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

### Mobile Airways Sentinel Network M

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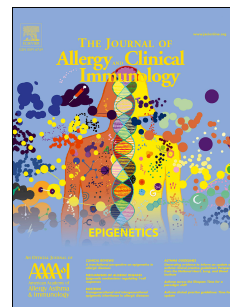
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# Accepted Manuscript

ARIA Phase 4 (2018): Change management in allergic rhinitis and asthma multimorbidity using mobile technology

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830

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916  
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918 **Abstract**

919

920 Allergic Rhinitis and its Impact on Asthma (ARIA) has evolved from a guideline using the best  
921 approach to integrated care pathways (ICPs) using mobile technology in AR and asthma  
922 multimorbidity. The proposed next phase of ARIA is Change Management (CM) with the aim of  
923 providing an active and healthy life to rhinitis sufferers and to those with asthma multimorbidity  
924 across the life cycle whatever their gender or socio-economic status in order to reduce health and  
925 social inequities incurred by the disease. ARIA has followed the 8-step model of Kotter to assess and  
926 implement the impact of rhinitis on asthma multimorbidity and to propose multimorbid guidelines. A  
927 second change management strategy is proposed by ARIA Phase 4 to increase self-medication and  
928 shared decision making in rhinitis and asthma multimorbidity. An innovation of ARIA has been the  
929 development and validation of IT evidence-based tools (MASK: Mobile Airways Sentinel Network)  
930 that can inform patient decisions on the basis of a self-care plan proposed by the health care  
931 professional.

932 **Article type:** Rostrum933 **Key words:** Change management, rhinitis, asthma, ARIA,934 **Word count:** 3852

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940 **Abbreviations**

- 941 AHA: Active and Healthy Ageing
- 942 AIRWAYS ICPs: Integrated care pathways for airway diseases
- 943 AIT: Allergen immunotherapy
- 944 AR: Allergic rhinitis
- 945 ARIA: Allergic Rhinitis and its Impact on Asthma
- 946 BAMSE: Barn Allergi Milj. Stockholm Epidemiologi Projektet
- 947 CDSS: Clinical decision support system
- 948 CM: Change management
- 949 CM2: Second phase of change management
- 950 DG CONNECT: Directorate General for Communications Networks, Content & Technology
- 951 DG Santé: Directorate General for Health and Food Safety
- 952 DG: Directorate General
- 953 EAACI: European Academy of Allergy and Clinical Immunology
- 954 EFA: European Federation of Allergy and Airways Diseases Patients' Associations
- 955 EGEA: Epidemiological study on the Genetics and Environment of Asthma, bronchial hyperresponsiveness and atopy
- 956 EIP on AHA: European Innovation Partnership on Active and Healthy Ageing
- 957 EIP: European Innovation Partnership
- 958 ELF: European Lung Foundation
- 959 EQ-5D: Euroqol
- 960 ERS: European Respiratory Society
- 961 EUFOREA: European Forum for Research and Education in Allergy
- 962 GARD: WHO Global Alliance against Chronic Respiratory Diseases
- 963 HCP: Health care professional
- 964 ICP: Integrated care pathway
- 965 ICT: Information and communication technology
- 966 IT: Information technology
- 967 JA-CHRODIS: Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle
- 968 MACVIA-LR: contre les MALadies Chroniques pour un Vieillissement Actif (Fighting chronic diseases for AHA)
- 969 MASK: Mobile Airways Sentinel network
- 970 MAS: German Multicenter Allergy Study
- 971 MeDALL: Mechanisms of the Development of Allergy
- 972 mHealth: mobile health
- 973 OTC: Over the counter
- 974 POLLAR: Impact of air POLLution on Asthma and Rhinitis
- 975 QOL: Quality of life
- 976 SCUAD: Severe chronic upper airway disease
- 977 SDM: Shared decision making
- 978 TRL: Technology Readiness level
- 979 VAS: Visual analogue scale
- 980 WHO: World Health Organization
- 981 WPAI-AS: Work Productivity and Activity questionnaire

## 982 Introduction

983 Allergic Rhinitis and its Impact on Asthma (ARIA) has evolved from a guideline using the best  
984 approach <sup>1,5</sup> to integrated care pathways (ICPs) using mobile technology in AR and asthma  
985 multimorbidity <sup>6</sup>. The term co-morbidity is commonly used for allergic diseases, but multimorbidity  
986 might be more appropriate. Comorbidity is the presence of one or more additional diseases co-  
987 occurring with a primary disease or the effect of such additional disorders or diseases. Multimorbidity  
988 is a term which means co-occurring diseases in the same patient <sup>7,8</sup>.

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

993 Change is inevitable in health care. ARIA has followed a change management (CM) strategy in the  
994 past, but a new revised plan should be considered in order to fill the gaps of knowledge translation into  
995 practice and to increase the benefits of self-care in care pathways (ICPs) using the currently-available  
996 ICT tools <sup>12</sup>. These changes should prepare and support individuals, teams and organizations in  
997 making organizational change centered around the patient for more efficient care.

## 998 1- Background

### 999 1-1- The four ARIA phases

1000 ARIA was initiated during a World Health Organization (WHO) workshop in 1999 <sup>2</sup> and has evolved  
1001 in four phases:

1002 Phase 1: Development of an evidence-based document to provide a guide for the diagnosis and  
1003 management of AR and asthma multimorbidity <sup>1,2</sup>. In 2008, ARIA was updated using the same  
1004 recommendation system <sup>1,13</sup>. ARIA has been disseminated and is implemented in over 70 countries  
1005 around the world <sup>14</sup>.

1006 Phase 2: In its 2010 Revision, ARIA was the first chronic respiratory disease guideline to adopt the  
1007 GRADE (Grading of Recommendation, Assessment, Development and Evaluation) approach, an  
1008 advanced evidence evaluation and recommendation methodology for guidelines <sup>3,5</sup>. When guidelines  
1009 are made using the same methodology, the recommendations are similar <sup>5,15</sup>.

1010 Phase 3: ARIA focused on the implementation of emerging technologies for individualized and  
1011 predictive medicine to develop ICPs for the management of AR and asthma by a multi-disciplinary  
1012 group centered around the patients<sup>16,19,20,23</sup> (MASK: Mobile Airways Sentinel Network).

1013 The proposed ARIA phase 4 is CM to provide an active and healthy life to rhinitis and asthma  
1014 sufferers across the life cycle whatever their gender or socio-economic status with the aim to reduce  
1015 health and social inequities globally.

## 1016 **1-2- Shared decision making and patient empowerment**

1017 In SDM, both the patient and the physician contribute to the medical decision-making process, placing  
1018 the patient at the centre of the decision-making paradigm<sup>24</sup>. Physicians explain treatments and  
1019 alternatives to patients who then choose the treatment option that best aligns with their beliefs,  
1020 lifestyles and goals along with the benefits and risks<sup>25</sup>. In contrast to SDM, the traditional medical  
1021 care system places physicians in a position of authority, with patients playing a passive role in care.  
1022 Patients want greater involvement in SDM<sup>26</sup>. An innovation of SDM in ARIA is the use of IT  
1023 evidence-based tools that can inform patient decisions on the basis of a guided self-management plan  
1024 proposed by their health care professionals<sup>27</sup>. In asthma, the effectiveness of four SDM studies shows  
1025 improvement of control and some other parameters but more studies are needed to confirm the data<sup>28</sup>.

## 1026 **1-3- Change management**

1027 Change is inevitable in health care. However, many change projects fail due to varied belief and  
1028 cultural circumstances, poor planning, unmotivated staff, deficient communication, or excessively  
1029 frequent changes<sup>29</sup>.

1030 CM aims to prepare and support individuals, teams and organizations in making organizational  
1031 change. It proposes methods redirecting or redefining resources, business processes, budget allocation  
1032 and/or modes of operation. When properly applied, CM significantly changes healthcare and its  
1033 organization. However, health systems differ largely between countries or even regions and a  
1034 combination of CM with ICPs may be more relevant allowing each organization to use the CM  
1035 principles according to their needs and regulations. CM deals with different disciplines from  
1036 healthcare, behavioral and social sciences to IT and business solutions.

1037 Although theories may seem abstract and impractical for healthcare practice, they can help in planning  
1038 solutions to common healthcare problems<sup>29</sup>. The Lewin's 3-Step model is widely used<sup>30,31</sup>:  
1039 unfreezing, moving, and refreezing<sup>31</sup>. Lippitt<sup>32</sup> and Kotter<sup>12</sup> have added intermediate steps (Table 1)  
1040<sup>29</sup>.

1041 Several models of organizational and personal change have been reviewed for respiratory diseases<sup>33</sup>.  
1042 Kotter's theory has been applied to different fields of medicine<sup>34,36</sup> and pharmacies<sup>37</sup>.

## 1043 **2- ARIA Phases 1 and 2 followed the Kotter's 8-step change model**

### 1044 **2-1- Goals**

1045 Guidelines such as GINA (Global INitiative for Asthma)<sup>38,39</sup>, GOLD (Global initiative for Lung  
1046 Diseases)<sup>40,41</sup>, EPOS<sup>42</sup> and ARIA<sup>2,3,13</sup> developed a CM strategy that was very effective and produced  
1047 many updates and revisions while having a positive impact on clinical care and influencing research  
1048 priorities.

1049 Most guidelines are condition specific but ARIA was unique as it included for the first time the  
1050 multimorbid component of the airway diseases. Although it followed the patient's perspectives,  
1051 epidemiologic evidence<sup>43</sup> and some supporting mechanistic studies<sup>44</sup>, this concept was not accepted  
1052 by the leadership of GINA who considered neither the asthma-rhinitis multimorbidity concept nor the  
1053 benefit for the patients.

### 1054 **2-2- The 8-step model**

#### 1055 **2-2-1- Establish a sense of urgency**

1056 The sense of urgency should identify and highlight the potential threats and the repercussions that  
1057 might arise in the future by examining the opportunities which can be tapped through effective  
1058 interventions. In AR and asthma, in the 1990s, the sense of urgency was to provide guidelines that  
1059 could reduce both the burden of the diseases and the deaths (in asthma). Although there were papers  
1060 indicating the links between the upper and lower airways<sup>45,46</sup>, the impact of rhinitis on asthma was not  
1061 fully recognized and ARIA was initiated to better reconize the inter-relationships between the two  
1062 diseases and to propose multimorbid guidelines.

#### 1063 **2-2-2- Create a guiding coalition**

1064 The ARIA working group was initiated during a WHO meeting (December 1999) and evolved as a  
1065 powerful group with 400 members in 70 countries<sup>14</sup>. Members have been working together for years  
1066 and include all stakeholders needed for CM<sup>1,6</sup>. The patients' organization EFA (European Federation  
1067 of Allergy and Airways Diseases Patients' Associations) has always been an active member of ARIA.

#### 1068 **2-2-3- Develop a vision and strategy**



1069 The ARIA vision has always been to provide a guide for the diagnosis and management of AR and  
1070 asthma multimorbidity, including developing countries,<sup>1, 2</sup> using the best available evidence<sup>3,5</sup>. ARIA  
1071 has established two major targets: the recognition and implementation of the asthma-rhinitis  
1072 multimorbidity as well as a new classification (intermittent-persistent and mild-moderate severe AR)  
1073 to meet patients' expectations. Moreover, ARIA priorities have always included primary care  
1074 physicians, pharmacists and patients' organizations.

#### 1075 **2-2-4- Communicate the change vision**

1076 One of the ARIA strengths has been to communicate its vision effectively worldwide. Over 1,000  
1077 papers have been posted on Pubmed from over 50 countries using the ARIA recommendations<sup>14</sup>. The  
1078 number of training sessions in over 70 countries cannot be counted. ARIA has been endorsed by many  
1079 governments and international organizations: ARIA recommendations have been used for the labeling  
1080 of allergen immunotherapy by the European Medicine Agency.

#### 1081 **2-2-5- Empower others to act on the vision**

1082 Organizational processes and structures are in place and are aligned with the overall organizational  
1083 vision. However, a continuous check is needed for barriers and for people who are resisting change.  
1084 We have implemented proactive actions to remove the obstacles involved in the process of change.

1085 ARIA has been recognized as the major rhinitis and asthma multimorbidity guideline for years in most  
1086 countries except for the US and Japan. However, the recent US guidelines are using the evidence-  
1087 based approach of ARIA (GRADE: Grading of Recommendations, Assessment, Development and  
1088 Evaluation), and the recommendations are similar<sup>15, 47, 48</sup> to those of ARIA<sup>5</sup>. The recent Japanese  
1089 guidelines for AR are also making bridges with ARIA<sup>49</sup>.

#### 1090 **2-2-6- Generate short-term wins**

1091 As proposed by Kotter<sup>12</sup>, creating short-term wins early in the change process, instead of having one  
1092 long-term goal, can give a feeling of victory in the early stages of change, which will reinforce support  
1093 to the strategy.

1094 The concept of asthma and rhinitis multimorbidity is now globally accepted in developed and  
1095 developing countries<sup>50</sup>. It is now recognized that multimorbidity is independent of IgE-mediated  
1096 allergy<sup>8,51</sup> and new phenotypes of severe airway disease have been identified. The implementation of  
1097 the multimorbid concept in clinical practice has a direct benefit for the patient whose nasal symptoms  
1098 are often more bothersome than asthma.

## 1099 **2-2-7- Consolidate gains and produce more change**

1100 The goals of step 7<sup>12</sup> are to achieve continuous improvement by analysing the success stories  
1101 individually and improving from those individual experiences. These goals are exactly those that have  
1102 been followed by ARIA for the past 18 years.

## 1103 **2-2-8- Anchor new approaches in the culture and institutionalize the changes**

1104 The goals of step 8<sup>12</sup> are met by the ARIA strategy:

- 1105 1. Discuss widely the successful stories related to change initiatives.
- 1106 2. Ensure that the change becomes an integral part of the practice and is highly visible.
- 1107 3. Ensure that the support of the existing as well as the new leaders continues to extend towards the  
1108 change.

## 1109 **2-3- Results, drawbacks and solutions**

1110 ARIA has fully achieved its goals following the 8-step Kotter's model of (Figure 1). The outcome  
1111 assessment can be measured (i) by the numbers of citations of ARIA. ARIA 2001 has been cited 1750  
1112 times, ARIA 2008 over 2300 times (only paper in asthma cited >200 times a year) and ARIA 2010  
1113 710 times. This initiative is far better cited than GINA. (ii) By the countries that have endorsed ARIA  
1114 in their national allergy program: Finland, Malaysia, Philippines, Portugal, Singapore. (iii) By the  
1115 approval of treatments by agencies: The European Medicines Agency used the ARIA classification in  
1116 the approval of Acarizax® (mite sublingual immunotherapy).

1117 Some drawbacks have been pointed out in Kotter's change model<sup>12</sup>. In particular, the model is  
1118 essentially top-down and may discourage any scope for participation or co-creation. In ARIA, we  
1119 considered that the first CM model was a great success but that its life cycle had come to an end. It  
1120 was then decided within the coalition to propose a new CM model based on patients' needs and  
1121 emerging technologies (CM2 model).

1122 Since the Kotter model cannot be redesigned, we proposed a new maturity CM model based on the  
1123 same Kotter's 8-step change model<sup>12</sup>. We used ARIA Phase 3 (care pathways for rhinitis and asthma  
1124 multimorbidity using mobile technology)<sup>6</sup> to better plan the second CM model (CM2 model) and  
1125 make new assumptions with a patient's centered approach.

## 1126 **3- The Allergy Diary strengthens change management**

### 1127 **3-1- MASK**

1128 In 2012, the European Commission launched the European Innovation Partnership on Active and  
1129 Healthy Ageing (DG Santé and DG CONNECT) (52). The B3 Action Plan, devoted to innovative  
1130 integrated care models for chronic diseases, selected integrated care pathways for airway diseases  
1131 (AIRWAYS ICPs)<sup>53,54</sup> with a life cycle approach<sup>55</sup> as the model of chronic diseases. An AIRWAYS  
1132 ICPs Action Plan was devised<sup>53</sup>, implemented<sup>54</sup> and scaled up<sup>56,57</sup>. AIRWAYS ICPs is a GARD  
1133 (WHO Global Alliance for Chronic Respiratory Diseases)<sup>58</sup> research demonstration project (Figure  
1134 2).

1135 MASK, the ARIA Phase 3, is an AIRWAYS ICPs tool<sup>6,59</sup>. It represents a Good Practice focusing on  
1136 the implementation of multi-sectoral care pathways using emerging technologies with real life data in  
1137 rhinitis and asthma multi-morbidity. MASK follows the JA-CHRODIS (Joint Action on Chronic  
1138 Diseases and Promoting Healthy Ageing across the Life Cycle, 2<sup>nd</sup> EU Health Programme 2008-2013  
1139 <sup>60</sup>) recommendations for good practices<sup>18</sup>.

1140 MASK was initiated to reduce the global burden of rhinitis and asthma, by giving the patient a simple  
1141 tool to better prevent and manage respiratory allergic diseases. More specifically, MASK should help  
1142 to (i) understand the disease mechanisms and the effects of air pollution in allergic diseases (ii) better  
1143 appraise the burden incurred by medical needs but also indirect costs, (iii) propose novel  
1144 multidisciplinary care pathways integrating pollution and patients' literacy, (iv) improve work  
1145 productivity, (v) propose the basis for a sentinel network at the EU level for pollution and allergy and  
1146 (vi) assess the societal implications of the project to reduce health and social inequalities globally.

### 1147 **3-2- The Allergy Diary**

1148 The mobile technology of MASK is the *Allergy Diary*, an App (Android and iOS) freely available for  
1149 AR and asthma sufferers in 23 countries (16 EU countries, Argentina, Australia, Brazil, Canada,  
1150 Mexico, Switzerland and Turkey) and 16 languages (translated and back-translated, culturally adapted  
1151 and legally compliant)<sup>6</sup> (Figure 3). Anonymized users fill in a simple questionnaire on asthma and  
1152 rhinitis upon registration and daily assess the impact of the disease using a visual analogue scale  
1153 (VAS)<sup>61</sup> for global allergy symptoms, rhinitis, conjunctivitis, asthma and work. Moreover, a  
1154 questionnaire is applied every week to assess disease impact on patients' QOL (EQ-5D)<sup>21</sup>.

1155 Data of pilot studies in up to 17,000 users and over 95,000 days are available. The *Allergy Diary* has  
1156 been validated<sup>19</sup> and has shown that (i) totally anonymized geolocation can be used in 23 countries (in  
1157 preparation), (ii) data can be analyzed in 23 countries and 17 languages, (iii) sleep, work productivity  
1158 and daily activities are impaired in AR<sup>16,17</sup>, (iv) daily work productivity is associated with AR  
1159 severity<sup>16</sup>, (v) the everyday use of medications can be monitored proposing a novel assessment of

1160 treatment patterns <sup>20</sup>, (vi) novel patterns of multimorbidity have been identified <sup>22</sup> and confirmed in  
1161 epidemiological studies <sup>8, 62</sup> and (vii) over 70% of AR patients self-medicate and are non-adherent to  
1162 medications (Menditto, in preparation).

1163 The *Allergy Diary* (TRL 9, Technology Readiness level 9) represents a validated mHealth tool for the  
1164 management of AR. Asthma has also been monitored but data have not yet been analyzed. Economic  
1165 impact can be monitored using work productivity. The results of the *Allergy Diary* have made  
1166 innovative approaches of AR possible and are directly strengthening CM strategies in ARIA.

### 1167 **3-3- Transfer of Innovation of MASK**

1168 A Transfer of Innovation (Twinning) project has been funded by the European Innovation Partnership  
1169 on Active and Healthy Ageing (EIP on AHA) using MASK in 25 Reference Sites or regions across  
1170 Europe, Argentina, Australia, Brazil, Columbia and Mexico <sup>63</sup>. The number of countries is increasing  
1171 and MASK should be rapidly operative in the US, China, India (in English only) and Japan. This will  
1172 improve the understanding, assessment of burden, diagnosis and management of rhinitis in old age by  
1173 comparison with an adult population. The Twinning has been tested in Germany (Region Kohl-  
1174 Bonn) in a pilot study that has now been extended to the other German cities and countries of the  
1175 Twinning project.

### 1176 **3-4- Clinical decision support system**

1177 Clinical decision support systems (CDSS) are software algorithms that advise health care providers on  
1178 the diagnosis and management of patients based on the interaction of patient data and medical  
1179 information. They should be based on the best evidence to aid patients and health care professionals to  
1180 jointly determine treatment (SDM). In allergic rhinitis, the MASK CDSS is incorporated into a tablet  
1181 interoperable with the *Allergy Diary* <sup>64</sup> for health care professionals (*ARIA Allergy Diary Companion*)  
1182 <sup>6, 59</sup>. This is based on an algorithm to aid clinicians to select pharmacotherapy for AR patients and to  
1183 stratify their disease severity <sup>65</sup>. This approach will be adapted for the patient's guided self-care in a  
1184 context of SDM.

### 1185 **3-5- POLLAR**

1186 Interactions between air pollution, sleep and allergic diseases are clear but insufficiently understood.  
1187 POLLAR (Impact of Air POLLution in Asthma and Rhinitis) is a new Horizon 2020 project of the  
1188 EIT Health (European Institute of Innovation and Technology for Health) that will embed  
1189 environmental data into the *Allergy Diary*. POLLAR aims at combining emerging technologies  
1190 (including the *Allergy Diary*, Technology Readiness level TRL9 meaning that the system is proven in  
1191 operational environment) with machine learning to (i) understand the effects of air pollution in AR and

1192 its impact on sleep, work and asthma, (ii) assess societal consequences, shared with citizens, and  
1193 professionals (iii) propose preventive strategies including a sentinel network and (iv) develop  
1194 participative policies.

## 1195 **4- ARIA Phases 3 and 4 deploy a novel Kotter's 8-step change model**

### 1196 **4-1- Goals**

1197 Although the first CM model developed by the ARIA Initiative was a great success, there are still  
1198 unmet needs in the treatment of asthma and rhinitis multimorbidity. In ARIA Phase 4, we encourage  
1199 the participation of all the stakeholders.

### 1200 **4-2- The 8-step model**

#### 1201 **4-2-1- Establish a sense of urgency**

1202 ICPs will include multi-disciplinary structured care plans detailing the key steps of patient care  
1203 including self-care as proposed by AIRWAYS ICPs<sup>53</sup> (Integrated care pathways for airway diseases).  
1204 GRADE-based guidelines for physicians are available for AR and their recommendations are similar<sup>3,</sup>  
1205<sup>5,15</sup>. However, they are based on the assumption that patients regularly use their treatment and are not  
1206 tested with real-life data. Unfortunately, adherence to treatment is very low and real-life studies do not  
1207 necessarily accord with all recommendations<sup>20</sup>. New-generation guidelines embedding real life data  
1208 are being developed.

#### 1209 **4-2-2- Create a guiding coalition**

1210 The ARIA working group initiated in 1999 includes over 500 members in 70 countries<sup>14</sup>. A successful  
1211 coalition working on CM2 has been identified within the group.

1212 The AIRWAYS ICPs coalition was established in 2014 and is part of the European Innovation  
1213 Partnership on Active and Healthy Ageing (DG Santé and DG CNECT)<sup>53</sup>. Moreover, many national  
1214 and European scientific societies (European Academy of Allergy and Clinical Immunology (EAACI),  
1215 European Respiratory Society (ERS) and International Primary Care Respiratory Group (IPCRG)),  
1216 and other patients' organization (European Lung Foundation (ELF), Asthma UK) have joined the  
1217 coalition. It is a WHO GARD (WHO Global Alliance against Chronic Respiratory Diseases)  
1218 demonstration project. Finally, the transfer of innovation of ARIA has been carried out to the  
1219 Reference Sites of the European Innovation Partnership on Active and Healthy Ageing<sup>63</sup>.

1220 This CM2 guiding coalition is already in place in EUFOREA (European Forum for Research and  
1221 Education in Allergy and Airways Diseases, <http://www.euforea.eu>)<sup>66</sup>.

#### 1222 **4-2-3- Develop a vision and strategy**

1223 The vision of ARIA phase 4 is to provide CM2 for AR and asthma multimorbidity in order to develop  
1224 SDM with the ultimate goal of improving AR and asthma control while maintaining quality-of-life  
1225 and reducing costs, using mobile technology and real-time data management to inform decisions.

1226 The strategy for realizing the changes is based on the patient-centered implementation of ICPs<sup>53</sup> using  
1227 IT solutions such as the *Allergy Diary*<sup>6</sup>.

#### 1228 **4-2-4- Communicate the change vision**

1229 The updated vision (CM2) will use the experience of the first CM strategy. It has already been  
1230 discussed among the ARIA CM coalition members and the present paper is the first to be published.  
1231 However, it takes time to address the concerns of all stakeholders, and papers published recently on  
1232 the Allergy Diary may help to convince many. ARIA is involving a maximum number of people to  
1233 deploy the CM vision.

1234 The integration of new paths of understanding health and change is a requirement for the strategy. The  
1235 CM2-model clearly expands and strengthens the potential for actual change to occur and take hold in  
1236 all kinds of organizations and institutions. Supplementary to the ambition of change in existing  
1237 practices and institutions, it is also important to consider the integration of other modes of  
1238 communication and dissemination on the basis of healthy behaviour. A central example is the general  
1239 need to raise the level of health literacy in society. The general public should clearly not be perceived  
1240 simply as “patients waiting for something to happen”. They should have the ability to navigate and  
1241 understand health messages, an essential tool for self-managing wellbeing, even before any actual  
1242 condition or major challenge actually occurs. But to do so, one must consider how to improve this  
1243 health literacy by integrating it much better into the educational system and cultural settings to which  
1244 it applies. This is a very long-term investment in self-care and prevention. A later target audience with  
1245 a higher level of health literacy will naturally also ensure an easier adoption of subsequent health  
1246 messages, possibly using ICT<sup>67</sup>. The basis for understanding is simply enhanced compared to the  
1247 previous scenario. In a similar line of thinking, one could also consider a wider community-oriented  
1248 approach to dissemination. This could also cover social media and self-help groups, as some of the  
1249 later patients would benefit not only from both personal previous experience and knowledge about  
1250 these ailments, but also from a supportive environment, that would be better able to support and help  
1251 these citizens/friends/family members – regardless of age – in their attempt to adapt to new modes of

1252 behavior. This is a wider application of the CM2-model and should also be considered in our work to  
1253 help patients and citizens.

#### 1254 **4-2-5- Empower others to act on the vision**

1255 Organizational processes and structures are in place and are aligned with the overall organizational  
1256 vision. However, we need to continuously check for barriers and for those who are resistant to change  
1257 and focus on the education of both physicians and patients on how to achieve the best outcomes of  
1258 treatment. We are acting proactively to remove the obstacles involved in the process of change.

#### 1259 **4-2-6- Generate short-term wins**

1260 We propose to create new short-term (e.g. 12 months) and medium-term (e.g. 24 months) targets. In  
1261 2018, a high-level meeting organized by POLLAR will approach the *improvement in care pathway*  
1262 design to enhance patient participation, health literacy and self-care through technology-assisted  
1263 'patient activation'. In this meeting, rhinitis and asthma multimorbidity will be used as a model of  
1264 non-communicable disease (Figure 4). Three major aspects of ICPs will be considered: self-care,  
1265 pharmacy care and next-generation guidelines in which the recommendations of the GRADE-  
1266 guidelines on AR<sup>5,15</sup> will be tested in real life using MASK.

#### 1267 **4-2-7- Consolidate gains and produce more change**

1268 Most of the goals of Kotter's change model step-7<sup>12</sup> have been met by the ARIA CM and will be  
1269 further developed in CM2.

## 1270 **Conclusions**

1271

1272 For the past 18 years, ARIA has had the major goal of providing a guide for the diagnosis and  
1273 management of AR and asthma multimorbidity applicable to developing countries<sup>1,2</sup> using the best  
1274 evidence<sup>3-5</sup>. ARIA Phases 1 and 2 were developed in accordance to Kotter's 8 step change model and  
1275 can be used as a model of CM in chronic diseases. However, there are still unmet needs for the  
1276 management of rhinitis and asthma in real life.

1277 A second CM model has been proposed by ARIA Phases 3 and 4. It was initiated by the development  
1278 in 23 countries of an App that showed partly unexpected results. Patients with AR (and possibly with  
1279 asthma) do not follow physicians' advice: they self-medicate. There is an urgent need to harness this  
1280 information and to update our concept of treatment as well as treatment adherence using mobile  
1281 technology and care pathways. This is the goal of ARIA Phase 4 and the second wave of CM.

ACCEPTED MANUSCRIPT



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1467 **Table 1: Examples of planned change management models.** Adapted from (31)

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<b>Lewin (68)</b>	<b>Kotter (12)</b>	<b>Lippitt (32)</b>
<b>Unfreezing</b>	<i>Step 1: Establish a sense of urgency Step 2: Create a guiding coalition Step 3: Develop a vision and strategy</i>	<i>Phase 1: Diagnose the problem Phase 2: Assess motivation and capacity for change Phase 3: Assess change agent's motivation and resources</i>
<b>Moving</b>	<i>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</i>	<i>Phase 4: Select a progressive change objective Phase 5: Choose appropriate role of the change agent</i>
<b>Refreezing</b>	<i>Step 8: Anchor new approaches in the culture and institutionalize the changes</i>	<i>Phase 6: Terminate the helping relationship</i>

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1474 **Figure 1: Change management strategy of ARIA Phases 1 and 2**

1475 ARIA: Allergic Rhinitis and its Impact on Asthma, BAMSE: Barn Allergi Milj. Stockholm Epidemiologi Projektet , EGEA:  
1476 Epidemiological study on the Genetics and Environment of Asthma, bronchial hyperresponsiveness and atopy, GRADE,  
1477 MAS: German Multicenter Allergy Study, MASK: Mobile Airways Sentinel network, MeDALL: Mechanisms of the  
1478 Development of Allergy, SDM: Share decision making, T2: Type 2 immunity

1479 **Figure 2: Links between ARIA and MASK for change management**

1480 AIRWAYS-ICPs: Integrated Care Pathways for airway diseases (European Innovation Partnership on Active and  
1481 Healthy Ageing), WHO CC: World Health Organisation Collaborating Center, DigitalHealthEurope: Digital  
1482 Transformation of Health in Europe (H2020), Euriphi: Better Health and care, economic growth and sustainable  
1483 health systems (H2020), GA<sup>2</sup>LEN: Global Allergy and Asthma European network (FP6), GARD: Global Alliance against  
1484 Chronic Respiratory Diseases, Good Practice of DG Santé: Good Practice on digitally-enabled, integrated, person-  
1485 centred care of the Directorate-General for Health and Food Safety (European Commission), ICP: Integrated care  
1486 pathway, MACVIA-LR: Contre les Maladies Chroniques pour un Vieillissement Actif (European Innovation Partnership  
1487 on Active and Healthy Ageing), MeDALL: Mechanisms of the Development of ALLergy (FP7), POLLAR: Impact of air  
1488 POLLution in Asthma and Rhinitis (EIT Health), SPAL: EU Development and Structural Funds, Sunfrail, Twinning:  
1489 Vigour: (Evidence-Based Guidance to Scale-up Integrated Care in Europe, 3<sup>rd</sup> Health Programme).

1490  
1491 **Figure 3: The Allergy Diary**

1492  
1493 GPDR: General Data Protection Regulation (<https://www.eugdpr.org>)  
1494

1495  
1496 **Figure 4: Change management based on next-generation ICPs**

1497  
1498  
1499  
1500

ACCEPTED MANUSCRIPT

F1

### Current knowledge (2000)

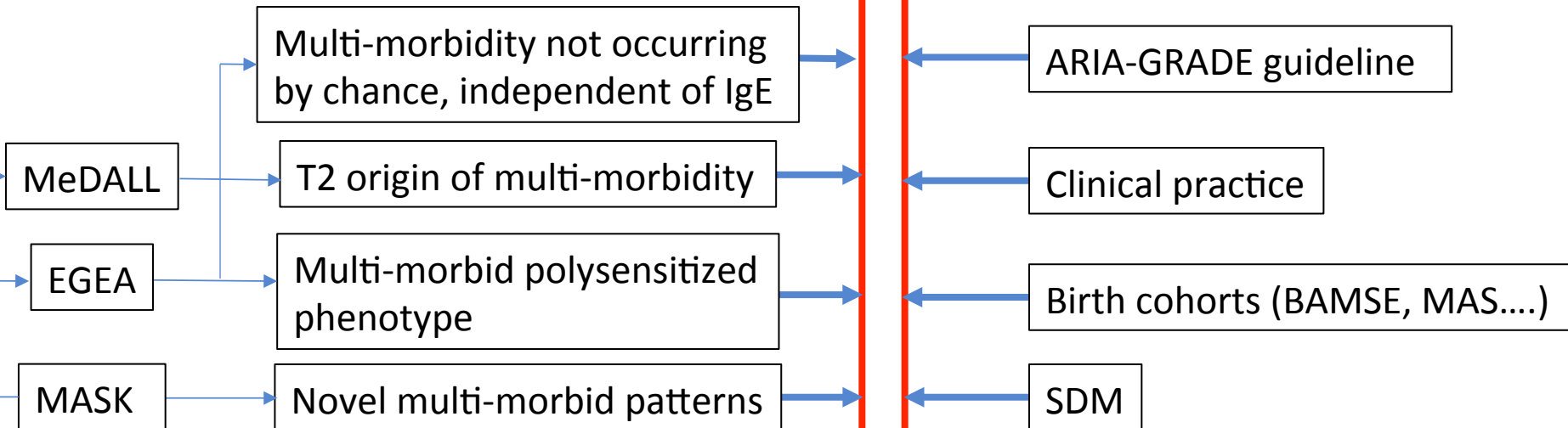
- Clinical practice: allergic multi-morbidity is common and represents a patient's need
  - ECRHS: epidemiologic evidence for allergic multi-morbidity
  - Nasal and bronchial biopsies confirm commonalities in rhinitis and asthma



2000

Mechanistic, epidemiological and clinical studies reinforcing the ARIA multi-morbidity concept

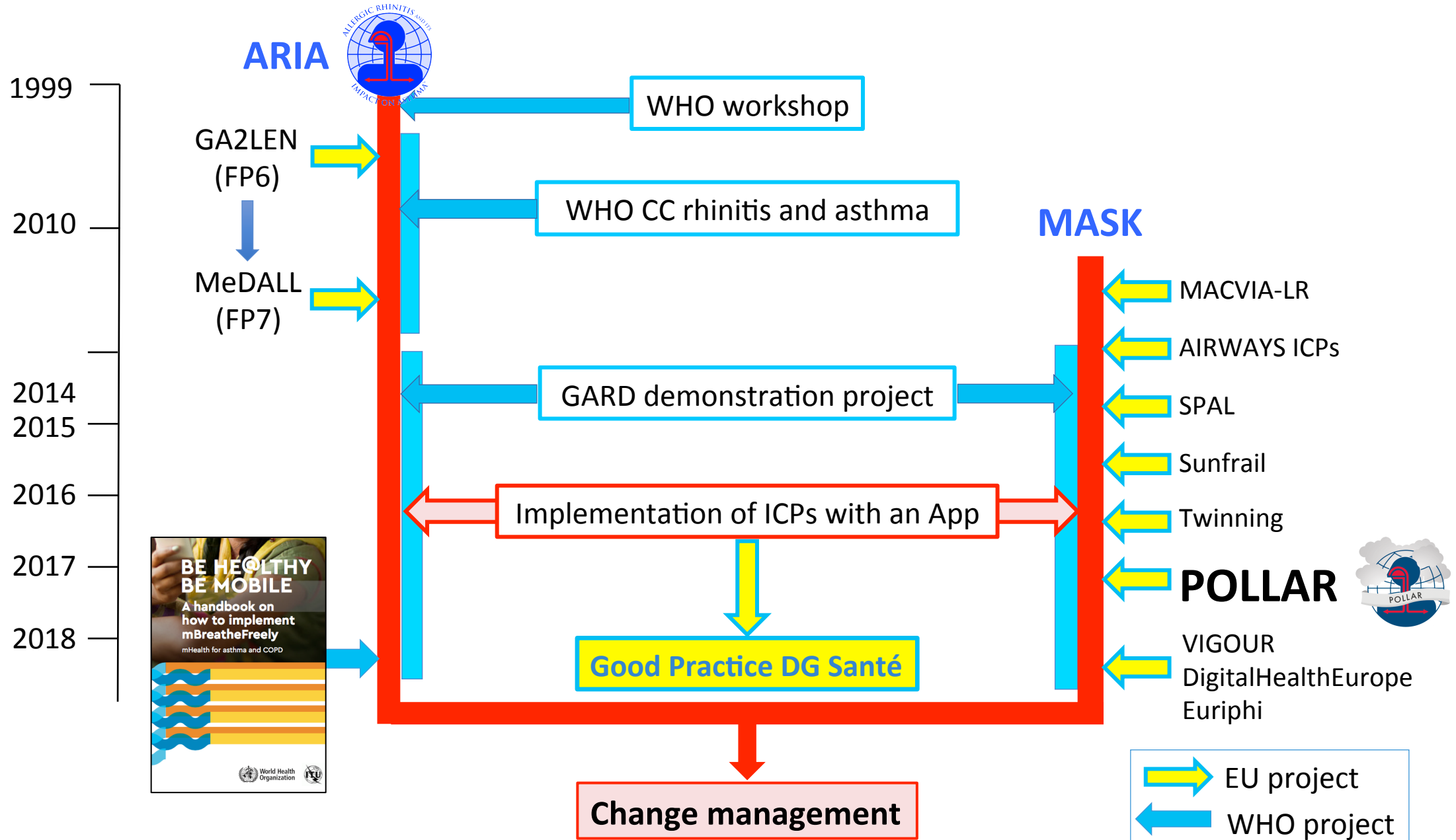
2010



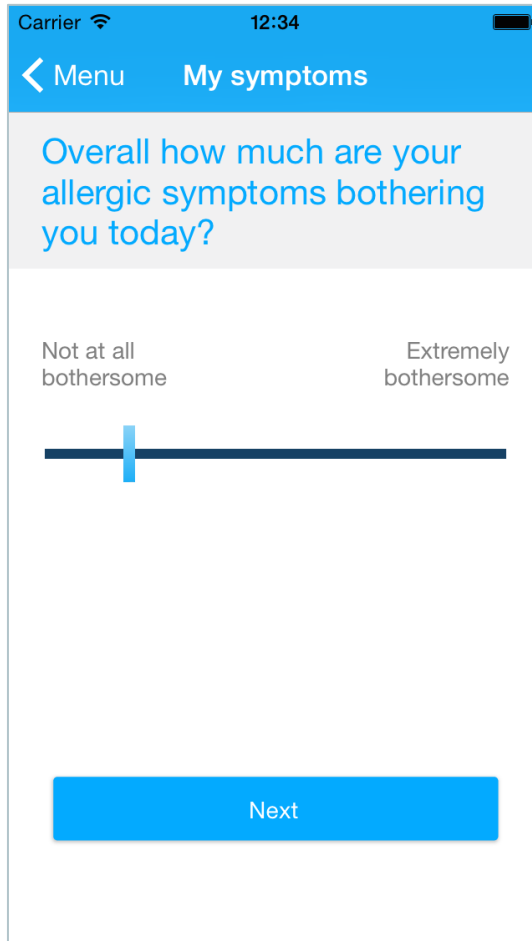
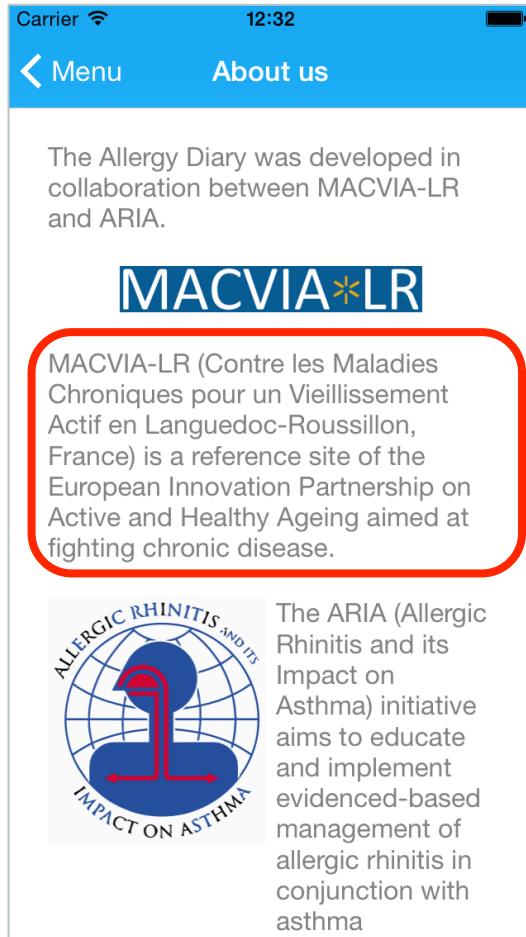
2017

**Change management: allergic multi-morbidity is adopted in clinical practice worldwide**





# The Allergy Diary: MASK-air

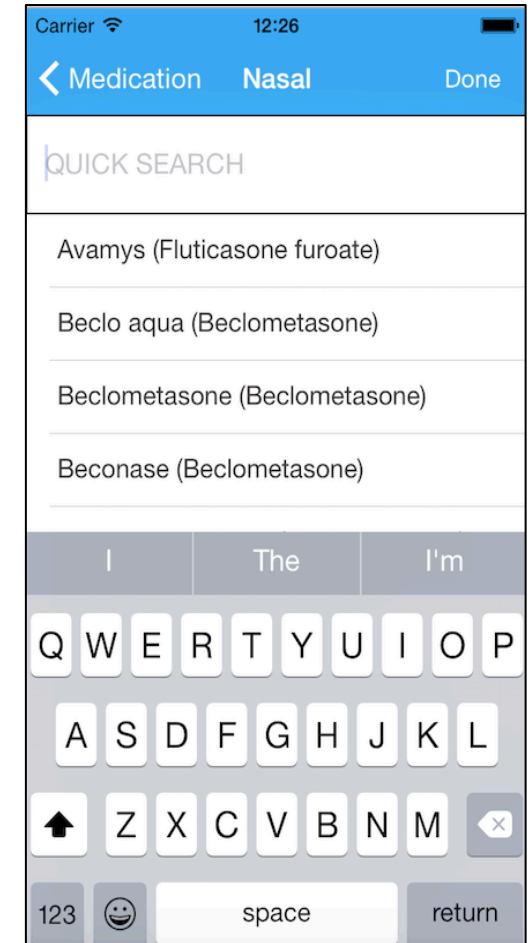


How much are your nose symptoms bothering you today?

How much are your eye symptoms bothering you today?

How much are your asthma symptoms bothering you today?

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**25,000 users**  
**180,000 VAS days**  
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