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EAACI POSITION PAPER



The role of mobile health technologies in allergy care: An EAACI position paper

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Abstract

Mobile health (mHealth) uses mobile communication devices such as smartphones and tablet computers to support and improve health-related services, data and information flow, patient self-management, surveillance, and disease management from

the moment of first diagnosis to an optimized treatment. The European Academy of Allergy and Clinical Immunology created a task force to assess the state of the art and future potential of mHealth in allergology. The task force endorsed the "Be He@lthy, Be Mobile" WHO initiative and debated the quality, usability, efficiency, advantages, limitations, and risks of mobile solutions for allergic diseases. The results are summarized in this position paper, analyzing also the regulatory background with regard to the "General Data Protection Regulation" and Medical Directives of the European Community. The task force assessed the design, user engagement, content, potential of inducing behavioral change, credibility/accountability, and privacy policies of mHealth products. The perspectives of healthcare professionals and allergic patients are discussed, underlining the need of thorough investigation for an effective design of mHealth technologies as auxiliary tools to improve quality of care. Within the context of precision medicine, these could facilitate the change in perspective from clinician- to patient-centered care. The current and future potential of mHealth is then examined for specific areas of allergology, including allergic rhinitis, aerobiology, allergen immunotherapy, asthma, dermatological diseases, food allergies, anaphylaxis, insect venom, and drug allergy. The impact of mobile technologies and associated big data sets are outlined. Facts and recommendations for future mHealth initiatives within EAACI are listed.

KEYWORDS

allergy, mobile health technology, digital health, position paper, EAACI

1 | BECOMING WIRELESS-THE FRANTIC EVOLUTION OF INFORMATION AND COMMUNICATION TECHNOLOGIES

Today's world is connected wirelessly. This is reflected by the fact that the number of mobile phone subscriptions has overtaken the number of people on the planet, a phenomenon being accompanied by an increase in broadband connections for these phones, which creates a ubiquitous mobile infrastructure.¹ This chance has been seized by a multitude of companies, developers, private entrepreneurs, and start-ups, which have created an avalanche of mobile applications (apps) with services mainly focused on entertainment, infotainment, and the ease of daily life procedures. Interestingly, the development of healthcare-related apps and devices represents the fastest growing area within the information and communication technology (ICT) sector. This offers immense opportunities for global healthcare systems facing the challenge of improving patient care by making it more precise, efficient, and cost-effective while improving accessibility especially for remote areas. To date, most of the evolution in the mobile health (mHealth) sector has been driven by private companies, but central structures to ensure the quality of existing and new products have not yet been established. This urgent need has

been recognized by the World Health Organization (WHO),² the European Union, national governments, and a multitude of medical associations.³

As millions of patients suffering from allergic diseases may benefit from mHealth innovations, the European Academy of Allergy and Clinical Immunology (EAACI) created a task force to assess the state of the art as well as the future potential of ICT in the field of allergy. The evaluation of 136 mobile applications in 2016 depicted a broad heterogeneity in terms of content and quality. As the mobile health environment is a very dynamic field, some of these may no longer exist or comply with regulatory requirements. Very few apps had been clinically validated and many were not based on guidelines or clinical evidence. Since then, various studies have evaluated the advantages, usability, efficiency, and risks of mobile health technologies in allergic rhinitis,⁴⁻⁶ asthma,⁷⁻⁹ atopic dermatitis,¹⁰ food allergy,^{11,12} and anaphylaxis.¹³

Recognizing this scenario, the EAACI Task Force has created a position paper, summarizing general aspects such as legal regulations and evaluation criteria, before evaluating the role of mHealth technologies in the respective allergic diseases. Finally, a roadmap for future actions of EAACI for the improvement of patient care through mHealth strategies will be depicted, considering possible limitations. A selected list of allergy-related apps will be given in the Appendix S1.

2 | ENDORSEMENT OF MHEALTH POLICY BY WHO AND AMERICAN COLLEGE OF ALLERGY, ASTHMA AND IMMUNOLOGY

2.1 | "Be He@lthy, Be Mobile"—a WHO Initiative

The "Be He@lthy, Be Mobile" (BHBM) initiative is a global partnership led by the World Health Organization (WHO) and the International Telecommunication Unit (ITU).¹⁴ It supports the scale-up of mHealth within national health systems to help combat diabetes, cancers, cardiovascular, and chronic respiratory diseases. As mobile technologies and Internet access are also widely spread in countries with low average incomes, the WHO recognized mobile health technologies as a valuable tool in providing health care to populations in remote areas or with limited access to health infrastructure. Training and self-empowerment become especially important in these cases. The handbook "mBreatheFreely" refers to the use of mobile technology to provide health information and support for people living with asthma and COPD. It provides guidance for governments and policymakers to develop, implement, and evaluate an mBreatheFreely program for the prevention and control of both diseases. The health messaging provided uses evidence-based behavior change techniques to help persons at risk of or affected by asthma and COPD to prevent and manage these conditions.

In addition to guidance for the implementation of concrete programs, the WHO also initiated an mHealth Technical Evidence Review Group. Together with a panel of external experts, this group created a checklist of 16 items to standardize and improve the quality of mHealth evidence reporting.¹⁵

2.2 | Telemedicine in allergy (Position Paper of the American College of Allergy, Asthma and Immunology)

The American College of Allergy, Asthma and Immunology (ACAAI) created a task force to evaluate the advantages and limitations of digital technologies within the broader scope of telemedicine.³ In summary, ACAAI considers telemedicine a valuable method for healthcare delivery, especially to patients in rural or remote areas. The paper states that it may enhance patient-doctor collaborations and improve adherence as well as health outcomes. By facilitating access to specialists, it is valuable especially for allergic patients whose condition requires prompt assessment, a need often hindered by long waiting lists for appointments with specialists. Although underlining the strength and positive potential of eHealth, the authors mention various challenges, such as standardized regulations, privacy, security, licensing, credentialing, and reimbursement. This position paper gives a valuable general background for the evaluation of mHealth services in allergy care.

3 | REGULATORY BACKGROUND

3.1 | Legal background for centralized quality control and risk management

To access markets, minimize risks, and gain relevance by providing the necessary level of trust, mHealth services must meet requirements of numerous legal domains. Unfortunately, many of these lack international harmonization. For instance, medical liability and remote treatment are not covered by multinational treaties or acts and differ across Europe. Thus, an international standard covering all legal aspects of mHealth in detail is not achievable. However, certain legal areas offer instruments for creating multinational standards. For example, the "General Data Protection Regulation"¹⁶ incentivizes the development of domain-specific Codes of Conduct by providing proof of compliance within the whole of Europe; an example addressing mHealth can be found online.¹⁷ Any standardization initiative should use such tools extensively. To reflect the importance of full compliance in nonharmonized legal domains, those initiatives should additionally identify and implement equal international requirements as far as possible-supplemented by the obligation of a full legal compliance assessment for each territory in which a service is provided. In addition, technologies incorporating medical diagnosis and intervention should be registered as a medical device (Medical Device Directive 43/42/EWG) and obtain CE certification (CE1, CE2). Regulations and their interpretations are evolving, and as such, any recommendations will need to be regularly updated.

3.2 | Evaluation criteria for mHealth tools

Any medical intervention or tool, including mHealth apps, may have potential risks and benefits.¹⁸ Several tools to assess health app quality have been developed. The first methods covered mainly usability,¹⁹ while others focused on the development and life cycle of the app.²⁰ The Health Care Information and Management Systems Society published a guideline to evaluate the usability, but did not include any information quality criteria.²¹ Newer tools have been developed, informed by systematic reviews of the literature, and validated for internal consistency and interrater reliability, such as MARS,²² U-MARS (an end-user version),²³ and Enlight.²⁴ MARS and U-MARS evaluate engagement, functionality, aesthetics, information (including credibility), and subjective quality. Enlight also incorporates domains to assess therapeutic potential and tool generalizability. A recent systematic review identified relevant quality domains of user-facing eHealth programs such as usability, visual design, user engagement, content, behavior change/persuasive design, influence of social presence, therapeutic alliance, classification, credibility/accountability, and privacy/security, and highlights a high degree of agreement on these criteria around the globe.²⁵ Several institutions are beginning to offer mHealth accreditation.

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4 | STAKEHOLDERS ROLE

4.1 | The use of mHealth technologies from the patients' perspective

Patients may use mHealth for multiple reasons, which may not be aligned with the aims and objectives of clinicians.²⁶ "Patient centred care should be personalised, pro-active and patient driven."²⁷ Healthcare needs and wants have to be differentiated. App design should incorporate facultative use to enable tailoring.²⁸ To ensure patient-centeredness and relevance, patients should be involved at every phase of the design, implementation, and updating process.¹⁵ For patient management, apps could be offered as part of information giving, monitoring, and self-management to facilitate patient participation. Patients need to have confidence in the validity of any app used; thus, the provenance should be explicit.^{29,30}

4.2 | The use of mHealth technologies from the healthcare professionals' (HCP) perspective

Healthcare professionals are co-end users of mHealth, and only then, with patient assent. The mismatch of priorities between patients and clinicians need to be reconciled prior to developing any mHealth intervention to create a therapeutic partnership between patient, clinician, and mHealth.¹⁵ Secondary concerns of HCPs include incorporating data into electronic healthcare records and clinical responsibility for their use.¹⁸ HCPs' attitudes and systems (IT, organizational, and incentivization) will need significant reorientation to incorporate mHealth into routine medical care, which will require permissive cultural and organizational changes.^{31,32}

mHealth is an integral part of clinical care as an auxiliary feature aimed at improving quality of care, patient outcomes, and delivering efficiencies. The immediacy of app interaction and how this is provided (algorithmically or personally) need to be addressed. Research is needed to understand the patterns of patient usage of apps as well as the impact of mHealth technologies that require a prescription or formal physician oversight (digital therapeutics). Within the context of personalized precision medicine, mHealth apps could facilitate the change in the model of care from clinician- to patient-centered care.³³

5 | MHEALTH IN ALLERGIC DISEASES

5.1 | Allergic rhinitis

Currently, the impact of mHealth on the diagnosis of rhinitis is small, with a limited number of mHealth tools for allergic rhinitis (AR) diagnosis published in peer-reviewed journals.^{5,34-36} Several others, from which published data are pending, are available on the market. Recent advances in integrated biosensors, wireless communication, and power harvesting techniques are spawning a new breed of

point-of-care devices. However, AR is a very common disease and any diagnostic device connectable to a smartphone (eg, peak nasal inspiratory flow meters, intranasal biosensors) will need to be inexpensive to be affordable.

The monitoring of the control of allergic multimorbidities (rhinitis, conjunctivitis, and asthma) has in contrast been approached by several apps. *Allergymonitor*, for example, allows the monitoring of symptoms and medication intake, which is then matched to local pollen concentrations.^{5,36,37} The *MASK* (Mobile Airways Sentinel Network) *MASK-Air*, initially called *Allergy Diary*, uses a visual analog scale (VAS) for nose, eye, and asthma symptoms, work impairment, and a global assessment.³⁸ The data collected by the users of this app have led to new insights on work productivity, treatment patterns, and phenotypes of allergic diseases.

Another promising aim for mHealth tools is improving our understanding of how patients adhere to medication adaptively. Lack of understanding of medication usage is common in all chronic diseases. Studies of patients using the MASK app show that users' behavior is often not in accord with guidelines, but patients frequently treat themselves as needed, which results in only less than 5% taking medication according to guideline recommendations.³⁹ These results prompted ARIA to develop a self-management strategy rather than targeting an increase in adherence. Nevertheless, Internet-based telemonitoring improves the taking of intranasal corticosteroid (INCS) and improves disease knowledge among children and adolescents with seasonal allergic rhinoconjunctivitis.⁶ Push notifications offer a promising strategy for enhancing engagement with smartphone-based health interventions in allergic rhinitis.

Mobile apps also have the potential of discovering new allergic disease patterns through the acquisition of large data sets. For example, *MASK* unearthed novel patterns of allergic multimorbidity, which had not been demonstrated in a previous study (Mechanisms of the Development of Allergy MeDALL).⁴⁰ When applying this new information, novel patterns (asthma, rhinitis, and conjunctivitis) could then be confirmed on re-analysis of MeDALL data.⁴¹

5.2 | Pollen, fungal spores, and aerobiology

People affected by pollen allergy need accurate pollen information/ forecasts to assist allergy diagnosis, allergen avoidance, and symptom management, thus improving quality of life.^{42,43} Monitoring and forecasting should not be limited to pollen or spore concentrations, but also include other environmental information such as ozone levels, sulfides, nitrogen dioxide, particulate matter, and others, as these agents, in addition to their nonspecific effects, may enhance pollen allergenicity.⁴⁴

The assessment of pollen and spore levels may aid the identification of clinically relevant allergies to specific plants or fungi as well as guiding decisions concerning allergen immunotherapy.³⁶

Nowadays, allergic symptoms may be documented electronically in pollen diaries (eg, refs^{5,34}). The advantages of such online diaries are comprised of continuous monitoring of allergic symptoms,

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enabling comparisons of different years/seasons and with different aerobiological particles, among them pollen and fungal spore concentrations. Users learn more about their symptomatic pattern, track down a possible pollen allergy (when compared with pollen concentrations), and thus may be willing to visit an allergist/medical doctor earlier asking for advice, diagnosis, and treatment. In the future, the combination of tracking symptoms and evaluating the personal exposure (outdoor/indoor exposure) will play a role.

However, certain quality criteria (eg, the inclusion of pollen data elaborated by institutions capable of monitoring/assessing and evaluating aerobiological data bearing the scientific and ethical responsibility) should be defined especially concerning accurate pollen and pollutant forecasts and their incorporation into mHealth for pollen allergy sufferers to maximize benefits.⁴⁵

5.3 | Allergen immunotherapy

mHealth technology, including telemonitoring, integrated care pathways (ICPs), and clinical decision support systems (CDSS) are suggested as potential tools to aid decision-making for AIT, as well as the identification of clinical responders to treatment.⁴⁶⁻⁴⁸ If algorithms are based on evidence-based clinical recommendations for AIT such as outlined in the EAACI guidelines,⁴⁹⁻⁵¹ this technology has the potential to optimize the precision for prescriptions,³⁶ as well as efficacious and evidence-based products in AIT. When AIT is initiated, mHealth technology may in addition effectively increase patients' adherence,⁵² which is reported to be low in AIT.^{53,54} Patient support programs (PSPs) have suggested improving adherence by integrating and optimizing communication, educational, motivational, and behavioral modification components.^{55,56} These could be implemented in mHealth technology, for example, electronic reminder systems, e-communication channels, the use of "push"-messaging, gaming, including social networks with caregivers and peers.⁵⁵ mHealth telemonitoring is a promising tool to monitor clinical benefits and side effects of AIT including improvement of symptoms and quality of life or medication reduction. These technologies are already in use, for example, as e-diaries in clinical trials of AIT aiming to collect clinical data in real time for research and AIT product development.⁵⁷ In addition, real-life monitoring of large populations of patients receiving AIT in routine clinical practice both during treatment and after treatment cessation ("carry-over" effect) may become possible with mHealth technologies. Additionally, such large data sets offer the potential of identifying unmet needs to be investigated in the future.⁴⁷ These may include prospective evaluation of adherence in a real-life population and long-term clinical effects after cessation of AIT (which is not feasible in randomized controlled trials for ethical reasons, costs, and patients' willingness) or pharmacoeconomic evaluations. The latter is of great importance for payors and health systems.

5.4 | Asthma

mHealth not only provides tools to support patients with asthma in self-monitoring and decision-making, but also offers a variety of digital therapeutics to support disease management.^{58,59} In fact,

mHealth has the potential to enhance the quality of care, improve adherence to therapy, and detect deterioration of symptoms by continuous monitoring and feedback to patients. A meta-analysis demonstrated improved asthma control with the use of mHealth, though the quality of apps was substantially heterogeneous.²⁸

Many asthma apps have been developed and are available for use,⁶⁰ mainly by adults, but some also for school-age children and adolescents.^{7,61-64} Registering the use of a reliever inhaler has been used to monitor pediatric asthma control and to provide feedback through an electronic treatment plan.⁷

The importance of users' feedback has been underlined by the outcome of a project including adolescent volunteers (13-18 years old) who evaluated two asthma apps (AsthmaMD and Asthma Pulse).⁶² The suggested improvements included push reminders (to take medication and to purchase refill), asthma-related games, fun factors, and a built-in flow meter.⁶³ Recording clinical and functional endpoints (ie, symptoms, FEV1, PEF) on a daily basis, together with allergen and pollutant exposure, facilitates continuous asthma monitoring. Smartphone-based technologies for the assessment of objective parameters, such as lung function or lung sounds, have been developed and are currently being evaluated. Receiving mHealth data prospectively in addition to history taking may improve diagnostic precision. mHealth can support tailored asthma patient education, provide reminders, and improve self-management (eg, trigger avoidance, use of rescue therapy, and behavioral guidance during exacerbations). Existing randomized controlled trials (RCTs) have mainly focused on comparing the effect of apps on asthma control to paper-based asthma management.^{64,65}

However, there is lack of long-term RCTs of mHealth for the improvement of asthma control.⁶⁶ With regard to this, in a hopeful manner, results from the recently completed multicenter Horizon 2020 EU-funded project "My Air Coach," aimed at developing an innovative asthma monitoring system, will be able to answer current unmet needs in the field.⁹

5.5 | Dermatological diseases

Mobile health can play a role in the care of patients with dermatological allergic diseases, such as atopic dermatitis, contact dermatitis, chronic urticaria, and cutaneous manifestations of drug hypersensitivity. Once the diagnosis has been confirmed, apps can be useful for the monitoring of complaints and other symptoms, the support of patient self-management, the facilitation of professional-patient communication, telemedicine, and peer support or research.

The severity and extent of disease can be measured over time for better self-control of the disease in form of a patient diary. Using validated questionnaires, which are available in apps, a graphical display of scores over time is shown and patients or caregivers get insight into the course of the disease and the effect of the use of medication or topical therapy. There are several validated instruments for scoring severity of dermatological diseases,^{67,68} and the Patient Oriented Score of Atopic Dermatitis (PO-Scorad) has been deployed for use in a mobile app⁶⁹ as well as the Atopic Dermatitis Activity Score and the Patient Oriented Eczema Measure of the University of Nottingham.⁷⁰ Other specific tools measure the impact of chronic skin diseases on sleep quality, using wearable sleep and/or itch trackers. Medication reminders or adherence apps remind patients to use their medication in time and might help to support action plans.⁷¹

Apps including information about the disease, playful information for children, treatment, living with the disease, videos, and patient stories can support self-management in patients. Patient portal apps, which allow patients to view their medical file, send e-consultations, and request e-repeat prescriptions, may facilitate patient-doctor communications.⁷²⁻⁷⁴ This may also be supported by apps to share photographs between the patient and HCPs as well as between doctors for teledermatology. Automated image recognition may deliver additional support for professionals. mHealth can also gather data for research purposes and support communication within patient groups.

Skin test results can be assessed and recorded on the skin and in clearly positive or negative outcomes could also be evaluated by morphometric analysis, documented, followed up, and shared by apps. Computer- or mobile-based morphometric analysis is easier regarding the erythema as compared to the wheal associated with positive skin test reactions, because color changes (erythema, blanching due to compression of vessels in the wheal, reflections by vesicles/blisters in the patch test) are easier to detect than the swelling of the wheal. Digital photodocumentation of skin prick test, patch test, and intradermal test results could be collected and analyzed by mHealth. The principal correlation between doctor-based and computer-based morphometric evaluations of positive skin test responses has been reported ⁷⁵; however, no program or algorithm has been proposed for practical use yet.

5.6 | Food allergy

In a recent study, a total of 77 food allergy apps were analyzed.⁷⁶ While some of them exclusively provide information (24.6%), the majority (67.5%) includes various tools, such as food scanners (27.5%), food diaries (23.5%), and symptom trackers (21.5%). Only six apps contained both food allergy education material and tools. Additional features included allergy-friendly restaurant locators and educational games for children. However, no app enabled the creation of a personalized Food Allergy Action Plan generated by a specialized HCP. The authors concluded that most of the food allergy apps examined offered an incomplete spectrum of information for patients.⁷⁶ In contrast to other fields of allergy, no studies have been performed in order to evaluate the benefit of food allergy-related mHealth technologies.

Mobile health in food allergy may play a role for different stakeholders including patients and patient organizations, doctors, and allergy organizations but also the food industry ^{11,12,77-83}. Within food allergy, different levels of medical management can be approached by mHealth tools. At the level of diagnosis, mobile health tools can support patients for the documentation of symptoms. With respect to the labeling of allergenic substances in food items, EU legislation has provided a list of food allergens, which are required to be labeled. Barcodes are already used for food labeling and support patients for the identification of appropriate products. Apps dedicated to the identification of declared allergens in food products (eg, ShopWell®, ipiit®, and others) are widely distributed, but lack validation and often do not declare their source of information. Other apps support allergy patients in the selection of appropriate products, based on their specific allergen profile (eg, FoodMaestro App®). In case of an accidental contamination during food processing, effective alert systems for patients are desirable. Further, tools translating food names into images or other languages are useful for food allergic patients when traveling to countries where their native language is not spoken.

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Other mobile health applications in food allergy support selfmanagement for acute reactions. These tools are similar to those used for anaphylaxis in general and will be discussed below.

Taken together, mobile health could have a significant impact on the management of food allergy. However, clinical validation of high-quality tools is necessary before their distribution in order to avoid overdiagnosis and the occurrence of avoidable reactions due to inaccurate information. Close collaboration between the different stakeholders and further research are urgently needed.

5.7 | Anaphylaxis

Currently, mHealth tools are primarily used in patients with anaphylaxis for educational and interventional purposes.^{13,84} Potential stakeholders are patients and patient organizations as well as doctors and allergy organizations. Educational materials can increase the knowledge among the above-mentioned target groups but also other individuals such as teachers, nurses, preschool personnel, and family members or other persons who may need to act during an anaphylactic reaction. The recognition of key symptoms can be supported by offering visual examples (photographs, videos). The performance of acute treatment measures, especially the application of an adrenalin autoinjector (AAI), can be enhanced through anaphylaxis action plans delivered via mHealth technologies. This support may be implemented through direct audio instructions or automated emergency calls. Novel alert systems to identify carriers of epinephrine autoinjectors and emergency departments in proximity are currently in development and require a further evaluation.

Automatic alerts signaling to the patient the expiration of his/her adrenalin autoinjector have already been successfully used.^{85,86} As anaphylaxis is life-threatening but rare, the development and implementation of mobile training tools is of high priority to facilitate repeated training and thus optimize the competence of patients, doctors, and other persons involved. Large amount of materials are available.^{87,88} A recent clinical trial on the use of a smartcase for epinephrine autoinjectors showed improved satisfaction related to decreased anxiety among patients using the device.⁸⁹ Further, participants reported on improved adherence to carrying the injector and better involvement

in anaphylaxis management. Despite these promising results, future research needs to include prospective clinical trials assessing the improved clinical outcome of anaphylactic patients within the context of mobile health tools.

5.8 | Venom allergy

Although mHealth technologies may be very useful for prevention and management of venom allergy, the number of existing applications is limited. Apps could be used to graphically report the presence of different Hymenoptera species or noncommon species in certain regions. Hikers or travelers may use them to make pictures of species, which will be automatically identified and reported. This can be used as a base for warning systems of potentially dangerous insects. Moreover, mHealth can serve to communicate with emergency departments or authorities in isolated regions or when no help is present in case of a potentially severe allergic reaction.¹³ mHealth also might help to record and identify the culprit insect after a stinging event. Hence, all these possible applications could improve the identification of Hymenoptera venom-allergic patients and could contribute to the prevention of severe reactions. With regard to the recognition and management of acute reactions, please refer to the chapter on anaphylaxis (5.7).

Furthermore, mobile applications should be developed to monitor the treatment course of venom immunotherapy (VIT), including dosage, local or systemic adverse reactions, and reminders of the subsequent appointment to receive the next dose. Studies are needed to assess whether mHealth may also improve adherence and make patients co-responsible for their own treatment, as well as increase the awareness of the importance and suitability of venom immunotherapy.

5.9 | Drug allergy

mHealth apps for drug allergy have been developed mainly for educational purposes to help distinguish adverse drug reactions between those which are pharmacologically explicable and those due to immediate or delayed hypersensitivity.⁹⁰

Very few apps specifically dealing with drug allergy have been developed. Therefore, there is an urgent need for applications providing information in the following areas: different manifestations of drug hypersensitivity, drug interactions/cross-reactivity, common differential diagnoses, frequent elicitors of different types of drug hypersensitivity, and a list of brand names indicating related generic drugs in different countries. It should also include suggested therapeutic alternatives when a drug or class of drugs is implicated. Quality control in the development of apps is especially relevant in the field of drug allergy as unintended use of drugs the patient is allergic to is quite common and reactions can be potentially lifethreatening. Apps aimed at the distinction between hypersensitivity reactions and those caused by other mechanisms are not recommended for use by patients, as this requires specialized professional assessment. Also, the re-evaluation of previously recorded but possibly yet unconfirmed drug allergies may be assisted by digital health technology.

5.10 | Complementary and alternative medicine

Apps on complementary and alternative medicine (CAM) have been developed, promising allergy relief with practices such as acupressure and hypnotherapy, but also diagnosis (eg, detection of food sensitivities with a compatible heart monitor via "Bulletproof Food Detective"). EAACI has expressed opposition to unconventional diagnostic tests and discourages their use.^{91,92} Products and methods of CAM are not free of adverse effects.⁹³ A competent mHealth app should be in accordance with evidence-based medicine; thus, the use of CAM apps is not indicated.

6 | RESEARCH

In addition to the transfer of information between patient and HCP, mHealth technologies entail new opportunities for research, especially epidemiological studies. These will profit greatly from the integration of real-life patient experience with increased technological savvy.

Mobile health technology offers enormous possibilities for allergy research in several aspects: epidemiology, surveillance, health economics, public health, clinical diagnosis, and monitoring therapy.

- Epidemiology: Data collection through apps allows extremely rapid collection of data from populations of allergic patients; this will tremendously increase the dimensions of epidemiological studies in all areas of medicine, including allergology.
- Surveillance: The use of electronic clinical diaries makes the daily monitoring of symptoms of huge amounts of patients possible, allowing easy and cost-effective real-life studies on the use and efficacy of drug therapy and allergen immunotherapy; additional data on pollen and spore concentrations lay the foundation for establishing individual exposure-symptom thresholds.
- Health Economics: Apps dedicated to monitoring patients treated in real-life conditions will allow rapid and valid collection of data for health economic studies aimed at measuring the economic impact of new and old diagnostic procedures and treatments.
- Public Health: Allergy apps offer the possibility of daily monitoring the entire population of patients, whose position in a given administrative area is identifiable with geolocalization tools; this possibility will facilitate the development of public health programs aimed at managing pollen allergy and other diseases whose symptoms are triggered by environmental factors; this will open up opportunities to treat pollen allergy at community level, thus improving the cost-benefit ratio of allergy care in the population.

- Clinical Diagnosis: Mobile health has great potential to improving allergy diagnosis in this new Era of Precision Medicine; for example, the use of electronic clinical diaries allows matching the data of the individual patient with the trajectories of environmental triggers registered by public agencies, identifying the patterns of triggers relevant for the patient, and implementing appropriate and personalized prevention strategies.
- Apps linked to diagnostic device: Smartphones are becoming the conveyor of objective data acquired by all sorts of diagnostic devices and biosensors; apps integrate these data with other information acquired or entered by the patient and allow a steady monitoring of the patient symptoms and parameters; research in this area will change the way of advancing diagnosis of allergic diseases.

7 | FACTS AND RECOMMENDATIONS

The advantages and opportunities illustrated above in the management of the allergic patient are counterbalanced by a long list of barriers. EAACI takes these challenges seriously while planning activities in this novel area of medicine:

7.1 | Patient-doctor relationship

Facts: mHealth technologies offer valuable possibilities of communication and consultation even outside of regular office hours. Furthermore, delocalization of the patient's data could facilitate remote second consultations with allergy specialists.

Recommendation: Direct and close contact between HCPs and patients (blended care) is fundamental for good patient care and should never be totally replaced by digital technology.

7.2 | Quality control (medical + technical)

Facts: Patients and HCPs will be increasingly encouraged to use allergy apps whose quality, safety, efficacy, reliability, and appropriateness are not verified by any public health authority or scientific organization. It is also often difficult to evaluate the technical appropriateness of apps and related devices connected to the smartphone.

Recommendation: The CE certification as a medical device should always be a precondition for the certification or distribution of an allergy app. Still, a certification does not free the physician of the responsibility to monitor the use and data outputs of applications.

7.3 | Legislation

Facts: European (and non-European) regulations on mobile health technology are growing in number, relevance, and heterogeneity (see Section 3.1).

Recommendations: Apps certified or produced by EAACI must respect recent rules (EU–General Data Protection Regulation) established at

European level and their future upgrade. Moreover, country-specific rules will have to be taken into account at local level.

7.4 | Licensing

Facts: The use of mobile health and telemedicine in the management of the allergic patient allows delivery of remote care by doctors who may have no license or credentials to practice as a doctor in general or even an allergy specialist where the patient is living.

Recommendations: Medical licensing systems need to be adapted to this new situation.

7.5 | Privacy and confidentiality

Facts: Privacy and protection of sensitive data is one of the most common weak points of allergy apps available on the digital market.

Recommendations: EAACI will not recommend the use of allergy apps that are not compliant with the current European and local legislation on this matter.

7.6 | Data overload

Facts: Although the easy and rapid collection of large data sets is a great advantage of mHealth technologies, the processing and evaluation of these data represents a significant challenge for HCPs.

Recommendations: App developers should pay attention to this fact and integrate solutions for manageable data sets including incorporation into EMR (electronic medical/health records). To provide continuous and safe care, further actions related to the interpretation of acquired data need to be planned carefully in advance.

7.7 | Ethical prerequisites

Facts: The rapid development of mHealth technologies enables external persons, companies, and institutions to access the private sphere of a multitude of users. This accessibility does not only facilitate data collection, but also interventions. Both actions require consideration of ethical aspects.

Recommendations: Apart from legal aspects, EAACI emphasizes that any development and performance of apps requires careful ethical consideration.

7.8 | Reimbursement

Facts: In most countries, the time and expertise spent by doctors and specialists in assisting their patients through apps or other telemedicine tools is not paid; this limits more rapid adoption of new technology. Health insurance companies/systems and public administration are slowly acknowledging this problem, but reimbursement practices are in their infancy and rather sparse and episodic. *Recommendations*: The use of validated mHealth tools should be reimbursed if used for improved care in the clinical practice of doctors.

7.9 | Interference with disease management plans

Facts: Improper use of apps and other telemedicine tools may threaten the continuity of the relationship between the patient and his doctor, increasing the tendency to inappropriately self-care unguided by a proper disease self-management plan.

Recommendations: Doctors should be aware of this risk and address it directly with their patients. Both parties should know the apps and devices used by the patient. mHealth should be established as a form of blended care within any integrated care pathway.

7.10 | Interoperability

Facts: The harmonization of different data management systems is a significant challenge for IT developers and HCPs.

Recommendations: The integration of mHealth data into electronic health records, for example, at hospitals, outpatient clinics, or within primary care is fundamentally important to ensure continuity of care.

7.11 | Accessibility

Facts: A non-negligible proportion of the European population does not have access to a smartphone nor has sufficient health and digital literacy.⁹⁴

Recommendations: The experience acquired by WHO programs on mHealth in low- and middle-income countries may be useful to face this challenge also in Europe.

7.12 | Accreditation and training

Facts: There is no accreditation system for the use by doctors of mobile health technology, nor is this area part of the curriculum for doctors or specialists; the level of awareness and education of doctors in the use of mobile health technology is extremely low.

Recommendations: The correct and careful use of mobile health technologies and telemedicine tools should become part of the curriculum in the training of healthcare professionals in order to ensure an adequate level of awareness.

7.13 | Research

Facts: Mobile health technology offers enormous possibilities for research. Published studies on the use of mobile health in allergic diseases are still very limited.

Recommendations: Research on the use of mHealth in allergic diseases requires urgent funding and expansion in every area, such as epidemiology, surveillance, health economics, public health, clinical diagnosis, monitoring therapy.

8 | CONCLUSIONS

Allergology, as any other area of medicine, will be deeply influenced by mobile health technology. Allergists and their patients have a new way of communication, through the phone camera, sound recording system, motion sensors, texting, and ultimately by using diagnostic devices and diagnostic algorithms incorporated within the mobile phone itself. The revolution that these possibilities are bringing in epidemiology, care, and research has already arrived. The role of doctors, and in particular allergists, will be progressively altered. To contribute to this trend, the EAACI Task Force for mHealth and Allergy has designed a two-year-long action plan that will be implemented under EAACI leadership. Accordingly, EAACI recognizes the advent of the mHealth era in medicine and contributes to its development proactively.

CONFLICTS OF INTEREST

Dr. Matricardi reports personal fees from TPS, outside the submitted work; Dr. Blank reports non-financial support from ALK-Abelló, grants, personal fees and non-financial support from Bencard Allergie GmbH, personal fees from Teomed AG, grants and personal fees from Thermo Fisher Scientific, grants from Allergy Therapeutics, outside the submitted work. Dr. Bousquet reports personal fees from Chiesi, Cipla, Hikma, Menarini, Mundipharma, Mylan, Novartis, Sanofi-Aventis, Takeda, Teva, Uriach, other from KYomed-Innov, outside the submitted work; Dr. Fonseca reports personal fees from AstraZeneca, GSK, Novartis, Teva, grants from Novartis, Mundipharma, outside the submitted work; and I'm a partner at MEDIDA, Lda, a small company developing mHealth technologies. Dr. Hellings reports grants and personal fees from Mylan, during the conduct of the study; personal fees from Sanofi, personal fees from Allergopharma, personal fees from Stallergenes, outside the submitted work; Dr. Hoffmann Sommergruber reports grants from Austrian Science Funds, outside the submitted work; .Dr. Mösges reports personal fees from ALK, grants from ASIT biotech, personal fees from allergopharma, personal fees from Allergy Therapeutics, grants and personal fees from Bencard, grants from Leti, grants, personal fees and non-financial support from Lofarma, non-financial support from Roxall, grants and personal fees from Stallergenes, grants from Optima, personal fees from Friulchem, personal fees from Hexal, personal fees from Servier, personal fees from Klosterfrau, non financial support from Atmos, personal fees from Bayer, non-financial support from Bionorica, personal fees from FAES, personal fees from GSK, personal fees from MSD, personal fees from Johnson&Johnson, personal fees from Meda, personal fees and non-financial support from Novartis, non-financial support from Otonomy, personal fees from Stada, personal fees from UCB, non-financial support from Ferrero, grants from BitopAG, grants from Hulka, personal fees from Nuvo, grants from Ursapharm, personal fees from Menarini, personal fees from Mundipharma, personal fees from Pohl-Boskamp, outside the submitted work; .Dr. Pfaar reports grants and personal fees from

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AUTHOR CONTRIBUTIONS

PMM, SD, AA-P, DAA, CA, EB, MB, JB, J-CC, ÖC, IE-G, JG, PG, AFK, FM, ÁMC, AN, JO, GP, CP, DP-F, OP, MR, SS-G, L-AVP and GV participated in the EAACI Taskforce mHealth & Allergy and contributed to the evaluation of apps. PMM, SD, DA-A, MA-M, UB, SB, MB, JB, KB, VC, J-CC, ÖC, RM, OP, CP, DR, HO-M, JW and MW participated in the writing group producing the first draft of the text. PMM, SD, DA-A, UB, SB, JBu, KB, JAF, IG, PH, KH-S, RM, MO, GP, OP, CP, DR, ST, L-AVP, HO-M, JW and IA participated in at least one of the task force meetings (Zurich/Berlin). MSB, TE and JS contributed specific expertise in the area of mobile health/telemedicine in allergology and reviewing the text. All the remaining Authors also contributed throughout the 2-years-long project and have discussed and approved the final version of the document.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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