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Rhinitis, Sinusitis, and Upper Airway Disease

Methodology for the Development of the Allergic Rhinitis and Its Impact on Asthma (ARIA)-EAACI 2024–2025 Guidelines: From Evidence-to-Decision Frameworks to Digitalised Shared Decision-Making Algorithms





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ABSTRACT

The Allergic Rhinitis and its Impact on Asthma (ARIA) guidelines produced their first edition in 1999, with subsequent revisions in 2008, 2010, 2016 and 2019. A new iteration of ARIA—ARIA 2024–2025—in collaboration with EAACI is currently being developed, focusing on the management of allergic rhinitis. ARIA 2024–2025 follows the GRADE framework and is endorsed by the European Academy of Allergy and Clinical Immunology (EAACI). A set of approaches has been used to develop guideline questions, including surveying key opinion leaders and using artificial intelligence (AI)-based tools to analyse web searches on allergic rhinitis and to generate questions. Each prioritised guideline question is assessed through an Evidence-to-Decision (EtD) framework. EtDs support the systematic and transparent formulation of recommendations, comprising 12 criteria for which the best available evidence should be sought. In the context of ARIA-EAACI 2024–2025, such evidence is derived not only from randomised controlled trials but also—among others—from patient-generated data sources that better reflect the affected individuals' perspectives. Moreover, ARIA-EAACI 2024–2025 incorporates evidence on planetary health. Developed guideline recommendations will support the creation of digitalised decision algorithms and care pathways. This paper describes the methodology used to develop the person-centred, digitally enabled and AI-assisted ARIA-EAACI 2024–2025. Among others, it describes (i) the development and prioritisation of guideline questions, (ii) sources of evidence for EtDs and (iii) the development of digitalised decision algorithms and care pathways.

1 | Introduction

Allergic rhinitis (AR) is one of the most common chronic conditions globally, often co-occurring with asthma and conjunctivitis [1–3]. It impairs quality of life and affects social life, school and work productivity, and is associated with substantial economic costs [1, 4]. AR is an excellent candidate for testing innovation in guidelines: the vast inter-individual differences in exposures and in personal beliefs, preferences and values require a person-centred approach. In addition, AR is often self-managed, with limited contact with health services.

The Allergic Rhinitis and its Impact on Asthma (ARIA) initiative first proposed guidelines for AR and asthma multimorbidity in 1999 [5]. ARIA has evolved from the first multimorbidity guideline in respiratory diseases using the Shekelle evidence-based model [5] to the GRADE (Grading of Recommendations, Assessment, Development and Evaluation) framework for evidence-based guidelines [6, 7]. In fact, ARIA 2016 was used as the clinical scenario on how to interpret and use a guideline in a review published in the *Journal of the American Medical Association* [8]. ARIA 2010 and 2016 devised a medication algorithm [6, 7]. However, digitalisation was not implemented.

In 2019, next-generation guidelines using real-life MASK-air data and allergen exposure chamber studies proposed digitally enabled person-centred care for the first time [9]. The next iteration, ARIA-EAACI 2024–2025, is endorsed by the European Academy of Allergy and Clinical Immunology and will result in a person-centred, digitally enabled, artificial intelligence (AI)-assisted guideline [10] (Figure 1).

ARIA-EAACI 2024–2025 is formulating recommendations based on the use of the GRADE Evidence-to-Decision (EtD) framework. The EtD supports the systematic and transparent formulation of recommendations for each prioritised guideline question [11, 12]. It comprises 12 criteria for which the best available evidence should be sought. In ARIA-EAACI 2024–2025, such evidence is not only based on data from randomised controlled trials (RCTs) but also from other sources, including studies using data directly provided by patients. In fact, although RCTs are the gold standard for assessing the efficacy of medical interventions, they present several limitations. In this context, in AR, well-designed pragmatic trials and observational studies using direct patient data can be a source of complementary evidence (Bousquet, submitted), providing insights into the reality of day-to-day clinical practice.

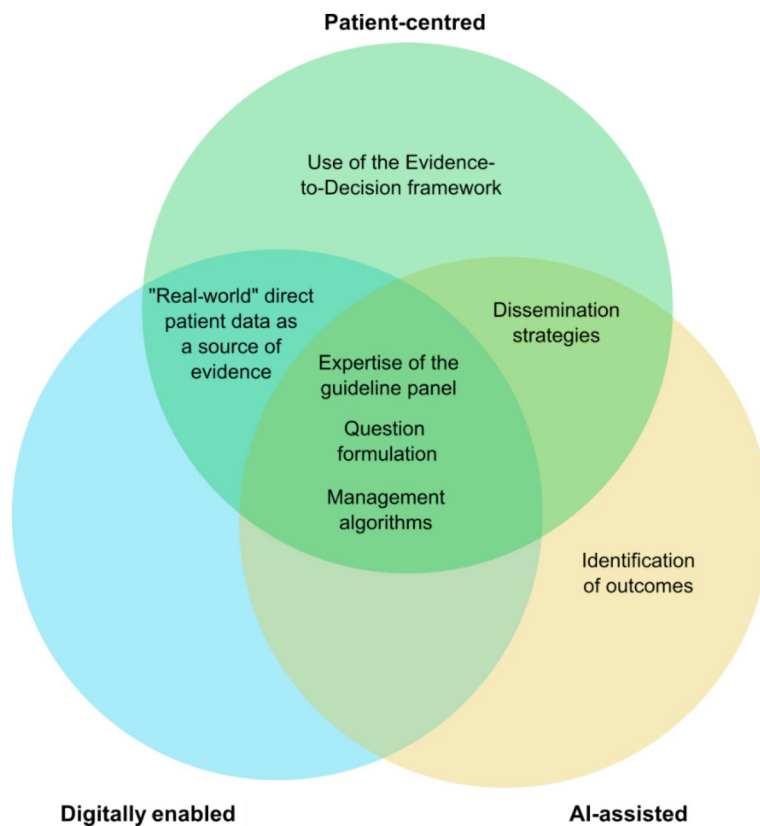


FIGURE 1 | Graphical representation of the tasks of the Allergic Rhinitis and its Impact on Asthma (ARIA-EAACI) 2024–2025 guidelines and their classification as patient-centred, digitally enabled and artificial intelligence (AI)-assisted.

In addition to being informed by multiple sources of evidence, ARIA-EAACI 2024–2025 will be innovative in its final result (Table 1). In addition to recommendations, ARIA-EAACI 2024–2025 will result in a set of personalised and digitalised algorithms that can be embedded in an app. For example, the MASK-air mHealth app is a Class IIa medical device, in which algorithms can be tested and implemented into the clinical workflow of allergists [13, 15]. Henceforth, recommendations will be included in digitalised management algorithms considering multiple clinical scenarios. Algorithm digitalisation has several advantages, including patient empowerment and flexibility for the implementation of updates in the perspective of a living ARIA guideline. Digital divide (e.g., age-related) aspects do however need to be considered.

In this paper, we aim to present the methodology for the development of ARIA 2024–2025 and to provide a rationale for the creation of digitalised guideline algorithms.

2 | ARIA-EAACI 2024–2025: Patient-Centred, Digitally Enabled, AI-Assisted Guidelines

2.1 | Patient Empowerment

ARIA-EAACI 2024–2025 is being devised throughout the different stages on a person-centred basis (Figure 1). First, AR patients have been included in the guideline panel. Second, to ensure that guideline questions are person-centred, questions were formulated pertaining to (i) findings and hypotheses from studies based on data directly provided by patients

in MASK-air and (ii) AI-supported approaches that analysed popular online search queries on AR posed by internet users [16].

Third, we are using the EtD framework to develop our recommendations—the EtDs imply that the formulation of recommendations is not solely based on the desirable and undesirable effects of the interventions, but also on aspects such as patients' values and the acceptability of interventions by the different interest holders (considering aspects such as patients' satisfaction with medications or the speed of onset of action of treatments) [11, 12].

Fourth, patient behaviours are being considered to support the formulation of recommendations. As an example, we are considering steroid phobia for recommendations related to intranasal corticosteroids (INCS) [17]. In addition, we are considering that most patients do not use medication regularly, but rather on an as-needed basis. This has been observed in studies using MASK-air direct patient data [18], and the few RCTs comparing as-needed versus regular treatment for AR did not find any major differences [19–26].

Finally, the ARIA-EAACI 2024–2025 guidelines will result in the development of management algorithms that will be implemented in an mHealth app that can be accessed by patients.

2.2 | Digital Enablement

Digital enablement is a cornerstone of ARIA-EAACI 2024–2025: (i) findings and hypotheses from studies using mHealth data

TABLE 1 | Summary of innovative approaches followed in the development of the ARIA-EAACI 2024–2025 guidelines.

Task	“Classical” approaches followed in the ARIA-EAACI 2024–2025 guidelines	Innovative approaches followed in the ARIA-EAACI 2024–2025 guidelines
Formulation of guideline questions	<ul style="list-style-type: none"> – Identification of previous guideline questions; – Formulation of guideline questions by experts. 	<ul style="list-style-type: none"> – Identification of questions based on direct patient-reported data (MASK-air app); – AI-assisted identification of questions posed by Internet users in online searches; – Direct generation of questions by AI tools.
Identification of outcomes	<ul style="list-style-type: none"> – Identification of outcomes by experts. 	<ul style="list-style-type: none"> – Identification of outcomes by AI tools.
Completing the evidence-to-decision frameworks		
Desirable and undesirable effects	<ul style="list-style-type: none"> – Use of evidence from systematic reviews (of RCTs). 	<ul style="list-style-type: none"> – Use of pharmacovigilance data.
Values	<ul style="list-style-type: none"> – Use of evidence from systematic reviews of values and preferences. 	<ul style="list-style-type: none"> – Assessment of utilities based on direct patient data (MASK-air app) [study included in the systematic review of values and preferences].
Resources used and cost-effectiveness	<ul style="list-style-type: none"> – Use of data from the scientific literature and health technology assessment reports. 	<ul style="list-style-type: none"> – Assessment of indirect costs based on direct patient data (MASK-air app) – Survey of ARIA experts on the costs of medications.
Equity		<ul style="list-style-type: none"> – Survey of ARIA experts on the availability of medication; – Systematic consideration of medications in the World Health Organisation List of Essential Medicines.
Acceptability	<ul style="list-style-type: none"> – Use of data from the scientific literature (e.g., for onset of action). 	<ul style="list-style-type: none"> – Use of direct patient data (MASK-air app) to assess adherence, frequency of co-medication and treatment satisfaction with different medications.
Planetary Health	<i>(planetary health not usually considered in guidelines)</i>	<ul style="list-style-type: none"> – Consideration of planetary health.
Considering multimorbidity		<ul style="list-style-type: none"> – Explicit consideration of multimorbidity in subgroup considerations.
Building treatment algorithms	<ul style="list-style-type: none"> – Already proposed in the former ARIA iterations [13, 14] 	<ul style="list-style-type: none"> – Building and implementation of digitalised algorithms in an AI-assisted process involving a multidisciplinary team.

Abbreviations: AI, artificial intelligence; RCT, randomised controlled trial.

enabled the formulation of guideline questions, (ii) mHealth direct patient data are used as a source of evidence and (iii) management algorithms will be digitalised into an mHealth app (Figure 1). A market research study has analysed available mHealth apps for AR and has concluded that MASK-air is available in the largest number of countries and has the highest number of scientific publications [27]. Moreover, MASK-air is one of the few apps reporting asthma multimorbidity. Therefore, MASK-air was selected as the app from which data are retrieved to provide evidence for guideline development and to implement digitalised algorithms.

MASK-air is available in 30 countries. It has been used by more than 40,000 patients, who have reported over 700,000 days of use [15]. MASK-air is a patient-centred Medical Device regulation Class IIa. It is a Good Practice of the Directorate General Health and Food Safety of the European Commission [28] as well as an OECD (Organisation of Economic Cooperation and

Development) Best Practice for Integrating Care to Prevent and Manage Chronic Diseases [13].

MASK-air comprises a daily monitoring questionnaire assessing the impact of rhinitis and asthma symptoms by means of validated visual analogue scales (VASs) [29, 30]. In addition, users are asked (i) to enter their daily medications via a regularly updated scroll list that contains country-specific prescribed and over-the-counter medications and (ii) to provide feedback on their satisfaction with their medication. MASK-air also includes additional questionnaires, namely the Control of Allergic Rhinitis and Asthma Test (CARAT) [31], the Work Productivity and Activity Impairment Questionnaire: Allergy Specific (WPAI-AS) [32, 33], and EQ-5D [34, 35]. Model predictions of pollen concentrations and air pollution obtained from the Finnish Meteorological Institute (<https://silam.fmi.fi>) [36, 37] and, for some species, from Copernicus Atmosphere Monitoring Service

(<http://atmosphere.copernicus.eu>) are available daily within a 10 km radius in Europe in geolocalised patients. Table S1 presents some of the relevant findings of MASK-air studies for the development of ARIA-EAACI 2024–2025.

2.3 | Use of AI

In the context of ARIA-EAACI 2024–2025, AI helped in the development of guideline questions and the identification of outcomes (Figure 1). In particular, a large language model-based chatbot was prompted to (i) classify online search queries into those conveying questions [16], (ii) suggest guideline questions [16] and (iii) suggest potentially relevant outcomes. In addition, AI was used to support the systematic review on patients' values and preferences in AR [38]. In ARIA-EAACI 2024–2025, we plan to use AI to support (i) the writing of plain language summaries and (ii) the development of the digitalised algorithms.

3 | Panel Selection

ARIA group members involved in ARIA-EAACI 2024–2025 include (i) the steering committee, (ii) the guideline panel, (iii) the ARIA review group and (iv) the ARIA Junior Members (Table S2).

The ARIA guideline panel includes 30 experts and is responsible for (i) suggesting and prioritising guideline questions and outcomes, (ii) participating in group meetings, (iii) providing input when discussing the available evidence for each guideline question, (iv) reviewing evidence summaries, (v) making judgements for each EtD criterion, (vi) drafting guideline recommendations, (vii) reviewing and writing the final report and (viii) supporting guideline dissemination.

The guideline panel was set in such a way as to ensure (i) the inclusion of experts with different profiles (physicians specialised in allergy, otorhinolaryngology, paediatrics and primary care, pharmacists, patients, methodologists and AI experts), (ii) representativeness in terms of gender, age and country and (iii) that at least 50% of the members did not have a conflict of interest (CoI). All members were required to complete the "Guideline Group or Panel Member Certification Course" (now termed "Certified Guideline Panel Member" course) of the International Guideline Training and Certification Programme INGUIDE.

To increase the diversity of the received inputs, we invited an ARIA review group (including members from low- and middle-income countries) and ARIA Junior Members to participate in certain guideline tasks. Tasks for these groups include (i) providing input on non-prioritised questions, (ii) reviewing formulated recommendations and (iii) participating in the development of the management algorithms.

4 | Development and Prioritisation of the Guideline Questions

In ARIA-EAACI 2024–2025, several different approaches were used for the development of guideline questions (Figure 2;

Table 2), including person-centred approaches. The developed questions were then prioritised to select those for which recommendations would be drafted.

4.1 | Development of Targeted Guideline Questions

4.1.1 | Building on Established Knowledge: Questions From Previous ARIA Guidelines (Physician-Centred Approach)

We retrieved all questions regarding the pharmacological and non-pharmacological treatment of AR that had been answered in ARIA 2010 and 2016 and the US Practice Parameters [39].

4.1.2 | Insights From Experts: Questions From Panel Members (Key Opinion Leader-Centred Approach)

We surveyed guideline panel members on relevant questions regarding the pharmacological or non-pharmacological treatment of AR. To avoid duplicate questions, we provided panel members with the list of guideline questions that had been answered in the previous ARIA guidelines or identified through analysis of MASK-air studies.

4.1.3 | Leveraging Direct Patient-Reported Data: Questions From MASK-air Studies (Person-Centred Approach)

To formulate questions based on observations of day-to-day practice and patients' experience, two guideline methodologists (BSP and RJV) (i) read all the original studies that used MASK-air data and (ii) formulated guideline questions based on the main messages and hypotheses raised by these studies.

4.1.4 | AI-Supported Development of Guideline Questions (Person-Centred Approach)

To better reflect patients' beliefs and needs, AI was used in the development of guideline questions [16]. We retrieved popular queries on AR (identified using Google Trends) and used ChatGPT 4.0 to classify them into those conveying potentially relevant questions or not [16]. Queries identified as potentially conveying relevant questions were then manually transformed into guideline questions.

We also prompted ChatGPT 4.0 to assume the role of a patient or of a healthcare provider and to generate potentially relevant guideline questions [16].

4.2 | Prioritisation of Guideline Questions

Developed guideline questions were voted for prioritisation by the guideline panel members who rated the priority of each question on a scale of 1–9 (9 indicating highest priority) [40] according to the criteria and signalling questions displayed in

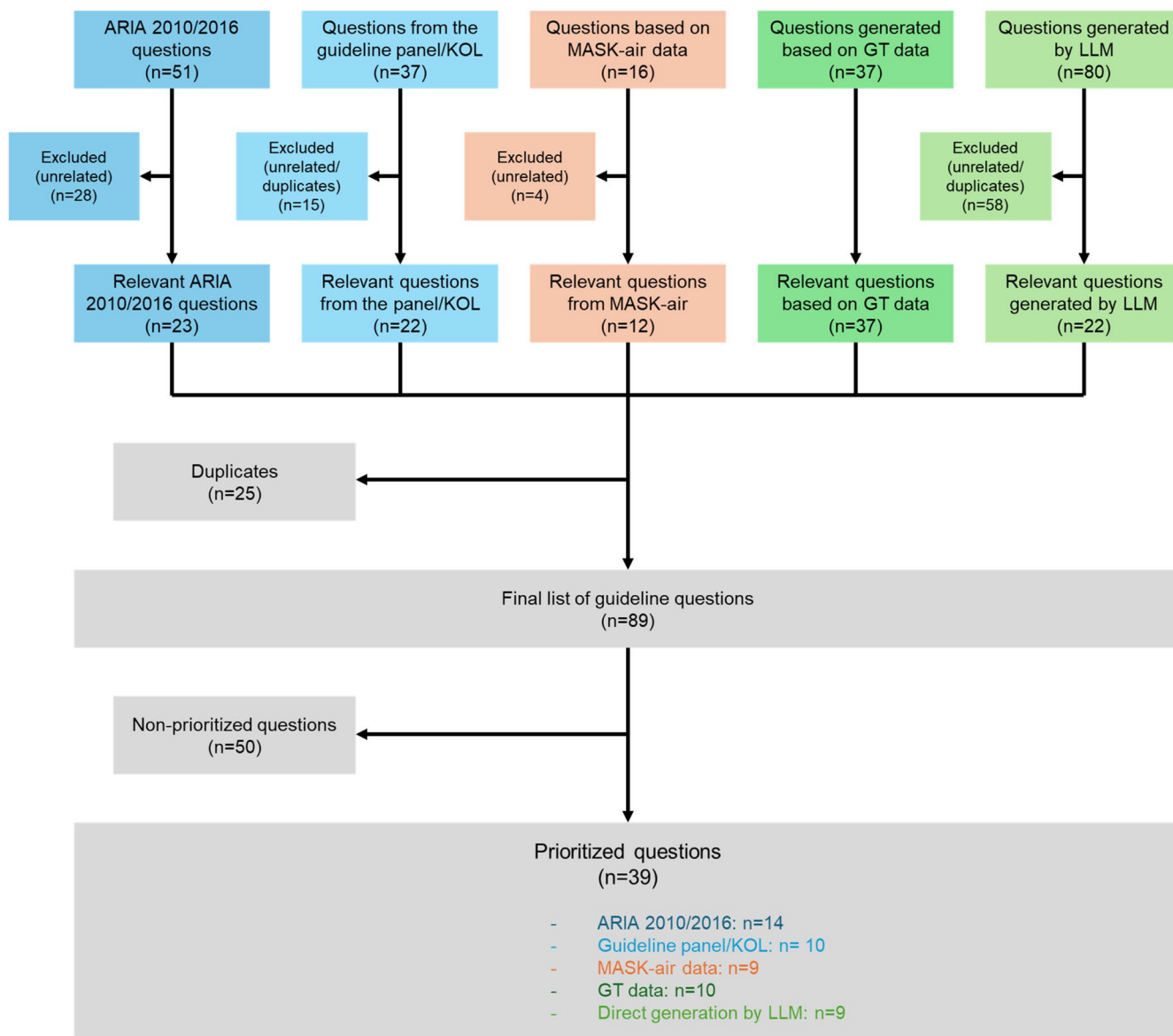


FIGURE 2 | Flow diagram for the formulation of guideline questions. GT, Google Trends; KOL, key opinion leaders.

Box S1. For a question to be prioritised, a mean priority rate of at least 6.3 or a median rate of at least 7 was required.

Among the 89 unique developed questions, 39 were voted by the guideline panel members as “prioritised questions”. Non-prioritised questions were sent to the ARIA review group. The review group could recommend prioritising some of those questions or even propose new questions of interest. Overall, three additional questions were added further to feedback from the review group.

5 | Identification and Prioritisation of the Outcomes

For the formulation of guideline recommendations, interventions need to be judged in terms of their desirable and undesirable effects. This implies assessing the effect of interventions on a set of pre-selected outcomes (ideally not more than seven).

In ARIA-EAACI 2024–2025, a set of potentially relevant outcomes was identified by considering (i) an initial proposal by the guideline co-chairs, (ii) outputs from a large language model, (iii) subsequent suggestions by guideline panel members and (iv) a systematic review of patients' values. For each identified outcome, we developed health outcome descriptors to create common definitions that describe the outcomes with respect to symptoms, time horizon, testing and treatment and consequences [41] (example in Box S2). This ensured that panel members displayed a common understanding when discussing each of the outcomes.

Guideline panel members were then asked to rate the priority of each outcome on a scale of 1–9 (9 indicating the highest priority). Of the 28 outcomes voted for prioritisation, the five rated as being of highest priority were nasal symptoms, quality-of-life impairment, eye symptoms, total symptoms and serious adverse events (AEs). Since these top outcomes only included one undesirable effect (serious AEs), we considered a sixth outcome

TABLE 2 | Full list of guideline questions voted for prioritisation and methods used for their generation.

Guideline question	Method for question generation					Prioritised
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	Direct generation by LLM	
Should continuous long-term treatment vs. as-needed treatment be used in patients with allergic rhinitis?			×	×		×
Should co-medication vs. medication up dosing be used in patients with allergic rhinitis that is poorly controlled despite pharmacologic treatment?			×			×
Should pharmacologic treatment adjustment according to seasonality in pollen or other allergen exposure vs. no adjustment be used in patients with allergic rhinitis?			×			×
Should pharmacologic treatment adjustment according to air pollution levels vs. no adjustment be used in patients with allergic rhinitis?			×			×
Should intranasal H1 antihistamines vs. no treatment be used for the treatment of allergic rhinitis?	×			×		×
Should oral H1 antihistamines vs. no treatment be used for the treatment of allergic rhinitis?	×			×		×
Should intracocular H1 antihistamines vs. no treatment be used for the treatment of ocular symptoms in patients with allergic rhinitis?	×			×		×
Should intranasal glucocorticosteroids vs. no treatment be used for the treatment of allergic rhinitis?	×			×		×
Should oral leukotriene-receptor antagonists vs. no treatment be used for the treatment of allergic rhinitis?	×			×		×
Should intranasal decongestants vs. no treatment be used for the treatment of allergic rhinitis?	×			×		×
Should new-generation oral H1 antihistamines vs. old-generation oral H1 antihistamines be used for the treatment of allergic rhinitis?	×					×
Should intranasal H1 antihistamines vs. intranasal glucocorticosteroids be used for the treatment of allergic rhinitis?	×			×		×

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation					
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	Direct generation by LLM	Prioritised
Should intranasal H1 antihistamines vs. oral H1 antihistamines be used for the treatment of allergic rhinitis?	×					×
Should intranasal H1 antihistamines vs. intranasal chromones be used for the treatment of allergic rhinitis?	×					×
Should intranasal glucocorticosteroids vs. oral H1 antihistamines be used for the treatment of allergic rhinitis?	×				×	×
Should a combination of an intranasal H1 antihistamine and an intranasal glucocorticosteroid vs. an intranasal glucocorticosteroid alone be used for the treatment of allergic rhinitis?	×					×
Should a combination of an intranasal H1 antihistamine and an intranasal glucocorticosteroid vs. an intranasal H1 antihistamine alone be used for the treatment of allergic rhinitis?	×					×
Should a combination of an oral H1 antihistamine and an intranasal glucocorticosteroid vs. an intranasal glucocorticosteroid alone be used for the treatment of allergic rhinitis?	×				×	×
Should a combination of an oral H1 antihistamine and an intranasal glucocorticosteroid vs. an oral H1 antihistamine alone be used for the treatment of allergic rhinitis?		×				×
Should a combination of an oral leukotriene-receptor antagonist and an oral H1 antihistamine vs. an oral H1 antihistamine alone be used for the treatment of allergic rhinitis?		×				×
Should any specific individual intranasal glucocorticosteroid vs. other individual intranasal glucocorticosteroids be used for the treatment of allergic rhinitis?		×				×
Should a monoclonal antibody vs. no treatment be used for the treatment of patients with moderate to severe allergic rhinitis?		×				×
Should masks vs. no masks be used for preventing exposure to air pollution and other triggers in patients with allergic rhinitis?		×				×
Should air purifiers vs. no air purifiers be used for the management of patients with allergic rhinitis?		×			×	×

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation					Prioritised
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	Direct generation by LLM	
Should patient diaries vs. no patient diaries be used for monitoring in patients with allergic rhinitis?		×				×
Should digital patient diaries vs. nondigital patient diaries be used for monitoring elderly patients with allergic rhinitis?			×			×
Should a dual approach combining both long-term and short-term monitoring vs. long-term monitoring alone be used in patients with allergic rhinitis?			×			×
Should a systematic diagnostic screening for asthma vs. no systematic screening be used in patients with allergic rhinitis?			×		×	×
Should a systematic diagnostic screening for allergic rhinitis vs. no systematic screening be used in patients with asthma?			×			×
Should a systematic assessment of the effect of allergic rhinitis on quality of life, work productivity, and/or school performance vs. no systematic assessment be used in patients with allergic rhinitis?			×			×
Should therapy adherence monitoring vs. no therapy adherence monitoring be used in treated patients with allergic rhinitis?		×				×
Should modern methods to increase adherence (e.g., shared decision-making, guided self-management) vs. traditional methods to increase adherence be used for the management of patients with allergic rhinitis?		×				×
Should patient education and self-management strategies vs. no patient education and self-management strategies be used in patients with allergic rhinitis?		×			×	×
Should any specific individual oral H1 antihistamine vs. other individual oral H1 antihistamines be used for the treatment of allergic rhinitis?				×		×
Should a combination of an intranasal H1 antihistamine and an intranasal glucocorticosteroid vs. no treatment be used for the treatment of allergic rhinitis?				×		×

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation				Prioritised
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	
Should intraocular H1 antihistamines be used for the treatment of ocular symptoms in patients with allergic rhinitis?					×
Should a systematic diagnostic screening for nonallergic triggers (such as irritants or pollutants) vs. no systematic screening be used in patients with allergic rhinitis?					×
Should a systematic diagnostic screening for sinusitis vs. no systematic screening be used in patients with allergic rhinitis?					×
Should digital platforms (like smart watches, fitness trackers and mobile apps) vs. no digital platforms be used in patients with allergic rhinitis?					×
Should oral glucocorticosteroids vs. no treatment be used for the treatment of allergic rhinitis?	×			×	
Should intranasal glucocorticosteroids vs. no treatment be used for the treatment of allergic rhinitis?	×				
Should intranasal cromones vs. no treatment be used for the treatment of allergic rhinitis?	×				
Should intranasal ipratropium bromide vs. no treatment be used for the treatment of allergic rhinitis?	×			×	
Should oral decongestants vs. no treatment be used for the treatment of allergic rhinitis?	×			×	
Should intranasal glucocorticosteroids vs. oral leukotriene-receptor antagonists used for the treatment of allergic rhinitis?	×				×
Should oral leukotriene-receptor antagonists vs. oral H1 antihistamines be used for the treatment of allergic rhinitis?	×				×
Should oral leukotriene-receptor antagonists vs. intranasal H1 antihistamines be used in patients with allergic rhinitis?		×			×

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation					
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	Direct generation by LLM	Prioritised
Should intraocular H1 antihistamines vs. nasal H1 antihistamines be used for the treatment of ocular symptoms in patients with allergic rhinitis?		×				
Should a combination of an intranasal decongestant and an oral H1 antihistamine vs. an oral H1 antihistamine alone be used for the treatment of allergic rhinitis?		×				
Should a combination of oral decongestants and H1 antihistamines vs. oral H1 antihistamines alone be used for the treatment of allergic rhinitis?	×			×		
Should nasal irrigation alone vs. no treatment be used for the treatment of allergic rhinitis?			×	×	×	
Should nasal irrigation as an add-on to pharmacologic treatment vs. pharmacologic treatment alone be used for the treatment of allergic rhinitis?			×			
Should nasal barriers (e.g., petroleum jelly) vs. no nasal barriers be used for preventing exposure to air pollution in patients with allergic rhinitis?		×				
Should sunglasses vs. no sunglasses be used for preventing exposure to air pollution and other triggers in patients with allergic rhinitis?		×				
Should temperature-controlled laminar airflow devices vs. no temperature-controlled laminar airflow devices be used for the management of patients with allergic rhinitis?		×				
Should drying bed linen and clothes indoors vs. drying bed linen and clothes outdoors be used for preventing exposure to pollen in patients with allergic rhinitis?		×			×	
Should anti-Fel d1 cat food vs. regular cat food be used in cats of patients with allergic rhinitis with allergies to cats?			×			
Should early warning systems vs. no early warning systems be used in patients with allergic rhinitis?		×				

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation				Prioritised
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	
Should a routine olfactory test vs. no routine olfactory test be used for the monitoring of patients with allergic rhinitis?		×			
Should a systematic assessment of disease control vs. a systematic assessment of disease severity be used in patients with allergic rhinitis?		×			
Should a systematic diagnostic screening for conjunctivitis vs. no systematic screening be used in patients with allergic rhinitis?		×			
Should a systematic screening for local allergic rhinitis vs. no systematic screening for local allergic rhinitis be used in patients with rhinitis clinically triggered by airborne allergens but with negative results on skin prick tests and specific IgE to environmental allergens?		×			
Should pharmacologic treatment in the morning vs. pharmacologic treatment in the evening be used for the treatment of allergic rhinitis?				×	
Should intracocular decongestants vs. no treatment be used for the treatment of ocular symptoms in patients with allergic rhinitis?				×	
Should more than 1 daily oral H1 antihistamine vs. 1 single daily oral H1 antihistamine be used for the treatment of allergic rhinitis?				×	
Should H1 antihistamines vs. decongestants be used for the treatment of allergic rhinitis?				×	
Should any specific individual intranasal decongestant vs. other individual intranasal decongestants be used for the treatment of allergic rhinitis?				×	×
Should any specific individual oral decongestant vs. other individual oral decongestants be used for the treatment of allergic rhinitis?				×	
Should any specific individual intranasal H1 antihistamine vs. other individual intranasal H1 antihistamines be used for the treatment of allergic rhinitis?				×	

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation				Prioritised
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	
Should any specific individual intraocular H1 antihistamine vs. other individual intraocular H1 antihistamines be used for the treatment of ocular symptoms in patients with allergic rhinitis?				×	
Should a combination of oral decongestants and acetaminophen vs. oral decongestants alone be used for the treatment of allergic rhinitis?				×	
Should a combination of oral H1 antihistamines and acetaminophen vs. oral H1 antihistamines alone be used for the treatment of allergic rhinitis?				×	
Should a combination of oral H1 antihistamines and expectorant medications (mucoactive agents) vs. oral H1 antihistamines alone be used for the treatment of allergic rhinitis?				×	
Should inhaled glucocorticosteroids (antiasthmatics) vs. no treatment be used for the treatment of allergic rhinitis?				×	
Should cough suppressants vs. no treatment be used for the treatment of allergic rhinitis?				×	
Should expectorant medications (mucoactive agents) vs. no treatment be used for the treatment of allergic rhinitis?				×	
Should acetaminophen vs. no treatment be used for the treatment of allergic rhinitis?				×	
Should nonsteroidal anti-inflammatory drugs vs. no treatment be used for the treatment of allergic rhinitis?				×	
Should decongestant topical ointments vs. no treatment be used for the treatment of allergic rhinitis?				×	
Should specific sleep positions vs. other sleep positions be used for the management of allergic rhinitis?				×	
Should humidifiers vs. no intervention be used for the management of allergic rhinitis?				×	

(Continues)

TABLE 2 | (Continued)

Guideline question	Method for question generation					
	ARIA 2010–2016	Guideline panel/KOL	MASK-air data	Generation based on web search queries	Direct generation by LLM	Prioritised
Should nasal strips vs. no intervention be used for the management of allergic rhinitis?				×		
Should intranasal decongestants vs. oral decongestants be used for the treatment of allergic rhinitis?					×	
Should intranasal ipratropium bromide vs. intranasal glucocorticosteroids be used for the treatment of allergic rhinitis?					×	
Should psychological support or stress management techniques vs. no psychological intervention be used in patients with allergic rhinitis?					×	
Should tailored advice on physical activity vs. no specific advice be used in patients with allergic rhinitis?					×	
Should a systematic diagnostic screening for sleep disturbances, including sleep apnea, vs. no systematic screening be used in patients with allergic rhinitis?					×	
Should telemedicine vs. in-person visits alone be used in patients with allergic rhinitis?					×	

Abbreviations: ARIA, Allergic Rhinitis and its Impact on Asthma; KOL, key opinion leaders; LLM, large language models.

corresponding to the occurrence of any AE. The latter corresponded to the undesirable effect outcome with the second highest priority rating.

6 | Emphasising Diverse Populations

6.1 | Age Groups

For each guideline recommendation, we provide subgroup considerations for children. To gather evidence on the effectiveness and safety of AR treatments in children, we conducted systematic reviews solely assessing the paediatric population.

Between adolescents and adults, similar AR control levels were found using evidence from MASK-air [42]. On the other hand, there seem to be differences for individuals over 75 years of age [43], despite the lack of available evidence.

6.2 | Sex

Sex impacts health, with relevant effect modification and implications on the prevention, screening, diagnosis and treatment of allergic diseases [44]. This is particularly true during puberty and pregnancy [45–47]. However, since most studies do not provide evidence on the effect of interventions according to sex, more data are needed to incorporate sex-specific considerations in the guidelines.

6.3 | Patients With Multimorbid Asthma and/or Conjunctivitis

There is mounting evidence that AR alone and AR + asthma multimorbidity represent two distinct phenotypes [48] (Table S3). Such evidence—obtained from the MeDALL (Mechanisms of the Development of Allergy) study [49] and MASK-air data [50]—is grounded on insights into polysensitisation and multimorbidity, advances in mHealth for novel phenotype definition, confirmation in canonical epidemiologic studies and genomic findings. Therefore, subgroup considerations for patients with asthma were provided in the guidelines whenever justified.

Differences between AR alone and AR + conjunctivitis were identified with MASK-air data [51–54] and confirmed in canonical epidemiologic studies. These studies have shown that ocular symptoms (i) are more common in AR + asthma than in AR alone [54], (ii) are associated with the severity of nasal symptoms [55, 56] and (iii) are important to consider in severe asthma [55]. These data indicate that conjunctivitis should be considered as a separate disease in AR or AR + asthma and should be embedded in the multimorbid phenotype. However, more data are needed to incorporate this phenotype in guidelines.

7 | Obtaining Evidence for Evidence-to-Decision Frameworks

Recommendations were generated using EtDs [11, 12]. In its standard form, the EtD comprises 12 criteria, including

problem priority, desirable effects, undesirable effects, certainty of evidence [in desirable and undesirable effects], values and preferences, balance of effects, resources required, certainty of evidence of required resources, cost-effectiveness, equity, acceptability and feasibility [11, 12]. In addition, in ARIA-EAACI 2024–2025, a 13th criterion, Planetary Health, was considered [57]. The next subsections of this paper will discuss the evidence sources used to inform each EtD criterion. An example of an EtD (comparison between fixed combinations of INCS + intranasal antihistamines [INAH] vs. INCS) is available in the Appendix S1.

7.1 | Desirable and Undesirable Effects of Interventions

7.1.1 | Pairwise and Network Meta-Analyses of Randomised Controlled Trials

There was insufficient evidence regarding the comparative efficacy and safety of pharmacological treatments of AR before the beginning of this project. We therefore decided to conduct systematic reviews with pairwise or network meta-analyses to inform the comparative effectiveness of treatments [58]. Overall, for informing ARIA 2024–2025, we planned to conduct six systematic reviews of RCTs comparing the desirable and undesirable effects of oral and intranasal medications:

- i. Systematic review and pairwise meta-analysis comparing intranasal medications versus placebo in adults;
- ii. Systematic review and network meta-analysis comparing intranasal medications in adults;
- iii. Systematic review and network meta-analysis comparing intranasal medications in children;
- iv. Systematic review and pairwise meta-analysis comparing intranasal versus oral medications in adults;
- v. Systematic review and network meta-analysis comparing individual oral medications in adults and children;
- vi. Systematic review and network meta-analysis comparing classes of intranasal and oral medications in adults and children.

Three systematic reviews [59–61] and two protocols [62, 63] have been published. In line with the prioritised outcomes for ARIA-EAACI 2024–2025, these systematic reviews assessed the effects of each individual medication or medication class on nasal symptoms, ocular symptoms, rhinoconjunctivitis-related quality of life and AEs. Pairwise and network meta-analyses including both active comparisons and comparing medications with placebo provided information on untreated patients [59–61]. Network meta-analyses of active comparisons provided information on treated patients [59].

As for the main results of the published studies, both the pairwise and the network meta-analysis on intranasal medications have found that azelastine-fluticasone, fluticasone furoate and fluticasone propionate were the medications with the highest probability of resulting in moderate or large improvements in the assessed outcomes [59, 60]. Considering the differential

impact on ocular symptoms, fluticasone furoate or fluticasone propionate may be particularly indicated for patients with severe nasal symptoms but no or mild ocular symptoms, while azelastine-fluticasone may be an adequate option for patients with moderate to severe ocular symptoms.

In addition, the network meta-analysis on intranasal medications found that azelastine-fluticasone and fluticasone furoate were the medications with the highest probability of being the most efficacious, as they frequently resulted in clinically meaningful larger improvements when compared to other active treatments [59]. In children, evidence was scarcer than in adults. However, despite being efficacious and safe, the efficacy of AR treatments in children does not seem to be as high as in adults.

On the other hand, the meta-analysis comparing intranasal versus oral medications provided evidence that intranasal medications are more effective than oral ones (namely, oral antihistamines or oral leukotriene-receptor antagonists) [61].

Differences in the frequency of undesirable effects (AEs or serious AEs) were trivial for most comparisons between individual medications or between different medication classes [59, 61].

7.1.2 | Pharmacovigilance Data

Considering limitations of RCTs in registering AEs (e.g., limited number of participants, short period of follow-up and restricted eligibility criteria) [64, 65], we analysed pharmacovigilance data to provide further information on the undesirable effects of interventions. We queried the VigiBase database on reported AEs to individual medications of different classes used for the treatment of AR. VigiBase, the World Health Organization global database of AE reports for medicines and vaccines, is the largest pharmacovigilance database [66]. The analysis of its data allowed us to identify the 15 most commonly reported AEs for each intervention being compared in each question. For each AE, we calculated the respective reporting odds ratio to identify signals of disproportionate reporting [67]. For example, in the comparison between INCS and INAH, we found that cataract and glaucoma were proportionally more commonly reported with INCS than with INAH.

7.2 | Values

Healthcare interventions typically result in benefits and harms. Values concern the relative importance patients place on specific benefits and harms [38, 68]. We performed a systematic review to provide a comprehensive overview of the values of patients with AR [38]. We observed that (i) patients generally value the efficacy of interventions more than their AEs, and (ii) patients consider nasal symptoms (particularly nasal obstruction) as those with the highest impact. One of the included studies of that systematic review was based on direct patient data from MASK-air, involving the computation of utilities in different European countries according to the level of rhinitis control and the presence of comorbid asthma [69]. The results of the study were coherent with a questionnaire sent to ARIA members [70].

7.3 | Resources Required and Cost-Effectiveness

7.3.1 | Global Survey on Medication Costs

The cost of medications is highly variable across countries. Moreover, medication costs change with time, particularly when generic drugs are made available or when medications become over-the-counter. Therefore, to gather information on this criterion, we conducted a survey asking ARIA experts about the availability and lowest costs of individual rhinitis medications in their countries (Figure 3).

7.3.2 | MASK-air Data on Indirect Costs Associated With Rhinitis Control

We used data from MASK-air to quantify indirect costs resulting from productivity losses associated with worse rhinitis control. MASK-air includes WPAI:AS, a validated questionnaire that measures the impact of allergies on absenteeism and presenteeism [32]. Based on these data, we estimated the underlying indirect costs in 40 countries according to the level of rhinitis control [71]. Overall, median work impairment (including both absenteeism and presenteeism) stood at 4.6% (P25-P75 = 0.8%–15.1%) for well-controlled weeks, ascending to 27.7% (P25-P75 = 12.4%–46.0%) and 60.7% (P25-P75 = 38.5%–80.2%) for partially and poorly controlled weeks, respectively. For example, in Germany, this translates into median weekly monetary losses of 42.3 US dollars (US\$) adjusted for purchasing power parity (PPPs) for well-controlled weeks, 259.7 US\$ PPPs for partially controlled weeks, and 554.2 US\$ PPPs for poorly controlled weeks (difference of 511.9 US\$ per week from poor to good control). For other Western European countries, the difference ranges from 200 to 695 US\$ [71].

7.3.3 | “Cost-Utility” Assessments Based on Health Technology Assessment Reports and MASK-air Data

There is a scarcity of recent cost-effectiveness and cost-utility studies on AR treatments. We therefore considered cost data from the survey to ARIA experts and either (i) utilities data estimated from a health technology assessment report [72] or (ii) MASK-air data on levels of the VAS of EQ-5D associated with each intervention. The use of VAS EQ-5D data reported in MASK-air was justified since (i) the identified health technology assessment report did not assess all medication classes and (ii) there is a lack of available studies estimating utilities associated with different treatments for AR.

7.4 | Equity

7.4.1 | Global Survey on the Availability of Medications

To assess across-country differences in the availability of medications for AR, we conducted a survey asking ARIA experts about the availability of individual rhinitis medications in their countries (Figure 3).

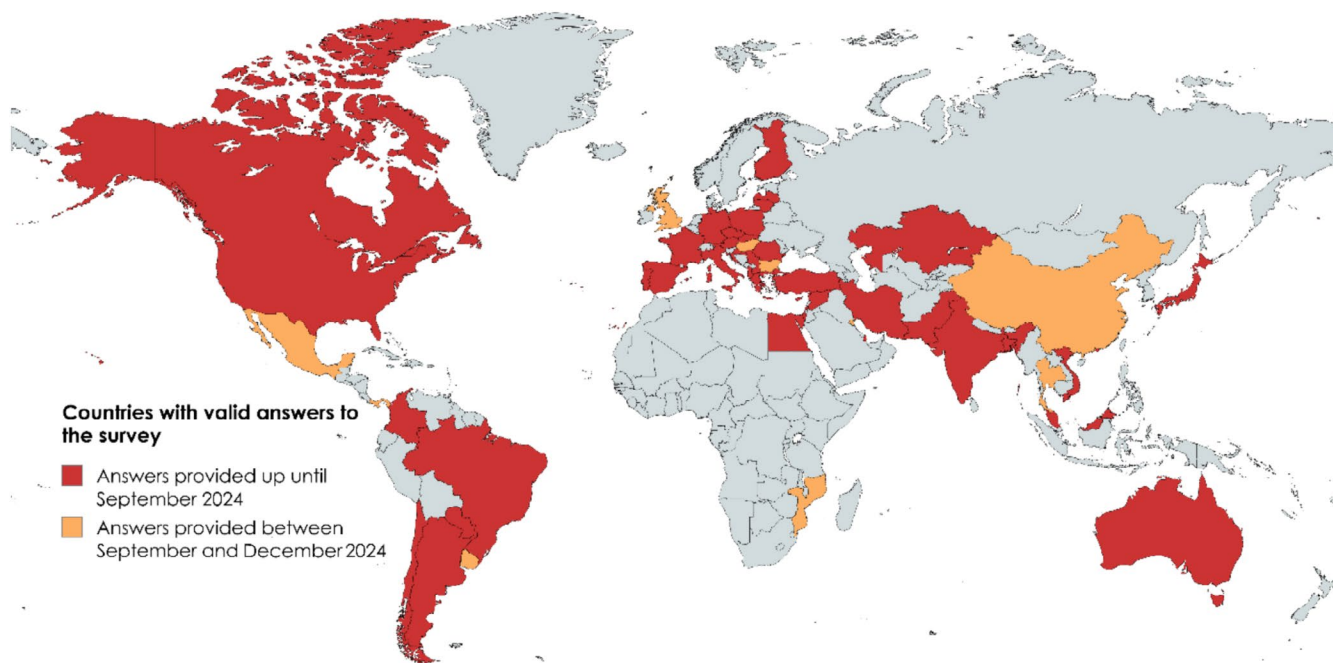


FIGURE 3 | Countries with valid answers to the survey sent to ARIA experts on the availability and costs of allergic rhinitis medication. The answers provided up until September 2024 were used to inform the ARIA-EAACI 2024–2025 guidelines.

7.4.2 | World Health Organization List of Essential Medicines

We assessed the medications for AR included in the World Health Organization List of Essential Medicines [73]. Only intranasal budesonide, oral loratadine and intranasal xylometazoline are on this list. According to information from local experts, medications available in this list are provided free of charge in some low-income countries.

7.5 | Acceptability and Feasibility

7.5.1 | Assessment of Patient Satisfaction With Treatment in MASK-air Data

Patients' satisfaction with their treatment is a patient-reported outcome measure distinct from quality of life and symptoms [74]. In its daily monitoring questionnaire, the MASK-air app includes a question assessing (through a 0–100 VAS) how satisfied patients are with their rhinitis treatment on that day. We have analysed VAS satisfaction data for each treatment class or individual medication in single medication and in co-medication. In addition, we have built multivariable regression models to compare different medications on VAS satisfaction levels.

7.5.2 | Assessment of Co-Medication Use in the MASK-air Data

We assessed MASK-air data to compare different individual medications and medication classes on the frequency of their use in co-medication. MASK-air studies have consistently found

that when patients use co-medication, they tend to report more severe rhinitis symptoms [18, 75]. This finding may be explained by the fact that patients tend to increase their medication use when feeling less well controlled.

7.5.3 | Assessment of Patients' Adherence to Treatment in the MASK-air Data

RCTs tend to assess strategies involving the daily use of medications and, henceforth, require a high adherence to treatment (usually 70%). However, in MASK-air, two studies have addressed adherence to rhinitis treatment and have found that most AR patients are not adherent [76, 77]. In particular, most patients use treatment on an as-needed basis when feeling symptomatic [18]. Therefore, to inform about the acceptability of interventions, we analysed MASK-air data to compare the adherence to different rhinitis medication classes.

7.5.4 | Speed of Onset of Action of Medications: Rapid Evidence Review

We conducted a rapid evidence review to assess the speed of onset of action of AR medications based on ARIA 2019 and other sources [9]. We took into account the guideline published by the European Medicines Agency on the “clinical development of medicinal products for the treatment of allergic rhinoconjunctivitis” [78], and considered the onset of action of medications. Evidence on the onset of action of medications for AR may originate from three study types: standard phase III double-blind RCTs, park setting studies (natural exposure) and allergen exposure chamber studies (artificial exposure). In this rapid review, we found that medications

containing INAH act within 5–30mins, whereas most INCS need hours to be effective.

7.6 | Planetary Health

The concept of Planetary Health emphasises the inherent connection between the health of humans and the health of the planet, on which human health depends [79]. There is increasing understanding that clinical decision guidelines need to incorporate a planetary health dimension [80]. The consideration of Planetary Health in ARIA started with the participation in an EU High-Level meeting (Finnish Presidency of the European Union and DG Research) on Planetary Health [81–83].

ARIA-EAACI 2024–2025 considered aspects of Planetary Health in the formulation of guideline recommendations by having Planetary Health criteria in the EtD [57, 80]. For example, for comparisons between intranasal versus oral treatments, aspects such as the global warming potential of the different packaging types and manufacturing places were considered for available evidence.

8 | Issuing Judgements and Actionable, Patient-Centred Recommendations for Each Guideline Question

In the EtDs, evidence is provided for each criterion, so that the guideline panel can make a judgement. Based on the judgements provided for all criteria, the panel is then able to issue a recommendation for the respective guideline question.

The ARIA-EAACI 2024–2025 guideline panel held regular on-line meetings to make judgements on the EtD criteria and formulate guideline recommendations. In each case, consensus among members of the panel without CoI was sought. If consensus was not reached, a formal voting process was set (using the anonymous voting feature of GRADEpro), although restricted to guideline panel members without CoI.

We drafted recommendations as suggested by the GRADE working group. GRADE recommendations are characterised by (i) a directionality (i.e., whether there is favouring of the intervention, of the comparison, or of neither the intervention nor the comparison) and (ii) a strength (i.e., whether the recommendation is strong or conditional). Strong recommendations posit

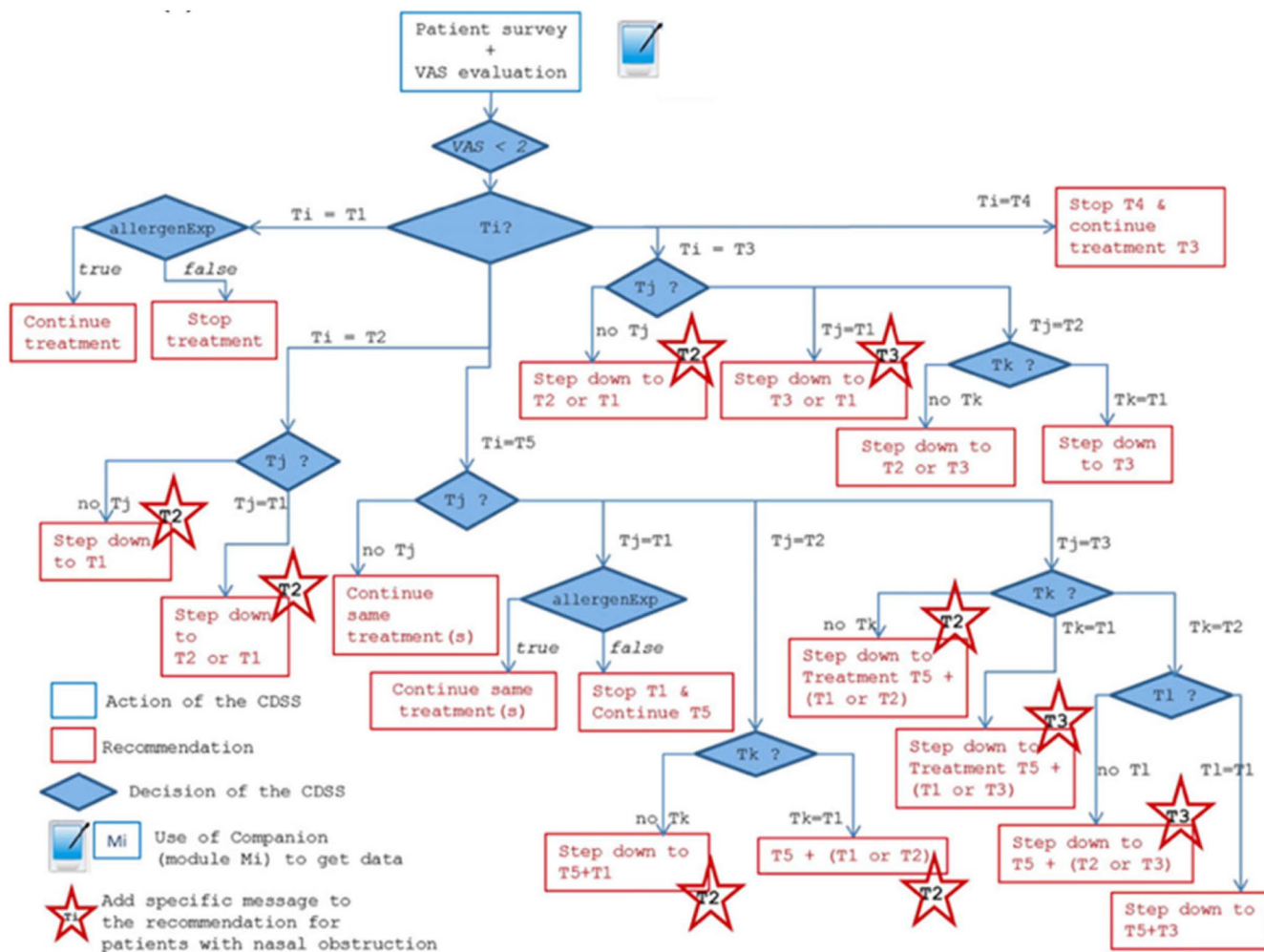


FIGURE 4 | Example of an electronic clinical decision support system (ARIA 2016) (example for patients with well-controlled allergic rhinitis). Ti = Class of current treatment (in case of polypharmacy, Ti = maximum class); Tj, Tk and Tl = Medications added to Ti, order of class $l < k < j < i$. T1 = antihistamine (oral, intranasal and eye drops), leukotriene-receptor antagonist, chromone (intranasal and eye drops); T2 = intranasal corticosteroid (INCS); T3 = INCS + azelastine; T4 = add short course of oral corticosteroids; T5 = consider referral and allergen-specific immunotherapy.

that the intervention should be applied to most individuals. Conditional recommendations indicate that the recommendation may not be applicable to relevant subsets of patients and that variability in the clinical practice may be appropriate [84, 85]. In addition, recommendations should inform on the underlying certainty of evidence (quality of the whole body of evidence, considering altogether desirable and undesirable effects).

After drafting guideline recommendations, the guideline panel proposes subgroup considerations for children and, if justified, patients with asthma. If necessary, the guideline panel also (i) suggests implementation considerations (e.g., in aspects related to the application of recommendations in low- and middle-income countries), (ii) discusses aspects related to monitoring and evaluation and/or (iii) highlights related research priorities.

9 | From Recommendations to Action: Building Digitalised Decision Algorithms

In ARIA 2010–2016, a simple algorithm was proposed in treated and untreated patients. In ARIA-EAACI 2024–2025, we will propose more management algorithms, considering a diverse set of scenarios in terms of patients (e.g., controlled and treated, uncontrolled and treated or uncontrolled and untreated), settings (e.g., primary care or specialised allergy care) or regions (e.g., low- and middle-income countries or high-income countries; the survey we conducted among ARIA experts will support such tailoring, as it informs on the availability and price of medication in different countries). The scenarios will be jointly proposed by the guideline panel group, the review group and ARIA Junior members. The corresponding algorithms will be built based on the formulated recommendations.

In ARIA 2010–2016, an algorithm was developed [14]. Moreover, an electronic clinical decision system provided evidence-based treatment recommendations. The app interfaces used to collect the necessary information had been described, and the management algorithms had been programmed into the MASK-air app using Titanium Appcelerator for iOS tablets [86] (Figure 4 and Figure S1). However, since MASK-air was not at that time an MDR Class IIa, the digitalised algorithms were not implemented. In ARIA 2024–2025, the developed management algorithms will be digitalised and implemented in MASK-air.

10 | Conclusions

ARIA-EAACI 2024–2025 will provide major advances for the management of patients with AR. Building on several different sources of evidence, ARIA-EAACI 2024–2025 will adopt a patient-centred perspective and promote shared decision-making. The formulation of recommendations will be fully based on the GRADE working group methodology. Nevertheless, the development of ARIA-EAACI 2024–2025 will contribute per se to methodological innovations for the guideline development process in aspects such as the use of AI to support the development of questions, or the incorporation of evidence from multiple complementary sources (Table 1). As its end product, ARIA-EAACI 2024–2025 aims not only at producing a set of recommendations but also at developing a set of digitalised

management algorithms, which will be essential in promoting a continuative and long-standing integration of these guidelines into daily care.

Affiliations

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Conflicts of Interest Management

Conflicts of interest (CoIs) of all participants were managed according to the Guidelines International Network (GIN) CoI declaration and management principles reviewed by the AWMF (*Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V.*) [87]. A CoI was defined as an individual having "current material interests outside of ARIA that could influence or could be perceived as influencing his/her decisions, actions, or presentations."

Before participation, all guideline panel members and members of the evidence-synthesis team completed a standardized disclosure-of-interests (DoI) form provided by the AWMF. This form collected information about current and previous (past 3 years) interests in the healthcare sector, including direct financial interests and indirect (e.g., non-financial and intellectual) interests. Guideline panel members were required to report all interests in the DoI form, regardless of whether they would see such interests as having a thematic reference to the guideline or representing a conflict of interest.

Staff providing administrative support to ARIA-EAACI 2024–2025 judged every DoI form in the assessment on whether a disclosed interest was considered a CoI. The completed DoI forms are to be made available to all panel members during the project. At every meeting, guideline panellists were reminded of the DoI forms and prompted to make new disclosures. ARIA staff and members reviewed new disclosures, but previously documented disclosures or judgments are never removed or changed. The forms will receive a final update prior to guideline submission and will be included with the published guidelines.

The guideline panel was composed so that most of its members did not have a CoI. Absence of CoI is required for those chairing the panel discussions and gathering and summarising evidence for the EtDs. No individual was excluded from the guideline panel due to direct or indirect CoI. However, only those without CoI were allowed to make judgements or participate in the voting process for judgements or recommendations.

Conflicts of Interest

J. Bousquet reports personal fees from Cipla, Menarini, Mylan, Novartis, Purina, Sanofi-Aventis, Teva, Noucor, other from KYomed-Innov, other from Mask-air-SAS, outside the submitted work. M. Hyland reports

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Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section. **Appendix S1:** all70100-sup-0001-AppendixS1.docx.