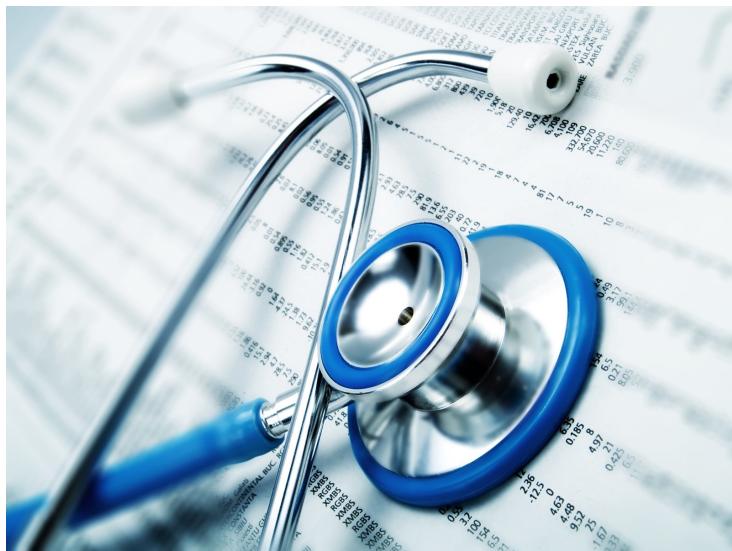


Treating Allergic Rhinitis with Digital Health and Real-Life Care Pathways

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Akansh Khurana, CEO, THB - Technology, Healthcare & Big Data Analytics share his views on treating Allergic Rhinitis with Digital Health



Allergic rhinitis (AR) is usually a longstanding condition that often goes undiagnosed in primary care settings. In AR, the oversensitive immune system reacts to allergens like dust, pollen, mould, or fur/skin flakes of certain animals. The allergen/s cause swelling of blood vessels, nasal congestion, and increased mucus production, resulting in runny nose. AR may lead to sleep difficulty, drowsiness, decreased productivity and concentration. It can also make asthma worse and lead to other serious conditions.

AR can be seasonal, where allergy symptoms occur as a result of seasonal changes. Pollen is the most common cause of seasonal AR. When allergic symptoms occur throughout the year, it is termed as perennial AR. Dust mites, mould, or animal/s can be a source of perennial AR. Viral rhinitis, drug-induced rhinitis, and hormonal rhinitis occur without allergies. Certain food products, exercise, cold/dry air, air pollution, and strong smells can also trigger rhinitis.

Recent research highlights that severe, refractory, and mixed forms of AR are increasing and represent a certain socio-economic burden. More than half of the patients with AR use multiple medications and don't feel satisfied with the symptoms scores. Also, AR is generally not considered as an important disease: many patients do not take appropriate medical advice, self-diagnose/self-medicate or take alternative/complementary medicines.

High Burden of Uncontrolled AR in India

Scientific research from different parts of India has reported a sharp increase in IgE-mediated allergic reactions. Diverse climates, rapid urbanization, vegetation/deforestation, and food habits have given rise to various allergens - pollen spores, fungi, and dust mites. This diversity changes the protein content and antigenicity to the allergens. According to the Indian College of Allergy, Asthma, and Applied Immunology (ICAAI) guidelines, more data is required to understand the interplay between allergens and allergic symptoms.

Skin prick test is still used in India as the first-line method to detect IgE-mediated allergic reactions. These extracts are usually not standardized and are of low quality. In comparison, western countries utilize advanced diagnostic tools like ImmunoCAP and allergen microarray based on recombinant technology. Such tools have revolutionized molecular diagnosis. Western countries have also progressed in therapeutic measures for allergy-immunotherapy with hypoallergenic variants, allergen-derived peptides/fragments, and genetically engineered allergen derivatives. Immunotherapeutic tools like these are sparsely used in India.

Integrated Care Pathways: MASK and POLLAR

Integrated care pathways (ICPs) are multidisciplinary, patient-centric care plans. They enable integration of technologies to assess the disease based on the best evidence and algorithms. An ICP tracks clinical records, documents the care provided, and facilitates continuous quality improvement.

MASK (Mobile Airways Sentinel Network) is a patient-centred ICP developed by the European Commission. It is a mobile phone app (formerly *Allergy Diary*, now called MASK-air) available in 23 countries. This app uses a visual analogue scale to assess the symptoms of AR and work productivity. MASK aims to provide clinical care pathways in rhinitis and asthma multimorbidity including the geolocation of AR patients.

POLLAR (Impact of air POLLution on Asthma and Rhinitis) combines data from MASK-air and uses machine learning to understand the interactions between allergic diseases, sleep, and air pollution. It allows queries on the allergen, pollen, and existing pollution data. The geographic information system maps the results and warns users about pollen or pollution risk level in their region.

These apps stratify AR patients based on the severity of rhinitis and response to treatment. Therapy can be selected based on age, prominent symptoms, severity, patient preferences, and cost. Health care professionals and patients can make joint decisions on treatment and step-up or step-down therapy depending on AR control. Data from these apps is also utilized in research and clinical trials.

Guidance for Industry

U.S. Department of Health and Human Services, Food and Drug Administration, and Center for Drug Evaluation and Research have introduced a guidance document (2018) to assist sponsors in the development of drug products for the treatment of AR. It addresses issues related to trial design, efficacy, and safety of new products. The document recommends that real-world setting should be used in AR for dose exploration studies as other exposure models may not accurately predict the real-world clinical responses. It also encourages web and technology-based tools for day-by-day monitoring of patients. Sponsors are encouraged to define clinically meaningful endpoints and provide a rationale for this selection when designing AR protocols. Continuous collection of efficacy and safety data after treatment discontinuation is also suggested.

Exploring Opportunities with Real-World Data for AR In India

Stakeholders in the healthcare system can utilize real-world data (RWD) to understand the interaction between allergic sensitization and causative agents. Correlation between environment, geographical location, occupation, residence, age, sex, ethnicity, comorbidities, concomitant medications, compliance, and frequency of hospitalizations can be identified in real-life populations. This information can also be used to support randomized clinical trials and research studies.

Patient engagement platforms can be used to inform high-risk patients in advance and allow doctors to track treatment progress, obtain clinical data, compare multiple interventions, estimate risk-benefit, and provide the best advice to the patient. It is possible to explore not just the effectiveness of the interventions but also inquire where these are most and least effective.

THB, Asia's largest and fastest-growing clinical intelligence company, recently conducted a real-world evidence study from the data of 113K AR patients in India. It was found that only 10% of patients receive a timely diagnosis of AR out of all those who complain of allergy-like symptoms, 70% of the patients received a confirmed diagnosis of AR after more than 6 months, and 20% remained undiagnosed due to a lack of awareness. Substantial population across India was found to have high sensitization to common AR triggers, indicating the need for timely diagnosis.

Mobile technologies combined with RWD/RWE have potential to identify gaps in current therapy and offer new tools in the management of chronic diseases like AR. These technology-assisted pathways are set to transform the digital health ecosystem and optimize patient care and participation.