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ORIGINAL ARTICLE

Burden of allergic rhinitis and impact of MP-AzeFlu from the patient perspective: pan European patient survey

G. Walter Canonica[a,b], Ludger Klimek[c], Sarah Acaster[d], Ralph Dollner[e], Ranbir Kaulsay[f], Siu Hing Lo[d], David B. Price[g,h,i], Glenis K. Scadding[j], Erkka Valovirta[k] and Petra Zieglmayer[l,m]

[a]Personalized Medicine, Asthma and Allergy, Humanitas Clinical and Research Center IRCCS, Milan, Italy; [b]Department of Biomedical Sciences, Humanitas University, Milan, Italy; [c]Zentrum für Rhinologie und Allergologie, Wiesbaden, Germany; [d]Acaster Lloyd Consulting Ltd, London, UK; [e]Division of Head, Neck and Reconstructive Surgery, Department of Otorhinolaryngology, Oslo University Hospital Rikshospitalet, Oslo, Norway; [f]Beacon Hospital and Bon Secours Hospital, Dublin, Ireland; [g]Optimum Patient Care, Cambridge, UK; [h]Observational and Pragmatic Research Institute, Singapore, Singapore; [i]Division of Applied Health Sciences, Centre of Academic Primary Care, University of Aberdeen, Aberdeen, UK; [j]Royal National Throat, Nose and Ear Hospital, London, UK; [k]Department of Lung Diseases and Clinical Immunology, University of Turku and Terveystalo Allergy Clinic, Turku, Finland; [l]Power Project GmbH, Vienna Challenge Chamber, Vienna, Austria; [m]Karl Landsteiner University, Krems, Austria

ABSTRACT

Objective: The aims of this survey were to (1) assess the burden of allergic rhinitis (AR) from the patient perspective, (2) investigate MP-AzeFlu use in real life and its impact on patients' lives and (3) explore factors associated with treatment satisfaction.

Methods: A cross-sectional, quantitative, online, questionnaire-based survey was conducted in seven European countries (March–June 2019). Questions explored AR burden and treatment satisfaction. Satisfaction was assessed using the Treatment Satisfaction Questionnaire for Medication 9-item (TSQM-9; max score = 100). Participants (aged ≥18 years) had a doctor/healthcare provider confirmed AR diagnosis and used MP-AzeFlu within the last year.

Results: Pre-MP-AzeFlu treatment, participants ($n = 1004$) reported an average of 3.3 (SD:3.5) doctor visits/year, 8.1 (SD:11.0) days/year absenteeism and 15.8 (SD:18.9) days/year presenteeism due to AR. Only 48% of participants used MP-AzeFlu twice/day as recommended. Post-MP-AzeFlu 57% of participants reported better QoL, 47% reported fewer doctor visits and 52% discontinued polypharmacy. Absenteeism and presenteeism were reduced by 2.5 (SD 10.0) and 7.3 (SD:16.0) days/year, respectively. 70% of participants were more/much more satisfied with MP-AzeFlu versus previous AR treatment(s), and ≥70% were satisfied/extremely satisfied with its ability to prevent/treat AR, relieve symptoms and with its onset of action. Mean global, effectiveness and convenience TSQM-9 scores were 70.0 (SD:19.8), 68.3 (SD:21.6) and 72.7 (SD:20.4), respectively. Treatment satisfaction and effectiveness were significantly improved when MP-AzeFlu was taken as recommended.

Conclusions: The impact of AR on patients' lives remains high. Real-life use of MP-AzeFlu reduces that impact and is associated with a high level of effectiveness, convenience and global satisfaction.

Abbreviations: AR: allergic rhinitis; ARIA: allergic rhinitis and its impact on asthma; EAACI: European Academy of Allergy and Clinical Immunology; EUFOREA: European Forum for Research and Education in Allergy and Airway diseases; HCP: healthcare provider; HCRU: healthcare resource utilisation; HDM: house dust mite; INS: intranasal corticosteroid; NO: Norway; PAR: perennial allergic rhinitis; QoL: quality of life; RCT: randomized controlled trial; SAR: seasonal allergic rhinitis; SD: standard deviation; TSQM-9: Treatment Satisfaction Questionnaire for Medication 9-item

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Introduction

Allergic rhinitis (AR) is frequently under-diagnosed, self-managed and sub-optimally treated[1–3]. Poly-pharmacy is common, adherence to treatment regimens is poor and, unsurprisingly nasal and ocular symptom burden remains high[1,4,5]. These symptoms impair daily activities[6], negatively impact patient quality of life (QoL)[7,8] and reduce productivity, both at work and school[1,5,9]. AR is rarely found in isolation; 20–60% of those with AR also have clinical asthma[10,11], with the presence of symptomatic AR associated with worsening asthma control[12]. AR is a costly disease to manage (mostly due to indirect costs), but direct costs are not insubstantial estimated at €210.30/patient per year in a recent Swedish survey[13]. However, most patients are not satisfied with their AR treatment[5,14].

CONTACT Petra Zieglmayer p.zieglmayer@vcc.at Huetteldorferstrasse 44, Vienna 1150, Austria

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Knowledge of patient preferences and expectations from their AR treatment helps to explain why so many remain dissatisfied. In terms of treatment expectations, these are often high; one survey conducted in Belgium found that four out of every 10 patients attending a specialist for their AR expected to be cured by the prescribed treatment[15]. In terms of preference, AR patients want treatments that are rapidly acting, provide complete symptom relief, target both nasal and ocular symptoms and have a long duration of action[1,16–18]. Preference for some of these attributes has been quantified in the UK; for example, AR patients are over 6 times more likely to prefer an AR treatment that provides complete symptom relief versus mild symptom relief (all other attributes being equal) and are willing to pay £0.98 for each hour of onset faster than 8 h, or £43.81 for a treatment which provides complete relief versus mild symptom relief[16].

There has, therefore, been a shift towards a more patient-centred approach to AR management, involving patients in decision making, recognizing they are individuals with associated values and preferences[19,20]. The most up to date AR treatment guidelines and algorithms support this patient-centered approach[21,22]. The Allergic Rhinitis and its Impact on Asthma (ARIA) next generation guidelines (2020) encourage healthcare providers (HCPs) to consider both patient preference and AR management behavior in real-life (e.g. poor adherence and treatment switching)[21]. Similarly, the European Forum for Research and Education in Allergy and Airway diseases (EUFOREA) encourage patient participation in the decision-making process and in goal setting, and emphasize the need to match therapy to these goals and to patient preference[23]. Patient-reported outcome measures are, therefore, now regarded as at least as important as the traditional objective measures of disease as they provide unique and complementary information[24]. Indeed, higher patient treatment satisfaction is a significant predictor of more favourable clinical outcomes[25].

The aims of this survey were to (i) assess the burden of AR from the patient perspective, (ii) investigate how patients use MP-AzeFlu (Dymista, Mylan, USA) in real life, (iii) evaluate the impact of MP-AzeFlu on patients' lives and (iv) explore factors associated with treatment satisfaction.

Methods

Survey design

This was a cross-sectional, quantitative, online, questionnaire-based survey to assess patient satisfaction with MP-AzeFlu treatment. MP-AzeFlu comprises an intranasal corticosteroid (INS; fluticasone propionate) and an intranasal antihistamine (azelastine) in an advanced formulation, delivered as a single spray and is indicated for the treatment of moderate/severe AR[26]. The survey was conducted in seven European countries (Austria, Finland, Germany, Ireland, Italy, Norway and the UK) from the end of March to April 2019 (Austria, Germany, Italy) and from mid-April to June 2019 (Finland, Ireland, Norway and the UK). The survey protocol was reviewed and received exempt status determination by an independent review board (Western Institutional Review Board) prior to participant recruitment (13 December 2019).

Recruitment

Potential participants were recruited *via* a healthcare agency (Global Perspectives, UK & Spain) who used panel and bespoke ad-hoc recruitment from HCP referral, relevant charities, patient associations/communities and social media. These patients were invited to complete the survey *via* e-mail and were provided with the survey address (web link) and unique identifier, which they could use to access the online survey. The aim was to recruit 1000 AR participants; $n = 200$ from Germany, Italy and the UK and $n = 100$ from Austria, Finland, Ireland and Norway. Once target sample sizes were reached, recruitment was closed.

Patients

Those following the link were screened in accordance with the inclusion/exclusion criteria (online supplement: appendix A). Those residing in one of the aforementioned countries, aged $\geq$18 years, with a doctor/HCP confirmed diagnosis of AR, and who had started using MP-AzeFlu within the last 7 years, had used it to treat AR symptoms within the last 12 months and were willing/able to provide informed consent were included. If eligible, patients were next directed to consent information and asked to provide informed consent *via* an online consent form (online supplement; appendices B and C). All subjects were free to withdraw from participation in this survey at any time, and for any reason. Willing and eligible participants then completed the online survey (online supplement; appendix D).

Survey

The survey was developed by Acaster Lloyd Consulting in collaboration with Mylan. It included 4 domains: (i) your health, (ii) your treatment for AR, (iii) satisfaction with MP-AzeFlu and (iv) about you. For non-English speaking countries, the survey and other study materials were translated into the local language. The "your health" section of the survey included questions on age at diagnosis, type of AR, triggers, symptoms, impact on QoL, as well as impact on daily living and on co-morbid asthma. The "your treatment for AR" section captured information on previous AR treatment, healthcare resource utilization (HCRU), absenteeism, presenteeism, reasons for using MP-AzeFlu, treatment pattern (e.g. frequency, polypharmacy), and expectations from treatment. Response options for items concerning allergy triggers and type of treatments were adapted to cover all relevant allergens and treatments in each country. Information on employment status and highest level of education achieved was captured in the "about you" section of the survey. Depending on the nature of the question, participants either selected a provided option or options (e.g. AR treatment(s) used), inputted information (e.g. number of days absent/year due to AR), or expressed their opinion using a 5- or 7-point

Likert scale (e.g. the Treatment Satisfaction Questionnaire for Medication 9-item (TSQM-9) rated overall satisfaction with MP-AzeFlu from 1: extremely dissatisfied to 7 extremely satisfied). The full list of questions and provided response options are provided in the online supplement (appendix D).

Satisfaction with MP-AzeFlu

Satisfaction with MP-AzeFlu was assessed using the TSQM-9[27] plus additional questions. The abbreviated form is divided into three domains: effectiveness, convenience and global satisfaction, each scored from 0 to 100. Instructions to patients were modified for the current survey to reflect the non-interventional nature of the survey and online administration. All modifications were approved by the scale's licence holder.

Statistics

All survey items were summarized using descriptive statistics. Change scores in QoL between on and off treatment were calculated. For healthcare visits, productivity and use of other treatments pre- and post-MP-AzeFlu change scores were calculated. Changes were categorised as "worse/more impact/more healthcare visits," "no change" or "improved/less impact/fewer healthcare visits." Data were also described by country of residence. Country differences in participant socio-demographics and MP-AzeFlu treatment satisfaction measures were tested using simple regression models or chi-square tests as appropriate.

Post-hoc analyses were also conducted to compare TSQM global satisfaction, effectiveness and convenience scores for patients on MP-AzeFlu only ($n = 708$) vs MP-AzeFlu plus ≥ 1 other AR treatment ($n = 296$) and for patients with AR only ($n = 513$) and those with AR and asthma ($n = 470$). All statistical tests were two-sided and p-values of $< .05$ were considered statistically significant. No corrections for multiple testing were applied.

Results

Participants

A total of 1004 MP-AzeFlu users completed the online survey (Austria: $n = 100$, Finland: $n = 100$, Germany: $n = 202$; Ireland: $n = 101$; Italy: $n = 201$; Norway: $n = 100$; UK: $n = 200$).

Socio-demographic profile of MP-AzeFlu users (*Table 1*)

Participants had a mean age of 37.7 (standard deviation (SD): 12.0) years, were gender balanced, with the majority being employed full time (67%) and educated to degree level or higher (67%). Age, employment status and educational level differed by country (each $p < .001$).

Table 1. Socio-demographic characteristics of MP-AzeFlu users.

		Total ($N = 1004$)	Austria ($n = 100$)	Finland ($n = 100$)	Germany ($n = 202$)	Ireland ($n = 101$)	Italy ($n = 201$)	Norway ($n = 100$)	UK ($n = 200$)
Age	Mean (SD)	37.7 (12.0)	35.2 (11.9)	35.1 (14.0)	39.9 (11.8)	37.8 (12.1)	38.0 (10.5)	32.6 (9.8)	40.0 (12.7)
Sex *N* (%)	Male	523 (52%)	64 (64%)	42 (42%)	112 (55%)	44 (44%)	110 (55%)	48 (48%)	103 (52%)
Employment status *N* (%)	Employed, full-time	673 (67%)	66 (66%)	51 (51%)	151 (75%)	63 (62%)	134 (67%)	59 (59%)	149 (75%)
	Employed, part-time	141 (14%)	12 (12%)	17 (17%)	22 (11%)	19 (19%)	33 (16%)	13 (13%)	25 (13%)
	Retired	45 (4%)	8 (8%)	9 (9%)	12 (6%)	1 (1%)	4 (2%)	2 (2%)	9 (5%)
	Unemployed/homemaker	68 (7%)	7 (7%)	10 (10%)	7 (3%)	10 (10%)	14 (7%)	6 (6%)	14 (7%)
	Student	56 (6%)	6 (6%)	13 (13%)	8 (4%)	6 (6%)	8 (4%)	14 (14%)	1 (1%)
	Other	9 (1%)	0 (0%)	0 (0%)	0 (0%)	1 (1%)	3 (1%)	4 (4%)	1 (1%)
	Prefer not to say	12 (1%)	1 (1%)	0 (0%)	2 (1%)	1 (1%)	5 (2%)	2 (2%)	1 (1%)
Educational level *N* (%)	No formal qualifications	46 (4%)	2 (2%)	15 (15%)	3 (1%)	3 (3%)	4 (2%)	9 (9%)	10 (5%)
	Below degree	267 (27%)	7 (7%)	16 (16%)	7 (3%)	33 (33%)	98 (49%)	23 (23%)	83 (42%)
	Degree or higher	670 (67%)	90 (90%)	65 (65%)	188 (93%)	63 (62%)	96 (48%)	65 (65%)	103 (52%)
	Prefer not to say	21 (2%)	1 (1%)	4 (4%)	4 (2%)	2 (2%)	3 (1%)	3 (3%)	4 (2%)

Abbreviation. SD, standard deviation.

Table 2. Clinical characteristics of MP-AzeFlu users.

		Total ($N = 1004$)	Austria ($n = 100$)	Finland ($n = 100$)	Germany ($n = 202$)	Ireland ($n = 101$)	Italy ($n = 201$)	Norway ($n = 100$)	UK ($n = 200$)
Age at diagnosis[a]	*N*	927	86	92	190	89	191	94	185
	Mean (SD)	24.3 (13.9)	23.9 (13.6)	21.1 (13.5)	27.9 (14.5)	23.4 (13.9)	24.5 (12.3)	24.0 (11.1)	22.8 (15.8)
Type of AR *N* (%)	Seasonal	661 (66%)	77 (77%)	61 (61%)	149 (74%)	65 (64%)	127 (63%)	60 (60%)	122 (61%)
	Mixed	299 (30%)	15 (15%)	34 (34%)	44 (22%)	33 (33%)	67 (33%)	36 (36%)	70 (35%)
	Perennial	44 (4%)	8 (8%)	5 (5%)	9 (4%)	3 (3%)	7 (3%)	4 (4%)	8 (4%)
AR	Grass pollen	703 (70%)	64 (64%)	61 (61%)	123 (61%)	77 (76%)	164 (82%)	61 (61%)	153 (77%)
Triggers, *N* (%)	Birch pollen	528 (53%)	61 (61%)	79 (79%)	140 (69%)	25 (25%)	73 (36%)	58 (58%)	92 (46%)
Multiple options allowed	Other tree pollen	373 (37%)	36 (36%)	42 (42%)	70 (35%)	34 (34%)	86 (43%)	31 (31%)	74 (37%)
	Other pollen	291 (29%)	31 (31%)	38 (38%)	63 (31%)	32 (32%)	60 (30%)	24 (24%)	43 (22%)
	Dust mite	460 (46%)	35 (35%)	21 (21%)	78 (39%)	53 (52%)	121 (60%)	52 (52%)	100 (50%)
	Mould	288 (29%)	16 (16%)	34 (34%)	49 (24%)	31 (31%)	65 (32%)	31 (31%)	62 (31%)
	Animal(s)	268 (27%)	24 (24%)	29 (29%)	41 (20%)	30 (30%)	48 (24%)	41 (41%)	55 (28%)
	Mugwort	–	–	–	–	–	–	19 (19%)	–
	Other	28 (3%)	5 (5%)	4 (4%)	4 (2%)	2 (2%)	3 (1%)	7 (7%)	3 (2%)
	Don't know	15 (1%)	1 (1%)	2 (2%)	1 (1%)	4 (4%)	1 (1%)	1 (1%)	5 (3%)
Allergic rhinitis symptoms *N* (%)	Blocked nose	642 (64%)	52 (52%)	81 (81%)	124 (61%)	61 (60%)	147 (73%)	69 (69%)	108 (54%)
Multiple options allowed	Itchy nose	601 (60%)	61 (61%)	64 (64%)	124 (61%)	52 (51%)	125 (62%)	56 (56%)	119 (60%)
	Runny nose	668 (67%)	62 (62%)	75 (75%)	132 (65%)	57 (56%)	147 (73%)	55 (55%)	140 (70%)
	Sneezing	709 (71%)	71 (71%)	74 (74%)	136 (67%)	65 (64%)	156 (78%)	58 (58%)	149 (75%)
	Itchy eyes	644 (64%)	53 (53%)	66 (66%)	131 (65%)	61 (60%)	126 (63%)	69 (69%)	138 (69%)
	Red eyes	507 (51%)	51 (51%)	48 (48%)	108 (53%)	41 (41%)	116 (58%)	55 (55%)	88 (44%)
	Watery eyes	499 (50%)	50 (50%)	53 (53%)	112 (55%)	48 (48%)	96 (48%)	36 (36%)	104 (52%)
	Itchy mouth	205 (20%)	24 (24%)	19 (19%)	39 (19%)	14 (14%)	33 (16%)	22 (22%)	54 (27%)
	Sinus pressure	278 (28%)	20 (20%)	24 (24%)	49 (24%)	46 (46%)	43 (21%)	35 (35%)	61 (31%)
	Cough	326 (32%)	29 (29%)	36 (36%)	64 (32%)	37 (37%)	63 (31%)	36 (36%)	61 (31%)
	Sore throat	292 (29%)	14 (14%)	31 (31%)	54 (27%)	34 (34%)	60 (30%)	34 (34%)	65 (33%)
	Headache	312 (31%)	29 (29%)	31 (31%)	53 (26%)	39 (39%)	53 (26%)	45 (45%)	62 (31%)
	Wheezing	239 (24%)	9 (9%)	34 (34%)	35 (17%)	25 (25%)	49 (24%)	38 (38%)	49 (25%)
	Other	11 (1%)	2 (2%)	0 (0%)	2 (1%)	1 (1%)	2 (1%)	3 (3%)	1 (1%)
	None	2 (0%)	1 (1%)	0 (0%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	0 (0%)
Asthma diagnosis	Yes	470 (47%)	38 (38%)	36 (36%)	79 (39%)	51 (51%)	101 (50%)	57 (57%)	108 (54%)
	No	513 (51%)	60 (60%)	63 (63%)	118 (58%)	46 (47%)	98 (49%)	40 (40%)	88 (44%)
	Don't know	21 (2%)	2 (2%)	1 (1%)	5 (2%)	4 (4%)	2 (1%)	3 (3%)	4 (2%)
Change in asthma treatment when last experiencing AR[b] *N* (%)	Yes	297 (63%)	17 (45%)	22 (61%)	43 (54%)	33 (65%)	64 (63%)	34 (60%)	84 (78%)
	No	160 (34%)	19 (50%)	13 (36%)	35 (44%)	18 (35%)	33 (33%)	19 (33%)	23 (21%)
	Don't know	13 (3%)	2 (5%)	1 (3%)	1 (1%)	0 (0%)	4 (4%)	4 (7%)	1 (1%)
Changes in asthma treatment if not on AR medication[b] *N* (%)	No change	121 (26%)	17 (45%)	10 (28%)	19 (24%)	12 (24%)	28 (28%)	10 (18%)	25 (23%)
	Inc. reliever	228 (49%)	15 (39%)	17 (47%)	34 (43%)	22 (43%)	52 (51%)	32 (56%)	56 (52%)
	Inc. preventer	143 (30%)	7 (18%)	15 (42%)	23 (29%)	11 (22%)	24 (24%)	27 (47%)	36 (33%)
	Steroid	93 (20%)	6 (16%)	5 (14%)	17 (22%)	12 (24%)	20 (20%)	13 (23%)	20 (19%)
	Monoclonal antibody	25 (5%)	0 (0%)	0 (0%)	8 (10%)	2 (4%)	6 (6%)	4 (7%)	5 (5%)
	Other	4 (1%)	1 (3%)	0 (0%)	1 (1%)	0 (0%)	0 (0%)	2 (4%)	0 (0%)

[a]Excluding participants who did not know their age of diagnosis; [b]Excluding participants who did not have an asthma diagnosis. Abbreviations. AR: allergic rhinitis; SD, standard deviation.

Clinical characteristics (*Table 2*)

The average age of AR diagnosis was 24.3 (13.9) years. Most participants considered that they had either seasonal AR (SAR; 66%) or SAR + perennial AR (PAR; 30%). Grass and birch pollen were the most common triggers (70% and 53%, respectively), but the ratio of grass to birch pollen allergy varied by country. House dust mite (HDM) allergy was reported by 46% of participants; lowest in Finland (21%) and highest in Italy (60%), but Ireland, Norway and the UK had a HDM trigger prevalence of ≥50%. The most common symptoms experienced by participants were those usually assessed in AR trials (i.e. nasal congestion, itching, rhinorrhoea and sneezing and ocular itching, watering and redness). But other symptoms (usually not assessed in trials) were also reported by ≥20% of patients including itchy mouth, sinus pressure, cough, sore throat, headache, and wheezing.

Burden of AR when not treated (*Table 3*)

Quality of life

Almost half of all participants ($n = 471$; 47%) reported poor or fair QoL when not on treatment, ranging from 31% in the UK to 62% in Finland. Of these patients, the most negatively affected areas of life were daily activities (75%), followed by sleep (52%), leisure activities (51%), social activities (42%) and emotional well-being (39%). Daily activities were rated as the most negatively impacted area of life by most participants in all countries, with the exception of Norway where sleep was considered by most participants to have the greatest impact.

Symptoms

Nasal congestion was reported overall as having the greatest impact on participants' lives when not on AR treatment (18%), followed by runny nose and itchy eyes (16% each) and then sneezing (12%). Nasal congestion also had the greatest impact on participants from Austria, Finland, Germany and Italy. However, for Ireland it was runny nose and for participants from Norway and the UK it was itchy eyes.

Healthcare resource utilization

When not on MP-AzeFlu treatment participants reported an average of 3.3 (SD 3.5) doctor visits/year, 1.7 (SD 3.1) allergy specialist visits/year, 1.2 (SD 2.5) nurse visits/year and 4.2 (SD 5.6) pharmacist visits/year due to AR. Poly-pharmacy was common, with 48% of participants reporting use of 2 or more AR treatments prior to MP-AzeFlu (Austria: 46%; Finland: 47%; Germany: 49%; Ireland: 48%; Italy: 48%; Norway: 56%; UK: 44%).

Absenteeism and presenteeism

When not on MP-AzeFlu treatment, participants reported an average of 8.1 (SD 11.0) days missed from work and 15.8 (SD 18.9) days when productivity was negatively impacted due to AR. Overall, 59% of participants considered that their productivity was negatively impacted by ≥50% due to their AR.

Impact of AR on asthma (*Table 2*)

Forty-seven percent of participants also reported having comorbid asthma. Among these patients, almost two-thirds of them (63%) stated that they changed their asthma treatment when last experiencing AR symptoms; 49% reporting an increase in reliever and 30% an increase in preventer medication.

Pattern of MP-AzeFlu use in real life

On average, participants began using MP-AzeFlu 2.6 (SD 1.5) years ago. The majority (57%) reported using it in the past week; with 27%, 10% and 6% of participants confirming use in the last 1, 3 and 12 months, respectively (S-Table 1). When experiencing symptoms, 36% of participants said they used MP-AzeFlu every day and 64% used it intermittently. Germany had the highest prevalence of intermittent users (74%) and Finland, the least (49%) (S-Table 1). In terms of dosing, 48% of participants said they used MP-AzeFlu twice a day (as recommended) (Figure 1). Half of participants (50%) reported initiating MP-AzeFlu as soon as symptoms started, and 20% within 1–2 days of symptom start. The majority of participants either used MP-AzeFlu every day they expected symptoms (47%) or on days they experienced symptoms (45%) (S-Table 1).

Reasons for using MP-AzeFlu and perceived benefits and improvements

The most common reasons given for starting MP-AzeFlu were that previous treatment did not relieve nasal symptoms (30% of participants), did not relieve ocular symptoms (26%), did not work at all (25%), did not work quickly enough (25%), did not last long enough (25%), and/or did not relieve other symptoms (20%) (S-Table-2). Participants reported continuing to use MP-AzeFlu due to its effect on nasal (54%) and ocular symptoms (44%), and the perception of a more rapid onset (36%) and longer duration of action (20%) compared to other AR treatments (S-Table-2). Most patients expected MP-AzeFlu to start working within 15 mins (33%) or 30 mins (32%) and to feel a maximum response within 1 h (29%), a few hours (29%) or within a day (20%) (S-Table-2).

Impact of MP-AzeFlu

Quality of life

Overall, only 54% of patients reported good to excellent QoL when experiencing AR symptoms prior to MP-AzeFlu use, rising to 91% of patients when treated with MP-AzeFlu (Table 3; Figure 2A). A similar pattern was noted in each country (S-Table 3). The average change in QoL between off and on MP-AzeFlu was 0.9 (SD 1.3) on a scale from 1 (poor) to 5 (excellent), corresponding to a 35% improvement in QoL

Table 3. Burden of AR experienced by survey participants before MP-AzeFlu treatment.

		Total ($N = 1004$)	Austria ($n = 100$)	Finland ($n = 100$)	Germany ($n = 202$)	Ireland ($n = 101$)	Italy ($n = 201$)	Norway ($n = 100$)	UK ($n = 200$)
Symptom with	Blocked nose	170 (18%)	19 (20%)	23 (25%)	34 (18%)	13 (14%)	36 (19%)	12 (13%)	33 (18%)
Greatest impact when not on	Itchy nose	41 (4%)	5 (5%)	4 (4%)	6 (3%)	2 (2%)	11 (6%)	2 (2%)	11 (6%)
treatment *N* (%)	Runny nose	149 (16%)	17 (18%)	19 (20%)	32 (17%)	18 (20%)	28 (15%)	9 (10%)	26 (14%)
Multiple options allowed	Sneezing	111 (12%)	10 (11%)	7 (8%)	15 (8%)	7 (8%)	31 (16%)	9 (10%)	32 (17%)
	Itchy eyes	145 (16%)	9 (10%)	9 (10%)	32 (17%)	12 (13%)	31 (16%)	16 (18%)	36 (19%)
	Red eyes	58 (6%)	11 (12%)	4 (4%)	11 (6%)	3 (3%)	14 (7%)	8 (9%)	7 (4%)
	Watery eyes	73 (8%)	10 (11%)	6 (6%)	31 (17%)	5 (5%)	9 (5%)	3 (3%)	9 (5%)
	Itchy mouth	12 (1%)	5 (5%)	0 (0%)	2 (1%)	0 (0%)	3 (2%)	1 (1%)	1 (1%)
	Sinus pressure	40 (4%)	3 (3%)	1 (1%)	4 (2%)	15 (16%)	4 (2%)	6 (7%)	7 (4%)
	Cough	35 (4%)	0 (0%)	6 (6%)	8 (4%)	3 (3%)	8 (4%)	1 (1%)	9 (5%)
	Sore throat	11 (1%)	0 (0%)	1 (1%)	4 (2%)	1 (1%)	3 (2%)	0 (0%)	2 (1%)
	Headache	49 (5%)	4 (4%)	3 (3%)	6 (3%)	8 (9%)	4 (2%)	13 (14%)	11 (6%)
	Wheezing	38 (4%)	0 (0%)	10 (11%)	2 (1%)	5 (5%)	8 (4%)	11 (12%)	2 (1%)
Quality of life when not on	Excellent	100 (10%)	6 (6%)	5 (5%)	11 (5%)	17 (17%)	11 (5%)	9 (9%)	41 (21%)
treatment *N* (%)	Very good	227 (23%)	20 (20%)	12 (12%)	44 (22%)	15 (15%)	46 (23%)	25 (25%)	65 (33%)
	Good	206 (21%)	21 (21%)	21 (21%)	38 (19%)	27 (27%)	40 (20%)	25 (25%)	34 (17%)
	Fair	216 (22%)	19 (19%)	38 (38%)	37 (18%)	22 (22%)	41 (20%)	20 (20%)	39 (20%)
	Poor	255 (25%)	34 (34%)	24 (24%)	72 (36%)	20 (20%)	63 (31%)	21 (21%)	21 (11%)
Most negatively affected	Sleep	243 (52%)	17 (32%)	40 (65%)	51 (47%)	18 (43%)	55 (53%)	28 (68%)	34 (57%)
areas of life when not on	Daily activities	335 (75%)	34 (64%)	54 (87%)	86 (79%)	31 (74%)	79 (76%)	27 (66%)	44 (73%)
treatment[a] *N* (%)	Leisure activities	242 (51%)	32 (60%)	37 (60%)	70 (64%)	15 (36%)	40 (38%)	19 (46%)	29 (48%)
	Social activities	196 (42%)	20 (38%)	23 (37%)	56 (51%)	8 (19%)	39 (38%)	24 (59%)	26 (43%)
	Emotional well-being	185 (39%)	16 (30%)	28 (45%)	49 (45%)	16 (38%)	41 (40%)	11 (27%)	24 (40%)
Sample in employment or education[a]	N	891	85	81	183	90	183	92	177
Doctor visits per year	Mean (SD)	3.3 (3.5)	2.8 (2.6)	2.2 (2.4)	3.1 (3.8)	3.7 (2.7)	3.5 (3.4)	3.3 (2.3)	3.7 (4.7)
Allergy specialist visits per year	Mean (SD)	1.7 (3.1)	1.6 (1.8)	1.8 (6.9)	1.7 (2.4)	1.2 (1.8)	2.0 (2.6)	1.6 (1.8)	1.7 (2.6)
Nurse visits per year	Mean (SD)	1.2 (2.5)	0.9 (1.6)	1.8 (2.7)	0.6 (2.3)	1.4 (2.5)	0.9 (1.9)	1.3 (2.0)	1.9 (3.1)
Pharmacist visits per year	Mean (SD)	4.2 (5.6)	4.0 (4.5)	6.7 (8.8)	3.6 (4.8)	5.7 (6.5)	4.4 (5.8)	2.4 (2.9)	3.8 (4.4)
Days off work per year[a]	Mean (SD)	8.1 (11.0)	6.9 (9.9)	6.0 (11.1)	8.5 (11.6)	6.7 (7.5)	8.7 (11.8)	9.7 (10.7)	8.3 (11.4)
Days of productivity affected while at work per year[a]	Mean (SD)	15.8 (18.9)	19.1 (20.5)	12.9 (16.4)	17.0 (19.0)	10.3 (14.6)	15.9 (17.1)	21.4 (24.6)	13.9 (18.2)
Extent of productivity impact	0%	13 (1%)	1 (1%)	2 (2%)	2 (1%)	2 (2%)	4 (2%)	1 (1%)	1 (1%)
N (%)	10%	41 (5%)	4 (5%)	3 (4%)	6 (3%)	5 (6%)	9 (5%)	2 (2%)	12 (7%)
	20%	84 (9%)	3 (4%)	7 (9%)	20 (11%)	10 (11%)	16 (9%)	6 (7%)	22 (12%)
	30%	123 (14%)	14 (16%)	10 (12%)	27 (15%)	15 (17%)	24 (13%)	15 (16%)	18 (10%)
	40%	114 (13%)	15 (18%)	12 (15%)	19 (10%)	10 (11%)	25 (14%)	11 (12%)	22 (12%)
	50%	156 (18%)	13 (15%)	9 (11%)	39 (21%)	19 (21%)	33 (18%)	14 (15%)	29 (16%)
	60%	148 (17%)	21 (25%)	13 (16%)	29 (16%)	8 (9%)	29 (16%)	18 (20%)	30 (17%)
	70%	107 (12%)	7 (8%)	11 (14%)	23 (13%)	8 (9%)	24 (13%)	13 (14%)	21 (12%)
	80%	60 (7%)	5 (6%)	9 (11%)	9 (5%)	5 (6%)	13 (7%)	9 (10%)	10 (6%)
	90%	24 (3%)	0 (0%)	4 (5%)	7 (4%)	6 (7%)	3 (2%)	1 (1%)	3 (2%)
	100%	21 (2%)	2 (2%)	1 (1%)	2 (1%)	2 (2%)	3 (2%)	2 (2%)	9 (5%)

[a]Only participants who had poor or fair quality of life when not on treatment were asked about negatively affected areas of life. Abbreviations. AR, allergic rhinitis; SD, standard deviation.

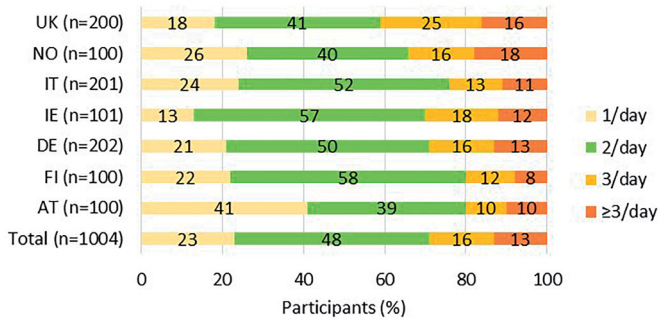

Figure 1. Participant reported daily frequency of MP-AzeFlu use, overall ($n = 1004$) and by country. Abbreviations. AT, Austria; DE, Germany; FI, Finland; IE, Ireland; IT, Italy; NO, Norway; UK, United Kingdom.

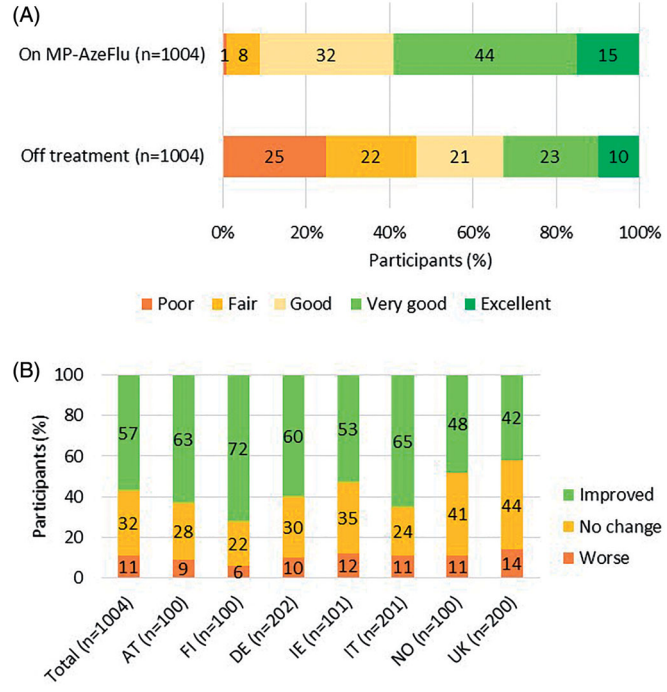

Figure 2. Participant reported (A) quality of life and (B) change in quality of life before and after treatment with MP-AzeFlu, overall ($n = 1004$) and by country. Abbreviations. AT, Austria; DE, Germany; FI, Finland; IE, Ireland; IT, Italy; NO, Norway; UK, United Kingdom.

when on MP-AzeFlu compared with off treatment (S-Table 4). Overall, 57% of participants reported better QoL on MP-AzeFlu, 32% reported no change and 11% reported worse QoL (Figure 2B).

Healthcare resource utilization

Overall, MP-AzeFlu use was associated with 0.9 (SD 2.8) fewer doctor visits and 1.6 (SD 4.1) fewer pharmacist visits/year, a 27% and 38% reduction, respectively. Survey participants from each country reported a reduction in the number of doctor and pharmacist visits on MP-AzeFlu (S-Table-4). 47% of participants reported fewer doctor visits (Figure 3A), and 46% reported fewer pharmacist visits/year on MP-AzeFlu (Figure 3B). Using MP-AzeFlu was associated

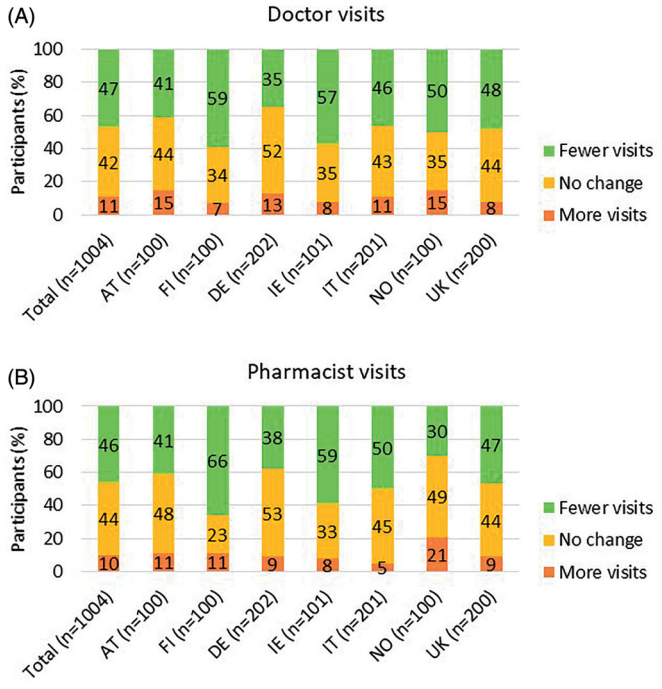

Figure 3. % of participants who reported more, fewer or no change in the number of (A) doctor and (B) pharmacist visits since using MP-AzeFlu, overall ($n = 1004$) and by country. Abbreviations. AT, Austria; DE, Germany; FI, Finland; IE, Ireland; IT, Italy; NO, Norway; UK, United Kingdom.

with decreased use of other AR treatments. Post MP-AzeFlu use, 29% of participants reported poly-pharmacy use (vs 48% pre-treatment). Among those who reported polypharmacy use pre-MP-AzeFlu, 52% of participants reported discontinuation of polypharmacy since using MP-AzeFlu.

Absenteeism and presenteeism

Compared to off treatment, participants treated with MP-AzeFlu reported a reduction in absenteeism of 2.5 (SD 10.0) days/year and a reduction in presenteeism of 7.3 (SD 16.0) days/year, a 31% and 46% reduction, respectively. A similar pattern was observed for each country (S-Table 4). When treated with MP-AzeFlu, 46% of participants reported fewer days absent from work due to AR, (Figure 4A). 57% reported fewer days with reduced productivity (Figure 4B), and 51% reported that their AR symptoms had less impact on their productivity (Figure 4C).

MP-AzeFlu satisfaction

Relative satisfaction

70% of participants were more or much more satisfied with MP-AzeFlu compared to their previous AR treatment (Figure 5A). Previous AR treatments reported included: oral anti-histamines (51%), intranasal anti-histamines (33%), sodium cromoglycate (17%), leukotriene receptor antagonist (10%), INS (14%), eye drops (38%) and immunotherapy (7%), with 48% of participants stating that they used $\geq$2 treatments. Some inter-country difference in relative satisfaction rating was noted among countries, ranging from 63% of

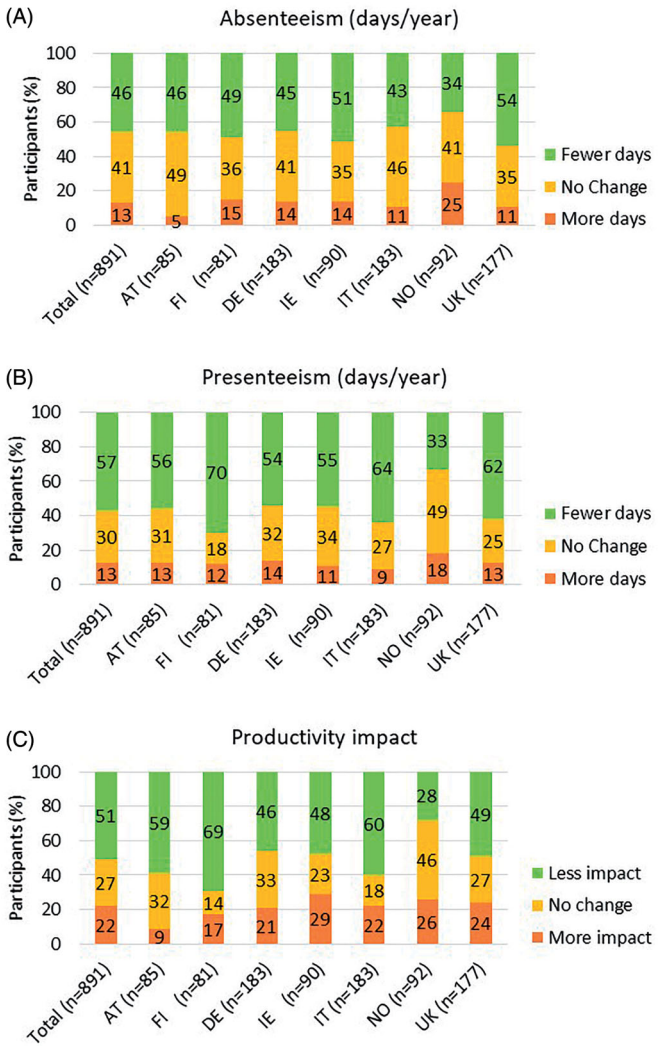

Figure 4. % of participants who reported more, fewer or no change in (A) number of days off work, (B) number of days with productivity impacted by AR and (C) productivity impact since using MP-AzeFlu, overall ($n = 891$) and by country. Abbreviations. AT, Austria; DE, Germany; FI, Finland; IE, Ireland; IT, Italy; NO, Norway; UK, United Kingdom.

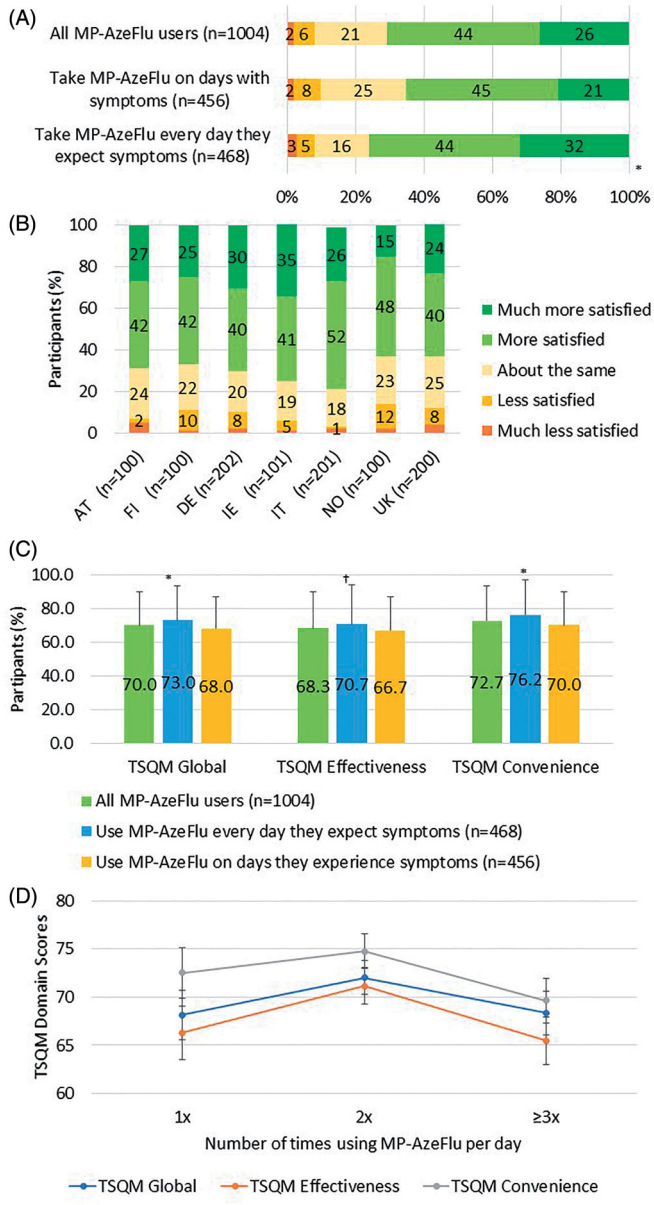

Figure 5. Participant satisfaction with MP-AzeFlu compared to previous AR treatment (A) for all participants and by treatment pattern (B) by country, (C) measured using the TSQM-9 (all participants and by treatment pattern) and (D) measured using the TSQM-9 according to dosing schedule (once daily: $n = 228$; twice daily: $n = 481$; ≥3 times/day: $n = 292$. Abbreviations. AT, Austria; DE, Germany; FI, Finland; IE, Ireland; IT, Italy; NO, Norway; TSQM-9, Treatment Satisfaction Questionnaire for Medication-9 item; UK, United Kingdom. *$p < .001$; †$p < .01$.

participants in Norway (who were more or much more satisfied with MP-AzeFlu) to 78% in Italy (Figure 5B). Satisfaction rating was also dependent on MP-AzeFlu usage pattern. Significantly ($p < .001$) more participants (76%) were more or much more satisfied with MP-AzeFlu than their previous AR treatment when MP-AzeFlu was used every day symptoms were expected, compared to 66% of participants who used it only on symptom days (Figure 5A).

TSQM-9

The mean TSQM Global satisfaction score with MP-AzeFlu was 70.0 (SD 19.8) (Figure 5C) and was significantly ($p < .01$) different between countries, ranging from 64.0 in Norway to approximately 72 in Ireland, Italy and the UK. Overall, 93% of participants reported feeling somewhat to extremely confident of the benefits of MP-AzeFlu, 92% were somewhat to extremely certain that the benefits outweighed the risks and 75% stated that they were satisfied to extremely satisfied with MP-AzeFlu (Table 4).

The average TSQM-9 effectiveness score with MP-AzeFlu was 68.3/100.0 (SD 21.6) (Figure 5C) and was significantly ($p < .01$) different between countries, ranging from 63.4 in Norway to 72.9 in the UK. More than or equal to 70% of participants reported that they were satisfied to extremely satisfied with the ability of MP-AzeFlu to prevent or to treat their AR, with the way MP-AzeFlu relieved symptoms and with its onset of action (Table 4).

The average TSQM-9 convenience score for MP-AzeFlu was 72.7/100.0 (SD 20.4) (Figure 5C). Overall, 74% of participants reported that MP-AzeFlu was easy to extremely easy to use and 75% considered it was convenient to extremely convenient to take it as instructed (Table 4).

Table 4. TSQM global satisfaction, effectiveness and convenience with MP-AzeFlu treatment.

		Total ($N = 1004$)	Austria ($n = 100$)	Finland ($n = 100$)	Germany ($n = 202$)	Ireland ($n = 101$)	Italy ($n = 201$)	Norway ($n = 100$)	UK ($n = 200$)
TSQM-9 global satisfaction									
TSQM Global Satisfaction subscale[a] score (0–100)	Mean (SD)	70.0 (19.8)	66.4 (19.5)	70.6 (21.0)	69.5 (21.3)	71.8 (20.4)	72.0 (17.9)	63.9 (17.5)	72.2 (19.6)
Overall, how confident are you that taking this medication is a good thing for you? *N* (%)	Not at all confident	18 (2%)	4 (4%)	2 (2%)	6 (3%)	1 (1%)	0 (0%)	1 (1%)	4 (2%)
	A little confident	55 (5%)	6 (6%)	3 (3%)	12 (6%)	6 (6%)	6 (3%)	9 (9%)	13 (7%)
	Somewhat confident	293 (29%)	35 (35%)	32 (32%)	53 (26%)	25 (25%)	63 (31%)	42 (42%)	43 (22%)
	Very confident	411 (41%)	35 (35%)	39 (39%)	86 (43%)	41 (41%)	83 (41%)	38 (38%)	89 (45%)
	Extremely confident	227 (23%)	20 (20%)	24 (24%)	45 (22%)	28 (28%)	49 (24%)	10 (10%)	51 (26%)
How certain are you that the good things about your medication outweigh the bad things? *N* (%)	Not at all certain	13 (1%)	4 (4%)	2 (2%)	3 (1%)	1 (1%)	0 (0%)	1 (1%)	2 (1%)
	A little certain	67 (7%)	7 (7%)	7 (7%)	16 (8%)	7 (7%)	8 (4%)	11 (11%)	11 (6%)
	Somewhat certain	331 (33%)	39 (39%)	27 (27%)	60 (30%)	36 (36%)	73 (36%)	41 (41%)	55 (28%)
	Very certain	386 (38%)	39 (39%)	39 (39%)	85 (42%)	34 (34%)	77 (38%)	32 (32%)	80 (40%)
	Extremely certain	207 (21%)	11 (11%)	25 (25%)	38 (19%)	23 (23%)	43 (21%)	15 (15%)	52 (26%)
Taking all things into account, how satisfied or dissatisfied are you with this medication? *N* (%)	Extremely dissatisfied	11 (1%)	2 (2%)	1 (1%)	5 (2%)	1 (1%)	0 (0%)	1 (1%)	1 (1%)
	Very dissatisfied	22 (2%)	1 (1%)	3 (3%)	6 (3%)	2 (2%)	3 (1%)	3 (3%)	4 (2%)
	Dissatisfied	36 (4%)	4 (4%)	5 (5%)	4 (2%)	3 (3%)	6 (3%)	7 (7%)	7 (4%)
	Somewhat satisfied	186 (19%)	21 (21%)	20 (20%)	36 (18%)	22 (22%)	31 (15%)	20 (20%)	36 (18%)
	Satisfied	258 (26%)	25 (25%)	21 (21%)	54 (27%)	15 (15%)	59 (29%)	32 (32%)	52 (26%)
	Very satisfied	288 (29%)	31 (31%)	27 (27%)	54 (27%)	31 (31%)	65 (32%)	28 (28%)	52 (26%)
	Extremely satisfied	203 (20%)	16 (16%)	23 (23%)	43 (21%)	27 (27%)	37 (18%)	9 (9%)	48 (24%)
TSQM-9 effectiveness									
TSQM Effectiveness subscale[a] score (0–100)	Mean (SD)	68.3 (21.6)	64.6 (22.5)	69.9 (21.0	67.7 (24.3)	68.8 (21.7)	67.7 (21.1)	63.4 (17.3)	72.9 (20.4)
How satisfied or dissatisfied are you with the ability of the medication to prevent or treat your condition? *N* (%)	Extremely dissatisfied	37 (4%)	9 (9%)	2 (2%)	8 (4%)	3 (3%)	6 (3%)	1 (1%)	8 (4%)
	Very dissatisfied	53 (5%)	4 (4%)	5 (5%)	11 (5%)	2 (2%)	20 (10%)	7 (7%)	4 (2%)
	Dissatisfied	34 (3%)	3 (3%)	4 (4%)	5 (2%)	6 (6%)	3 (1%)	7 (7%)	6 (3%)
	Somewhat satisfied	168 (17%)	22 (22%)	17 (17%)	31 (15%)	23 (23%)	23 (11%)	25 (25%)	27 (14%)
	Satisfied	282 (28%)	31 (31%)	23 (23%)	59 (29%)	22 (22%)	63 (31%)	35 (35%)	49 (25%)
	Very satisfied	276 (27%)	19 (19%)	32 (32%)	55 (27%)	24 (24%)	59 (29%)	20 (20%)	67 (34%)
	Extremely satisfied	154 (15%)	12 (12%)	17 (17%)	33 (16%)	21 (21%)	27 (13%)	5 (5%)	39 (20%)
How satisfied or dissatisfied are you with the way the medication relieves your symptoms? *N* (%)	Extremely dissatisfied	29 (3%)	8 (8%)	1 (1%)	8 (4%)	2 (2%)	4 (2%)	1 (1%)	5 (3%)
	Very dissatisfied	38 (4%)	4 (4%)	5 (5%)	10 (5%)	2 (2%)	11 (5%)	3 (3%)	3 (2%)
	Dissatisfied	29 (3%)	2 (2%)	3 (3%)	2 (1%)	4 (4%)	5 (2%)	6 (6%)	7 (4%)
	Somewhat satisfied	179 (18%)	20 (20%)	14 (14%)	41 (20%)	24 (24%)	25 (12%)	24 (24%)	31 (16%)
	Satisfied	281 (28%)	26 (26%)	32 (32%)	53 (26%)	19 (19%)	71 (35%)	34 (34%)	46 (23%)
	Very satisfied	276 (27%)	27 (27%)	26 (26%)	44 (22%)	33 (33%)	61 (30%)	26 (26%)	59 (30%)
	Extremely satisfied	172 (17%)	13 (13%)	19 (19%)	44 (22%)	17 (17%)	24 (12%)	6 (6%)	49 (25%)
How satisfied or dissatisfied are you with the amount of time it takes the medication to start working? *N* (%)	Extremely dissatisfied	21 (2%)	5 (5%)	2 (2%)	8 (4%)	2 (2%)	2 (1%)	1 (1%)	1 (1%)
	Very dissatisfied	41 (4%)	2 (2%)	4 (4%)	13 (6%)	2 (2%)	13 (6%)	2 (2%)	5 (3%)
	Dissatisfied	30 (3%)	1 (1%)	3 (3%)	7 (3%)	5 (5%)	6 (3%)	6 (6%)	2 (1%)
	Somewhat satisfied	201 (20%)	20 (20%)	19 (19%)	38 (19%)	26 (26%)	35 (17%)	27 (27%)	36 (18%)
	Satisfied	294 (29%)	31 (31%)	27 (27%)	50 (25%)	26 (26%)	67 (33%)	34 (34%)	59 (30%)
	Very satisfied	260 (26%)	24 (24%)	29 (29%)	52 (26%)	25 (25%)	51 (25%)	24 (24%)	55 (28%)
	Extremely satisfied	157 (16%)	17 (17%)	16 (16%)	34 (17%)	15 (15%)	27 (13%)	6 (6%)	42 (21%)
TSQM-9 convenience									
TSQM Convenience subscale[a] score (0–100)	Mean (SD)	72.7 (20.4)	73.4 (21.5)	74.3 (21.3)	71.8 (22.3)	73.7 (18.7)	72.8 (17.6)	68.0 (19.8)	74.2 (20.9)
How easy or difficult is it to use the medication in its current form? *N* (%)	Extremely difficult	10 (1%)	2 (2%)	0 (0%)	4 (2%)	0 (0%)	1 (1%)	1 (1%)	2 (1%)
	Very difficult	24 (2%)	2 (2%)	5 (5%)	6 (3%)	2 (2%)	3 (2%)	2 (2%)	4 (2%)
	Difficult	33 (3%)	2 (2%)	1 (1%)	13 (6%)	3 (3%)	7 (3%)	4 (4%)	3 (2%)
	Somewhat easy	187 (19%)	19 (19%)	15 (15%)	31 (15%)	21 (21%)	46 (23%)	23 (23%)	32 (16%)
	Easy	223 (22%)	21 (21%)	29 (29%)	38 (19%)	20 (20%)	51 (25%)	24 (24%)	40 (20%)
	Very easy	265 (26%)	20 (20%)	21 (21%)	57 (28%)	27 (27%)	52 (26%)	28 (28%)	60 (30%)
	Extremely easy	262 (26%)	34 (34%)	29 (29%)	53 (26%)	28 (28%)	41 (20%)	18 (18%)	59 (30%)
How easy or difficult is it to plan when you will use the medication each time? *N* (%)	Extremely difficult	14 (1%)	2 (2%)	2 (2%)	4 (2%)	0 (0%)	0 (0%)	2 (2%)	4 (2%)
	Very difficult	16 (2%)	2 (2%)	3 (3%)	5 (2%)	2 (2%)	0 (0%)	1 (1%)	3 (2%)
	Difficult	37 (4%)	1 (1%)	2 (2%)	10 (5%)	3 (3%)	5 (2%)	7 (7%)	9 (5%)
	Somewhat easy	223 (22%)	26 (26%)	17 (17%)	42 (21%)	20 (20%)	49 (24%)	29 (29%)	40 (20%)
	Easy	226 (23%)	17 (17%)	25 (25%)	42 (21%)	26 (26%)	58 (29%)	16 (16%)	42 (21%)
	Very easy	274 (27%)	30 (30%)	27 (27%)	55 (27%)	32 (32%)	51 (25%)	29 (29%)	50 (25%)

(*continued*)

Table 4. Continued.

		Total ($N = 1004$)	Austria ($n = 100$)	Finland ($n = 100$)	Germany ($n = 202$)	Ireland ($n = 101$)	Italy ($n = 201$)	Norway ($n = 100$)	UK ($n = 200$)
How convenient or inconvenient is it to take the medication as instructed? *N* (%)	Extremely easy	214 (21%)	22 (22%)	24 (24%)	44 (22%)	18 (18%)	38 (19%)	16 (16%)	52 (56%)
	Extremely inconvenient	14 (1%)	2 (2%)	0 (0%)	5 (2%)	0 (0%)	1 (1%)	1 (1%)	5 (3%)
	Very inconvenient	23 (2%)	2 (2%)	7 (7%)	6 (3%)	1 (1%)	1 (1%)	2 (2%)	4 (2%)
	Inconvenient	31 (3%)	3 (3%)	3 (3%)	7 (3%)	6 (6%)	4 (2%)	4 (4%)	4 (2%)
	Somewhat inconvenient	178 (18%)	15 (15%)	12 (12%)	33 (16%)	18 (18%)	35 (17%)	31 (31%)	34 (17%)
	Convenient	252 (25%)	25 (25%)	20 (20%)	47 (23%)	25 (25%)	57 (28%)	32 (32%)	46 (23%)
	Very convenient	282 (28%)	32 (32%)	24 (24%)	59 (29%)	28 (28%)	62 (31%)	17 (17%)	60 (30%)
	Extremely convenient	224 (22%)	21 (21%)	34 (34%)	45 (22%)	23 (23%)	41 (20%)	13 (13%)	47 (24%)

[a]Treatment Satisfaction Questionnaire for Medication (TSQM) Convenience subscale score as calculated using the official guidelines in the TSQM User Manual. The TSQM global satisfaction, effectiveness and convenience subscales are based on the average of the three questions directly below them. Abbreviation. SD, standard deviation.

TSQM-9- assessed satisfaction (global, effectiveness and convenience domains) were significantly influenced by MP-AzeFlu pattern of use, showing significant ($p \leq .01$) improvement when MP-AzeFlu was used every day symptoms were expected versus when used only when symptomatic (Figure 5C). TSQM-9-assessed satisfaction (all domains) was also significantly impacted by MP-AzeFlu dosing-frequency (Figure 5D). Using MP-AzeFlu less often than recommended was associated with a 3.9-point decrease in TSQM-global score ($p < .05$) and a 4.9-point decrease in TSQM-effectiveness score ($p < .01$). Using MP-AzeFlu more often than twice a day was also associated with a reduction in satisfaction; a decrease of 3.7 ($p < .05$), 5.7 ($p < .001$) and 5.1 ($p < .01$) points in global, effectiveness and convenience scores, respectively (Figure 5D).

Post-hoc analyses

No significant ($p = .274$) difference in mean TSQM Global satisfaction score was noted for patients on MP-AzeFlu alone (70.4; SD 19.5) versus those on MP-AzeFlu plus $\geq$1 other AR treatment (68.9; SD 20.4) (S-Table 5). Similar TSQM effectiveness and convenience scores were also reported for those on MP-AzeFlu alone or on MP-AzeFlu plus other AR treatment(s). Although both patients with AR only and those with AR and asthma co-morbidity reported high TSQM global, effectiveness and convenience scores, those with AR only had significantly greater scores compared to those with AR and asthma (S-Table 5).

Discussion

There is an increasing trend to use real-world data to inform clinical practice in recognition of the value of the patient perspective and the need for a patient-centered approach to AR management. According to ARIA, guidelines are not sufficiently followed because they are not close enough to patients' needs and probably do not reflect real life[21]. Additionally, the European Academy of Allergy & Clinical Immunology (EAACI) has called on EU policy makers for pan-European awareness campaigns to drive recognition of the burden of allergic disease[28]. Our pan-European survey answers those calls to action, seeking to better understand the real-life AR disease and treatment landscapes, examine the symptomatic and economic burdens AR places on patients' lives, and discover how patients really use their AR treatment in real-life. We have also highlighted important gaps in patient knowledge about AR. For example, although only 34% of participants considered they had PAR or a PAR-component to their AR, almost half of them reported a HDM allergy. This means that PAR may be routinely under-recognized in real-life and consequently under-treated. These findings may be explained, in part, by the seasonality of HDM-allergy (with symptoms peaking in Spring and Autumn), which may be confused as SAR[29]. Indeed, this is the primary reason why ARIA proposed classifying AR according to duration of symptoms (i.e. intermittent/persistent) rather than by aetiology (i.e. SAR/PAR) [30]. The impact of MP-

AzeFlu (currently the most effective symptomatic AR treatment)[21,30,31] is assessed using outcomes which are relevant to patients, HCPs, and payers, including QoL, HCRU, absenteeism and productivity impact. This survey is the first to measure satisfaction with MP-AzeFlu using a validated questionnaire (TSQM-9) and shows an indirect link between satisfaction and patient reported outcomes.

With more than 150 million EU citizens suffering from chronic allergic disease, EAACI recognizes the burden of AR on both sufferers and healthcare economies[28]. Our survey quantifies this burden and highlights the debilitating effect AR has on patients' lives including the negative impact of symptoms (notably nasal congestion, rhinorrhoea and itchy eyes) on patient QoL, daily activities and sleep. The economic consequences of that impact are also evident from the high HCRU (e.g. 3.3 doctor visits/year for AR and a polypharmacy rate (pre-MP-AzeFlu) of 48%), absenteeism (8.1 days/year) and presenteeism (15.8 days/year) rates reported, most likely reflecting the severity of symptoms of those who received MP-AzeFlu. The high total cost of AR has previously been estimated at €1.3 billion annually in Sweden (for 9.5 million inhabitants), rising to €55–151 billion/annum in avoidable indirect costs due to failure to treat allergy properly in the EU[13,32]. Other AR surveys have reported a similarly high burden of AR[1,5,6,8,29,33–35]. In the UK, AR patients with moderate severe disease continued to experience significant nasal and ocular symptoms on treatment (even though 70.5% of them were on $\geq$2 AR therapies), visited their GP 1.61 times/year (due to dissatisfaction in one-third of cases) and were absent form work/school due to AR on 4.1 days/year[1]. Another observational study conducted in France, Italy and Spain found that 87% of patients with self-reported AR had attended an allergist in the last year[29]. Others reported that AR symptoms were severe enough to interfere with daily activities, reduce sleep quality, and negatively impact emotional well-being[6]. In agreement with our findings, the presence of AR symptoms (or failure to take AR medication) was associated with a worsening of asthma control in co-morbid patients, with severe rhinitis symptoms affecting asthma control to the same degree as smoking[1,12].

After allergen avoidance and saline douching, pharmacotherapy remains at the forefront of AR management to combat symptoms and their effects on patients' lives. International management guidelines provide treatment recommendations based on the best available evidence[23,36,37]. Traditionally this evidence has come from randomized controlled trials (RCTs), which assess the effect of pharmacotherapies under optimal conditions (e.g. good adherence and technique)[38]. However, in real life, patients' treatment behaviour can be far from optimal, a fact which is confirmed in our survey which showed a mis-alignment between guideline-directed treatment recommendations and every day treatment patterns. Participants reported using MP-AzeFlu in a way which is neither indicated nor studied in RCTs with respect to both daily usage and daily dosage; 64% of participants reported using MP-AzeFlu intermittently when experiencing symptoms, and 52% did not take it twice daily as recommended, and thus may not have derived full benefit from MP-AzeFlu. An intermittent pattern of use may be due to the fact that most patients suffer from several episodes of short-term AR symptoms and so rarely take their medication continuously for 14 days[1]. The recent introduction of m-health tools (e.g. patient apps to monitor symptoms and disease control) to AR management protocols has also shown a discordance between treatment recommendation and patient behaviour in real life. For example, a recent study using the *Mask-air* app found that 69% of AR patients were non adherent to medications[4]. Using the same app it was found that patients stop and start treatment, frequently switch treatments and increase the number of AR medications when they are unwell[39,40]. However, in the current survey participants showed a high degree of loyalty to MP-AzeFlu, with an average duration of use of 2.57 years.

Better AR control may be achieved by listening to patients, taking account of how they actually manage their AR and understanding the reason(s) for their treatment choices; this is the approach advocated by the ARIA Next Generation guidelines and the EUFOREA AR Pocket Guide[21,23]. In the current survey participants told us that insufficient nasal symptom relief, lack of effect, failure to target ocular symptoms and slow onset of action of previous therapies, were the main reasons they started to use MP-AzeFlu. Knowledge of how previous therapies have not met patients' expectations should enable physicians and pharmacists to select a treatment that will. Reasons for continued use are arguably just as important to know, as these may drive improved concordance with treatement regimens. Superior nasal and ocular symptom relief provided by MP-AzeFlu and a faster onset of action compared to other AR treatments were the most commonly reported reasons for its continued use. These perceived benefits of MP-AzeFlu were associated with an improvement in patient QoL, a reduction in the number of HCP visits, absenteeism and presenteeism, and a reduction in the use of AR polypharmacy. This reduction in HCRU is important when one considers that indirect costs, like presenteeism, account for 70% of the total cost of AR[13]. Evidence from RCTs, observational studies, and chamber studies back up these patient-reported outcomes[31,41,42]. In these studies, MP-AzeFlu improved patient QoL, provided twice the nasal and ocular symptom relief as an INS or an intranasal anti-histamine, rapid and sustained AR control in real-life and had an onset of action of 5 min[31,41,42].

Patient satisfaction with MP-AzeFlu was high, with mean TSQM-9 global, effectiveness and convenience scores of 70.0, 68.3 and 72.7, respectively. TSQM-9 scores were not statistically significantly different for those on MP-AzeFlu alone ($n = 708$) compared to the relatively small number on MP-AzeFlu plus another AR treatment ($n = 296$). This finding may simply be a consequence of unbalanced numbers between groups. However, TSQM-9 global, effectiveness and convenience scores were significantly higher for those participants with AR alone compared to those with both AR and asthma. This may have been due worse AR control in the co-morbid group, a confirmation of the one airway one disease concept. Future work to investigate AR treatment satisfaction in AR and asthma co-morbid patients stratified according to

asthma control, asthma treatment and adherence is warranted to further explore this issue.

MP-AzeFlu TSQM-9 scores appear to be higher or similar to those reported for other AR treatments using the same satisfaction questionnaire[43–45]. Comparative TSQM-9 scores for BDP (6 months treatment in PAR patients) were 70.5 for global, 71.6 for effectiveness and 80.6 for convenience[45]. Another small study of sub-cutaneous immunotherapy for HDM allergy reported TSQM-9 global, effectiveness and convenience scores of 58.9, 47.2 and 63.8, respectively[44]. Some country variation was noted in TSQM-9 scores in the current survey, notably Norway had the lowest global, effectiveness and convenience scores (63.9, 63.4 and 68.0) and the UK had the highest (72.2, 72.9 and 74.2). This may have been due to several factors including differences in health care systems, in survey population as well as the underlying severity of disease, its perceived impact on patients' lives and how MP-AzeFlu was used to treat it (Tables 1 and 3). Specifically, compared to the UK, Norway (NO) had a younger survey population (NO:32.6 vs UK:40.0 yrs), more students (NO:14% vs UK:1%), more participants who reported under-dosing with MP-AzeFlu (NO:26% vs UK:18%) and more participants with a poor QoL when not treated (NO:21% vs UK:11%). Norwegian participants also reported more absenteeism (NO: 9.7 days/yr vs UK:8.3 days/yr) and more days when productivity was affected by AR symptoms (NO:21.4 days/yr vs UK:13.9 days/yr). Conversely, the higher TSQM-scores recorded by UK participants (compared to those in NO) were associated with less pharmacy visits (UK:47% vs NO:30%), less days absent/year (UK:54% vs NO:34%) and fewer days productivity lost (UK:62% vs NO:33%). Furthermore, both relative and TSQM-9 assessed satisfaction was dependent on MP-AzeFlu pattern of use and dosing frequency, with greater satisfaction noted when MP-AzeFlu was used every day symptoms were expected and twice a day as recommended. These findings emphasize the importance of understanding AR from the patient perspective, contribute to our understanding of factors that can influence effectiveness and satisfaction with AR treatments in real life, and provide an indirect link between AR treatment satisfaction and outcomes.

Limitations of the current survey include a reliance on a patient-reported physician/HCP diagnosis of AR, assessment of AR severity, and use of MP-AzeFlu. This may have resulted in the inclusion of patients without AR, those with mild AR, and an over-estimation of MP-AzeFlu use. Additionally, the survey did not capture information on symptom severity or disease control and assessed MP-AzeFlu-treated patients only. To counterbalance these limitations, it should be noted that the survey was large, incorporating over 1000 participants from seven European countries. These participants were recruited from a variety of sources (e.g. patient panel, HCP referral, patient associations), and are arguably more representative of the AR population than patients included in RCTs[38,46]. Furthermore, as MP-AzeFlu is a prescription-only treatment in each of the countries included in this survey we may assume that it was prescribed according to its label (i.e. for moderate severe AR). Treatment satisfaction was assessed using the TSQM-9. This is a reliable and validated questionnaire that has been used in many therapy areas including AR studies, to assess patients' satisfaction with medication[27,43,45]. Use of the TSQM-9 provides confidence in the results obtained, facilitated cross-study comparison and enabled us to attribute any differences between patient response to real differences in perceptions of their outcomes, as opposed to differences in methodology or biases[47].

Conclusions

The impact of AR on patients' lives remains high. Real-life use of MP-AzeFlu reduces that impact and is associated with a high level of effectiveness, convenience and patient satisfaction. Our findings may be used to encourage frank and open physician-patient communication to achieve better AR outcomes, inform clinical trial design and used to provide a clearer picture of the costs of AR and benefits of effective AR treatment.

Transparency

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Declaration of financial/other relationships

GWC: has received research grants, as well as lecture or advisory board fees from A. Menarini, Alk-Albello, Allergy Therapeutics, AstraZeneca, Boehringer Ingelheim, Chiesi Farmaceutici, Genentech, Guidotti Malesci, GlaxoSmithKline, Hal Allergy, Merck, MSD, Mylan, Mundipharma, Novartis, Regeneron, Roche, Sanofi-Aventis, Sanofi-Genzyme, Stallergenes-Greer, UCB Pharma, Uriach Pharma, Valeas, and Vibor-Pharma.

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SA and SHL: are employees of Acaster Lloyd Consulting ltd., which received payment to design and implement this study and analyse the data.

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Author contributions

SA and SHL were involved in the conception and design of the survey. All authors were involved in the analysis and interpretation of the data, drafting of the paper and revising it critically for intellectual content. All authors approved of the final version of this manuscript and agreed to be accountable for all aspects of the work.

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ORCID

David B. Price http://orcid.org/0000-0002-9728-9992

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