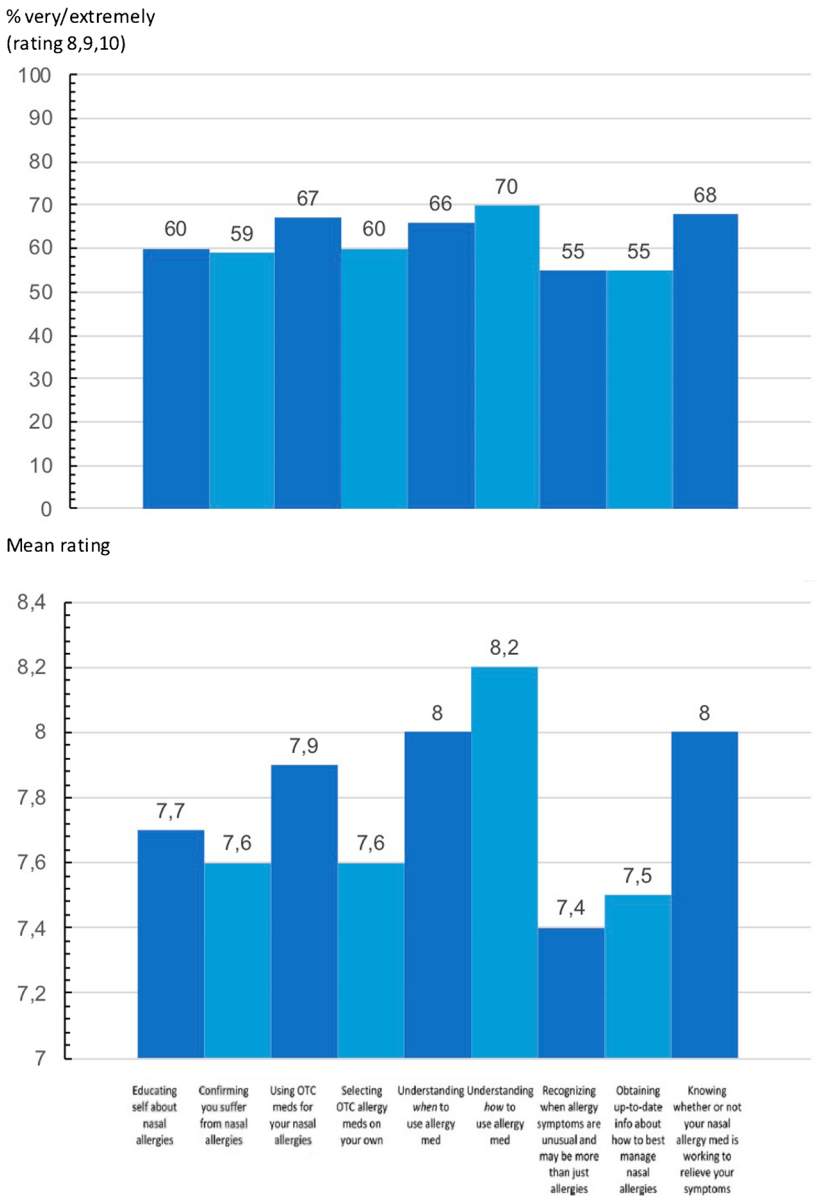


Fig. 2. Level of comfort performing each aspect of allergic rhinitis (AR) management without guidance from a health care practitioner (HCP). Patients were asked to assess their level of comfort on a scale of 0–10, with 0 signifying not at all comfortable, 5 signifying moderately comfortable, and 10 signifying extremely comfortable. Patients who were very or extremely comfortable responded with 8, 9, or 10 and are represented as percentage of total responders. The majority of patients were very or extremely comfortable with all aspects of AR management without guidance from an HCP, with mean ratings ranging from 7.4 to 8.2 [6].

recognize their symptoms as caused by allergies and are comfortable with the self-control of AR. AR patients indicated that they begin treatment with OTC medications and are likely to see a health professional if their symptoms worsen or they are not able to achieve relief with one or more OTC options. AR patients stated that they want more OTC options to control their disease effectively, and

INS users reported high levels of satisfaction with their medication [13]. In Latin America, 42% of adults with nasal allergies reported using OTC medications for their allergies when their symptoms worsen [7].

OTC Options for Allergic Symptoms

Possible reasons why AR is often not adequately treated include patients' reluctance to see a doctor for what they consider a minor problem, and concerns regarding the cost, lack of efficacy, or side effects of the available treatments, which may prevent or delay the start of treatment or lead to poor adherence to treatment. [14–16]. In a European study, half or two-thirds of patients delayed seeing a medical professional about their allergies until the symptoms became intolerable [14]. In another study, 63.9% of patients did not consult a doctor about allergy symptoms because they felt that their symptoms were not serious enough to bother a doctor, including 83.0% with mild AR, 46.5% with moderate AR, and 19.4% with severe RA [16]. However, since most US consumers are increasingly willing to self-medicate, the availability of OTC medications can help reduce these barriers to effective treatment [17]. OTC options for the treatment of AR include decongestants, oral antihistamines, cromolyn sodium, intranasal mast cell stabilizer, and, more recently, INS. Dosage and indications of individual OTC AR treatments are summarized in Table 1 [12]. In addition to the products listed in Table 1, first-generation antihistamines such as diphenhydramine and chlorpheniramine, as well as decongestants (pseudoephedrine, phenylephrine, and oxymetazoline), are available as OTC medications in various formulations and combinations. Since access to pseudoephedrine was controlled by moving it behind the counter, the use of phenylephrine has increased.

However, phenylephrine has been shown to be no better than placebo in the treatment of AR [18]. Although generally considered less effective than INS, oral decongestants and antihistamines have a faster onset of action [19] and may provide relief in ≤ 1 h. Since many patients take over-the-counter medications only as needed [20], these may be an appropriate option for some people.

INS were approved for its use as OTC in the USA in 2013, which makes them the newest class of AR treatment to be available without a prescription. Fluticasone propionate, budesonide, triamcinolone acetonide, and, more recently, fluticasone furoate have been approved for OTC use, and there are likely to be more agents passing from prescription to OTC in the coming years. Due to their status as relatively new on the scene, many patients may not be aware of the availability of over-the-counter INS. As a result, it may be necessary for health professionals to recommend and inform patients about their use. Since the different products available have different administration systems, it will be important for health professionals to also ensure that patients use the correct device technique. As discussed, negative perceptions of their sensory attributes (e.g., taste, smell, sensation), the perceived ease of use of the device, and concern about possible side effects of INS may also affect the use of these medications. It has been shown that most of the 48% of patients with AR are concerned about the possible side effects of INS, such as habituation, damage to mucous membranes, influence on other organs and weakened resistance to infection [21]. Despite these concerns, INS have a good safety record in general,

Table 1. Available OTC medications for management of allergic rhinitis [12]

Drug	Indication	Adult dose	Child dose
Intranasal steroids (INS)			
Triamcinolone acetonide	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose	• 2 sprays into each nostril once daily in the morning • 55 µg/spray	• Children ≥ 6 years of age • 1 spray into each nostril once daily in the morning
Fluticasone propionate	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose, itchy/watery eyes	• 2 sprays into each nostril once daily for 1 week • 1–2 sprays into each nostril once daily from week 2 to month 6 • 50 µg/spray	• Children ≥ 4 years of age • 1 spray in each nostril once daily
Budesonide	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose	• 2 sprays into each nostril once daily • Reduce to 1 spray in each nostril/day once symptoms improve • 32 µg/spray	• Children ≥ 6 years of age • 1 spray in each nostril once daily • Increase to 2 sprays in each nostril/ day if symptoms do not improve; reduce to 1 spray/day again once symptoms improve
Fluticasone furoate	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: nasal congestion, runny nose, sneezing, itchy nose, itchy/watery eyes	• 2 sprays into each nostril once daily • Reducing to 1 spray in each nostril/day once symptoms improve may be effective in maintaining control • 27.5 µg/spray	• Children ≥ 2 years of age • 1 spray in each nostril once daily • 27.5 µg/spray
Oral antihistamines (second generation)			
Loratadine	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy/watery eyes, itchy nose or throat	• 10-mg tablet once daily	• Children ≥ 6 years of age • 10-mg tablet once daily
Cetirizine	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy/watery eyes, itchy nose or throat	• 10-mg tablet once daily	• Children ≥ 6 years of age • 10-mg tablet once daily
Fexofenadine	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy/watery eyes, itchy nose or throat	• 180-mg tablet once daily	• Children ≥ 12 years of age • 180-mg tablet once daily

Table 1. (Continued)

Drug	Indication	Adult dose	Child dose
Oral antihistamine/decongestant			
Loratadine 10 mg/pseudoephedrine 240 mg • Children ≥ 12 years of age • 1 tablet every 24 h	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy/watery eyes, itchy nose or throat; temporarily relieves nasal congestion due to the common cold, hay fever, or other respiratory allergies; reduces swelling of nasal passages; temporarily relieves sinus congestion and pressure; temporarily restores freer breathing through the nose	• 1 tablet every 24 h	• 1 tablet every 24 h
Cetirizine 5 mg/ pseudoephedrine 120 mg	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy/watery eyes, itchy nose or throat; temporarily relieves nasal congestion due to the common cold, hay fever, or other respiratory allergies; reduces swelling of nasal passages; temporarily relieves sinus congestion and pressure; temporarily restores freer breathing through the nose	• 1 tablet every 12 h	• Children ≥ 12 years of age • 1 tablet every 24 h
Fexofenadine 180 mg/ pseudoephedrine 240 mg	Temporarily relieves the following symptoms of hay fever or other upper respiratory allergies: runny nose, sneezing, itchy/watery eyes, itchy nose or throat; temporarily relieves nasal congestion due to the	• 1 tablet every 24 h	• Children ≥ 12 years of age • 1 tablet every 12 h

Table 1. (Continued)

Drug	Indication	Adult dose	Child dose
	common cold, hay fever, or other respiratory allergies; reduces swelling of nasal passages; temporarily relieves sinus congestion and pressure; temporarily restores freer breathing through the nose		
Mast cell stabilizer			
Cromolyn sodium	Temporarily relieves the following symptoms of hay fever and other nasal allergies: runny/itchy nose, sneezing, allergic stuffy nose	• 1 spray into each nostril up to 6 times/day • 5.2 mg/spray	• Children ≥ 2 years of age • 1 spray into each nostril up to 6 times/day

with more than 20 years of clinical experience. [22, 23] For those products that are now available without a prescription, additional measures, such as a shorter duration of use, are applied to minimize risk and promote safe use in the self-care environment compared to prescription use. Reviews of safety data from INS studies of up to 1 year did not reveal evidence of harmful local effects to the nasal mucosa, increased risk of ocular events such as glaucoma or cataract, or suppression of the hypothalamic-pituitary-adrenal axis (HPA). [22, 23] However, it is important to bear in mind that glaucoma and cataract cases have been reported in patients taking long-term INS and are described as possible adverse effects in prescription information for the class. Similarly, some studies have found evidence of growth effects with INS, even in the absence of changes in the HPA axis, which could indicates a subtle systemic corticosteroid effect below the threshold of the commonly used assessments of HPA axis suppression. [24–26] In addition, the results of the most recent studies designed according to the updated guide of the United States Food and Drug Administration (FDA) that use more sophisticated methods to measure growth have indicated that the regular use of INS (12 months of use) daily at the recommended doses with triamcinolone and higher doses with fluticasone furoate, may produce small but statistically significant reductions in growth velocity. [25–27] The long-term clinical implications of these findings are not yet clear at this time, as no long-term studies have been conducted to evaluate the effect of INS (if any) on adults' final height. Using these more rigorous design elements recommended by the FDA, these potential effects should be considered when evaluating the benefits and risks for pediatric patients [27]. For children who require INS, the lowest effective dose to relieve symptoms should be used, and routine growth monitoring is recommended. Patients' preferences for the sensory attributes of INS can affect its use and long-term adherence, despite being preferred by health professionals. Patients' distaste for odor, immediate taste, aftertaste, throat deterioration, nose wear, and aerosol sensation in the nose and throat can affect their willingness to use and pay for intranasal products [28–30]. The cost of

OTC INS can be a barrier to its use. However, recently, the generic formulations of some OTC INS have become available, increasing competition and causing prices to fall, leading to greater accessibility.

Primary Care Provider and the Specialist in the Treatment of Allergic Rhinitis

For patients who have inadequate control or seek medical attention for the treatment of their symptoms, the HCP has the function of collecting a clinical history, including asking the patient about any history of asthma or the presence of asthma symptoms and select additional evaluation and therapy as appropriate [31, 32]. It is also necessary to perform an examination to exclude conditions not related to allergies, such as upper respiratory tract infection, rule out other more serious conditions, such as rhinorrhea of cerebrospinal fluid, sinonasal tumors, or chronic rhinosinusitis, as well as review concomitant medications that may cause nasal symptoms [3]. Patients with "alarming symptoms" should be referred to an specialist. These symptoms include bloody discharge, pain, nasal obstruction, nosebleeds, scabs, and nasal deformity due to a perforated septum [33].

Pharmaceutical Challenge in Allergic Rhinitis

Taking into account the challenges associated with AR and the needs identified, it is clear that the pharmacist has a role in the management of AR in practice, through a guided change management process. This is within the scope of pharmaceutical practice and in line with future models of integrated care [34]. Pharmacists are in an ideal position to manage this extremely important link in the care channels. Throughout the world, pharmacists receive advanced training in basic and clinical sciences. Given the importance of self-medication in many allergic diseases and in iatrogenic diseases, pharmaceutical interventions are well placed to maximize the benefits and minimize the adverse events associated with pharmacotherapy. This is particularly important in AR and the multimorbidity of asthma [35], as well as in elderly patients, many of whom have allergic diseases in combination with other chronic diseases [36]. In addition, most AR medications are available without a prescription (OTC) [11, 12]. The impact of changing prescriptions to over-the-counter medications has been profound in AR with a significant impact on reducing costs and utilization of healthcare resources [37, 38]. Therefore, as trusted health professionals in the community, pharmacists are well placed to play a critical role in identifying the symptoms of AR, recommending appropriate OTC treatment and integrating ICPs (integrated care pathways) into medical care teams. Pharmacists (together with patients, physicians, and other health professionals (HCPs)) face the relative merits and disadvantages of the various treatment options [39, 40]. Clinical practice guidelines for the management of AR developed in the last 20 years have improved the care of patients with AR and provide a critical framework for the management of AR [11, 31, 32]. These guidelines are increasingly important for health professionals in primary care, since, in most countries, few patients with AR consult a specialist doctor. In fact,

many patients with AR do not recognize their condition [5] and, as such, do not even consult a doctor [41, 42]. A large proportion of patients with AR actually self-manage, and the pharmacist is usually the first healthcare professional to whom a person with nasal symptoms take advice [43, 44]. The airways ICPs consider a multidisciplinary approach for AR and the management of multimorbidity of asthma, with the pharmacist at the forefront of the algorithm (Fig. 3). A large number of patients with AR use OTC medications and are treated in community pharmacies. However, pharmaceutical practice varies widely among countries and ICPs must be adapted to local needs, taking into account cultural barriers, socioeconomic considerations, health care practices, and available OTC medications [45–47].

Conclusions

The high prevalence of allergic rhinitis and its impact on the quality of life require new strategies to improve the quality of life of patients and to reduce health costs. Many patients prefer self-medication and the use of OTC drugs. Successful self-management of AR requires that patients be fully informed about the available treatment options, the proper use of nasal spray devices, the need for therapy based on prevention, and the avoidance of allergens. While most patients can self-medicate, many will need the guidance of a pharmacist and/or primary care physician who uses diagnostic and treatment algorithms to

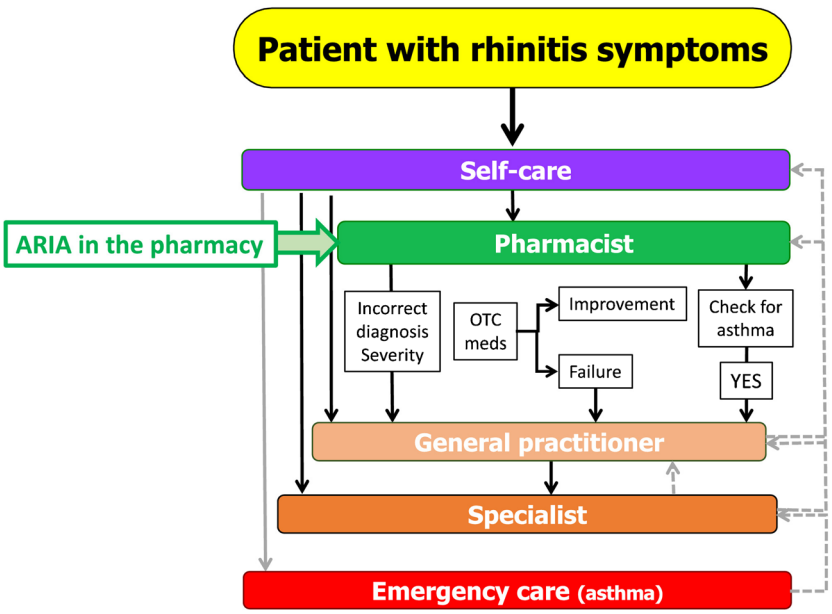


Fig. 3. Allergic rhinitis and its impact on asthma in the pharmacy initiative for AIRWAYS integrated care pathways in allergic rhinitis. This is a generic algorithm which varies between countries depending on regulations. The healthcare professional should ascertain that the treatment taken by the patient accords to best practices. In particular, regular use of short-acting ß2 agonist as a single treatment should be avoided. Similarly, prolonged use of intranasal vasoconstrictors in rhinitis should be avoided. Image from [34].

ensure optimal results. Education may be required for patients with moderate to severe AR symptoms to understand that INS are believed to be the most effective option, and that they are now available without a prescription. Health professionals, pharmacists, and primary care physicians should know the AR status of their patients and what measures they are taking to control it; know the use of mHealth apps that facilitate control and adherence; educate them about availability, adverse events, and the proper use of OTC medications, especially INS; and determine when to intervene and treat with prescription medications and, if necessary, consult a specialist [48].

Compliance with Ethical Standards

Conflict of Interest

Dr. Ivancevich reports personal fees from Faes Farma, personal fees from Eurofarma Argentina, other from Laboratorios Casasco, other from Sanofi, outside the submitted work. Dr. Neffen has nothing to disclose. Dr. Jorge Máspero has been advisor, received speaker fees or has been an investigator for the following companies: Eli Lilly, GlaxoSmithKline, Inmunotek, Menarini, Uriach, Astra Zeneca, Novartis, Boehringer Ingelheim, Sanofi Genzyme.

Human and Animal rights and Informed Consent

This article does not contain any studies with human or animal subjects performed by any of the authors.

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