Rostrum

Allergic Rhinitis and its Impact on Asthma (ARIA) Phase 4 (2018): Change management in allergic rhinitis and asthma multimorbidity using mobile technology

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Allergic Rhinitis and its Impact on Asthma (ARIA) has evolved from a guideline by using the best approach to integrated care pathways using mobile technology in patients with allergic rhinitis (AR) and asthma multimorbidity. The proposed next phase of ARIA is change management, with the aim of providing an active and healthy life to patients with rhinitis and to those with asthma multimorbidity across the lifecycle irrespective of their sex or socioeconomic status to reduce health and social inequities incurred by the disease. ARIA has followed the 8-step model of Kotter to assess and implement the effect of rhinitis on asthma multimorbidity and to propose multimorbid guidelines. A second change management strategy is proposed by ARIA Phase 4 to increase self-medication and shared decision making in rhinitis and asthma multimorbidity. An

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innovation of ARIA has been the development and validation of information technology evidence-based tools (Mobile Airways Sentinel Network [MASK]) that can inform patient decisions on the basis of a self-care plan proposed by the health care professional. (J Allergy Clin Immunol 2018;■■■:■■■-■■■.)

Key words: *Change management, rhinitis, asthma, Allergic Rhinitis and Its Impact on Asthma*

Allergic Rhinitis and its Impact on Asthma (ARIA) has evolved from a guideline using the best approach[1-5] to integrated care pathways (ICPs) using mobile technology in patients with AR and asthma multimorbidity.[6] The term *comorbidity* is commonly used for allergic diseases, but *multimorbidity* might be more appropriate. Comorbidity is the presence of 1 or more additional

Abbreviations used

AIRWAYS ICP:	Integrated care pathway for airway diseases
AR:	Allergic rhinitis
ARIA:	Allergic Rhinitis and its Impact on Asthma
CM:	Change management
CM2:	Second phase of change management
DG Santé:	Directorate General for Health and Food Safety
GINA:	Global Initiative for Asthma
GRADE:	Grading of Recommendation, Assessment, Development and Evaluation
ICP:	Integrated care pathway
IT:	Information technology
MASK:	Mobile Airways Sentinel Network
POLLAR:	Impact of Air Pollution on Asthma and Rhinitis
SDM:	Shared decision making

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diseases co-occurring with a primary disease or the effect of such additional disorders or diseases. Multimorbidity is a term that means co-occurring diseases in the same patient.[7,8]

ARIA provides an evidence-based approach for managing the patient's needs, but real-life data have shown that few patients use guidelines and that they often self-medicate (Menditto, in preparation). Moreover, patients largely use over-the-counter medications dispensed in pharmacies.[9-11] Self-care and shared decision making (SDM) centered around the patient should be used more frequently.

Change is inevitable in health care. ARIA has followed a change management (CM) strategy in the past, but a new revised plan should be considered to fill in the gaps of knowledge translation in practice and to increase the benefits of self-care in integrated care pathways (ICPs) by using the currently available information and communication technology tools.[12] These changes should prepare and support individuals, teams, and organizations in making organizational change centered around the patient for more efficient care.

BACKGROUND

The 4 ARIA phases

ARIA was initiated during a World Health Organization workshop in 1999[2] and has evolved in 4 phases.

Phase 1 included development of an evidence-based document to provide a guide for the diagnosis and management of AR and asthma multimorbidity.[1,2] In 2008, ARIA was updated using the same recommendation system.[1,13] ARIA has been disseminated and is implemented in more than 70 countries around the world.[14]

For Phase 2, in its 2010 revision, ARIA was the first chronic respiratory disease guideline to adopt the Grading of Recommendation, Assessment, Development and Evaluation (GRADE) approach, an advanced evidence evaluation and recommendation methodology for guidelines.[3,5] When guidelines are made using the same methodology, the recommendations are similar.[5,15]

In Phase 3 ARIA focused on the implementation of emerging technologies for individualized and predictive medicine to develop ICPs for the management of AR and asthma by a multidisciplinary group centered around the patients (Mobile Airways Sentinel Network [MASK]).[16-23]

The proposed ARIA Phase 4 is CM to provide an active and healthy lifestyle to patients with rhinitis and asthma across the lifecycle, irrespective of their sex or socioeconomic status, with the aim of reducing health and social inequities globally.

SDM and patient empowerment

In SDM both the patient and physician contribute to the medical decision-making process, placing the patient at the center of the decision-making paradigm.[24] Physicians explain treatments and alternatives to patients, who then choose the treatment option that best aligns with their beliefs, lifestyles, and goals along with the benefits and risks.[25] In contrast to SDM, the traditional medical care system places physicians in a position of authority, with patients playing a passive role in care. Patients want greater involvement in SDM.[26] An innovation of SDM in ARIA is the use of information technology (IT) evidence-based tools that can inform patients' decisions based on a guided self-management plan proposed by their health care professionals.[27] In asthmatic patients the effectiveness of 4 SDM studies shows improvement of control and some other parameters, but more studies are needed to confirm the data.[28]

CM

Change is inevitable in health care. However, many change projects fail because of varied beliefs and cultural circumstances, poor planning, unmotivated staff, deficient communication, or excessively frequent changes.[29]

CM aims to prepare and support individuals, teams, and organizations in making organizational change. It proposes methods for redirecting or redefining resources, business processes, budget allocation, and/or modes of operation. When properly applied, CM significantly changes health care and its organization. However, health systems differ largely between countries or even regions, and a combination of CM with ICPs might be more relevant, allowing each organization to use the CM principles according to their needs and regulations. CM deals with different disciplines from health care, behavioral, and social sciences to IT and business solutions.

Although theories might seem abstract and impractical for health care practice, they can help in planning solutions to common health care problems.[29] The Lewin 3-step model is widely used[30,31]: unfreezing, moving, and refreezing.[31] Lippitt et al[32] and Kotter[12] have added intermediate steps (Table I).[12,29,31-33]

Several models of organizational and personal change have been reviewed for respiratory diseases.[34] Kotter's theory has been applied to different fields of medicine[35-37] and pharmacies.[38]

ARIA PHASES 1 AND 2 FOLLOWED THE KOTTER 8-STEP CHANGE MODEL

Goals

Guidelines, such as Global Initiative for Asthma (GINA),[39,40] Global Initiative for Lung Diseases,[41,42] EPOS (European Position Paper on Rhinosinusitis and nasal polyps),[43] and ARIA,[2,3,13] developed a CM strategy that was very effective and produced many updates and revisions while having a positive effect on clinical care and influencing research priorities.

Most guidelines are condition specific, but ARIA was unique because it included, for the first time, the multimorbid component of airway diseases. Although it followed the patient's perspectives, epidemiologic evidence,[44] and some supporting mechanistic studies,[45] this concept was not accepted by the leadership of GINA, who considered neither the asthma-rhinitis multimorbidity concept nor the benefit for the patients.

The 8-step model

Establish a sense of urgency. The sense of urgency should identify and highlight the potential threats and repercussions that might arise in the future by examining the opportunities that can be tapped through effective interventions. In patients with AR and asthma, in the 1990s, the sense of urgency was to provide guidelines that could reduce both the burden of the disease and the mortality (in asthmatic patients). Although there were articles indicating the links between the upper and lower airways,[46,47] the effect of rhinitis on asthma was not fully recognized, and ARIA was initiated to better recognize the interrelationships between the 2 diseases and to propose multimorbid guidelines.

TABLE I. Examples of planned change management models

Lewin[33]	Kotter[12]	Lippitt et al[32]
Unfreezing	Step 1: Establish a sense of urgency Step 2: Create a guiding coalition Step 3: Develop a vision and strategy	Phase 1: Diagnose the problem Phase 2: Assess motivation and capacity for change Phase 3: Assess change agent's motivation and resources
Moving	Step 4: Communicate the change vision Step 5: Empower others to act on the vision Step 6: Generate short-term wins Step 7: Consolidate gains and produce more change	Phase 4: Select a progressive change objective Phase 5: Choose appropriate role of the change agent
Refreezing	Step 8: Anchor new approaches in the culture and institutionalize the changes	Phase 6: Terminate the helping relationship

Adapted from Antwi et al.[31]

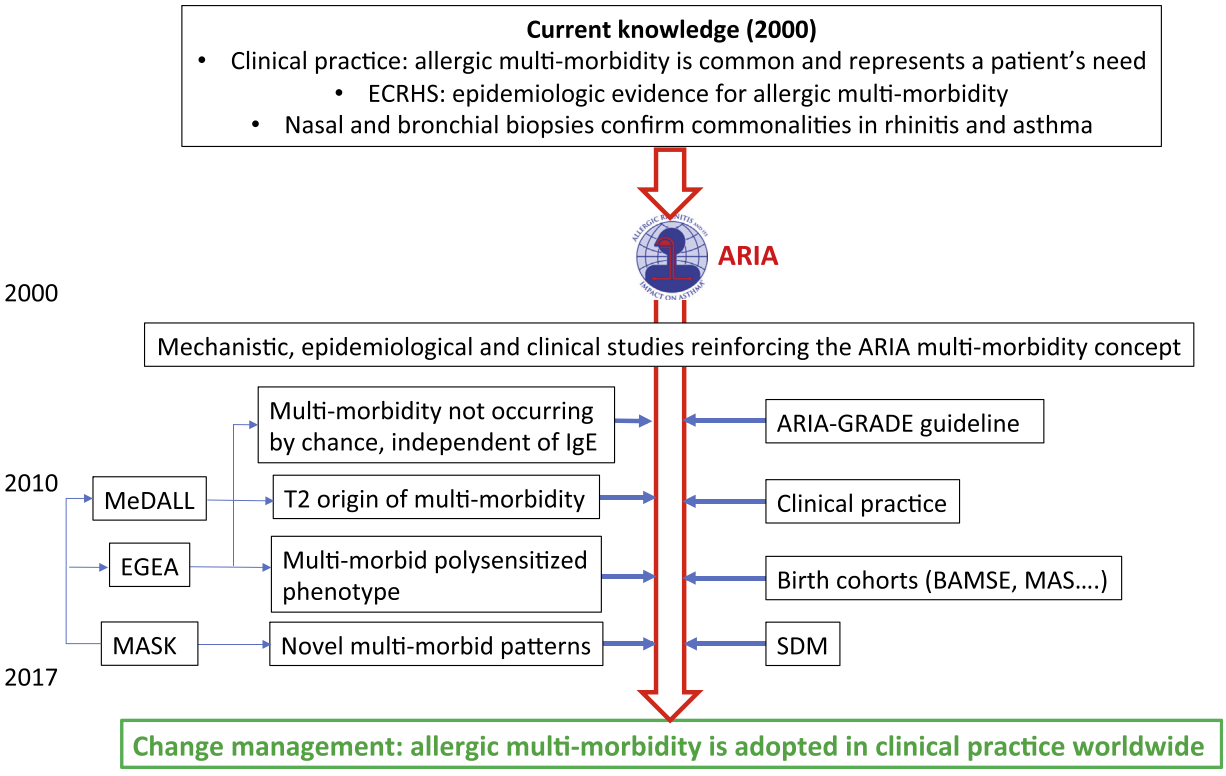

FIG 1. Change management strategy of ARIA Phases 1 and 2. *BAMSE*, Barn Allergi Milj. Stockholm Epidemiologi Projektet; *EGEA*, Epidemiological Study on the Genetics and Environment of Asthma, Bronchial Hyperresponsiveness and Atopy; *MAS*, German Multicenter Allergy Study; *MeDALL*, Mechanisms of the Development of Allergy; *T2*, type 2 immunity.

Create a guiding coalition. The ARIA Working Group was initiated during a World Health Organization meeting (December 1999) and evolved as a powerful group with 400 members in 70 countries.[14] Members have been working together for years and include all stakeholders needed for CM.[1,6] The patient organization European Federation of Allergy and Airways Diseases Patients' Associations has always been an active member of ARIA.

Develop a vision and strategy. The ARIA vision has always been to provide a guide for the diagnosis and management of AR and asthma multimorbidity, including developing countries,[1,2] by using the best available evidence.[3,5] ARIA has established 2 major targets: the recognition and implementation of the asthma-rhinitis multimorbidity, as well as a new classification (intermittent-persistent and mild-to-moderate severe AR) to meet patients' expectations. Moreover, ARIA priorities have always included primary care physicians, pharmacists, and patients' organizations.

Communicate the change vision. One of the ARIA strengths has been to communicate its vision effectively worldwide. More than 1000 articles have been posted on PubMed from more than 50 countries by using the ARIA recommendations.[14] The number of training sessions in more than 70 countries cannot be counted. ARIA has been endorsed by many governments and international organizations: ARIA recommendations have been used for the labeling of allergen immunotherapy by the European Medicines Agency.

Empower others to act on the vision. Organizational processes and structures are in place and are aligned with the overall organizational vision. However, a continuous check is needed for barriers and for people who are resisting change. We have implemented proactive actions to remove the obstacles involved in the process of change.

ARIA has been recognized as the major rhinitis and asthma multimorbidity guideline for years in most countries, except for the United States and Japan. However, the recent US guidelines are using the evidence-based approach of ARIA (GRADE), and the recommendations are similar[15,48,49] to those of ARIA.[5] The recent Japanese guidelines for AR are also creating bridges with ARIA.[50]

Generate short-term wins. As proposed by Kotter,[12] creating short-term wins early in the change process instead of having a single long-term goal can produce a feeling of victory in the early stages of change, which will reinforce support for the strategy.

The concept of asthma and rhinitis multimorbidity is now globally accepted in developed and developing countries.[51] It is now recognized that multimorbidity is independent of IgE-mediated allergy,[8,52] and new phenotypes of severe airway disease have been identified. The implementation of the multimorbid concept in clinical practice has a direct benefit for the patient whose nasal symptoms are often more bothersome than asthma.

Consolidate gains and produce more change. The goals of step 7[12] are to achieve continuous improvement by analyzing the success stories individually and improving from those individual experiences. These goals are exactly those that have been followed by ARIA for the past 18 years.

Anchor new approaches in the culture and institutionalize the changes. The goals of step 8[12] are met by the ARIA strategy:

1. Discuss widely the successful stories related to change initiatives.
2. Ensure that the change becomes an integral part of the practice and is highly visible.
3. Ensure that the support of both existing and new leaders continues to extend toward the change.

Results, drawbacks, and solutions

ARIA has fully achieved its goals following the 8-step Kotter model shown Fig 1. The outcome assessment can be measured in the following ways.

1. *By the numbers of citations of ARIA*: ARIA 2001 has been cited 1750 times, ARIA 2008 has been cited more than 2300 times (and is the only article on asthma cited >200 times a year), and ARIA 2010 has been cited 710 times. This initiative is far better cited than GINA.
2. *By the countries that have endorsed ARIA in their national allergy programs*: Finland, Malaysia, the Philippines, Portugal, and Singapore.
3. *By the approval of treatments by agencies*: The European Medicines Agency used the ARIA classification in the approval of Acarizax (mite sublingual immunotherapy).

Some drawbacks have been pointed out in the Kotter change model.[12] In particular, the model is essentially top-down and might discourage any scope for participation or cocreation. In ARIA we considered that the first CM model was a great success but that its lifecycle had come to an end. It was then decided within the coalition to propose a new CM model based on patients' needs and emerging technologies (second phase of change management [CM2] model).

Because the Kotter model cannot be redesigned, we proposed a new maturity CM model based on the same Kotter 8-step change model.[12] We used ARIA Phase 3 (care pathways for rhinitis and asthma multimorbidity using mobile technology)[6] to better plan the second CM model (CM2 model) and make new assumptions using a patient-centered approach.

THE ALLERGY DIARY STRENGTHENS CM MASK

In 2012, the European Commission launched the European Innovation Partnership on Active and Healthy Ageing (Directorate General for Health and Food Safety [DG Santé] and Directorate General for Communications Networks, Content & Technology).[53] The B3 Action Plan, which was devoted to innovative integrated care models for chronic diseases, selected integrated care pathways for airway diseases (AIRWAYS ICPs)[54,55] with a lifecycle approach[56] as the model of chronic diseases. An AIRWAYS ICPs Action Plan was devised,[54] implemented,[55] and scaled up.[57,58] AIRWAYS ICPs is a World Health Organization Global Alliance against Chronic Respiratory Diseases[59] research demonstration project (Fig 2).

MASK, ARIA Phase 3, is an AIRWAYS ICPs tool.[6,60] It represents a good practice focusing on the implementation of multisectoral care pathways using emerging technologies with real-life data in rhinitis and asthma multimorbidity. MASK follows the Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle (2nd EU Health Programme 2008-2013)[61] recommendations for good practices.[18]

MASK was initiated to reduce the global burden of rhinitis and asthma by giving the patient a simple tool to better prevent and manage respiratory allergic diseases. More specifically, MASK should help to (1) understand the disease mechanisms and effects of air pollution in patients with allergic diseases, (2) better appraise the burden incurred by medical needs but also indirect costs, (3) propose novel multidisciplinary care pathways integrating pollution and patients' literacy, (4) improve work productivity, (5) propose the basis for a sentinel network at the European Union level for pollution and allergy, and (6) assess the societal implications of the project to reduce health and social inequalities globally.

The Allergy Diary

The mobile technology of MASK is the Allergy Diary, an app (Android and iOS) freely available for patients with AR and asthma in 23 countries (16 European Union countries, Argentina, Australia, Brazil, Canada, Mexico, Switzerland, and Turkey) and 16 languages (translated and back-translated, culturally adapted, and legally compliant; Fig 3).[6] Anonymized users fill in a simple questionnaire on asthma and rhinitis on registration and daily assess the effect of the disease by using a visual analog scale[62] for global allergy symptoms, rhinitis, conjunctivitis, asthma, and work. Moreover, a questionnaire is applied every week to assess disease effect on patients' quality of life (EuroQol).[21]

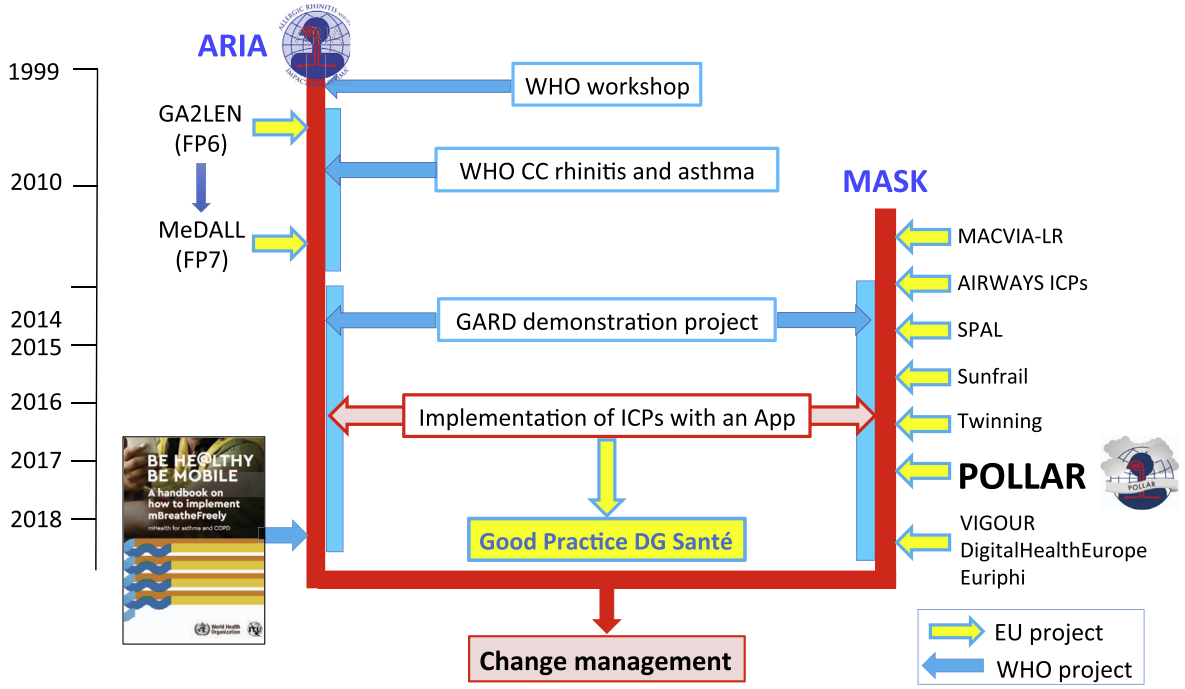

FIG 2. Links between ARIA and MASK for change management. *DigitalHealthEurope*, Digital Transformation of Health in Europe (H2020); *Euriphi*, Better Health and Care, Economic Growth and Sustainable Health Systems (H2020); *GA²LEN*, Global Allergy and Asthma European Network (FP6); *GARD*, Global Alliance against Chronic Respiratory Diseases; *Good Practice DG Santé*, Good Practice on digitally enabled, integrated, person-centered care of the Directorate-General for Health and Food Safety (European Commission); *MACVIA-LR*, Contre les Maladies Chroniques pour un Vieillissement Actif (European Innovation Partnership on Active and Healthy Ageing); *MeDALL*, Mechanisms of the Development of Allergy (FP7); *SPAL*, EU Development and Structural Funds; *Sunfrail* and *Twinning*, Vigour (Evidence-Based Guidance to Scale-up Integrated Care in Europe, 3rd Health Programme); *WHO CC*, World Health Organization Collaborating Center.

Data of pilot studies in up to 17,000 users and more than 95,000 days are available. The Allergy Diary has been validated[19] and has shown that (1) totally anonymized geolocation can be used in 23 countries (in preparation); (2) data can be analyzed in 23 countries and 17 languages; (3) sleep, work productivity, and daily activities are impaired in patients with AR[16,17]; (4) daily work productivity is associated with AR severity[16]; (5) everyday use of medications can be monitored, proposing a novel assessment of treatment patterns[20]; (6) novel patterns of multimorbidity have been identified[22] and confirmed in epidemiologic studies[8,63]; and (7) more than 70% of patients with AR self-medicate and are nonadherent to medications (Menditto, in preparation).

The Allergy Diary (Technology Readiness Level 9) represents a validated mobile health tool for the management of AR. Asthma has also been monitored, but data have not yet been analyzed. Economic effects can be monitored by using work productivity. The results of the Allergy Diary have made innovative approaches of AR possible and are directly strengthening CM strategies in ARIA.

Transfer of Innovation of MASK

A Transfer of Innovation (Twinning) project has been funded by the European Innovation Partnership on Active and Healthy Ageing by using MASK in 25 reference sites or regions across Europe, Argentina, Australia, Brazil, Colombia, and Mexico.[64] The number of countries is increasing, and MASK should be rapidly operative in the United States, China, India (in English only), and Japan. This will improve the understanding, assessment of burden, diagnosis, and management of rhinitis in old age by comparison with an adult population. Twinning has been tested in Germany (Region Kohln-Bonn) in a pilot study that has now been extended to the other German cities and countries of the Twinning project.

Clinical decision support system

Clinical decision support systems are software algorithms that advise health care providers on diagnosis and management based on the interaction of patient data and medical information. They should be based on the best evidence to aid patients and health care professionals to jointly determine treatment (SDM). In patients with AR, the MASK clinical decision support system is incorporated into a tablet interoperable with the Allergy Diary[65] for health care professionals (ARIA Allergy Diary Companion).[6,50] This is based on an algorithm to aid clinicians to select pharmacotherapy for patients with AR and to stratify their disease severity.[66] This approach will be adapted for the patient's guided self-care in the context of SDM.

Impact of Air Pollution on Asthma and Rhinitis

Interactions between air pollution, sleep, and allergic diseases are clear but insufficiently understood. Impact of Air Pollution on

FIG 3. Allergy Diary. *GPDR,* General Data Protection Regulation (https://www.eugdpr.org).

Asthma and Rhinitis (POLLAR) is a new Horizon 2020 project of the European Institute of Innovation and Technology for Health that will embed environmental data into the Allergy Diary. POLLAR aims at combining emerging technologies (including the Allergy Diary, which is Technology Readiness Level 9, meaning that the system is proved in an operational environment) with machine learning to (1) understand the effects of air pollution in patients with AR and its effects on sleep, work, and asthma; (2) assess societal consequences shared with citizens and professionals; (3) propose preventive strategies, including a sentinel network; and (4) develop participative policies.

ARIA PHASES 3 AND 4 DEPLOY A NOVEL KOTTER 8-STEP CHANGE MODEL

Goals

Although the first CM model developed by the ARIA initiative was a great success, there are still unmet needs in the treatment of asthma and rhinitis multimorbidity. In ARIA Phase 4 we encourage the participation of all the stakeholders.

The 8-step model

Establish a sense of urgency. ICPs will include multidisciplinary structured care plans detailing the key steps of patient care, including self-care, as proposed by AIRWAYS ICPs.[54] GRADE-based guidelines for physicians are available for AR, and their recommendations are similar.[3,5,15] However, they are based on the assumption that patients regularly use their treatment and are not tested with real-life data. Unfortunately, adherence to treatment is very low, and real-life studies do not necessarily accord with all recommendations.[20] New-generation guidelines embedding real-life data are being developed.

Create a guiding coalition. The ARIA Working Group initiated in 1999 includes more than 500 members in 70 countries.[14] A successful coalition working on CM2 has been identified within the group.

The AIRWAYS ICPs coalition was established in 2014 and is part of the European Innovation Partnership on Active and Healthy Ageing (DG Santé and Directorate General for Communications Networks, Content & Technology).[54] Moreover, many national and European scientific societies (the European Academy of Allergy and Clinical Immunology, the European Respiratory Society, and the International Primary Care Respiratory Group), and other patients' organization (European Lung Foundation and Asthma UK) have joined the coalition. It is a World Health Organization Global Alliance against Chronic Respiratory Diseases demonstration project. Finally, the transfer of innovation of ARIA has been carried out to the reference sites of the European Innovation Partnership on Active and Healthy Ageing.[64]

This CM2 guiding coalition is already in place in the European Forum for Research and Education in Allergy and Airways Diseases (http://www.euforea.eu).[67]

Develop a vision and strategy. The vision of ARIA Phase 4 is to provide CM2 for AR and asthma multimorbidity to develop SDM with the ultimate goal of improving AR and asthma control while maintaining quality of life and reducing costs by using mobile technology and real-time data management to inform decisions.

The strategy for realizing the changes is based on the patient-centered implementation of ICPs[54] using IT solutions, such as the Allergy Diary.[6]

Communicate the change vision. The updated vision (CM2) will use the experience of the first CM strategy. It has already been discussed among the ARIA CM coalition members, and the present article is the first to be published. However, it takes time to address the concerns of all stakeholders, and articles

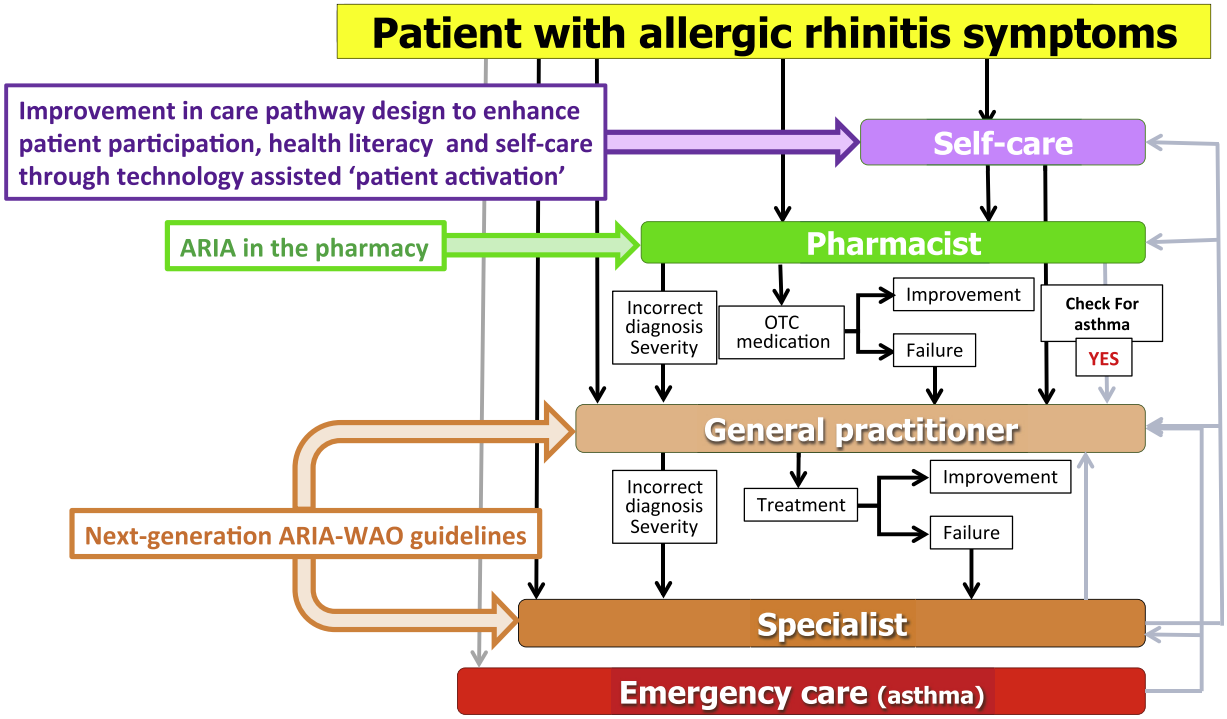

FIG 4. Change management based on next-generation ICPs.

published recently on the Allergy Diary might help to convince many. ARIA is involving a maximum number of people to deploy the CM vision.

The integration of new paths of understanding health and change is a requirement for the strategy. The CM2 model clearly expands and strengthens the potential for actual change to occur and take hold in all kinds of organizations and institutions. Supplementary to the ambition of change in existing practices and institutions, it is also important to consider the integration of other modes of communication and dissemination on the basis of healthy behavior. A central example is the general need to increase the level of health literacy in society. The general public should clearly not be perceived simply as patients waiting for something to happen. They should have the ability to navigate and understand health messages, an essential tool for self-managing well-being, even before any actual condition or major challenge actually occurs. However, to do so, one must consider how to improve this health literacy by integrating it much better into the educational system and cultural settings to which it applies. This is a very long-term investment in self-care and prevention. A later target audience with a higher level of health literacy will naturally also ensure an easier adoption of subsequent health messages, possibly using information and communication technology.[68] The basis for understanding is simply enhanced compared with the previous scenario.

In a similar line of thinking, one could also consider a wider community-oriented approach to dissemination. This could also cover social media and self-help groups because some of the latter patients would benefit not only from both personal previous experience and knowledge about these ailments but also from a supportive environment, which would be better able to support and help these citizens/friends/family members, regardless of age, in their attempt to adapt to new modes of behavior. This is a wider application of the CM2 model and should also be considered in our work to help patients and citizens.

Empower others to act on the vision. Organizational processes and structures are in place and are aligned with the overall organizational vision. However, we need to continuously check for barriers and for those who are resistant to change and focus on the education of both physicians and patients on how to achieve the best outcomes of treatment. We are acting proactively to remove the obstacles involved in the process of change.

Generate short-term wins. We propose to create new short-term (eg, 12 months) and medium-term (eg, 24 months) targets. In 2018, a high-level meeting organized by POLLAR will approach the improvement in care pathway design to enhance patient participation, health literacy, and self-care through technology-assisted "patient activation." In this meeting rhinitis and asthma multimorbidity will be used as a model of non-communicable disease (Fig 4). Three major aspects of ICPs will be considered: self-care, pharmacy care, and next-generation guidelines in which the recommendations of the GRADE guidelines on AR[5,15] will be tested in real life by using MASK.

Consolidate gains and produce more change. Most of the goals of the Kotter change model step 7[12] have been met by the ARIA CM and will be further developed in CM2.

CONCLUSIONS

For the past 18 years, ARIA has had the major goal of providing a guide for the diagnosis and management of AR and asthma multimorbidity applicable to developing countries[1,2] by using the best evidence.[3-5] ARIA Phases 1 and 2 were developed in accordance to the Kotter 8-step change model and can be used as a model of CM in patients with chronic diseases. However, there

are still unmet needs for the management of rhinitis and asthma in real life.

A second CM model has been proposed by ARIA Phases 3 and 4. It was initiated by the development in 23 countries of an app that showed partly unexpected results. Patients with AR (and possibly with asthma) do not follow physicians' advice: they self-medicate. There is an urgent need to harness this information and to update our concept of treatment, as well as treatment adherence, by using mobile technology and care pathways. This is the goal of ARIA Phase 4 and the second wave of CM.

MASK Study Group

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