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Guidance to 2018 good practice:

Citation for published version:

The MASK study group, Bousquet, J, Bedbrook, A, Czarlewski, W, Onorato, GL, Arnavielhe, S, Laune, D, Mathieu-Dupas, E, Fonseca, J, Costa, E, Lourenço, O, Pinnock, H, Ryan, D & Sheikh, A 2019, 'Guidance to 2018 good practice: ARIA digitallyenabled, integrated, personcentred care for rhinitis and asthma', *Clinical and translational allergy*, vol. 9, no. 16. https://doi.org/10.1186/s13601-019-0252-0

Digital Object Identifier (DOI):

10.1186/s13601-019-0252-0

Link:

Link to publication record in Edinburgh Research Explorer

Document Version:

Publisher's PDF, also known as Version of record

Published In: Clinical and translational allergy

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REVIEW

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Guidance to 2018 good practice: ARIA digitally-enabled, integrated, person-centred care for rhinitis and asthma

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Abstract

Aims: Mobile Airways Sentinel Network (MASK) belongs to the Fondation Partenariale MACVIA-LR of Montpellier, France and aims to provide an active and healthy life to rhinitis sufferers and to those with asthma multimorbidity across the life cycle, whatever their gender or socio-economic status, in order to reduce health and social inequities incurred by the disease and to improve the digital transformation of health and care. The ultimate goal is to change the management strategy in chronic diseases.

Methods: MASK implements ICT technologies for individualized and predictive medicine to develop novel care pathways by a multi-disciplinary group centred around the patients.

Stakeholders: Include patients, health care professionals (pharmacists and physicians), authorities, patient's associations, private and public sectors.

Results: MASK is deployed in 23 countries and 17 languages. 26,000 users have registered.

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¹ MACVIA-France, Fondation Partenariale FMC VIA-LR, CHU Arnaud de

EU grants (2018): MASK is participating in EU projects (POLLAR: impact of air POLLution in Asthma and Rhinitis, EIT Health, DigitalHealthEurope, Euriphi and Vigour).

Lessons learnt: (i) Adherence to treatment is the major problem of allergic disease, (ii) Self-management strategies should be considerably expanded (behavioural), (iii) Change management is essential in allergic diseases, (iv) Education strategies should be reconsidered using a patient-centred approach and (v) Lessons learnt for allergic diseases can be expanded to chronic diseases.

Keywords: App, Asthma, Care pathways, MASK, mHealth, Rhinitis, DG Santé

Introduction

In all societies, the burden and cost of allergic and chronic respiratory diseases (CRDs) is increasing rapidly. Most economies are struggling to deliver modern health care effectively. There is a need to support the transformation of the health care system for integrated care with organizational health literacy. MASK (Mobile Airways Sentinel Network) [1] is a new development of the ARIA (Allergic Rhinitis and its Impact on Asthma) initiative [2, 3]. It works closely with POLLAR (Impact of Air POLLution on Asthma and Rhinitis, EIT Health) [4], and collaborates with professional and patient organizations in the field of allergy and airway diseases. MASK proposes real-life care pathways (ICPs) centred around the patient with rhinitis and/or asthma multimorbidity. It uses mHealth monitoring of environmental exposure and considers biodiversity. With the help of three EU projects (DigitalHealthEurope, Eurifi and Vigour) recently accepted on the digital transformation of health, MASK proposes a second change management strategy. The first one was the ARIA change management associated with the recognition and wide acceptance by all stakeholders of the essential links between rhinitis and asthma. The second one deals with change management of care pathways for rhinitis and asthma [5].

In the context of implementing communication on the digital transformation of health and care, specifically in relation to chapter 5 of the document "Digital tools for citizen empowerment and for person-centred care", DG SANTE has taken steps towards supporting the scaling-up and wider implementation of good practices in the field of digitally-enabled, integrated, person-centred care. This work was carried out in collaboration with the newly-established Commission Expert Group, the "Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases".

For this purpose, DG SANTE—in collaboration with the Commission's Joint Research Centre—organized a "marketplace" workshop with the Joint Research Centre in Ispra, the third biggest European Commission site after Brussels and Luxembourg. The aim of this workshop was for representatives from Member States and other countries participating in the 3rd Health Programme to learn more about the 10 good practices and key policy initiatives in the domain of digitally-enabled, integrated, person-centred care, with a view to possible transfer and replication of the presented practices.

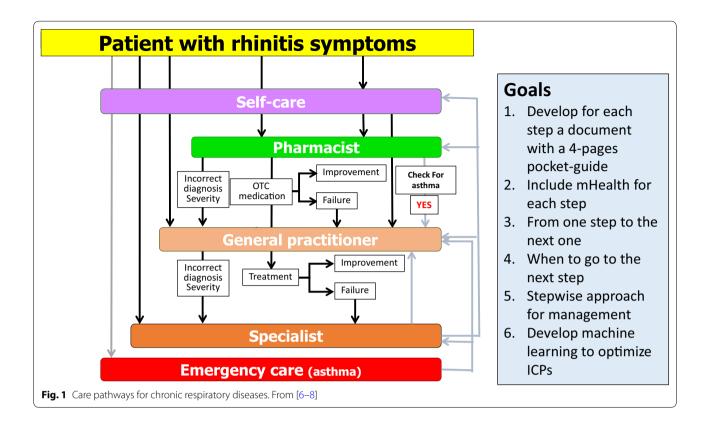
The current paper reviews the questions raised during the workshop concerning the good practice on allergic rhinitis and asthma: ARIA digitally-enabled, integrated, person-centred care for rhinitis and asthma multimorbidity using real-world evidence [1]. This practice is a GARD (Global Alliance against Chronic Respiratory Diseases) demonstration project.

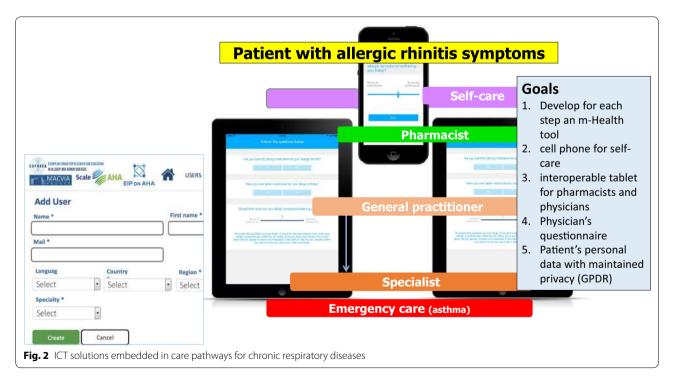
The practice

The practice includes the care pathways defined in 2014 [6-8] (Fig. 1) as well as ICT (Information and Communication Technology) solutions (cell phones for patients, inter-operable tablets for health care professionals and a web-based questionnaire for physicians) [1, 9] (Fig. 2). The aim is to develop a change management strategy for chronic diseases [5].

MASK is a patient-centred ICT system [8]. A mobile phone app (the Allergy Diary, now called MASK-air), central to MASK, is available in 23 countries. It has been validated [10] and found to be an easy and effective method of assessing the symptoms of allergic rhinitis (AR) and work productivity [10–13]. MASK follows the checklist for the evaluation of Good Practices developed by the European Union Joint Action JA-CHRODIS (Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle) [14]. One of the major aims of MASK is to provide care pathways [15] in rhinitis and asthma multimorbidity [16] including a sentinel network using the geolocation of users [17]. It can also inform the App users of the pollen and/ or pollution risk level in their area, by means of geolocation (Table 1).

The practice has been developed for allergic rhinitis (and asthma multimorbidity), being the most common chronic disease globally [18, 19] and affecting all age groups from early childhood to old age. There are several unmet needs that should be addressed in an ICP. Moreover, the lessons learnt will benefit all chronic





diseases since rhinitis is considered as a mild disease although it impairs social life, school and work productivity considerably [20]. It is estimated that, in the EU, work loss accounts for $30-100 \text{ b} \in$ annually. Moreover, it is essential to consider mild chronic diseases and to establish health promotion and management strategies

Table 1 The ICT solution

App (MASK-air) deployed in 23 countries: TRL9 (Technology Readiness level), Electronic clinical decision support system (ARIA e-CDSS): TRL 7, e-physician questionnaire deployed in 16 countries: TRL9 MASK-air good practice [1, 14] 5-year work App: 26,000 users, 23 countries, 17 languages GDPR including geolocation [105] GP of the EIP on AHA, follows CHRODIS [14] Based on 11 EU grants (MeDALL [106], GA²LEN [107]) including—in 2018—POLLAR [4], VIGOUR, DigitalHealthEurope and Euriphi From a validated "research" tool (2004-2018) to large scale deployment (2019-) Validation with COSMIN guidelines [40] Baseline characteristics [12] Work productivity [41, 42] EQ-5D [43] Novel phenotypes of allergic diseases [44] Adherence to treatment and novel approaches to inform the efficacy of treatment [45]. Patient's organizations and scientific societies involved GARD (WHO alliance) Presented during WHO and EU ministerial meetings Next-generation care pathways meeting (Dec 3, 2018) with the EIP on AHA, POLLAR (EIT Health) and GARD 47 MASK papers in 12 languages [99, 108, 109] Dissemination according to the EIP on AHA [26] Transfer of innovation (TWINNING [110]) Interoperable platform with MASK 25 RS plus Argentina, Australia, Brazil, Canada, Mexico [99, 108, 109] 700 patients enrolled GDPR solutions being solved ARIA e-CDSS [9, 111] Interoperable platform with MASK Based on an expert meeting Electronic version available GDPR solutions being solved Developments App for home services App for sleep App for COPD App for other chronic diseases

early in life in order to prevent a severe outcome and to promote healthy ageing [21].

Level of care integration

MASK is used for the integration of primary and specialist care, of primary-secondary-tertiary health care, as well as of health and social care for disease management.

Deployment

Many of the GPs that are developed in one region (country) take into account health systems, availability of treatments and legal considerations which makes it difficult to scale up the practice without customization. MASK has taken the opposite direction starting with a tool immediately available in 10 languages and 14 countries and regularly scaled up. Moreover, the tool is included in a generic ICP (Fig. 2) that can be customized easily in any country globally.

Geographical scope of the practice

MASK was developed in English and is currently available in 23 countries and 17 languages (Table 2).

New countries

Deployment is in process in Bolivia, Colombia, Japan and Peru. The involvement of developing countries is needed to offer a practice for middle- and low-income countries that will benefit poverty areas of developed countries and that will be in line with the mission of GARD. Deployment to the US is being discussed with the National Institute for Allergy and Infectious diseases (NIH).

Transfer of innovation of allergic rhinitis and asthma multimorbidity in the elderly (MASK Reference Site Twinning, EIP on AHA)

The EIP on AHA includes 74 Reference Sites. The aim of this TWINNING is to transfer innovation from the MASK App to other reference sites. The phenotypic characteristics of rhinitis and asthma multimorbidity in adults and the elderly have been compared using validated mHealth tools (i.e. the Allergy Diary and CARAT [22]) in 23 Reference Sites or regions across Europe, Argentina, Australia, Brazil and Mexico [23].

Individuals/institutions reached

ARIA has been implemented in over 70 countries globally [3], and several governments use the practice. Approximately 26,000 users have registered to the MASK database. 700 patients have been enrolled in the Twinning. Due to privacy, there is no possibility of assessing users who have reported data.

Timeframe

The project was initiated in 1999 during a World Health Organization (WHO) workshop (ARIA) and undergoes continuous developments. The ARIA initiative, commenced during a WHO workshop in 1999 [2], has been further developed by the WHO Collaborating Center

Table 2 List of countries using MASK-air

Country/	Dec 🔽	Nov 🔽	Oct 🔽	Sep 🔽	Aug 🔽	July 🔽	June 🔽	May 🔽	April 🔽	March 🔽	Feb 🔽	Jan 🔽
AR	233	229	219	187	133	131	127	122	110	102	85	6
AT	874	869	863	861	856	850	844	795	749	739	727	714
AU	368	357	326	310	294	288	284	269	257	244	232	215
BE	286	281	276	263	255	251	242	217	192	185	179	170
BR	2967	2915	2853	2799	2726	2682	2645	2568	2514	2449	2377	2297
CA	68	68	66	66	60	58	57	51	47	44	42	38
СН	1765	1756	1751	1745	1738	1733	1729	1646	1075	947	930	915
cz	73	71	67	66	65	63	59	51	25	16	8	5
DE	1515	1476	1447	1415	1367	1340	1296	1172	1001	943	884	849
DK	198	196	195	194	192	189	185	173	164	161	160	156
ES	1341	1313	1264	1230	1180	1151	1105	1015	940	885	834	777
FI	642	627	614	605	597	595	581	555	514	503	492	468
FR	1779	1755	1729	1697	1668	1644	1607	1476	1146	1089	1074	1049
GB	1435	1399	1363	1333	1297	1281	1239	1157	1087	1060	1029	988
GR	465	453	432	420	410	406	396	374	353	330	298	282
IT	2617	2570	2522	2490	2463	2445	2419	2348	2222	2159	2114	2057
LT	740	726	711	695	679	675	657	611	533	474	460	424
MX	1566	1537	1497	1461	1357	1324	1285	1234	1175	1135	1050	975
NL	1755	1741	1717	1707	1683	1665	1626	1442	735	677	650	621
PL	1745	1711	1673	1637	1594	1550	1489	1333	1127	1075	1044	1006
РТ	2704	2683	2661	2642	2615	2597	2570	2497	2452	2353	2323	2284
SE	272	265	252	249	237	232	231	214	199	197	190	183
TR	498	477	469	453	435	431	424	408	376	363	331	291
Total	25906	25475	24967	24525	23901	23581	23097	21728	18993	18130	17513	16770

AR Argentina, AT Austria, AU Australia, Be Belgium, BR Brazil, CA Canada, CH Switzerland, CZ Czech Republic, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB Great Britain, GR Greece, IT Italy, LT Lithuania, MX Mexico, NL The Netherlands, PL Poland, PT Portugal, SE Sweden, TR Turkey

for Asthma and Rhinitis (2002–2013). The initial goals (Phase 1) were (1) to propose a new AR classification, (2) to promote the concept of multimorbidity in asthma and rhinitis and (3) to develop guidelines with all stakeholders that could be used globally for all countries and all populations. ARIA has been disseminated and implemented in over 70 countries [3, 19, 24–32]. It was developed as a guideline [19] using the GRADE approach [33–39].

MASK, the Phase 3 ARIA initiative, is focusing on (1) the implementation of multi-sectoral care pathways (2) using emerging technologies (3) with real world data (4) for individualized and predictive medicine (5) in rhinitis and asthma multimorbidity (6) by a multi-disciplinary group or by patients themselves (self-care) using the AIRWAYS ICPs algorithm (7) across the life cycle [8, 17]. It will be scaled up using the EU EIP on AHA strategy [26].

Phase 4 began in 2018. It concerns "change management" and includes the impact of air pollution in asthma and rhinitis (EIT Health 2018–2019: POLLAR, Impact of Air POLLution in Asthma and Rhinitis) [4] as well as the digital transformation of health and care (DigitalHealthEurope, Euriphi and Vigour). Developments for 2019 include a multimorbidity App and the deployment of an app for home services.

The MASK project is intended to be sustainable and a business plan has been initiated.

The medium-term future is to develop care pathways for the prevention and control of chronic diseases to sustain planetary health. A symposium during the Finnish Presidency of the EU Council is planned for October 2019.

Scientific evidence and conceptual framework for configuring the practice

The scientific evidence is based on a validated "research" tool (The Allergy Diary, –2018) that has led to large scale deployment (MASK-air, 2019–):

- Validation of the app using COSMIN guidelines [40].
- Baseline characteristics informed [12].
- Work productivity associated with the control of allergic diseases [41, 42].
- EQ-5D is available and has been found to correlate to baseline characteristics [43].
- Novel phenotypes of allergic diseases have been discovered [44].

• Adherence to treatment is extremely low and novel approaches to inform the efficacy of treatment have been proposed [45] leading to novel studies for a better understanding of guidelines [46, 47].

Evidence of impact

MASK has identified novel phenotypes of allergic diseases [44] that have been confirmed in classical epidemiologic studies by re-analyzing them [48–51]. One of the studies used the MASK baseline characteristics [49]. These phenotypes allowed the re-classification of allergic multimorbidity and the discovery of a new extreme phenotype of allergic diseases that need to be considered in the stratification of patients.

MASK has shown real-life mHealth data for the first time in allergy treatment in 9,950 users [1, 45]. This led to next-generation care pathways for allergic diseases (meeting co-organized by POLLAR, a member of EIT Health, EIP on AHA and GARD (WHO alliance): 3-12-2018) and proposed a change management strategy [5].

MASK is involved in an EIT Health project (POLLAR) which assesses the interactions between air pollution, asthma and rhinitis [4].

With the EIP on AHA, MASK is involved in 3 EU projects on the digital transformation of health and care (DigiHealthEurope, Euriphi and Vigour).

MASK is also involved in a large project on Planetary Health in a side event which will take place during the Presidency of the EU council (Finland). This event will gather researchers, academic leaders and other experts from European institutions as well as other stakeholders and will discuss Planetary Health global challenges and their scientific solutions. Experts on human health as well as on effects of climate change, urbanization and food production will be invited to prepare a European initiative to promote effective and sustainable research on planetary health issues. The event similarly aims at raising political awareness about the need for multidisciplinary and systemic approaches to Planetary Health issues globally and in the EU. The multimorbid App developed by MASK may be used in the project.

Contextual relevance

The practice addresses a public health priority

Chronic respiratory diseases (CRDs) are major non-communicable diseases (NCDs) [18]. Rhinitis and asthma multimorbidity is common and the two diseases should be considered jointly [19]. Asthma is the most common NCD in children and rhinitis is the most common chronic disease in Europe. They often start early in life, persist across the life cycle and cause a high disease burden in all age groups [19]. By 2020, rhinitis will affect at least 20% of the old age population [52-56]. These diseases represent an enormous burden associated to medical and social costs and they impact health and social inequalities.

The practice is based on a local/regional/national strategic action plan

The Polish Presidency of the EU Council (3051st Council Conclusions) made the prevention, early diagnosis and treatment of asthma and allergic diseases a priority to reduce health inequalities [57, 58]. The 3206th Cyprus Council Conclusions [59] recommended that the diagnosis and treatment of chronic diseases should be initiated as early as possible to improve AHA. Debates at the European Parliament recommended the early diagnosis and management of CRDs in order to promote active and healthy ageing (AHA) [60–62].

The practice is also a WHO-associated project: Initial workshop (1999), WHO Collaborating Center for rhinitis and asthma (2004–2014), Global Alliance against Chronic Respiratory Diseases (GARD) [63, 64] demonstration project (2015–).

Unmet needs

Several unmet needs have been identified in allergic diseases. They include (1) suboptimal rhinitis and asthma control due to medical, cultural and social barriers [65, 66], (2) better understanding of endotypes [67], phenotypes and multimorbidities, (3) assessment of allergen and pollutants as risk factors to promote sentinel networks in care pathways, (4) stratification of patients for optimized care pathways [68] and (5) promotion of multidisciplinary teams within integrated care pathways, endorsing innovation in clinical trials and encouraging patient empowerment [17, 69].

Overall goal

The general objective of AIRWAYS-ICPs [6–8] is to develop multi-sectoral ICPs for CRDs used across European countries and regions in order to (1) reduce the burden of the diseases in a patient-centred approach, (2) promote AHA, (3) create a care pathways simulator tool which can be applied across the life cycle and in older adults, (4) reduce health and social inequalities, (5) reduce gender inequalities, (6) use the lessons learned in CRDs for chronic diseases and (7) promote SDG3 (more specifically 3.4) (https://www.who.int/ sdg/targets/en/). In September 2015, the UN General Assembly established the Sustainable Development Goals (SDGs), a set of global goals for fair and sustainable health at every level from planetary biosphere to local community [70, 71], essential for sustainable development. SDG 3 prioritizes health and well-being for all ages.

The aim of AIRWAYS-ICPs is also to generalise the approach of the uniform definition of severity, control and risk of severe asthma presented to WHO [66] and allergic diseases [72] in order to develop a uniform risk stratification usable for chronic diseases in most situations.

MASK further refined AIRWAYS ICPs using mobile technology to promote the digital transformation of health and care in developed and developing countries for all age groups.

Target population

In the initial phase, the target population included all patients with allergic rhinitis and asthma multimorbidity. Rhinitis and asthma are considered as a model for all chronic diseases and the project is being extended to chronic diseases.

All patients able to use a smartphone (\geq 12 years) represent the target population. A special effort is being placed in underserved populations from developing countries as the practice is a GARD (Global Alliance against Chronic Respiratory Diseases, WHO alliance) demonstration project.

Stakeholders involved

Involvement in the design, implementation (including the creation of ownership), evaluation, continuity/ sustainability

As from the very first workshop in 1999, the ARIA initiative has included all stakeholders required to develop a WHO programme on CRDs (GARD). In particular, patient's organizations were involved. All health care professionals were also involved (physicians, primary care, pharmacists, other health care professionals). Another important component of ARIA was the deployment to developing countries [73]. Moreover, policy makers were also actively involved.

ARIA has grown regularly over the past 20 years and an ARIA chapter is ongoing in over 70 countries in all continents with a very active scaling up strategy [26]. MASK has used the ARIA working group to scale up the practice.

All stakeholders were highly receptive

The ARIA and now the MASK community is very cohesive and all members are extremely reactive. They have been particularly active in deploying MASK in the 23 countries and we have received requests from many other countries in which MASK-air is not yet available.

Resistance or conflict of interest: None

Implementation methodology/strategy

We used the scaling up strategy of the European Innovation Partnership on Active and Healthy Ageing and proposed a 5-step framework for developing an individual: (1) what to scale up: (1-a) databases of good practices, (1-b) assessment of viability of the scaling up of good practices, (1-c) classification of good practices for local replication and (2) how to scale up: (2-a) facilitating partnerships for scaling up, (2-b) implementation of key success factors and lessons learnt, including emerging technologies for individualized and predictive medicine. This strategy has already been applied to the chronic respiratory disease action plan of the European Innovation Partnership on Active and Healthy Ageing [26].

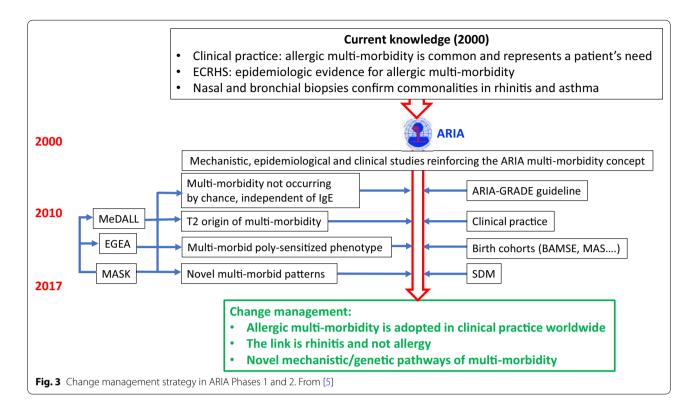
Consistency in the pace of delivery

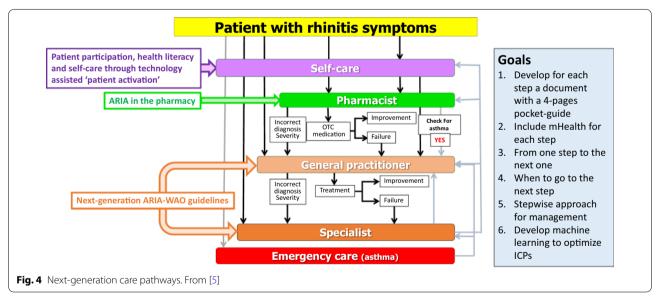
For the past 20 years, ARIA has been a success story in over 72 countries [3, 8, 19, 24, 25, 27, 28, 30–32, 38, 46, 74–100]. A Pocket Guide has been translated into 52 languages. MASK is following ARIA with the same group and the same strategy.

Main outcomes and evaluation of the practice

The ARIA strategy was to change management in the treatment of asthma and rhinitis since nasal symptoms-often the most troublesome-were not considered in most asthmatics. Over 85% of asthma in children and adolescents is associated with rhinitis, suggesting common pathways, whereas only 20-30% of rhinitis patients have asthma, suggesting rhinitisspecific genes. There is a link between asthma severity and rhinitis multimorbidity. Asthma is more severe in patients with rhinitis [101]. The strategy at all levels of care indicates that it is essential to consider multimorbidity in the management of asthma for the benefit of the patient and the satisfaction of the treatment as shown in many surveys (Fig. 3). Some studies have found that the ARIA strategy is more effective than free treatment choice [102]. Moreover, EMA has used the ARIA recommendations for the approval of a house dust mite immunotherapy tablet including asthma and rhinitis multimorbidity [103].

The change management strategy of MASK has not yet been evaluated. However, the results of the first studies indicate that the vast majority of patients are not adherent to treatment [45] and that nextgeneration care pathways are needed (Figs. 4 and 5).





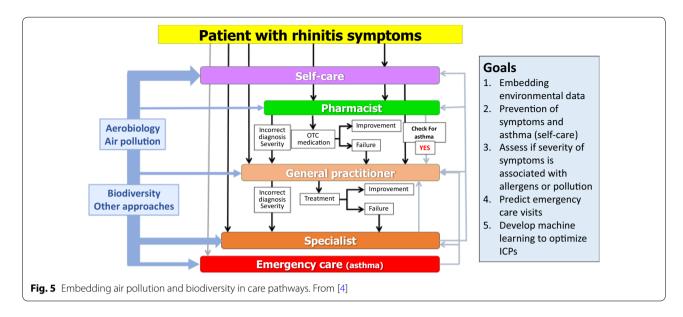
Next-generation care pathways were initiated in Paris, December 3, 2018, as part of POLLAR, MASK and GARD.

Additional (secondary) outcomes assessed

Work productivity and school performance are measured. When rhinitis and/or asthma are not well controlled, work productivity is impaired [1, 41, 43].

Sustainability of the practice

The MASK App, The *Allergy Diary*, was used to demonstrate the scientific value of the project [1]. It has been replaced by the commercial App, MASK-air, which is version 3.0 and which includes questionnaires (e.g. tobacco and allergens) and sleep (VAS and Epworth questionnaire [104]) (Fig. 6). A business plan is in place for the sustainability of the practice.





Communication about the practice and dissemination of results

A communication strategy has been set up [1] and includes a website (mask-air.com), media coverage, leaflets and newsletters, publications in scientific journals and lay press, partners' networks and events. The MASK community includes over 300 members in all countries in which MASK is deployed.

Budget required to implement the practice

The budget required to implement the MASK strategy is around 1.5 M \in . It will be provided by the private sector (1 M \in) and from EU grants, in particular a Structural and Development Fund. POLLAR has an additive budget of 2 M \in to embed outdoor air pollution and aerobiology data in the ICP using artificial intelligence.

It is difficult to estimate human resources since many physicians worked in the 23 countries for the translation,



adaptation of the practice and its implementation. It can be proposed that 50–100 h have been spent working in each country.

The practice has been presented to multiple national and international meetings.

Sustainability has been carefully evaluated and a business plan is in place.

Main lessons learned

- Adherence to treatment is the major problem of allergic disease.
- Self-management strategies should be considerably expanded (behavioural).
- Change management is essential in allergic diseases.
- Education strategies should be reconsidered using a patient-centred approach.
- Lessons learned for allergic diseases can be expanded to chronic diseases.

Improvement and expansion of the practice

An expert meeting took place at the Pasteur Institute in Paris, December 3, 2018, to discuss nextgeneration care pathways and lessons learnt (Fig. 7, Annex 1): (1) patient participation, health literacy and self-care through technology-assisted "patient activation", (2) implementation of care pathways by pharmacists and (3) next-generation guidelines assessing the recommendations of GRADE guidelines in rhinitis and asthma using real-world evidence (RWE) assessed by mobile technology. The meeting was organized by POLLAR and MASK in collaboration with GARD, patient's organizations and all European scientific societies in the field.

Abbreviations

AHA: active and healthy ageing; AIRWAYS ICPs: integrated care pathways for airway diseases; AR: allergic rhinitis; ARIA: allergic rhinitis and its impact on asthma; CDSS: clinical decision support system; CRD: chronic respiratory disease; DG CONNECT: directorate general for communications networks, content and technology; DG Santé: directorate general for health and food safety; EIP on AHA: European innovation partnership on AHA; EIP: European innovation partnership; EQ-5D: euroquol; Euforea: European forum for research and education in allergy and airways diseases; GARD: global alliance against chronic respiratory diseases; GP: good practice; HCP: health care professional; ICP: integrated care pathway; JA-CHRODIS: joint action on chronic diseases and promoting healthy ageing across the life cycle; MACVIA-LR: contre les MAladies chroniques pour un Vleillissement Actif (Fighting chronic diseases for AHA); MASK: Mobile airways sentinel networK; MeDALL: Mechanisms of the development of ALLergy (FP7); mHealth: mobile health; NCD: non-communicable disease; POLLAR: impact of air POLLution on Asthma and Rhinitis; QOL: quality of life; TRL: technology readiness level; VAS: visual analogue scale; WHO: World Health Organization; WPAI-AS: Work Productivity and Activity questionnaire.

Authors' contributions

All authors are MASK members and have contributed to the design of the project. Many authors also included users and disseminated the project in their own country. All authors read and approved the final manuscript.

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Acknowledgements

Practice presented during the Steering Group on Promotion and Prevention marketplace workshop on "digitally-enabled, integrated, person-centred care" best practices on 12–13 December 2018 in the premises of the Joint Research Centre in Ispra, Italy.

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Competing interests

Dr. Ansotegui reports personal fees from Mundipharma, Roxall, Sanofi, MSD, Faes Farma, Hikma, UCB, Astra Zeneca, outside the submitted work. Dr. Bosnic-Anticevich reports grants from TEVA, personal fees from TEVA, Boehringer Ingelheim, AstraZeneca, Sanofi, Mylan, outside the submitted work. Dr Bousquet reports personal fees and others from Chiesi, Cipla, Hikma, Menarini, Mundipharma, Mylan, Novartis, Sanofi-Aventis, Takeda, Teva, Uriach, others from Kyomed, outside the submitted work. Dr. Boulet reports and Disclosure of potential conflicts of interest-last 3 years research grants for participation to multicentre studies, AstraZeneca, Boston Scientific, GlaxoSmithKline, Hoffman La Roche, Novartis, Ono Pharma, Sanofi, Takeda.Support for research projects introduced by the investigator AstraZeneca, Boehringer-Ingelheim, GlaxoSmithKline, Merck, Takeda. Consulting and advisory boards Astra Zeneca, Novartis, Methapharm. Royalties Co-author of "Up-To-Date" (occupational asthma). Nonprofit grants for production of educational materials Astra-Zeneca, Boehringer-Ingelheim, GlaxoSmithKline, Merck Frosst, Novartis. Conference fees AstraZeneca, GlaxoSmithKline, Merck, Novartis. Support for participation in conferences and meetings Novartis, Takeda. Other participations Past president and Member of the Canadian Thoracic Society Respiratory Guidelines Committee; Chair of the Board of Directors of the Global Initiative for Asthma (GINA). Chair of Global Initiative for Asthma (GINA) Guidelines Dissemination and Implementation Committee; Laval University Chair on Knowledge Transfer, Prevention and Education in Respiratory and Cardiovascular Health; Member of scientific committees for the American College of Chest Physicians, American Thoracic Society, European Respiratory Society and the World Allergy Organization;1st Vice-President of the Global Asthma Organization "InterAsma". Dr. Casale reports grants and non-financial support from Stallergenes, outside the submitted work. Dr. Cruz reports grants and personal fees from GlaxoSmithKline, personal fees from Boehrinher Ingelheim, AstraZeneca, Novartis, Merk, Sharp & Dohme, MEDA Pharma, EUROFARMA, Sanofi Aventis, outside the submitted work. Dr. Ebisawa reports personal fees from DBV Technologies, Mylan EPD maruho, Shionogi & CO., Ltd., Kyorin Pharmaceutical Co., Ltd., Thermofisher Diagnostics, Pfizer, Beyer, Nippon Chemifar, Takeda Pharmaceutical Co., Ltd., MSD, outside the submitted work. Dr. Ivancevich reports personal fees from Euro Farma Argentina, Faes Farma, non-financial support from Laboratorios Casasco, outside the submitted work. Dr. Haahtela reports personal fees from Mundipharma, Novartis, and Orion Pharma, outside

the submitted work. Dr. Klimek reports grants and personal fees from ALK Abelló, Denmark, Novartis, Switzerland, Allergopharma, Germany, Bionorica, Germany, GSK, Great Britain, Lofarma, Italy, personal fees from MEDA, Sweden, Boehringer Ingelheim, Germany, grants from Biomay, Austria, HAL, Netherlands, LETI, Spain, Roxall, Germany, Bencard, Great Britain, outside the submitted work. V.KV has received payment for consultancy from GSK and for lectures from StallergensGreer, Berlin-CHemie and sponsorship from MYLAN for in the following proffesional training: ARIA masterclass in allergic rhinitis participation. Dr. Larenas Linnemann reports personal fees from GSK, Astrazeneca, MEDA, Boehringer Ingelheim, Novartis, Grunenthal, UCB, Amstrong, Siegfried, DBV Technologies, MSD, Pfizer., grants from Sanofi, Astrazeneca, Novartis, UCB, GSK, TEVA, Chiesi, Boehringer Ingelheim, outside the submitted work. Dr. Mösges reports personal fees from ALK, grants from ASIT biotech, Leti, BitopAG, Hulka, Ursapharm, Optima; personal fees from allergopharma, Nuvo, Meda, Friulchem, Hexal, Servier, Bayer, Johnson&Johnson, Klosterfrau, GSK, MSD, FAES, Stada, UCB, Allergy Therapeutics; grants and personal fees from Bencard, Stallergenes; grants, personal fees and non-financial support from Lofarma; non-financial support from Roxall, Atmos, Bionorica, Otonomy, Ferrero; personal fees and non-financial support from Novartis; Dr. Okamoto reports personal fees from Eizai Co., Ltd., Shionogi Co., Ltd., Torii Co., Ltd., GSK, MSD, Kyowa Co., Ltd., grants and personal fees from Kyorin Co., Ltd., Tiho Co., Ltd., grants from Yakuruto Co., Ltd., Yamada Bee Farm, outside the submitted work. Dr. Papadopoulos reports grants from Gerolymatos, personal fees from Hal Allergy B.V., Novartis Pharma AG, Menarini, Hal Allergy B.V., outside the submitted work. Dr. Pépin reports grants from AIR LIQUIDE FOUNDATION, AGIR à dom, ASTRA ZENECA, FISHER & PAYKEL, MUTUALIA, PHILIPS, RESMED, VITALAIRE, other from AGIR à dom, ASTRA ZENECA, BOEHRINGER INGEL-HEIM, JAZZ PHARMACEUTICAL, NIGHT BALANCE, PHILIPS, RESMED, SEFAM, outside the submitted work. Dr. Pfaar reports grants and personal fees from ALK-Abelló, Allergopharma Stallergenes Greer, HAL Allergy Holding B.V./HAL Allergie GmbH, Bencard Allergie GmbH/Allergy Therapeutics, Lofarma, grants from Biomay, ASIT Biotech Tools S.A, Laboratorios LETI/LETI Pharma, Anergis S.A., grants from Nuvo, Circassia, Glaxo Smith Kline, personal fees from Novartis Pharma, MEDA Pharma, Mobile Chamber Experts (a GA²LEN Partner), Pohl-Boskamp, Indoor Biotechnologies, grants from, outside the submitted work. Dr. Todo-Bom reports grants and personal fees from Novartis, Mundipharma, GSK Teva Pharma, personal fees from AstraZeneca, grants from Leti, outside the submitted work. Dr. Tsiligianni reports advisory boards from Boehringer Ingelheim and Novartis and a grant from GSK, outside the submitted work. Dr. Wallace reports and Indicates that she is the co-chair of the Joint Task Force on Practice Parameters, a task force composed of 12 members of the American Academy of Allergy, Asthma, and Immunology and the American College of Allergy, Asthma, and Immunology. Dr. Waserman reports other from CSL Behring, Shire, AstraZeneca, Teva, Meda, Merck, outside the submitted work. Dr. Zuberbier reports and Organizational affiliations: Commitee member: WHO-Initiative "Allergic Rhinitis and Its Impact on Asthma" (ARIA). Member of the Board: German Society for Allergy and Clinical Immunology (DGAKI). Head: European Centre for Allergy Research Foundation (ECARF) Secretary General: Global Allergy and Asthma European Network (GA²LEN). Member: Committee on Allergy Diagnosis and Molecular Allergology, World Allergy Organization (WAO).

Availability of data and materials

Not applicable.

Consent for publication

Not applicable.

Ethics approval and consent to participate Not applicable.

Funding

FMC VIA LR.

Publisher's Note

Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.

Received: 11 January 2019 Accepted: 4 February 2019 Published online: 11 March 2019

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