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ORIGINAL RESEARCH ARTICLE

Interest in a Mobile App for Two-Way Risk Communication: A Survey Study Among European Healthcare Professionals and Patients

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Abstract

Introduction Previously, an app has been developed for healthcare professionals (HCPs) and patients to report adverse drug reactions (ADRs) to national medicines agencies and to receive drug safety information.

Objective This study aimed to assess (1) European HCPs' and patients' interest in an app for this two-way risk communication; (2) their preferences and perceptions towards specific app characteristics; and (3) which HCPs and patients are particularly interested in the app. In addition, these aspects were studied specifically for the countries where such an app was already available, i.e. Croatia, The Netherlands, and The UK.

Methods European HCPs and patients were asked to complete a web-based survey developed in the context of the Web-Recognizing Adverse Drug Reactions (Web-RADR) project. Data on app interest and preferences and perceptions towards app characteristics were analysed descriptively. Logistic regression analyses were conducted to assess the association of HCP characteristics and patient characteristics on the level of interest in the app (i.e. very interested vs. not/somewhat interested).

Results In total, 399 HCPs and 656 patients completed the survey. About half of the patients (48%; ranging from 38% from The Netherlands to 54% from The UK), and 61% of the HCPs (ranging from 42% from The Netherlands to 54% from The UK) were very interested in the app. A faster means of reporting ADRs and easier access to the reporting form were the main perceived benefits. HCPs and patients who already use a health app were particularly interested in the app (HCPs: odds ratio [OR] 3.52; 95% confidence interval [CI] 1.96–6.30, patients: OR 1.64; 95% CI 1.19–2.27).

Conclusions An app is positively perceived by HCPs and patients for reporting ADRs quickly and for receiving drug safety information from national medicines agencies. In particular, HCPs and patients who already use other health apps were interested in the app.

Key Points

Interest in an app for two-way risk communication (i.e. to report adverse drug reactions [ADRs] to national medicines agencies and to receive drug safety information) is high among healthcare professionals (HCPs) and patients.

The app should be a faster way to report ADRs than conventional reporting options and should preferably offer additional information about drug–drug interactions and previously reported ADRs.

Strategies to disseminate an app on two-way risk communication could focus on targeting HCPs and patients who already use a health app since these persons were particularly interested in the app.

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1 Introduction

Healthcare professionals (HCPs) and patients have access to a plethora of health-related mobile apps but not every person is equally interested in such apps. Recently, a health app developed in the context of the Web-Recognizing Adverse Drug Reactions (Web-RADR) project (https://web-radr.eu/) was added to the available health-related apps. The goal of this app is to provide two-way risk communication, defined as the possibility to report adverse drug reactions (ADRs) to national medicines agencies/pharmacovigilance centres, and to receive drug safety information from these agencies [1]. Previously, in a qualitative study, we identified various factors that may influence the use of this app and showed that HCPs and patients were generally positive about its development [2]. However, these aspects should be validated in a larger population.

Considering the plethora of new technologies, including apps, theoretical models have been developed attempting to identify factors that influence the uptake of the new technology. An example is the Unified Theory of Acceptance and Use of Technology, which states that user characteristics play a moderating role in the acceptance of technology [3]. This indicates that not every HCP or patient will be interested in the app. Several studies have investigated whether interest in health apps is influenced by characteristics such as age, ethnicity/race, gender, current use of a health app, inability to work, income, educational degree, clinical characteristics or having a family member with a specific disease [4–8]. Although the studies consistently show that older people are generally less interested in health apps than younger people [4–8], the literature is inconclusive about other user characteristics. For instance, Latinos/Hispanics were less interested in one study [6] but more interested in another study [8] than Caucasians/white people. Likewise, one study showed that males were slightly less interested than females [7], whereas another study showed no gender differences [8].

The previous studies conducted in the USA [5–8] or Asia (i.e. Singapore) [4] focused on patients or the general population, and assessed a person's interest in a health app in general [6–8] or in apps to support adherence or self-management [4, 5]. A recent study about the VigiBIP® app, developed by the Toulouse University Pharmacovigilance Center for two-way risk communication, suggests that patients are interested in the app and that different ADRs may by reported via the app compared with conventional methods [9]. However, more studies on characteristics of HCPs and patients on their interest in apps for communicating health-related issues with national medicines agencies are needed.

The aim of the current study was to assess (1) European HCPs' and patients' interest in an app for two-way risk communication; (2) their preferences and perceptions towards specific characteristics of the app; and (3) which HCPs and patients are particularly interested in such an app. In addition, these aspects were specifically studied for the countries where such an app was already available, i.e. Croatia, The Netherlands and The UK. This knowledge can be used by national medicines agencies in the development or improvement of an app for two-way risk communication and in the development of strategies to inform potential users about the existence of the app.

2 Methods

2.1 Study Design and Survey Development

In this cross-sectional study, data were collected between July and October 2016 using web-based surveys. Two surveys (i.e. one for HCPs and one for patients) were developed in English by members of the Web-RADR project (see Electronic Supplementary Material 1 and 2 for the HCP and patient survey, respectively). The English-language surveys were translated by an official translation agency into Croatian, Dutch, French, German, Portuguese and Spanish. Web-RADR members checked whether the translations had the same meaning as the English version. The web-based format of the surveys was created using Unipark software (http://unipark.com/en/). A separate link was available for the HCP and patient survey in each of the languages.

The content of the surveys was based on the results of a qualitative study [2], input from members of other work packages of the Web-RADR project, and various HCP and patient organisations. The patient survey contained questions about ADR reporting in general; their opinion of an app to report ADRs, an app to receive safety information, and an app for two-way risk communication; reporting ADRs through an app of the national medicines agency; safety information and receiving such information through an app; and, finally, some general questions such as age, gender and the country in which they lived at the time of survey completion.

In some questions, the name of the national medicines agency/pharmacovigilance centre was mentioned. The Agenciju za lijekove i medicinske proizvode (HALMED), Nederlands Bijwerkingencentrum (Lareb), Medicines and Health Regulatory Agency (MHRA), l'Agence nationale de sécurité du médicament et des produits de santé (ANSM), Bundesinstitutes für Arzneimittel und Medizinprodukte, Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED) and la Agencia Española del

Medicamento y Productos Sanitarios (AEMPS) were mentioned in the Croatian, Dutch, English, French, German, Portuguese and Spanish versions of the survey, respectively.

Participants gave their implied consent to participate in the study by voluntarily completing the survey.

2.2 Participants and Data Collection

Any HCP or patient in Europe familiar with mobile apps was eligible to participate in this study. All HCPs were considered to be familiar with apps. Patients were informed that they should only complete the survey if they were familiar with apps. Various channels were used to reach HCPs and patients. For instance, European and national HCP and patient organisations distributed the survey among members via direct e-mail or advertisements on their websites and/or in their newsletters. The survey was also announced on Facebook and Twitter accounts, for instance on the account of the Web-RADR project. Recruitment strategies focused particularly on reaching HCPs and patients in Croatia, The Netherlands and The UK since the Web-RADR app on two-way risk communication was available in these countries at the time of this study. The pharmacovigilance centres in Croatia, The Netherlands and The UK also distributed the survey, for instance by posting a message on their respective websites. To encourage response rates, survey completers had the option to participate in a prize draw to win a €50 coupon.

2.3 Outcome Measure: Interest in the App

The outcome measure of this study was responders' interest in an app for two-way risk communication. Responders were asked to rate on a 4-point Likert scale to what extent they were interested in such an app (Table 1). Responders could also indicate that they did not know whether they had interest in the app.

2.4 Determinants: App Characteristics

Expectations and actual characteristics of an app may influence someone's intention to download and use an app [3]. Therefore, responders were asked about their preferences and perceptions regarding an app for two-way risk communication. For this, questions were asked about perceived benefits in using the app, the type of news of interest, interest in other functions in the app and the protection of the app. In addition, responders were asked about their intention to download an app for two-way risk communication.

2.5 Determinants: Healthcare Professional (HCP)/ Patient Characteristics

The following HCP characteristics were assessed as determinants for HCPs' interest in an app for two-way risk communication: age, gender, how often they already used health apps and whether they had ever reported an ADR to the national medicines agency. For patients, the following characteristics were assessed: age, gender, educational level, number of medicines, how often they already used health apps, whether they had ever experienced an ADR and whether they were aware they could report ADRs to the national medicines agency (Table 1).

2.6 Analyses

Descriptive statistics are presented for HCPs and patients separately. In addition, this is presented for countries in which the app was already available. Completers of the Croatian, Dutch or English version of the survey who indicated they were living in these countries at the time of the survey were included in these country-specific analyses. Differences across these countries were tested using Chi-squared (χ^2) tests. Three post hoc χ^2-tests were conducted in the case of $P < 0.05$ to test which countries differed from each other. The Bonferroni correction was applied for these post hoc analyses to correct for multiple testing. This implies that P values < 0.016 were considered statistically significant.

Logistic regression analyses were conducted to assess associations between responder characteristics and the dichotomised outcome measure, expressing a high interest in the app. For this, being very interested was contrasted with being somewhat or not interested (Table 1). In sensitivity analyses using generalised ordered logit models [10, 11], we assessed whether this dichotomisation resulted in a loss of information. Responders were excluded from the logistic regression analyses and generalised ordered logit models when they (1) selected another answer option than male/female on the question about their gender; (2) did not answer or answered 'don't know' on the question about the app interest (outcome variable); or (3) did not answer a question that was used as a determinant in these analyses.

All analyses were conducted using Stata® version 13 (Stata Corp., College Station, TX, USA). Microsoft Excel® 2010 (Microsoft Corp., Redmond, WA, USA) was used for the graphical presentation of the results.

Table 1 Questions and answer options used as outcome variable and determinants

Variable	Question	Answer options	Type of variable in analyses	Analyses of HCPs/patients
Outcome variable				
App interest	In general, how interested would you be in an app of the <national medicines agency> that you can use for both, reporting side effects/adverse drug reactions and receiving safety information?	Not interested at all Somewhat interested Interested Very interested Don't know	Dichotomous: not/(somewhat) interested vs. very interested Don't know → excluded	HCPs and patients
Determinants				
Age	What is your age?	Continuous	Continuous	HCPs and patients
Gender	What is your gender?	Male Female Other/prefer not to say	Dichotomous: male vs. female Other/prefer not to say → excluded	HCPs and patients
Educational level	What is your highest level of education completed?	No formal education or below Primary education Lower secondary education Upper secondary education Post-secondary but non-tertiary education First stage of tertiary education Second stage of tertiary education	Dichotomous: low/secondary education vs. tertiary education (first and second stage)	Patients
Number of medicines	How many different medicines are prescribed to you at the moment?	0 1 2 3 4 5 or more	Categorical: 0 medicines; 1–4 medicines (reference category); ≥ 5 medicines	Patients
Use health apps	How often do you use a health app?	Daily Weekly Monthly or less often Never	Dichotomous: never vs. other answer options	HCPs and patients
Experience of ADRs	Have you ever experienced a side effect of a medicine that you take or have taken in the past?	Yes No Don't know/don't remember	Dichotomous: no/don't know vs. yes	Patients
Awareness of reporting ADRs	Are you aware that you can report experienced side effects to the <national medicines agency>?	Yes No I have never heard of the <national medicines agency>	Dichotomous: no/I have never heard of the <national medicines agency> vs. yes	Patients

Table 1 continued

Variable	Question	Answer options	Type of variable in analyses	Analyses of HCPs/patients
Report ADR to national medicines agency	Have you ever reported an adverse drug reaction experienced by your patients to the <national medicines agency>?	Yes No Don't know/don't remember	Dichotomous: no/don't know vs. yes	HCPs

ADR adverse drug reaction, *HCPs* healthcare professionals

3 Results

3.1 Characteristics of the Responders

3.1.1 HCPs

In total, 399 HCPs completed the survey: 192 were from Croatia, 62 were from The Netherlands, 83 were from The UK and 62 (16%) were from other European countries (i.e. countries where the app was not rolled out) (see Electronic Supplementary Material 3). The age of the responders ranged from 20 to 71 years and most of the responders were women (68%). Sixteen percent of the 399 HCPs indicated they had never used a health app. More than half of the HCPs had at least heard about the Web-RADR app.

3.1.2 Patients

There were 656 patients who completed the survey, of whom 136 were from Croatia, 187 were from The Netherlands, and 100 were from The UK. The remaining 233 (36%) patients were from other European countries (i.e. countries where the app was not rolled out) (Electronic Supplementary Material 3). The age of the participants ranged from 12 to 89 years and most of the responders were women (65%). Nineteen percent of the 656 patients were not prescribed any medicines. Half of the patients indicated they had never used a health app even though they had to be familiar with apps in general to complete the survey, and most were not aware of the Web-RADR app (77%).

3.2 Outcome Measure: Interest in the App

Responders were generally interested in the app for two-way risk communication (Fig. 1). In total, 61% of the HCPs were *very interested* in such an app, which ranged from 42% in The Netherlands to 66% in Croatia (Fig. 1a). HCPs were somewhat more interested in the app than patients. About half of the patients (48%) were *very interested* in the app, which ranged from 38% in The Netherlands to 54% in The UK (Fig. 1b). Interest in an app for two-way risk communication was somewhat higher than interest in an app with single functionality (i.e. reporting of ADRs or receiving safety information).

3.3 Determinants: App Characteristics

3.3.1 Perceived Benefits in Using the App

With respect to the reporting functionality of the app, most of the HCPs and patients indicated that a faster way to report ADRs and easier access to the ADR reporting form were potential benefits of using the app. These answer options were selected by 83 and 73% of the HCPs, respectively (Table 2) and by 85 and 72% of patients, respectively (Table 3).

Keeping up-to-date with the latest drug safety news (84%) and increasing their drug safety knowledge (76%) were important benefits perceived by HCPs on using an app. The possibility to select medicines of interest was seen as the least beneficial option for HCPs (47%) (Table 2). Most of the patients saw it as a benefit that the app would allow them to check whether a symptom has previously been reported as an ADR (72%) (Table 3).

3.3.2 Type of News of Interest

HCPs liked an option to receive news about newly identified drug–drug interactions most (82%), followed by information about new indications of a drug (75%) (Table 2). They also liked the option to receive news for all approved marketed drugs (37%). However, the 'work-/preference-specific' answer options (i.e. drugs that they prescribe, drugs related to their work and all drugs they are interested in) were together selected by about 60% of the HCPs (Table 2).

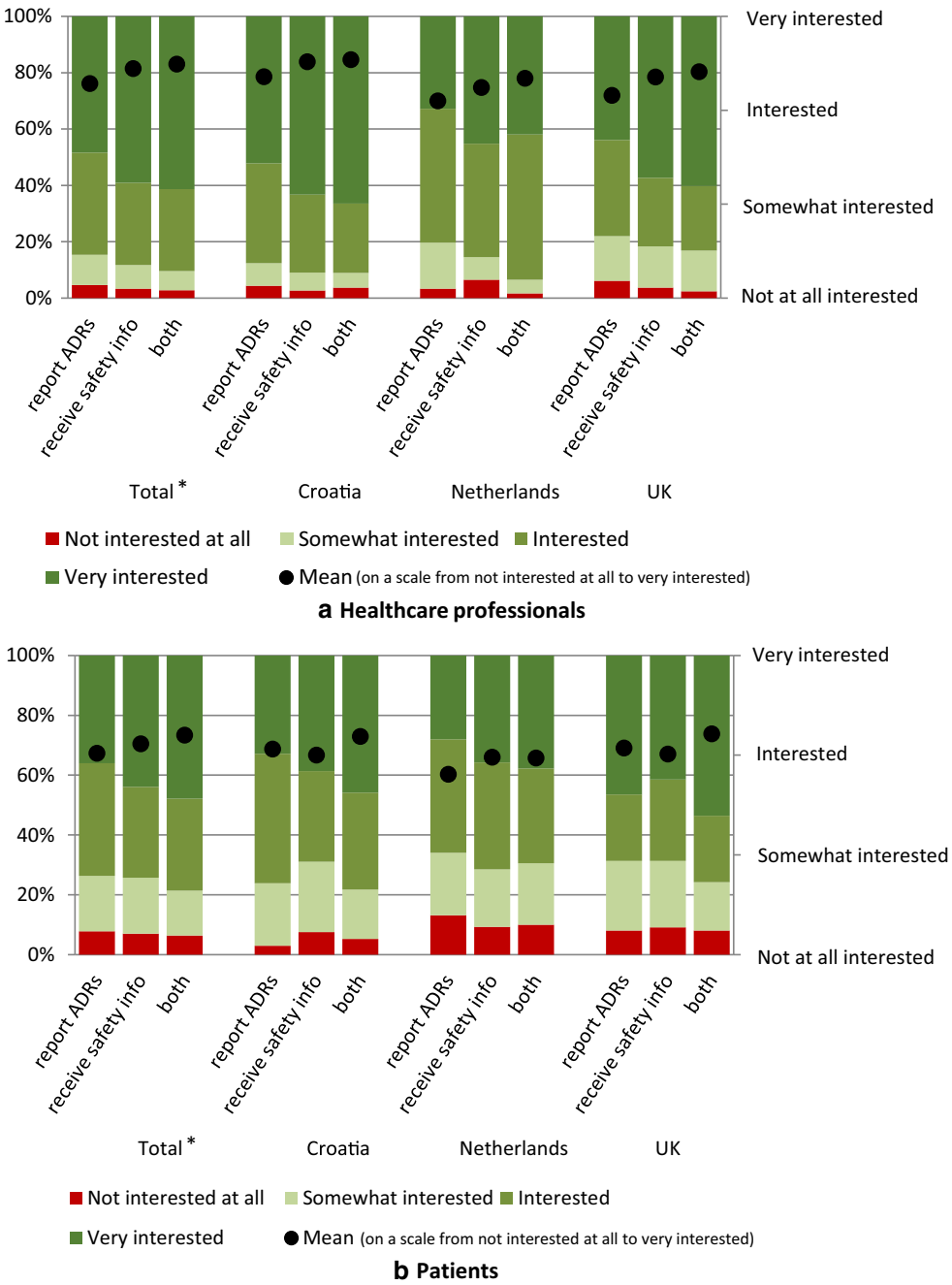

Fig. 1 **a** Healthcare professionals' interest in an app to report adverse drug reactions (8 responders were excluded; 4 did not complete this question and 4 answered 'I don't know'), to receive safety information (5 responders were excluded; 4 did not complete this questions and 1 answered 'I don't know'), and for both (i.e. two-way risk communication) (1 responder did not complete this question and was excluded). **b** Patients' interest in an app to report adverse drug reactions (15 responders were excluded; 2 did not complete this question and 13 answered 'I don't know'), to receive safety information (14 responders were excluded; 1 did not complete this question and 13 answered 'I don't know'), and for both (15 responders were excluded; 3 did not complete this question and 12 answered 'I don't know'). *All European responders. *ADRs* adverse drug reactions

Patients liked an option to receive drug safety updates (i.e. each newly identified severe ADR of a drug) most (84%), followed by newly identified interactions between drugs (71%) (Table 3). Only 6% of the patients liked an option to receive news about all marketed drugs.

3.3.3 Interest in Other Functions in the App

Many HCPs and patients selected additional functions that they would like in an app for two-way risk communication. Additional information functions were more often selected than additional reporting functions (Tables 2, 3). For HCPs this included information about known interactions between drugs (76%), followed by information about how to resolve an ADR (75%) and an overview of alternative drugs to the one for which an ADR is experienced (71%). Most patients liked an overview of ADRs previously reported by others (73%) and patient information leaflets (72%).

Table 2 Healthcare professionals' preferences and perceptions towards various characteristics of the app

	Total[a]	Croatia	The Netherlands	UK	*P*-value
Perceived benefits in using the app					
What benefits are there for you in using this app?[b,c]					
Faster way to report	317 (83)	152 (80)	51 (86)	62 (84)	0.532
Easier access to ADR report form	276 (73)	131 (69)	39 (66)	61 (82)	0.059
Continue report at a later stage	232 (61)	124 (66)	29 (49)	49 (66)	0.058
Upload a photo	203 (53)	91 (48)	34 (58)	40 (54)	0.383
Store previously reported ADRs	200 (53)	115 (61)	15 (25)	37 (50)	< 0.001
					HR–NL: < 0.001
					NL–UK: 0.004
					HR–UK: 0.109
Complete report offline and send it later	179 (47)	90 (48)	19 (32)	39 (53)	0.048
					HR–NL: 0.037
					NL–UK: 0.018
					HR–UK: 0.458
What are the likely benefits in using an app of the <national medicines agency> to receive safety information?[c,d]					
It will keep me up-to-date	318 (84)	159 (83)	45 (80)	68 (88)	0.429
Increased knowledge	290 (76)	155 (81)	35 (63)	58 (75)	0.014
					HR–NL: 0.004
					NL–UK: 0.111
					HR–UK: 0.285
Check whether symptom has been reported as ADR	248 (65)	125 (65)	33 (59)	55 (71)	0.322
Possibility to receive notifications	242 (64)	112 (59)	32 (57)	58 (75)	0.026
					HR–NL: 0.842
					NL–UK: 0.027
					HR–UK: 0.010
Select medicine of interest	180 (47)	84 (44)	19 (34)	42 (55)	0.058
Type of news of interest					
What type of news about medicines would be useful to you in an app?[e,f]					
Newly identified drug–drug interactions	314 (82)	166 (87)	40 (68)	62 (79)	0.003
					HR–NL: 0.001
					NL–UK: 0.120
					HR–UK: 0.124
New indications of a drug	286 (75)	165 (86)	28 (47)	51 (65)	< 0.001
					HR–NL: < 0.001
					NL–UK: 0.035
					HR–UK: < 0.001
NCA communications	273 (71)	139 (73)	32 (54)	60 (77)	0.009
					HR–NL: 0.007
					NL–UK: 0.005
					HR–UK: 0.482
Drugs that are taken off the market	262 (68)	126 (66)	37 (63)	58 (74)	0.288
Changes in the PIL	247 (64)	130 (68)	27 (46)	54 (69)	0.004
					HR–NL: 0.002
					NL–UK: 0.006
					HR–UK: 0.852

Table 2 continued

	Total[a]	Croatia	The Netherlands	UK	*P*-value
DHPCs	245 (64)	135 (71)	34 (58)	42 (54)	0.016
					HR–NL: 0.061
					NL–UK: 0.659
					HR–UK: 0.008
Educational materials	186 (49)	106 (56)	17 (29)	32 (41)	0.001
					HR–NL: < 0.001
					NL–UK: 0.140
					HR–UK: 0.031
Whether re-assessment is ongoing	162 (42)	74 (39)	16 (27)	41 (53)	0.009
					HR–NL: 0.104
					NL–UK: 0.003
					HR–UK: 0.038
Discontinuation of black triangle	149 (39)	77 (40)	9 (15)	46 (59)	< 0.001
					HR–NL: < 0.001
					NL–UK: < 0.001
					HR–UK: 0.005
For which medicines would you like to receive news?[g,h]					
All approved marketed drugs	137 (37)	61 (32)	20 (35)	33 (45)	0.001
All drugs I am interested in	72 (19)	44 (23)	8 (14)	9 (12)	HR–NL: 0.001
Drugs related to my work	98 (26)	60 (32)	10 (18)	15 (20)	NL–UK: 0.534
Drugs that I prescribe	66 (18)	23 (12)	19 (33)	17 (23)	HR–UK: 0.007
Interest in other functions in the app					
Please think about an app that you can use for both reporting ADRs and receiving safety information. Which other information functions would you like in such an app?[f,i]					
Interactions between drugs	303 (76)	176 (92)	34 (56)	50 (61)	< 0.001
					HR–NL: < 0.001
					NL–UK: 0.529
					HR–UK: < 0.001
How to resolve an ADR	296 (75)	148 (77)	42 (69)	57 (70)	0.270
Alternative drugs to the one causing the ADR	282 (71)	139 (72)	43 (70)	54 (66)	0.554
Drug product information	269 (68)	144 (75)	30 (49)	53 (65)	0.001
					HR–NL: < 0.001
					NL–UK: 0.064
					HR–UK: 0.080
Overview of previously reported ADRs	251 (63)	110 (57)	43 (70)	52 (63)	0.163
Prediction model	218 (55)	99 (52)	30 (49)	49 (60)	0.365
Quality alerts	154 (39)	72 (38)	15 (25)	41 (50)	0.008
					HR–NL: 0.064
					NL–UK: 0.002
					HR–UK: 0.054
Which other reporting functions would you like in such an app?[f,j]					
When the medicine cannot be dispensed	231 (68)	124 (72)	29 (64)	46 (66)	0.460
Medicine defects	216 (64)	105 (61)	23 (51)	50 (71)	0.083
Medication errors	205 (60)	106 (62)	18 (40)	44 (63)	0.023
					HR–NL: 0.009
					NL–UK: 0.016
					HR–UK: 0.858

Table 2 continued

	Total[a]	Croatia	The Netherlands	UK	*P*-value
Protection of the app					
How should an app for you to report ADRs and receive safety information of medicines be protected?[k,l]					
Entering an email address and password	109 (30)	63 (34)	11 (20)	21 (29)	0.152
Automatic login	257 (70)	122 (66)	43 (80)	51 (71)	
Intention to download the app					
How likely are you to download a free, limited space-taking app to report ADRs and receive safety information of medicines on your device?					
Not at all likely	9 (2)	1 (1)	1 (2)	6 (7)	< 0.001
Slightly likely	32 (8)	6 (3)	13 (21)	8 (10)	HR–NL: < 0.001
Moderately likely	82 (21)	35 (18)	15 (24)	19 (23)	NL–UK: 0.122
Very likely	276 (69)	150 (78)	33 (53)	50 (60)	HR–UK: < 0.001

Data are given as *n* (%)

ADRs adverse drug reactions, *DHPCs* direct healthcare professional communications, *HR* Croatia, *NCA* national competent authority, *NL* Netherlands, *PIL* patient information leaflet

[a]All European responders

[b]The number of responders that do not want to use an app to report ADRs was 12 and the number of responders that selected 'none' was 7. 19 responders selected 'Other'

[c]Percentages are calculated excluding the responders who selected 'None' and those who selected 'I do not want to use an app to report ADRs/receive safety information'

[d]6 responders selected 'None', 13 responders selected 'I do not want to use an app to receive safety information' and 6 selected 'Other'

[e]16 responders indicated that they did not want to receive safety information through an app and 10 selected 'Other'

[f]Percentages are calculated excluding those who selected 'No other information/reporting functions' or 'I do not want to receive safety information through an app'

[g]15 responders indicated 'None' and 11 responders selected 'Other'

[h]Percentages are calculated excluding those who selected 'None' and 'Other'

[i]2 responders were not interested in any other type of information function and 37 selected 'Other'

[j]The number of responders not interested in any other type of reporting function was 59 and 20 selected 'Other'

[k]One responder did not answer this question and 32 responders selected 'Other'

[l]Percentages are calculated excluding the responders who selected 'Other'

3.3.4 Protection of the App

Most of the HCPs preferred to use an app for two-way risk communication via an automatic login after entering their e-mail address and password once (70%) (Table 2). Although most patients also prefer an automatic login, this preference was less pronounced (57%) (Table 3).

3.3.5 Intention to Download the App

In total, 69% of the HCPs and 52% of the patients indicated that it is *very likely* that they will download the app. Only 2% of the HCPs (Table 2) and 6% of the patients (Table 3) indicated that this is *not likely at all*.

3.3.6 Countries in Which the App was Already Available

HCPs from Croatia appeared to have more positive views on potential benefits of the app, the addition of other functionalities and the intention to download the app than HCPs from The Netherlands and The UK (Table 2). HCPs from The Netherlands generally had a more negative view. HCPs from The UK were more positive to receive news in the app about discontinuation of a black triangle for a drug (59 vs. 40% in Croatia and 15% in The Netherlands; overall $P < 0.001$) and to receive quality alerts (50 vs. 38% in Croatia and 25% in The Netherlands; overall $P = 0.008$).

Patients from The UK had more positive views on various benefits of using the app than patients from Croatia and The Netherlands (Table 3). Patients from The Netherlands were more negative, particularly regarding potential benefits of continuing an unfinished report at a later moment (33 vs. 48% in Croatia and 56% in The UK; overall $P = 0.001$) and of not having to contact a HCP for every symptom they experience (24 vs. 50% in Croatia and 53% in The UK; overall $P < 0.001$). In addition, they were less positive about patient information leaflets (61 vs. 76% in both Croatia and The UK; overall $P = 0.004$), information on where to get help (36 vs. 63% in Croatia and

Table 3 Patients' preferences and perceptions towards various characteristics of the app

	Total[a]	Croatia	The Netherlands	UK	*P*-value
Perceived benefits in using the app					
What are the likely benefits for you in using this app?[b,c]					
Faster way to report	513 (85)	111 (85)	138 (85)	76 (81)	0.592
Easier access to report form	434 (72)	94 (72)	103 (64)	75 (80)	0.020
					HR–NL: 0.114
					NL–UK: 0.007
					HR–UK: 0.199
Store previous reports	290 (48)	63 (48)	70 (43)	46 (49)	0.569
Upload a photo	288 (47)	66 (51)	63 (39)	51 (54)	0.030
					HR–NL: 0.042
					NL–UK: 0.017
					HR–UK: 0.606
Continue a report at a later moment	264 (43)	62 (48)	53 (33)	53 (56)	0.001
					HR–NL: 0.009
					NL–UK: < 0.001
					HR–UK: 0.199
Complete report offline and send it later	262 (43)	53 (41)	54 (33)	50 (53)	0.008
					HR–NL: 0.190
					NL–UK: 0.002
					HR–UK: 0.066
What are the likely benefits for you in using an app of the < national medicines agency > to receive safety information?[c,d]					
Check whether symptom has been reported as ADR	441 (72)	89 (69)	106 (65)	73 (79)	0.048
					HR–NL: 0.433
					NL–UK: 0.014
					HR–UK: 0.086
Increased knowledge	388 (63)	84 (65)	90 (55)	62 (67)	0.079
It will keep me up-to-date	378 (62)	60 (47)	112 (68)	66 (72)	< 0.001
					HR–NL: < 0.001
					NL–UK: 0.565
					HR–UK: < 0.001
Possibility to receive notifications	341 (56)	42 (33)	84 (51)	62 (67)	< 0.001
					HR–NL: 0.001
					NL–UK: 0.012
					HR–UK: < 0.001
Select medicines of interest	311 (51)	51 (40)	70 (43)	52 (57)	0.033
					HR–NL: 0.587
					NL–UK: 0.033
					HR–UK: 0.013
Increased confidence when talking to my HCP	283 (46)	50 (39)	75 (46)	53 (58)	0.021
					HR–NL: 0.231
					NL–UK: 0.068
					HR–UK: 0.006
No need to contact HCP for every symptom	247 (40)	65 (50)	40 (24)	49 (53)	< 0.001
					HR–NL: < 0.001
					NL–UK: < 0.001
					HR–UK: 0.674
Type of news of interest					
What type of news about medicines would be useful to you in an app?[e,j]					

Table 3 continued

	Total[a]	Croatia	The Netherlands	UK	*P*-value
Safety updates	520 (84)	104 (78)	139 (84)	77 (85)	0.317
Newly identified drug interactions	439 (71)	85 (64)	105 (64)	79 (87)	< 0.001
					HR–NL: 0.961
					NL–UK: < 0.001
					HR–UK: 2009 < 0.001
Changes in the PIL	421 (68)	84 (63)	100 (61)	71 (78)	0.015
					HR–NL: 0.652
					NL–UK: 0.005
					HR–UK: 0.018
New approved used of a drug	324 (53)	69 (52)	69 (42)	43 (47)	0.221
Whether drug review is ongoing	310 (50)	57 (43)	64 (39)	55 (60)	0.003
					HR–NL: 0.477
					NL–UK: 0.001
					HR–UK: 0.010
News on how to take/store the drug	305 (49)	72 (54)	81 (49)	33 (36)	0.029
					HR–NL: 0.386
					NL–UK: 0.048
					HR–UK: 0.008
Experiences of other users of the drug	292 (47)	75 (56)	79 (48)	33 (36)	0.012
					HR–NL: 0.144
					NL–UK: 0.073
					HR–UK: 0.003
Drugs that are temporarily out of stock	243 (39)	45 (34)	65 (39)	28 (31)	0.342
For which medicines would you like to receive news?[g,h]					
All approved marketed drugs	36 (6)	10 (8)	8 (5)	7 (8)	< 0.001
All drugs I am interested in	161 (27)	52 (40)	20 (12)	20 (22)	HR–NL: < 0.001
All drugs to treat my disease	167 (28)	35 (27)	42 (26)	17 (19)	NL–UK: 0.112
Drugs prescribed to me	241 (40)	33 (25)	93 (57)	46 (51)	HR–UK: 0.001
Interest in other functions in the app					
Please think about an app that you can use for both reporting side effects and receiving safety information. Which other functions would you like in such an app?[i,j]					
Overview of ADRs previously reported	458 (73)	94 (70)	116 (67)	65 (68)	0.846
PIL	450 (72)	102 (76)	105 (61)	72 (76)	0.004
					HR–NL: 0.004
					NL–UK: 0.013
					HR–UK: 0.954
Store list of medicines	405 (64)	71 (53)	102 (59)	71 (75)	0.003
					HR–NL: 0.295
					NL–UK: 0.010
					HR–UK: 0.001
Information on where to get help	368 (59)	84 (63)	63 (36)	56 (59)	< 0.001
					HR–NL: < 0.001
					NL–UK: < 0.001
					HR–UK: 0.567
Reminder to take medicines	321 (51)	79 (59)	54 (31)	54 (57)	< 0.001
					HR–NL: < 0.001
					NL–UK: < 0.001
					HR–UK: 0.750
Option to report medicine defects	321 (51)	69 (51)	83 (48)	53 (56)	0.468

Table 3 continued

	Total[a]	Croatia	The Netherlands	UK	*P*-value
Learn from other patient experiences	299 (48)	77 (57)	73 (42)	50 (53)	0.024
					HR–NL: 0.008
					NL–UK: 0.101
					HR–UK: 0.469
Chat with others about own experiences	140 (22)	41 (31)	24 (14)	26 (27)	0.001
					HR–NL: < 0.001
					NL–UK: 0.007
					HR–UK: 0.597
Protection of the app					
How should an app for you to report side effects and receive safety information of medicines be protected?[f,k]					
Entering an email address and password	255 (43)	50 (39)	58 (38)	40 (44)	0.606
Automatic login	332 (57)	79 (61)	96 (62)	51 (56)	
Intention to download the app					
How likely are you to download a free, limited space taking app to report side-effects and receive safety information of medicines on your device?[l]					
Not at all likely	37 (6)	4 (3)	19 (10)	7 (7)	0.001
Slightly likely	87 (13)	11 (8)	41 (22)	17 (17)	HR–NL: < 0.001
Moderately likely	189 (29)	54 (40)	44 (24)	27 (27)	NL–UK: 0.572
Very likely	341 (52)	67 (49)	83 (44)	48 (48)	HR–UK: 0.035

Data are given as *n* (%)

ADRs adverse drug reactions, *DHPCs* direct healthcare professional communications, *HR* Croatia, *NCA* national competent authority, *NL* Netherlands, *PIL* patient information leaflet

[a]All European responders

[b]The number of responders who do not want to use an app to report ADRs was 22, the number of responders that selected 'none' was 27 and 36 selected 'Other'

[c]Percentages are calculated excluding the responders who selected 'None' and those who selected 'I do not want to use an app to report side effects/receive safety information'

[d]24 responders selected 'None', 20 responders selected 'I do not want to use an app to receive safety information' and 15 selected 'Other'

[e]39 responders indicated that they do not want to receive safety information through an app and 29 selected 'Other'

[f]Percentages are calculated excluding the responders who selected 'Other'

[g]27 responders indicated 'Not applicable' and 24 responders selected 'Other'

[h]Percentages are calculated excluding those who selected 'Not applicable' and 'Other'

[i]1 responder did not complete this question, 26 were not interested in any other function and 64 selected 'Other'

[j]Percentages are calculated excluding those who selected 'None/No other functions/I do not want to receive safety information through an app'

[k]4 responders did not answer this question and 65 responders selected 'Other'

[l]2 responders did not complete this question

59% in The UK; overall $P<0.001$), a reminder to take medicines (31 vs. 59% in Croatia and 57% in The UK; overall $P<0.001$), and a functionality to chat with others about their own experiences (14 vs. 31% in Croatia and 27% in The UK; overall $P = 0.001$).

3.4 Determinants: HCP/Patient Characteristics

Of the 399 HCPs and 656 patients who completed the survey, 390 and 636, respectively, were included in the analyses to assess the association between HCP/patient characteristics and being interested in the app (Electronic Supplementary Material 4).

3.4.1 HCP Characteristics

Of the four determinants included in the analyses of the HCPs, only the use of a health app was significantly associated with interest in the app. HCPs who at least sometimes use a health app were more often very interested than those who never use such an app (odds ratio [OR] 3.52; 95% confidence interval [CI] 1.96–6.30) (Fig. 2a). The sensitivity analyses per country of interest showed that

this HCP characteristic was statistically significant for The UK only (OR 9.50; 95% CI 3.11–29.05) (Electronic Supplementary Material 5). The generalised ordered logit model showed a similar influence of the use of health apps on the different levels of the outcome measure (Electronic Supplementary Material 6).

3.4.2 Patient Characteristics

Age and use of health apps were the patient characteristics significantly associated with interest in the app. Older patients were less often very interested in the app than younger patients (OR 0.98; 95% CI 0.97–0.997). Patients who at least sometimes use a health app were more often very interested than those who never use a health app (OR 1.64; 95% CI 1.19–2.27) (Fig. 2b). The country-specific analyses showed a statistically significant association of the use of health apps for The Netherlands only (OR 2.20; 95% CI 1.13–4.27) (Electronic Supplementary Material 7). Additional statistically significant associations were shown for The UK, where patients with a tertiary education level were less often very interested than patients with a low or

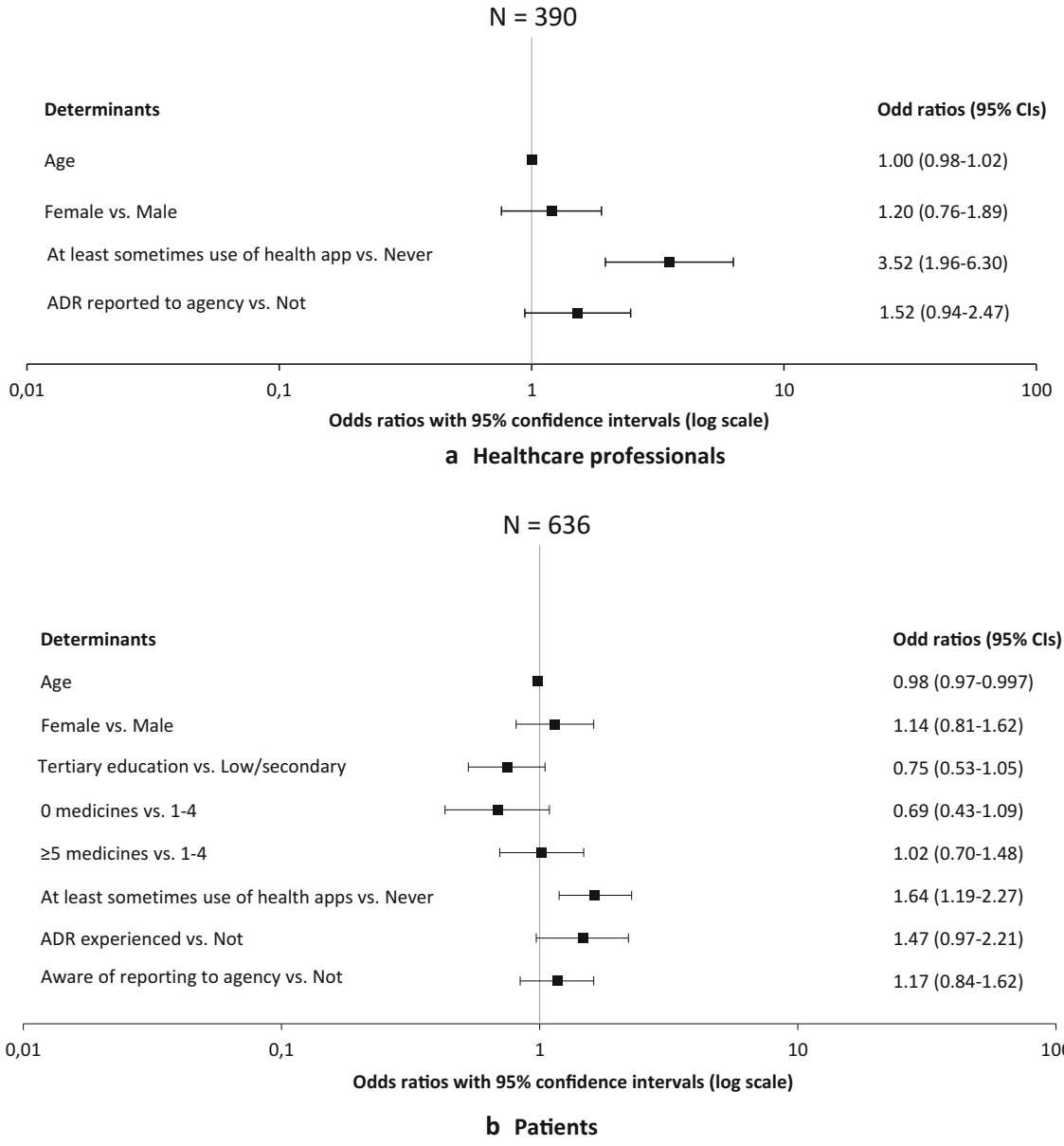

Fig. 2 Odds ratios with 95% confidence intervals of associations between **a** healthcare professional characteristics and being very interested in an app for two-way risk communication and **b** patient characteristics and being very interested in this app. *ADR* adverse drug reaction, *CI* confidence interval

secondary education level (OR 0.20; 95% CI 0.05–0.81), and patients who take no medicines were less often very interested than patients who take one to four medicines (OR 0.17; 95% CI 0.04–0.75). The generalised ordered logit model showed a similar effect of use of health apps on the different levels of the outcome measure but showed different patterns for other characteristics (Electronic Supplementary Material 6).

4 Discussion

This study showed that HCPs and patients were generally interested in an app for two-way risk communication and that, in particular, HCPs and patients who already use a health app are more interested in such an app. A main benefit for HCPs and patients of the reporting functionality in the app was that it can make the ADR reporting process faster and easier. Previous studies have shown that lack of time and difficulty in accessing reporting forms are the main barriers for HCPs to spontaneously report ADRs to national pharmacovigilance centres [12–14]. In contrast, literature suggests that patients may be willing to spend more time on reporting an ADR than HCPs [2] and one of the reasons for patients to spontaneously report an ADR is when they have the impression that HCPs have too limited time to accurately report ADRs [15]. However, in this study patients also preferred a reporting tool that is easy and fast to complete.

With respect to the information functionality of the app, HCPs would like the app to keep them up-to-date with the latest news and that it will increase their knowledge about drug safety. In addition, most HCPs liked to receive news about (newly identified) drug–drug interactions. Previously, it has been shown that HCPs' awareness of drug safety issues, for instance those communicated through direct healthcare professional communications (DHPCs), are suboptimal [16] as is their knowledge about drug–drug interactions [17]. Our study suggests that HCPs are aware of their lack of knowledge and that an app could be a tool to improve this.

Patients particularly liked an overview of ADRs previously reported by others, and patient information leaflets as information in an app. They indicated that a main benefit of the app would be to allow them to check whether a symptom was previously reported as an ADR. These findings are in line with previous studies showing that patients are sometimes uncertain about an association between a symptom and a drug [18–21], and may be uncertain about the exact drug causing the symptoms [22]. Providing such information in an app could reduce patients' uncertainty in confirming that their symptoms are caused by the drug(s) they are taking. Also, a previous study showed that one-third of patients did not discuss their medication symptoms with an HCP [23]. Almost half of the patients in our study indicated that the app could increase their confidence when talking to their HCP. This increased certainty about an ADR may improve the patient–HCP conversation about ADRs. In addition, it may increase patient reporting of ADRs to the national pharmacovigilance centres, but future studies will be needed to investigate such effects.

HCPs' and patients' preferences and perceptions towards the characteristics of the app in general were relatively similar. This suggests that the functionality of the app can be similar for HCPs and patients. However, the type of drugs for which responders would like to receive safety information differed between HCPs and patients, as HCPs liked the option to receive information for all drugs more. It should be possible to incorporate such user-specific preferences into the app. In addition, differences in other aspects of the app, such as appropriate terminology for these target groups, need to be considered [2].

Our finding that HCPs and patients who already use a health app are particularly interested in an app for two-way risk communication suggests that, in particular, those HCPs and patients may well be the most receptive group that should be informed about the existence of such an app. This could, for instance, be done via advertisements or a link to the app in other health apps. The high number of responders that liked other functionalities in an app for two-way risk communication also suggests that links to various other health apps may increase its usefulness. Ways to stimulate the interest of non-app users and encouraging their participation could benefit from further investigation.

4.1 Strengths and Limitations

A strength of this study is the assessment of interest in the app among both HCPs and patients. In addition, this is a first study assessing the role of user characteristics on the use of an app for two-way risk communication. Although we collected data from a large sample of HCPs and patients, a limitation is that the number of responders per country was still relatively low. Another limitation of this study was its methodology of a cross-sectional survey. We cannot be sure how representative it was of the studied countries. We present data for a subgroup of three countries in which the app was already available, but differences between countries should be interpreted cautiously since the characteristics of the responders differ across these countries. Moreover, the number of responders from countries other than the three countries in which the app was available was low. Therefore, it cannot be assumed that the included population is a representative sample of the European populations. Also, we do not have any

numbers relating to response rates since HCPs and patients were reached via various channels including advertisements and announcements. Furthermore, survey-answering tendencies may differ across countries, as has been shown previously [24]. Another limitation relates to the assessment of interest in the app. First, we could not use a validated measure to assess interest in the app since, to our knowledge, such a measure is not available. Second, interest is a first step for actually downloading and using the app but its actual use may be influenced by other factors [3]. Therefore, future studies are needed to evaluate the actual use of the app in different countries.

5 Conclusions

HCPs and patients in Europe are generally interested in an app for two-way risk communication, which supports its further development. Such an app should support easy and fast reporting of ADRs and provide information about drug–drug interactions and previously reported ADRs to its users. HCPs and patients who already use other health apps are particularly interested in the app. Therefore, dissemination strategies could focus on reaching these HCPs and patients.

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Compliance with Ethical Standards

Ethical approval The study protocol was submitted to (a member of) an ethics committee in The UK, The Netherlands and Germany. In The UK, approval was obtained from the UCL Research Ethics Committee (Project ID number 6855/001). In The Netherlands, the Medical Ethics Committee of the University Medical Center Groningen (METc UMCG) determined that ethical approval was not needed for this study (reference number M16.191043). In Germany, a review by an ethics committee was not necessary. Therefore, no further approval was deemed necessary for the other countries. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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