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## **The ARIA score of allergic rhinitis using mobile technology correlates with quality-of-life: The MASK study**

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## **Short title: Quality of life in rhinitis using a mobile application**

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## Abstract

Mobile technology has been used to appraise allergic rhinitis control but more data are needed. In order to better assess the importance of mobile technologies in rhinitis control, the ARIA (Allergic Rhinitis and its Impact on Asthma) score ranging from 0 to 4 of the *Allergy Diary* was compared with EQ-5D (EuroQuol) and WPAI-AS (Work Productivity and Activity Impairment in allergy) in 1,288 users in 18 countries. This study showed that quality-of-life data (EQ-5D visual analogue scale and WPA-IS Question 9) are similar in users without rhinitis and in those with mild rhinitis (scores 0-2). Users with a score of 3 or 4 had a significant impairment in quality-of-life questionnaires.

**Key words:** rhinitis, EQ-5D, ARIA, MASK, WPAI-AS

## Abbreviations

AHA: Active and Healthy Aging

AR: allergic rhinitis

ARIA: Allergic Rhinitis and its Impact on Asthma

EIP on AHA: European Innovation Partnership on Active and Healthy Ageing (DG CONNECT, DG Santé)

EQ-5D: EuroQuol

ICT: information and communications technology

MACVIA: Contre les MALadies Chroniques pour un VIellissement Actif

MASK: MACVIA-ARIA Sentinel Network

MAFEIP: Monitoring and assessment framework for the EIP on AHA

QOL: Quality of life

Q9: Question 9 of WPAI-AS

SF-36: Short Form 36 questions

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VAS: visual analogue scale

WPAI-AS: Work Productivity and Activity Impairment in allergy

## Introduction

Measures of allergic rhinitis (AR) control include symptom scores, patients' self-administered visual analogue scales (VAS), objective measures of nasal obstruction, a recent modification of the ARIA severity classification, or patients' reported outcomes such as QOL or scores with several items (1, 2). Mobile technology has been used to appraise AR control (3, 4). More information is however needed to fully understand the importance of these novel approaches.

MASK-rhinitis (MACVIA-ARIA Sentinel Network for allergic rhinitis), an ICT system centred around the patient (5), is one of the implementation tools of the B3 Action Plan of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA) (6). A mobile phone app (*Allergy Diary*) central to MASK-rhinitis belongs to the Fondation Partenariale FMC VIA-LR (Ministry of Education and Research, France). App users are asked to complete a short demographic questionnaire, EQ-5D (7-10) and WPAI-AS (11, 12), thus providing baseline characteristics of their disease. The *Allergy Diary* has been launched in 21 countries (3, 4). It was found to be an easy and effective method of assessing symptoms of AR and work productivity. The ARIA score is also available in the *Allergy Diary* adding the four components of the impact of AR (sleep, work and school performance, daily activities and bothersome symptoms).

The ARIA score of the *Allergy Diary* was compared with QOL scores of EQ-5D (7-10) and WPAI-AS (11, 12).

## Methods

### Design of the study

A cross-sectional study on a self-selected population was carried out from June 1, 2016 to June 1, 2017. EQ-5D (7-10) and/or WPAI-AS (11, 12) questionnaires are only available in some countries and not all of the *Allergy Diary* users filled in these questionnaires as they are optional. All users filled in the ARIA score. The ARIA score was compared with the EQ-5D visual analogue scale (VAS) and Question 9 (degree allergy affected regular activities) of the WPAI-AS.

The study is reported according to STROBE.

### Setting and users

All consecutive users from June 1, 2016 to June 1, 2017 who answered the questions of the EQ-5D (7-10) and/or WPAI-AS (11, 12) were included in the study in 18 countries. Some demographic characteristics (age, sex, country and language) were recorded. The App was used by people who found it on Internet, Apple App store, Google Play store or any other way. A few users were clinic patients that were asked by their physicians to use the app. However, due to anonymisation of data, no specific information was gathered.

## **Allergy Diary**

The app collects information on AR symptoms experienced (nasal and ocular), disease type (intermittent/persistent), how symptoms impact users' lives, and type(s) of AR treatment used (Table 1 online). The system has been deployed in 21 countries and in 16 languages (translated and back-translated, culturally adapted and legally compliant).

### **Ethics**

The Allergy Diary is CE1 registered but not considered by the Ethical Committee of the Cologne hospital of the MHRA (Medicines and Healthcare products Regulatory Agency - GOV.UK) as a medical device as it does not give any recommendations concerning treatment or diagnosis. The terms of use, translated into all languages and customized according to each country's legislation, allow the use of the results for research purposes. The data are anonymized except for geolocalized data that are never totally anonymous. An Independent Review Board approval was not needed.

### **Outcomes**

The ARIA score was calculated using the four Q4 questions of the *Allergy Diary* which include impact on daily activities, work and sleep and troublesome symptoms (Table 1 online). Each of the 4 items was ascribed a score of 1 ("Yes") or 0 ("No"). The total ARIA score ranged from 0 (no impairment) to 4 (severe impairment).

The electronic form of the EQ-5D-5L questionnaire (<https://euroqol.org>) was applied in the 10 available languages (Danish, Dutch, English, Finnish, French, German, Italian, Polish, Portuguese, Spanish) (Online supplement 1) and we assessed the global VAS level and mobility impairment as this was an absent domain in the assessment of AR impairment.

The electronic form of the WPAI-AS questionnaire was applied in the 10 available languages (same as above for EQ-5D) (11, 12) according to the package obtained from Reilly and associates ([www.reillyassociates.net/WPAI\\_General.html](http://www.reillyassociates.net/WPAI_General.html)). The percentage of impairment due to allergy for daily activities (Q9) was the outcome used. (Online supplement 2).

### **Classification of users**

Users with any positive answer to Q4 (Table 1 online) were classified as "rhinitis" (score 0-4). Those with a score of zero were classified as "no rhinitis" if they had no symptom (Q3, Table 1 online). Those with a positive answer were classified as "rhinitis" (score 0).

### **Statistical methods and analyses**

Some users filled in EQ-5D or WPAI-AS more than once for a single day. The first data were then used. A non-Gaussian distribution was found for some of the data (Shapiro-Wilk test). However, EQ-5D data are usually reported in means and SD. Since the number of observations was large, we used parametric analyses.

## Results

### Users

Of the 12,179 registered users, 1,287 filled in the EQ-5D questionnaire and 1,028 the WPAI-AS questionnaire (Table 2 online). Among the 843 users who filled in both questionnaires, there were 507 women (60%) and 336 men (40%), with a mean ( $\pm$  SD) age of  $35 \pm 14$  years.

### Main results

Similar levels of EQ-5D VAS and WPAI-AS Q9 were found for users with no rhinitis and for those with an ARIA score of 0 to 2. There was a significant reduction of EQ-5D VAS levels and a significant increase of WPAI-AS Q9 levels in users with an ARIA score of 3 or 4 (Table 1).

The repartition of users for both EQ-5D and WPAI-AS (Figure 1) shows that impairment occurred significantly more commonly for ARIA scores of 3 and 4 than for ARIA scores of 0-2. There were from 12 to 16% of users with an EQ-5D VAS level  $\geq 60$  in ARIA scores 0-2 whereas the level increased to 26 and 27% in users with an ARIA score of 3 or 4. There were from 19 to 31% of users with a Q9  $\geq 50$  in ARIA scores of 0-2 whereas the level increased to 51 and 53% in users with an ARIA score of 3 or 4.

## Discussion

This pilot study using mobile technology showed that QOL data (EQ-5D VAS and WPAI-AS Q9) are similar in users without rhinitis as in those with mild rhinitis (scores 0-2). Users with a score of 3 or 4 had a significant impairment in QOL.

### Strengths and limitations

The strengths and limitations of this study are those of mobile technology lengthily discussed previously (3, 4). In particular, there is a lack of patient characterization that is impossible using an App. However, every observational study we have performed using the *Allergy Diary* has confirmed its interest and was able to identify users with a severe disease. It is likely that mobile technology will become a very important tool for the understanding and management of AR.

One specific problem of the study is that there are more countries with EQ-5D or WPAI-AS reporting than translations in the App. It is not known which translations were employed by users.

In this study, we did not perform sub-analyses assessing the importance of symptoms or other factors. We did not investigate the treatments received. As this is a pilot study, these analyses will be carried out once the number of users will have increased.



## Generalizability

The EQ-5D scores observed in the study accord with those of previous studies (8, 10). Users with an ARIA score of 3 to 4 have a level similar to asthmatic patients with uncontrolled asthma (13, 14). Because of the equal weighing score of ARIA, it is difficult to know whether these differences may be due to specific symptoms (e.g. sleep). EQ-5D is a MAFEIP (Monitoring and assessment framework for the EIP on AHA) tool (15) and the present study is in line with the EIP on AHA. This is another important finding since the Transfer of Innovation of the Allergy Diary is an EIP on AHA scaling up project (16).

One of the major findings of the study is the very similar results with both tools supporting the use of the ARIA score to assess AR control using mobile technology. The WPAI-AS scores observed in the study are lower than those reported in patients selected by physicians (11, 17-19). This is because many users have mild rhinitis whereas in clinical trials or in patients selected by physicians AR is usually more severe.

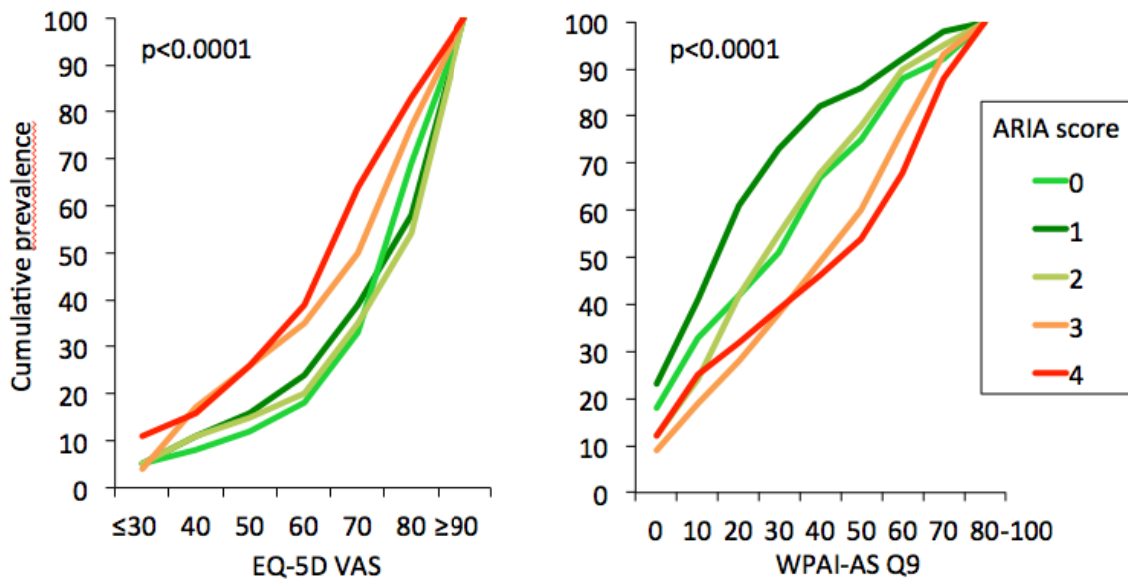
This study also suggests that, in real life, there is a phenotype of severe AR that needs to be considered in terms of public health and cost savings since the severe form causes disability. This phenotype is in focus in the Finnish Allergy Program (20).

**Table 1: Mean levels of EQ-5D and WPAI-AS depending on the ARIA score**

		EQ-5D VAS		WPAI-AS Q9	
		N	m ± sd	N	m ± sd
<b>No rhinitis</b>		48	80.0±19.0	49	27.5±25.5
<b>ARIA score</b>	<b>0</b>	83	77.0±21.3 <sup>a</sup>	71	29.9±27.3 <sup>d</sup>
	<b>1</b>	403	79.5±19.1	308	20.4±22.1
	<b>2</b>	368	76.2±20.2	268	30.1±23.9
	<b>3</b>	199	72.6±18.7 <sup>b</sup>	164	41.4±27.3
	<b>4</b>	186	67.7±23.0 <sup>c</sup>	168	45.8±27.7 <sup>e</sup>

$p_{a/b} < 0.0001$ ,  $p_{a/c} < 0.0001$ ,  $p_{d/e} < 0.0001$ , Student's t test

Figure 1: Repartition of users depending on EQ-5D visual analogue scale (A) and WPAI-AS Q9 (B)



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