ARIA digital anamorphosis: Digital transformation of health and care in airway diseases from research to practice

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481

482 **Short title : Digital transformation of care in rhinitis**

483

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492 **Abstract**

493 Digital anamorphosis is used to define a distorted image of health and care that may be viewed correctly
494 using digital tools and strategies. MASK digital anamorphosis represents the process used by MASK to
495 develop the digital transformation of health and care in rhinitis. It strengthens the ARIA change
496 management strategy in the prevention and management of airway disease. The MASK strategy is based on
497 validated digital tools. Using the MASK digital tool and the CARAT online enhanced clinical framework,
498 solutions for practical steps of digital enhancement of care are proposed.

499

500 **Key words:** asthma, digital transformation of health and care, rhinitis, MASK, ARIA, CARAT

501

502 **Abbreviations**

503 AIRWAYS-ICPs: Integrated care pathways for airway diseases
504 AIT: Allergen immunotherapy
505 AR: Allergic rhinitis
506 ARIA: Allergic Rhinitis and its Impact on Asthma
507 CARAT: Control of Allergic Rhinitis and Asthma Test
508 CDSS: Clinical decision support system
509 DB-PC-RCT: Double-blind, placebo-controlled, randomized trial
510 EFA: European Federation of Allergy and Airways Diseases Patients' Association
511 EIP on AHA: European Innovation Partnership on Active and Healthy Ageing
512 EIT: European Institute for Innovation and Technology
513 EQ5D: Euroquol
514 EU: European Union
515 GA^{2}LEN: Global Allergy and Asthma European network
516 GARD: Global Alliance against Chronic Respiratory Diseases
517 GRADE: *Grading* of *Recommendations* Assessment, Development and Evaluation
518 ICP: Integrated care pathway
519 IT: Internet technology
520 JA-CHRODIS: Joint Action on Chronic Diseases and Promoting Healthy Ageing across the Life Cycle
521 MACVIA: Fighting chronic diseases for active and healthy ageing
522 MASK-air®: (formerly Allergy Diary)
523 MASK: Mobile Airways Sentinel NetworK
524 MeDALL: Mechanisms of the Development of Allergy

525   POLLAR: Impact of air POLLution on Asthma and Rhinitis

526   QOL: Quality-of-life

527   RCT: Randomized controlled trials

528   RWD: Real-world data

529   RWE: Real-world evidence

530   SCIT: Subcutaneous immunotherapy

531   SLIT: Sublingual immunotherapy

532   SMS: Symptom-medication score

533   TRL: Technology Readiness Level

534   TWINNING: Transfer of Innovation

535   WHO: World Health Organization

536

Introduction

Anamorphosis - from the Greek *αναμόρφωση: transformation* - is used in several fields to describe the transformation of a distorted object (e.g. painting, architecture, entomology, biology). Digital technology reveals the day-to-day experience of patients and provides a new type of information that – when properly collected and interpreted - will restore the real expression of the disease. In this paper, anamorphosis is used to define a distorted image of health and care that may be viewed correctly using digital tools and strategies.

The strategic overview (Table 1, Figure 1 online) and the vision of MASK included several considerations (Table 2). The disease burden and the healthcare costs for people with allergic and chronic respiratory diseases are increasing rapidly (1). The transformation of the healthcare system for integrated care through leveraging developments in digital health is urgently needed (2). The term "digital health" includes advanced medical technologies, disruptive innovations and digital communication tools aiming to provide best practice healthcare (3). Smart devices and internet-based applications are largely used in airway diseases and are likely to address certain unmet needs (4). However, these new tools need to be tested: (i) for privacy rules, security, and legislation of the Medical Device Regulation (May 2020); (ii) for acceptability, usability and cost-effectiveness (5) and (iii) for validity. They should then be evaluated in the frame of the overall digital transformation of health and care, their impact on healthcare delivery as well as health outcomes. mHealth tools and strategies enabling the digital transformation of health and care, empowering citizens and building a healthier society represent a novel important step in health care. However, a practical integrated approach is required.

In 2014, on behalf of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) (6), AIRWAYS ICPs (Integrated Care Pathways for airway diseases) was initiated (7, 8). The objective was to launch a collaboration to develop multi-sectoral care pathways (ICPs) for chronic respiratory diseases in European countries and beyond as a Global Alliance Against Respiratory Diseases (GARD) demonstration project (Figure 1). MASK (Mobile Airways Sentinel NetworK) is the mHealth strategy of AIRWAYS ICPs and ARIA (9). It was based on the ARIA study group existing in 92 countries. MASK is deployed in 26 countries and 17 languages. MASK, as a practical ICT integrated approach, was initially developed as an app (MASK-air®) and is now an e-platform for allergic diseases and asthma.

The Control of Allergic Rhinitis and Asthma Test (CARAT) is a Patient-Reported Outcome that assesses the level of control of both asthma and AR using a single tool (10). It enables the implementation of the ARIA recommendations in the simultaneous assessment and management of both allergic rhinitis (AR) and asthma (11).

569 This paper proposes the ARIA change management strategy in the prevention and management of airway
570 disease (12). MASK digital anamorphosis represents the process used by MASK to develop the digital
571 transformation of health and care in rhinitis. It also strengthens ARIA change management. Using the
572 MASK digital tool and the CARAT online enhanced clinical framework, solutions for each practical step of
573 digital enhancement of care are provided.

574 ## Digital transformation of health and care in rhinitis and asthma

575 ## multimorbidity

576 ### The MASK e-platform

577 MASK, the Phase 3 ARIA (Allergic Rhinitis and its Impact on Asthma) initiative (11, 13) is a Good
578 Practice of DG Santé for digitally-enabled, patient's centered care (14). It has been developed from the
579 MASK-air® app to a flexible e-platform for allergic diseases and asthma. It includes: (i) a freely available
580 app (MASK-air®, formerly the Allergy Diary, Android and iOS) (13), (ii) tools to support health care
581 professionals in shared decision making through an interoperable electronic decision support system (e-
582 CDSS) (15), (iii) a web-based interoperable questionnaire for physicians (16), (iv) a questionnaire on
583 asthma and rhinitis (CARAT) for screening allergic diseases and assessing their control and (v) a sentinel
584 network for air quality and pollen seasons. Other tools can be added when needed.

585 The maturity level of the MASK Good Practice is presented in Table 3, and Table 1 online.

586 MASK is scaled up using the European Innovation Partnership on Active and Healthy Ageing (EIP on
587 AHA) strategy (16, 17).

588 ### MASK-air®

589 #### Characteristics

590 MASK-air® is an ICT (Information and Communication Technology) system centered around the patient
591 (18). It is operational in 25 countries and 18 languages. It uses a treatment scroll list which includes all of
592 the medications customized for each country. Furthermore, a visual analogue scale (VAS) assesses rhinitis
593 control (global allergy impact, nose, eyes, asthma), sleep and work productivity (19, 20). MASK-air® is
594 combined with prediction on allergen season and air quality (POLLAR: Impact of POLLution on Asthma

595 and Rhinitis, EIT Health-funded project) (21). MASK is available in 26 countries and 17 languages
596 including some middle-income countries (Table 2 online). Patients' organizations and scientific societies
597 are involved.

598 **Privacy, General Data Protection Regulation (GDPR) and Medical Device**
599 **Regulation (MDR)**

600 The General Data Protection Regulation (GDPR) regulates the processing of personal data in the European
601 Union (EU) (22, 23). MASK-air® follows the five main principles of personal data protection to be
602 respected during the development of the app: purpose, proportionality and relevance, limited retention
603 period, security and confidentiality, as well as the rights of the people who are involved in the management
604 of the personal data (including withdrawal and modification) (24). Moreover, MASK-air® uses k-
605 anonymity for geolocation (25). A double encription database has been set up.

606 MASK-air® is currently a Class 1 Medical Device but it will be upgraded to Class 2A with the new MDR to
607 be enforced in the EU in May 2020 (26).

608 **Validation**

609 There are absolute pre-requisites for the launch of an app. They include:
610 • Questions of MASK-air® were validated by patients (Madopa and STIMCO, unpublished) and are
611   easily understood by patients in different countries.
612 • MASK-air® followed COSMIN (COnsensus-based Standards for the selection of health Measurement
613   Instruments) guidelines (27).
614 • The independence of data has been confirmed (28).
615 • Translations have been validated using a back translation.
616 • MASK-air® has been implemented in the different situations in which it is used (14, 15, 18, 24, 27-37)
617 .

618 **CARAT**

619 CARAT (Control of Allergic Rhinitis and Asthma Test) is a validated questionnaire that can summarize the
620 clinical status of asthma and rhinitis (multimorbidity) of the previous 4 weeks. It complements the
621 frequent/daily self-assessment in the MASK-air app and the physician's clinical assessment.

Characteristics

The CARAT questionnaire has two domains: allergic rhinitis and asthma and 10-items regarding symptoms, sleep, activities and drug use within the past 4 weeks (38). CARAT's minimal clinically important difference can detect change over time (high responsiveness) (39). CARAT supports shared decisions between the patient and the physician as well as within the healthcare team. CARAT has been used in 19 countries globally including developing countries (40).

CARAT can be used in a range of different aims: (i) screening of patients with rhinitis or asthma in different setting including pharmacies (41), (ii) follow-up consultations together with lung function (42), (iii) patient self-management (43) and (iv) identifying patients with uncontrolled asthma at pharmacies (41). It should increase awareness of the level of disease control and strengthen the partnership between patients and doctors in the management of asthma and rhinitis by helping to define shared treatment goals.

CARAT has been used in epidemiology and clinical research (44): it has been included in international multicentre studies, such as the technology transfer of innovative practices (Twinning) project (16) and the observational longitudinal multicentre prospective study, the "@IT2020" study (45). CARAT has been implemented as a mHealth tool in several smartphone applications including MASK-air (18), InspirerMundi (46), the Adolescent Adherence Patient Tool (ADAPT) app (47), and Lung Manager (48).

Validation

CARAT has been thoroughly studied in cross-sectional and prospective studies conducted at all levels of MASK Care Pathways. It meets all COSMIN criteria for patient reported outcome (49).

CARAT has been used in clinical studies and in clinical practice. It has enabled comparison between groups as well as evaluation of individual patients over time (10, 38). The questionnaire has been deployed in patient care and/or research. CARAT has been implemented in different settings (Pharmacies, Primary Care, Secondary Care, epidemiology and clinical research) and technologies including mHealth tools (18, 41, 44, 46, 47, 50-52), but also in severe asthma in specialists (53).

New functionalities

CARAT has the potential to evolve to further strengthen multimorbidity assessment and to focus on more severe patients. This change can be carried out simply by reassessing questions that were excluded during the initial developing process (10). In particular, eye symptoms should be included as, within the

650 asthma-rhinitis multimorbidity, they are associated with more severe phenotypes as demonstrated by the
651 MASK-air app (33) and confirmed by an epidemiologic study with full medical observation (40).

Electronic clinical decision support system (eCDSS) for rhinitis

653 The interoperable electronic decision support system (eCDSS) (15) is based on an algorithm designed by
654 the ARIA expert group (54) and validated using real-world evidence (55). This eCDSS is to be used on
655 tablets by pharmacists and physicians.

Web-based physician's questionnaire for rhinitis and asthma

657 An interoperable questionnaire for physicians is available online on the Euforea website
658 (https://www.euforea.eu). Around 1,000 patients have been enrolled in the rhinitis-TWINNING using the
659 questionnaire. They are then followed up using the MASK-air® app (16).

Sentinel network for air quality and pollen prediction

661 POLLAR confirmed the interactions between air pollution, asthma and rhinitis in order to propose the
662 prediction of these environmental factors in MASK-air® (21, 36). It uses the MASK-air® app combined
663 with a new tool allowing queries on pollen and air quality, in geolocalized patients. Allergic symptoms of
664 the MASK-air® app are integrated with the Symptom Forecasting Model developed within the PASYFO
665 project of Copernicus Atmospheric Monitoring Service, which also supplies the meteorological, air quality
666 and pollen information for Europe. Additional pollen and global air quality forecasts are generated by the
667 SILAM model of the Finnish Meteorological Institute (FMI) (56-58). Machine learning will be used to
668 assess the relationship between air pollution, AR and asthma to further refine the prediction.

Patients' views

670 Many patients do not understand the needs and benefits of mHealth and may worry about data privacy
671 (Table 3). Thus, the uptake of mHealth is slow. On the other hand, too many patients over-rely on internet-
672 based information and on untested mHealth solutions. This attitude may have dangerous implications since
673 patients may receive an incorrect diagnosis or management strategy.

674   **Features required to satisfy patients.**

675   A qualitative study was carried out by MADOPA in 2016 for MASK to better understand the patients'
676   needs and expectations (Table 4).

677   **Implementation and communication strategy for patients**

678   Without a communication strategy, the app will not be largely used. However, the communication plan will
679   only be put in place for 2020 once the POLLAR module has been added. Documents are available in 17
680   languages and can be downloaded from the MASK website (https://www.*mask-air.com)*. They include
681   leaflets for patients, physicians and pharmacists as well as other documents. In Mexico, this strategy was
682   found to be effective. It will be deployed to other countries.

683   The communication strategy must involve local patient's organizations. It will be deployed with
684   the patients' organization EFA. The importance of patients' associations has always been recognized in
685   ARIA. For the digital transformation of health and care, they are even more important. The following
686   messages sent by the app need to be reinforced for the patients:

687   • Better understanding of the symptoms.
688   • Sentinel network linking aerobiology data and control.
689   • Improved adherence.
690   • Self-management.
691   • Patient empowerment.

692   # MASK achievements in digital anamorphosis

693   **Anamorphosis steps based on digital learning and Real-World Data**

694   MASK-air® has been used for 5 years and has evolved since its first inception. Major RWD results of the
695   MASK strategy (MASK-air®, POLLAR and CARAT) are presented in Table 5.

Health outcomes

In AR and asthma, a relevant outcome providing information on the cost-effectiveness of interventions is needed. EQ-5D (EuroQol), a standardized and validated non-disease specific instrument to describe and value health-related quality of life, has been used in allergic rhinitis (31, 59-64) but it cannot be used for daily assessment.   EQ-5D is one of the MASK-air® questionnaires (31). In MASK, VAS work correlates with other MASK outcomes (VAS global, nose, eye and asthma) (28, 29) and should be considered as a potentially useful allergic rhinitis outcome in intervention studies.

RWD make it possible health technology assessment.

Use of real-world data to develop next-generation care pathways for chronic respiratory diseases

Care pathways are structured multi-disciplinary care plans detailing the key steps of patient care (7). They promote the translation of guideline recommendations into local protocols and their application to clinical practice. ICPs have been proposed with a focus on mHealth technologies that should enhance self-management and adherence to guidelines and ICPs.

Next-generation care pathways for airway diseases follow the 2014 AIRWAYS integrated care pathways (ICPs) concept (Figures 1 and 2) (55). As a proof-of-concept for chronic disease care, RWD obtained from MASK provide a framework for real-life ICPs centred around the patient with rhinitis, using the mHealth monitoring of environmental exposure. This is implemented in collaboration with professional and patient organizations.

ARIA is constantly evolving and its most recent advance was determined following a meeting of experts/stakeholders in Paris in December 2018 (65, 66) (Table 6). Three aspects of care pathways were developed during this meeting: (i) Patient participation, health literacy and self-care through technology-assisted "patient activation", (ii) implementation of care pathways by pharmacists (67) and (iii) next-generation guidelines assessing the recommendations of GRADE (*Grading* of *Recommendations* Assessment, Development and Evaluation) guidelines in rhinitis and asthma using RWE (55) and AIT (68). Next-generation guidelines for the pharmacologic treatment of allergic rhinitis were developed using existing GRADE-based guidelines (69-71), RWD provided by mHealth Apps (33, 35, 72) and additive studies (allergen chamber studies (73)) to refine the MACVIA algorithm (54).

Network of centers of excellence in digital health

ARIA was established 20 years ago and includes more than 600 members in over 80 countries. In ARIA Phase 4 (change management for airways diseases), a network of centres of excellence has been organized. GA²LEN ARIACARE is one of the GA²LEN centres of excellence (74) and includes urticaria care (UCARE) (75) and atopic dermatitis care (ADCARE). Accreditation follows the UCARE proposals.

ARIACARE-Digital is a novel network with the aim to implement the digital transformation of health and care in airway diseases. Both members of MASK and others can join the network. ARIACARE-Digital has links with GA²LEN but is a separate entity.

Transfer of innovation (TWINNING)

Rhinitis-asthma TWINNING

A transfer of innovative practices (TWINNING) (16, 76) was performed with the aim to transfer and implement MASK-air®. The "Organization transferring the innovative practice" (originator organization) had the experience and know-how developed in rhinitis and asthma IT solutions. The "Organization adopting the innovative practice" (receiving/adopter organization) received the innovative practice and implemented it in its territory. The rhinitis TWINNING was deployed from MASK to 22 countries. Around 1,000 patients were enrolled in the study. The phenotypic characteristics of rhinitis and asthma multimorbidity in adults and the elderly were compared using validated information and communication technology (ICT) tools (i.e. MASK-air®, CARAT and a physician's questionnaire developed for the TWINNING). This improved the understanding, assessment of burden, diagnosis and management of rhinitis in the elderly by comparison with an adult population. The TWINNING was selected as a success story.

DigitalHealthEurope (DHE) Severe asthma TWINNING

In order to reduce the burden of severe asthma with a focus on old age people, the objectives of the transfer of innovation (DHE Severe Asthma TWINNING) are:

1. To form a European network for severe asthma in old age people globally (this does not currently exist):
2. To better understand the phenotype and treatment of severe asthma with possible differences between countries, age and gender;

753   3.   To include the results into the MASK Good Practice for disease stratification and personalized health
754   care with a vision to optimize the prescription of expensive treatments (biologics) and to follow-up the
755   patients using RWD;

756   4.   To be the basis for a further deployment beyond the funding including a network of centres of
757   excellence on severe asthma (ARIACARE and ARIACARE-Digital).

758   The DHE-TWINNING on SA (*Project acronym: H2020, DigitalHealthEurope Grant Agreement Number:*
759   *826353, Project full title:* **Support to a Digital Health and Care Innovation initiative in the context of**
760   **Digital Single Market strategy,** *Call identifier: SC1-HCC-05-2018*) was accepted September 16, 2019.

Ongoing and future MASK actions

Advance capabilities: the same IT tool from epidemiologic studies to clinical trials and clinical practice

764   Symptom-medication scores (SMSs) are needed to investigate the effect of AR treatments, in particular
765   allergen immunotherapy (77). Several scores have been proposed and the European Academy of Allergy
766   and Clinical Immunology has designed one (78). However, a recent MASK analysis (28) has found that
767   this commonly-used SMS is not very well correlated with VAS work used as an end point. When
768   considering MASK data (72), it is possible that some patients with very high levels of VAS global (and
769   work) may not be able to be controlled with current pharmacologic treatments and a new SMS has been
770   proposed. This SMS for rhinitis has been validated with MASK-air® data. Other artificial intelligence
771   analyses are being carried out to obtain an optimal score.

772   Real-world evidence (RWE) combines results of double-blind, placebo-controlled, randomized trials (DB-
773   PC-RCT) and RWD. However, observational studies provide clinically-relevant information in addition to
774   DB-PC-RCT (33, 35, 72). RWD can provide new insights into disease patterns and help improve the safety
775   and effectiveness of health interventions. The same SMS will allow the comparison of the results of DB-
776   PC-RCTs and RWD in population studies or for the individual patient (79). This will provide
777   complementary information to DB-PC-RCTs and a real-life approach. Since patients are using the app and
778   the same system, it will be possible - using machine learning - to target the efficacy of AIT at the individual
779   level and to propose automatic advice to the physician for the indication of AIT as well as an early stopping
780   rule in clinical practice (68).

781   Patient stratification is an important step for expensive treatments such as allergen immunotherapy in
782   allergic diseases or biologics in severe asthma. There are currently no validated genetic or blood
783   biomarkers for predicting or monitoring the efficacy of treatments at an individual patient level in allergic
784   diseases (80). mHealth biomarkers (SMS) (68) and eCDSS (15) may change the scope of AIT in allergic
785   diseases or biologics in asthma or chronic rhinosinusitis.

786   **Towards severe asthma**

787   The lessons learnt by MASK will be used to build MASK-asthma which will include (i) a standardized
788   assessment of severity and control, (ii) the development of an upgraded e-platform for severe asthma
789   including screening, assessment by physicians and follow up, (iii) the analysis of MASK-air® data in file
790   for asthma, (iv) a pan-European IT-based alert system for exacerbations, (v) MASK-asthma IT tools for
791   registries and databases, (vi) transfer of innovation, (vii) a digital network of centres of excellence
792   (ARIACARE-Digital) and (viii) the development of next-generation care pathways for severe asthma.

793   **United perspective for chronic diseases to sustain planetary health**

794   Planetary health refers to "the health of human civilization and the state of the natural systems on which it
795   depends" (81). Most risk factors for non-communicable diseases (NCDs) are associated with Planetary
796   health.

797   Digital tools can also empower patients in the context of the UN sustainable development goals and in
798   particular regarding those related to sustainability and natural resources (82). Future apps in AR could
799   consider providing information to promote behavioural changes that could reduce the planetary impacts of
800   human activity.

801   During a conference entitled "Europe That Protects: Safeguarding Our Planet, Safeguarding Our Health"
802   co-organized by the Finnish Institute for Health and Welfare, the Finnish Environment Institute and the
803   European Commission under the auspices of Finland's Presidency of the EU in 2019, a symposium was
804   held to better understand the digital transformation of health and care to sustain planetary health in airways
805   diseases. The Finnish Allergy Programme is a proof-of-concept of Planetary Health and MASK (Mobile
806   Airways Sentinel Network), a Good Practice of DG Santé on digitally-enabled, patient's centered care
807   pathways, is in line with the objectives of the Finnish Allergy Programme.

808 Lessons learnt in rhinitis and asthma multimorbidity (18) can be deployed to other NCDs for change
809 management in health care. A uniform approach can be used (12) for the development of next-generation
810 care pathways in chronic diseases embedding the risk factors involved in Planetary health.

811 This perspective is global since Planetary Health needs to be tackled in all countries and the World Health
812 Organization and the International Telecommunication Union recognize the importance of mHealth
813 globally and particularly in developing countries (5).

814 **Value added medicines: the example of the combination of intra-nasal**

815 **antihistamine and corticosteroid used as needed**

816 Value added medicines represent the concept of drug repurposing (83). They are medicines based on
817 known molecules that address healthcare needs and deliver relevant improvement for patients, healthcare
818 professionals and/or payers. MASK is a proof-of-concept of drug repurposing as it suggests the importance
819 of as needed treatment for AR. Value added medicines are medicines based on known molecules that
820 address healthcare needs (8, 13, 18), deliver relevant improvement for patients (32, 33, 73, 84), health care
821 professionals (32, 33) and payers (29-31, 34). It contributes to addressing unmet patient needs, moving
822 from a tailored and patient's specific approach. By answering patients' unmet needs, they represent a new
823 horizon for those who are currently looking forward to a better quality of life with their treatment.

824 ## Contribution of MASK to the EU Digital Single Market

825 The Digital Single Market (https://ec.europa.eu/digital-single-market/en), part of the Digital Agenda for
826 Europe 2020 program of the EU includes three "pillars": (i) Access to online products and services, (ii)
827 conditions for digital networks and services and (iii) growth of the European digital economy. MASK is
828 involved in this strategy by (i) the management of care process, (ii) digital networks (ARIACARE-digital
829 network), (iii) innovation to market (I2M) to foster the cross- border adoption of digitally driven
830 marketable solutions, (iv) the political, organizational, technological and financial readiness, (v) the
831 contribution to European co-operation and transferability, (vi) and the contribution to the European Digital
832 Transformation of Health and Care (Bousquet et al., submitted).

833 The digital transformation of health and care can improve the quality of health services and ultimately
834 people's health and well-being as well as the economy in line with EIT Health. In the context of
835 implementing communication on the digital transformation of health and care, DG SANTE, in
836 collaboration with the EU Commission Expert Group "Steering Group on Health Promotion, Disease

837   Prevention   and   Management   of   Non-Communicable   Diseases"

838   (https://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3622),

839   scaled-up good practices in the field of digitally-enabled, integrated, person-centred care. MASK was one

840   of the nine Good Practices selected, along with chronic disease and Parkinson's disease (14).

Political agenda

842   In the severe asthma TWINNING, the engagement through the Salerno local health agency of

843   ProMIS@Campania network (76) will ensure that adoption is progressively achieved through a

844   multicentric scale-up pilot. The good practice will then be scaled up to other Italian regions through the

845   National ProMIS network (85).

846   The EU political agenda is of great importance in supporting the digital transformation of health and care

847   for chronic respiratory diseases. The Polish Presidency of the EU Council (2011) prioritized the early

848   diagnosis, prevention and control of chronic respiratory diseases in children (86). AIRWAYS-ICPs

849   (Integrated care pathways for airway diseases) (7), initiated in 2014 by the EIP on AHA (6, 8), launched a

850   collaboration to develop multi-sectoral ICPs. It was a GARD (87) demonstration project (88).

851   Euforea (European Forum for Research and Education in Allergy and Airway Diseases) proposed a yearly

852   stepwise strategy at the EU or ministerial levels (89-91). Euforea organized an EU Summit in Vilnius,

853   Lithuania (March 2018) to propose multisectoral ICPs embedding guided self-management, mHealth and

854   air pollution in chronic respiratory diseases (92).

855   POLLAR (Impact of air POLLution on Asthma and Rhinitis, EIT Health) is focusing on the impact of

856   allergens and air pollution on airway diseases to propose novel ICPs integrating pollution, sleep and patient

857   literacy (21). Aquas, the Catalonia Health Agency is involved in POLLAR.

Change management

859   ARIA phase 4 focusses on Change Management with the aim of providing an active and healthy life to

860   rhinitis sufferers and to those with asthma multimorbidity across the life cycle - whatever their gender or

861   socio-economic status - in order to reduce health and social inequities incurred by the disease. ARIA has

862   followed the 8-step model of Kotter (93) to assess and implement the impact of rhinitis on asthma

863   multimorbidity and to propose multimorbid guidelines (12). A second change management strategy is

864   proposed by ARIA Phase 4 on the digital transformation of health and care.

Conclusion: towards a revolution in rhinitis and asthma management

The MASK strategy represents a proof-of-concept for other chronic diseases as asthma-rhinitis multimorbidity plays a key role in understanding asthma and can be used as a general model of multimorbidity. Moreover, asthma and rhinitis have a life-course approach whereas most chronic diseases start early in life but are only clinically evident in adulthood. The lessons learnt by the MASK strategy are therefore transposable to other chronic diseases.

Anamorphosis is a metaphor for reimagining and expanding on appearances and overcoming otherness. MASK digital anamorphosis makes it possible to look at data from a different angle. The data then appear to be different to their familiar, expected and/or generally-accepted form. Anamorphosis may be associated with fear as phenomenological otherness often accompanies new technology. Education for a better appraisal of mHealth by all stakeholders is therefore essential. Metaphorical language can facilitate communication and shape of thought, thus providing key challenges and opportunities for future research (105).

mHealth has the potential to profoundly impact healthcare (94). mHealth apps now represent an important evolution of health and care for allergic rhinitis and asthma multimorbidity. The Digital revolution is underway for rhinitis and asthma (5). Innovative health strategies and services will change management (6) and create a new kind of partnership between the patients, the health care providers and the health system.

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Funding source

Table 1: Strategic overview

	Acronym	Name	Dates
WHO-associated projects			
	ARIA	Allergic Rhinitis and its Impact on Asthma	1999-
	WHO collaborating Center on rhinitis and asthma		2004-14
	GARD	Global Alliance against Chronic Respiratory Diseases	2003-
EU grants and projects			
	GA^{2}LEN	Global Allergy and Asthma European Network (FP6)	2004-
	MeDALL	Mechanisms of the Development of Allergy (FP7)	2009-14
	Sunfrail		
	EIP on AHA	European Innovation Partnership on Active and Healthy Ageing (DG Santé & CONNECT)	2012-20
	Twinning	Transfer of Innovation	2017-9
	DHE Twinning	Transfer of innovation in severe asthma (H2020)	2019-20
	Vigour		2019-21
	POLLAR	Impact of Pollution on Asthma and Rhinitis (EIT health)	2018-9
	Good Practice DG Santé on digital health (DG Santé)		2018

ARIA: Allergic Rhinitis and its impact on Asthma, CARAT: Control of Allergic Rhinitis and Asthma Test, EAACI: European Academy of Allergy and Clinical Immunology, e-CDSS: electronic clinical decision support system, GA^{2}LEN: Global Allergy and Asthma European Network, GARD: Global Alliance against Chronic Respiratory Diseases, POLLAR: Impact of Pollution in Asthma and Rhinitis, WHO: World Health Organization

Table 2: Vision of MASK

1- The burden of rhinitis and asthma (multimorbidity) and unmet medical needs are unacceptable and require a novel approach to tackle them

2- Health care costs should be sustainable despite the increased prevalence of allergic diseases and the availability of new expensive treatments

3- mHealth should be applied to rhinitis and asthma to reduce unmet medical needs and sustain health care costs

4- A novel approach should embed medical knowledge, patient's needs and mHealth

5- The ultimate goal is change management for rhinitis and asthma

Table 3: Maturity level of MASK

MASK achievement	TRL	
App for rhinitis and mulitmorbidity (MASK-air®): available in 25 countries, 17 languages, 35,000 users	9	(18, 32, 72)
CARAT questionnaire for screening and control of rhinitis and asthma, available in 20 countries	9	(38-40)
e-physician questionnaire for rhinitis (available on the Euforea website) deployed in 23 countries and 17 languages	9	(16)
Embedding air quality (outdoor air pollution) and pollen data in MASK-air® (POLLAR)	9	(21)
e-CDSS for share decision making in rhinitis	7	(15)
EAACI-ARIACARE-digital network	8	
Allergy score	7	(28)
Embedding artificial intelligence in MASK-air®	3	

CARAT: Control of Allergic Rhinitis and Asthma Test, EAACI: European Academy of Allergy and Clinical Immunology,

e-CDSS: electronic clinical decision support system, POLLAR: Impact of Pollution in Asthma and Rhinitis

Table 4: Patients' needs and expectations of an mHealth app

A- Problems patients encounter using an app

- Fear of using an App (in particular in elderly patients)
- Customer loyalty problems (young adult patients)
- Not willing to use one App regularly
- Changing the App frequently
- Not understanding how to fill in the App
- Not understanding or not caring about what must be done (e.g. seeing a physician), despite clear results/instructions provided by the App
- Not feeling ill (usually males)
- Feeling too ill and filling in the App too much (females, some males also)

B- Patients' expectations

Patients' expectations	Existing feature in MASK	To be added to MASK	
		Feature	Expected
Advice to modify the treatment	Simple advice exists in line with the GDPR		
		More sophisticated advice will be ready with Medical Device Regulation (MDR) Class 2A	06-2021*
Pollen and pollution		POLLAR	6-2020
Visualization of control and medications	Existing but poorly found by patients and physicians	More user friendly and better information	6-2020
Help science to better understand the disease in order to get future benefits	Existing		

GDPR: General Data Protection Regulation, MASK: Mobile Airway Sentinel Network, POLLAR: Impact of Pollution in Asthma and Rhinitis

*: due to new regulation not yet published

Table 5: ARIA anamorphosis steps for the digital transformation of health and care in airway diseases towards change management

A*	Areas of innovation	Novel findings using RWD	Solutions for digital health	References
Innovation in phenotypes				
1	Allergic phenotypes (based on epidemiologic evidence)	MASK • found novel phenotypes of rhinitis, conjunctivitis and asthma. • suggested that a "severe phenotype" exists proposing a new stratification of allergic patients for optimized treatment. These finding were confirmed in classical epidemiologic studies.	A novel approach of multimorbidity is needed to select and stratify patients using artificial intelligence	(33) (95-98)
Innovation in diagnosis				
2	Diagnosis	Using the CARAT questionnaire: • Highly motivated and experienced allergists misdiagnose asthma and conjunctivitis in patients with rhinitis. • They have a different approach to assess severity.	The CARAT questionnaire is in MASK-air® and can be used in the physician's waiting room to help in the diagnosis of allergic diseases and to initiate stratification of patients.	Submitted
Innovation in management				
3	Adherence to treatment	• Patients often self-medicate and use OTC medications • Patients do not follow the physician's prescription • This attitude accords with the allergic physician's behaviour	Poor adherence of patients to treatment indicating that RCTs carried out in adherent patients do not reflect real life and that change management is needed with a new registration of medications (prn). Need to change practice and medication registration	(33, 35)
4	Novel approach for efficacy	• MASK shows that patients receiving co-medications are less well controlled than those receiving no	Guidelines assume that patients follow the doctor´s orders. Adherence to medication is	(18, 33, 72)

	assessment	treatment or single treatment. These observations are in contradistinction with guidelines. • Patients do not follow guidelines or the physician's prescriptions and self-medicate. Next-generation guidelines are needed. Chamber studies confirm the speed of onset of some treatments	turned to partnership using novel models of education (IT).	(73)
5	The same tool is used for RCTs, RWD, chamber studies and clinical practice	A symptom-medication score (SMS) based on MASK has been set up and can be used for all purposes.	• Assessment of SMS in RCTs, observational studies, chamber challenges and clinical practice. • Direct comparison of RCTs, observational studies, chamber challenges with RWD in patients. • Patient stratification for expensive treatments.	

Health outcomes

6	Health outcomes and impact	• There is a significant correlation between VAS work and VAS for global symptoms, nose, eye or asthma. Daily VAS work can be used for economic studies.	• Work productivity • EQ5D • Impact (sleep)	(29-31, 34, 99)

Next-generation care pathways

7	Next-generation care pathways	• Care pathways differ from guidelines. • Self-care. • Pharmacist • Physician • Patients	Next-generation care pathways are needed • To account for real-world evidence • To provide a holistic view of management and prevention of allergic symptoms and diseases	(55, 67, 68, 72, 100) (37)
8	Air pollution	• Air pollution impacts the severity of rhinitis.	• Embedding in MASK-air® current data and 3-day	(21, 36)

		• Prediction of pollution and the pollen season (POLLAR)	prediction for pollen season and air quality. • Alerts for peaks of pollen and pollution.	
Centres of excellence in digital health				
9	Centres of Excellence	ARIACARE-Digital is a novel network with the aim to implement the digital transformation of health and care in airway diseases	• ARIACARE-Digital	
Transfer of innovation				
10	Rhinitis-TWINNING	Completed (but still ongoing) TWINNING in rhinitis and asthma	• Web-based physician's questionnaire • MASK-air® combined	(16, 76)
11	Asthma-TWINNING	DHE TWINNING in severe asthma	• Asthma-e-platform • MASK-air® with asthma combined • ARIACARE-Digital	
Digital transformation of health and care to sustain Planetary Health				
12	POLLAR	• Impact of climate change, air pollution and biodiversity	• Climate change	(21, 36)
13	Finland's EU Presidency meeting, December 3-4, 2019	• Care pathways for rhinitis and/or asthma can be used as a model for all chronic diseases.	• The way to the digital transformation of health to sustain planetary health	Bousquet et al, in preparation

A*: anamorphosis

CARAT: Control of Allergic Rhinitis and Asthma Test, DHE: DigitalHealthEurope, EQ5D: EuroQuol, MASK: Mobile Airway Sentinel network, RCT: Randomized Control Trial, RWD: Real World Data, Twinning: Transfer of Innovation, VAS: Visual analogue scale

Table 6: Papers of next-generation care pathways in the digital transformation of health and care

	Title	Journal	Publication
1	From ARIA guidelines to the digital transformation of health in rhinitis and asthma multimorbidity	Eur Respir J	(9)
2	Mobile technology in allergic rhinitis: evolution in management or revolution in health and care?	JACI Practice	(5)
3	Next-generation ARIA care pathways for rhinitis and asthma: a model for multimorbid chronic diseases	CTA	(79)
4	2018 Good Practice: ARIA digitally-enabled, integrated, person-centred care for rhinitis and asthma *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*	CTA	(14)
5	Next-generation care pathways for allergic rhinitis and asthma multimorbidity: a model for multimorbid non-communicable diseases (Meeting Report. Part 1)	J Thorac Dis	(65)
6	Next-generation care pathways for allergic rhinitis and asthma multimorbidity: a model for multimorbid non-communicable diseases (Meeting Report. Part 2)	J Thorac Dis	(66)
7	ARIA pharmacy 2018: "Allergic rhinitis care pathways for community pharmacy"	Allergy	(67)
9	ARIA Care pathways for allergen-specific immunotherapy following the ARIA recommendations to fill gaps in knowledge (101)	Allergy	(68)
10	ARIA-EAACI Care pathways for allergen-specific immunotherapy Pocket Guide		
11	Next-generation ARIA guidelines for allergic rhinitis based on GRADE and real-world evidence, validating the management algorithm (54), following GRADE recommendations (69, 70, 102) and chamber studies (73, 103)	JACI	(79)
12	Digital transformation of health and care in asthma	Allergy	
13	2020 DHE Twinning on severe asthma		
14	Uniform stratification of severe chronic diseases in adults using		

	mobile technology: App-MM		
15	ARIA Phase 4 (2018): Change management in allergic rhinitis and asthma multimorbidity using mobile technology	JACI	(12)

App-MM: Appfor multimorbidity,ARIA: Allergic Rhinitis and its impact on Asthma, CARAT: Control of Allergic Rhinitis and Asthma Test, CTA: Clinical and Translational Allergy, DHE: DigitalHealthEurope, EAACI: European Academy of Allergy and Clinical Immunology, JACI: Journal of Alelrgy and Clinical Immunology, Twinning: Transfer of Innovation

Figure 1: Care pathways proposed in the MASK strategy (adapted from (6))

Figure 2: Next-generation ARIA care pathways

AIT: Allergen Immunotherapy

Conflict of interest

Transformation of Health and Care in the Digital Single Market

Chapter 5

"Digital tools for citizen empowerment and for person-centred care"

Patient with rhinitis and/or asthma symptoms

Self-care

Pharmacist

General practitioner

mHealth-guided management

Specialist

Emergency care (asthma)
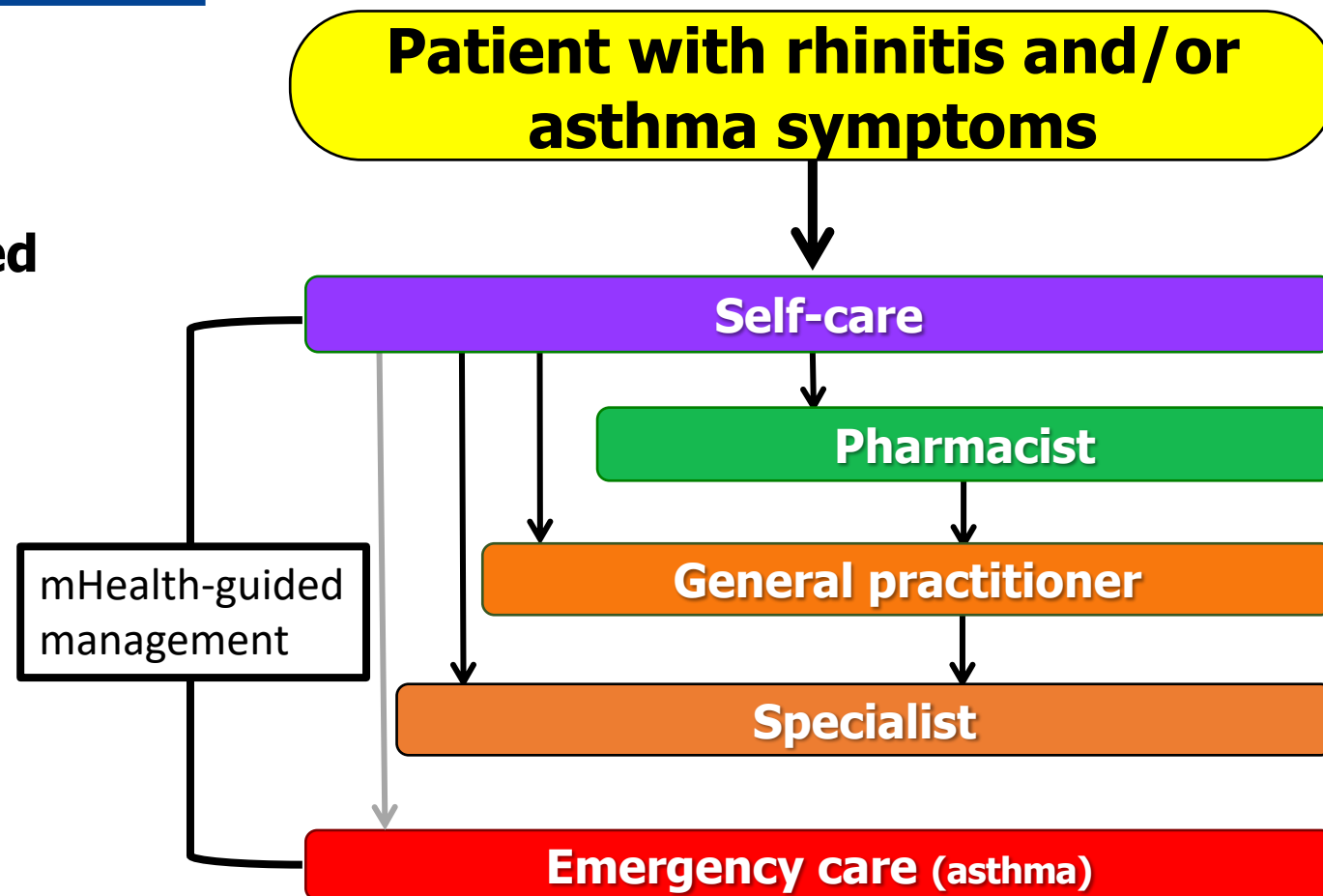
Differences exist between countries/regions and health care systems