

UCRAID (Ukrainian Citizen and refugee electronic support in Respiratory diseases, Allergy, Immunology and Dermatology) action plan

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Abbreviations: AIRWAYS ICPS, Integrated Care Pathways for airway diseases; ARIA, Allergic Rhinitis and its Impact on Asthma; COPD, chronic obstructive pulmonary disease; CRUSE, Chronic Urticaria Self Evaluation; CSU, chronic spontaneous urticaria; EU, European Union; GDPR, General Data Protection Regulation; GP, general practitioners; HCP, healthcare providers; MASK-air, Mobile Airways Sentinel Network for airway diseases; OECD, Organisation for Economic Co-operation and Development; PROM, Patient-Reported Outcome Measure; UCARE, Urticaria Center of Reference and Excellence; VAS, visual analogue scale; WHO, World Health Organization.

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Abstract

Eight million Ukrainians have taken refuge in the European Union. Many have asthma and/or allergic rhinitis and/or urticaria, and around 100,000 may have a severe disease. Cultural and language barriers are a major obstacle to appropriate management. Two widely available mHealth apps, MASK-air® (Mobile Airways Sentinel Network) for the management of rhinitis and asthma and CRUSE® (Chronic Urticaria Self Evaluation) for patients with chronic spontaneous urticaria, were updated to include Ukrainian versions that make the documented information available to treating physicians in their own language. The Ukrainian patients fill in the questionnaires and daily symptom-medication scores for asthma, rhinitis (MASK-air) or urticaria (CRUSE) in Ukrainian. Then, following the GDPR, patients grant their physician access to the app by scanning a QR code displayed on the physician's computer enabling the physician

to read the app contents in his/her own language. This service is available freely. It takes less than a minute to show patient data to the physician in the physician's web browser. UCRAID—developed by ARIA (Allergic Rhinitis and its Impact on Asthma) and UCARE (Urticaria Centers of Reference and Excellence)—is under the auspices of the Ukraine Ministry of Health as well as European (European Academy of Allergy and Clinical immunology, EAACI, European Respiratory Society, ERS, European Society of Dermatologic Research, ESDR) and national societies.

KEYWORDS

asthma, mHealth, rhinitis, Ukrainian refugees, urticaria

1 | INTRODUCTION

In 2014, on behalf of the European Innovation Partnership on Active and Healthy Ageing (EIP on AHA, DG CONNECT and DG Santé),¹ AIRWAYS ICPs (Integrated Care Pathways for airway diseases) was initiated.^{2,3} The objective was to launch a collaboration to develop multi-sectoral integrated care pathways (ICPs) for chronic respiratory diseases in European countries—and beyond—as a Global Alliance against chronic Respiratory Diseases (GARD) demonstration project.⁴ MASK-air (Mobile Airways Sentinel Network for airway diseases), the Phase 3 ARIA (Allergic Rhinitis and its Impact on Asthma) initiative,^{5–7} is the mHealth strategy of AIRWAYS ICPs (Airways Integrated Care Pathways).

The UCARE (Urticaria Center of Reference and Excellence) programme is a GA²LEN (Global Allergy and Asthma European Network) initiative with the aim of developing and accrediting an interactive network of urticaria centres of reference and excellence.⁸ Urticaria is a common, debilitating and often hard-to-treat condition that can be a challenge—especially when chronic—for both patients and treating physicians. Since its inception in 2016, the UCARE network has grown to over 160 member centres in more than 40 countries. Today, it is the biggest and most active consortium of urticariologists and urticaria centres with the largest global reach to patients affected by urticaria and its comorbidities. The members of the global UCARE network collaborate on scientific projects,^{9,10} improve patient care and provide physician and patient education. The UCARE LevelUp and UCARE 4U programmes are used for these objectives. In 2022, driven by results of its CURICT project,¹¹ UCARE launched the MASK-air® twin mHealth app, CRUSE®, for chronic spontaneous urticaria (CSU).

Refugees pose many health challenges to recipient countries, and it is important to assess the challenges Ukrainian refugees face in accessing health care and communicating with healthcare professionals in these countries. Ukrainian refugees have heterogeneous, significant and complex health needs. Among the most challenging are chronic non-communicable diseases including mental disorders, which require continuous long-term care and access to medicines.¹² Obtaining health care in recipient countries can be difficult for Ukrainian refugees¹³ who are frequently unassisted, vulnerable and misunderstood.¹⁴ Many Ukrainian refugees are not insured,

need to pay for their health care out of pocket and cannot afford medication.¹⁵ In countries that provide Ukrainian refugees with free health care, those with little or no funds may not be able to afford co-payment charges for prescriptions.¹² Ukrainian refugees may not know where to go when they need medical help and may have substantial and diverse informational needs (legal advice, transport and accommodation issues, accessing services and health care).¹⁶ Medical help is made difficult by the lack of patient health records and communication issues caused by the language barrier.^{13,17} Assessing patients by medical history and physical examination requires good communication between the patient and the physician and is severely hindered when they do not understand each other.¹⁷ Physicians are often on the frontline in providing care for these unassisted, vulnerable and often misunderstood population groups.¹⁴ The role of language assistance 'is particularly important in health care given the sensitivity of the issues involved and the high level of technical language proficiency required to communicate medical terminology'.^{18,19} However, there is a need for a global approach of the disease that may account for the diversity of the diseases²⁰ and not simply a word-by-word translator. This highlights the importance of a coordinated, interdisciplinary and culturally adapted approach for responding to these challenges.²¹ Potential solutions include involving professional and volunteer translators, web sites providing information in Ukrainian, as well as the use of QR codes and smartphone applications to enable translations and interpretations.^{16,17,21} Efforts aimed at improving the medical care for Ukrainian refugees should include (i) collecting robust data for health and disease monitoring and surveillance, (ii) providing health care to refugees and developing cost-effective and sustainable ways of financing this within and across recipient countries, (iii) improving the mobility and transferability of patients' health records and (iv) facilitating good communication between patients and physicians.^{12,13,16}

According to the UNHCR (United Nations, refugee agency), the number of forcibly displaced and stateless people in Europe rose to 21.8 million by the end of 2022 (<https://reporting.unhcr.org/operational/regions/europe>, accessed 8 July 2023). The UN Refugee Agency (UNHCR) estimated (24 January 2023) that just under 8 million Ukrainian refugees live across Europe (<https://data.unhcr.org/en/situations/ukraine>, last accessed 8 July 2023). Despite the

BOX 1 mHealth

mHealth has been defined by the Global Observatory for eHealth as a 'medical and public health practice supported by mobile devices, such as mobile phones'.²⁷ It can be segmented into (i) equipment/connected medical devices, (ii) mHealth services and (iii) mHealth apps (apps).²⁸ It includes patients and care providers using any digital technology—smartphones (apps), tablets, texting, calling, video conferencing or monitoring devices—to deliver and monitor health care and/or perform research.

distressing environment, communities have remained unified and efficient as they showcase the European principles of solidarity and humanitarianism.^{22,23} Around 5 million Ukrainian refugees have been registered for Temporary Protection or similar national European protection schemes (<https://data.unhcr.org/en/situations/ukraine>, last accessed, July 2023). It is estimated that 15%–20% suffer from allergic diseases, asthma and/or urticaria and that over 100,000 of them may have a severe disease. However, due to the stressful conditions, this number could be higher. In an analysis of public report data concerning the burden for Ukrainian refugees,²⁴ asthma and COPD (chronic obstructive pulmonary disease) were only present at a very low level. This suggests that asthma, COPD and allergic diseases are vastly under-recognised.

Although governments are offering a wide range of health services to the Ukrainian refugees, a culturally informed and medically-sound approach will be required to provide effective care. Moreover, it is vital to engage with refugees themselves to understand the barriers they face. Providing person-centred care is therefore essential.

Many different approaches have been proposed to help Ukrainian refugees. However, the crisis demands new solutions. Tools such as Google Translate can help but do not provide a structured medical history. Personal data protection and cross-border continuity of care could be ensured through the adoption of digital tools, such as the one proposed for the EU Digital COVID green Certificate, where people decide to share their personal information case by case.²⁵ A health-information system—using data from social media, mHealth apps (Box 1) and crowd-sourcing in a manner that respects data privacy—may be of interest.²⁶

There is an urgent need for an inexpensive and digitally-enabled, structured, person-centred system of care to help in shared decision-making between Ukrainian patients and European physicians for allergic diseases, asthma and/or urticaria. All levels of care are concerned (hospitals, specialists, GPs, nurses, pharmacists) (Table 1).

2 | AIMS OF THE ACTION PLAN

Following a proposal from Boleslaw Samolinski, who was in direct contact with Ukrainian colleagues, an ARIA proposition using

TABLE 1 Conceptualisation of the benefits and drawbacks of MASK-air® and CRUSE®.

1. Added value for access to primary health and specialised care for the continuity of care.
2. Improvement of the monitoring of patients.
3. Help for the integration between social and health care.
4. Use of the Apps without access to healthcare professionals is likely to be of little help.

MASK-air® was made in cooperation with a coalition. It was further developed to urticaria (Marcus Maurer) and resulted in the launch of the UCRAID (Ukrainian Citizen and refugee electronic support in Respiratory diseases, Allergy, Immunology and Dermatology) initiative. UCRAID aims to improve care for the Ukrainians with allergies and skin diseases, both in Ukraine and in countries of refuge. The MASK-air/CRUSE action plan describes and implements the first project of the UCRAID initiative.

Allergy, including asthma and allergic rhinitis, is the most common chronic disorder in children and adolescents, and chronic spontaneous urticaria manifests predominantly in females. The majority of Ukrainian refugees are women, children and adolescents.

'Language assistance is particularly important in health care, given the sensitivity of the issues involved and the high level of technical language proficiency required to communicate medical terminology'.¹⁸ According to many reports, 'it is key to engage with refugees themselves to understand the barriers they face'. ARIA has therefore proposed a digitally-enabled, person-centred system of care using MASK-air to help shared decision making (SDM) between Healthcare Workers and Ukrainian refugees. MASK-air® is a candidate Best Practice of OECD on person-centred care for chronic diseases. It is particularly suited for SDM.²⁹ CRUSE®, based on MASK-air®, extends the reach of this project to skin disorders, patients with skin diseases and their treating physician, including dermatologists. The next step will be to include a COPD module.

The Ukrainian patient will fill-in (in Ukrainian) the questionnaires and daily symptom-medication scores for asthma, rhinitis (MASK-air®) and urticaria (CRUSE®). Following the GDPR, the patient will grant his/her physician access to the content of the app. This is done by scanning a QR code displayed on the physician's (or healthcare provider's) computer (MASK-air®) and then sending this information by email (CRUSE®) or as a PDF (MASK-air® and CRUSE®). This will enable the physician to read the app contents in his/her own language. It takes less than 1 min to show patient data to the physician in the physician's web browser or to send the results by email (Table 2).

The MASK-air/CRUSE action plan will be implemented following the Change Management strategy of Kotter, already used in respiratory allergic diseases.³⁰

The study will be regularly monitored to assess its effectiveness and acceptance by the users.

Data collected with the MASK-air® and CRUSE® apps are also an important source of information for HCPs and national payers

TABLE 2 Problems regarding communication between refugees and healthcare professionals and possible solutions using MASK-air® and CRUSE®.

Problems	Solutions
Physicians are frequently on the frontline in providing care for vulnerable and often unassisted and misunderstood refugees. ¹⁴	It is essential to provide a simple solution that meets all requirements for better communication and shared decision making
The role of language assistance 'is particularly important in health care given the sensitivity of the issues involved and the high level of technical language proficiency required to communicate medical terminology'. ¹⁸	The solution should be adapted to the medical language and also reduce barriers between refugees and healthcare professionals
Many different approaches have been proposed to help the Ukrainian refugees. However, the crisis demands new solutions.	A novel and inexpensive solution is provided using a smart phone running in 27 countries (middle- and high-income countries)
It is key to engage with refugees themselves to understand the barriers they face (https://www.who.int/europe/news/item/17-01-2023-understanding-the-obstacles-faced-by-ukrainian-refugees-in-romania)	Person-centred care
Considering culturally tailored strategies to meet complex health and social needs may include liaising with local and national support organisations for Ukrainians and refugees. ¹⁹	Essential step
Wheals and angioedema, the hallmark clinical features of CSU, are transient and often not present when patients see their physician. Describing skin lesions in a foreign language is difficult.	The CRUSE® photodoc feature enables patients to document their skin lesions and share these images, as well as the documentation of disease status, with their physician.

with regards to the unmet and often misunderstood needs of this population.

3 | MAGNITUDE OF THE PROBLEM

After almost 1 year of war, it is important to understand the magnitude of the problem concerning the difficulties faced by the Ukrainian refugees in (i) accessing health care and (ii) communicating with the HCPs. An ARIA/UCARE-based assessment was carried out with several organisations. A simple questionnaire (Appendix S1) was sent to European, Georgian and Turkish ARIA and UCARE members. This questionnaire made it possible to (i) determine whether Ukrainian refugees consult specialists and (ii) recognise the unmet needs in Russian-speaking countries and others.

Categorical variables were compared using the Fisher's exact test, and continuous variables were compared using the *t*-test. We compared the answers of the respondents from countries where Russian is understood by at least 10% of the population (e.g. Baltic States, Poland, Bulgaria)³¹ with those from other countries.

We obtained 223 responses, of which 144 (64.6%) were from respondents who had seen at least one Ukrainian refugee in the clinical practice due to allergic diseases (Figure 1 online and Table 3). Thirty-nine respondents (27.1%) were from countries where Russian is more widely understood. Among the respondents who had seen at least one refugee, most had seen refugees with asthma ($N=119$; 82.6%) or rhinitis ($N=119$; 82.6%). Less than half had seen refugees with urticaria ($N=66$; 45.8%) (Table 3). Most respondents saw refugees in specialist or primary care consultations but 17 (11.8%) had seen them in the emergency department.

When in contact with refugees coming alone, 61.0% of respondents reported difficulties in communication. This percentage was lower for countries where Russian is better understood, but the difference was not significant (47.2% vs. 67.6%, $p=.115$) (Table 3). When communicating with refugees coming alone, 46.4% of respondents used electronic translating tools. In most cases, such tools were effective in decreasing communication difficulties (44/51–86.3%). The number of healthcare professionals facing these difficulties was lower—but not negligible—when refugees came accompanied by a person speaking Ukrainian and the respondent's native language ($N=55$; 48.6%). 31 (21.5%) respondents had not seen any refugees accompanied by a bilingual person. The percentage was higher for countries where Russian is more widely understood (53.8% vs. 11.4%; $p<.001$).

This study supports the MASK-air/CRUSE action plan and the UCRaid initiative. There is certainly a need for assistance to improve language problems. Digital solutions may help.

4 | NEW DEVELOPMENT OF MASK-AIR® AND CRUSE®

4.1 | MASK-air®

MASK-air® is a fully validated app³² for the management of rhinitis and asthma. It is operational in 27 countries and 19 languages (59,000 users) (Figure 1).^{33,34} The number of countries can easily be increased to get the full coverage of Europe (Appendices S2 and S3).

MASK-air is a Medical Device Class IIa under the European MDR (Medical Device Regulation). It includes a simple daily monitoring

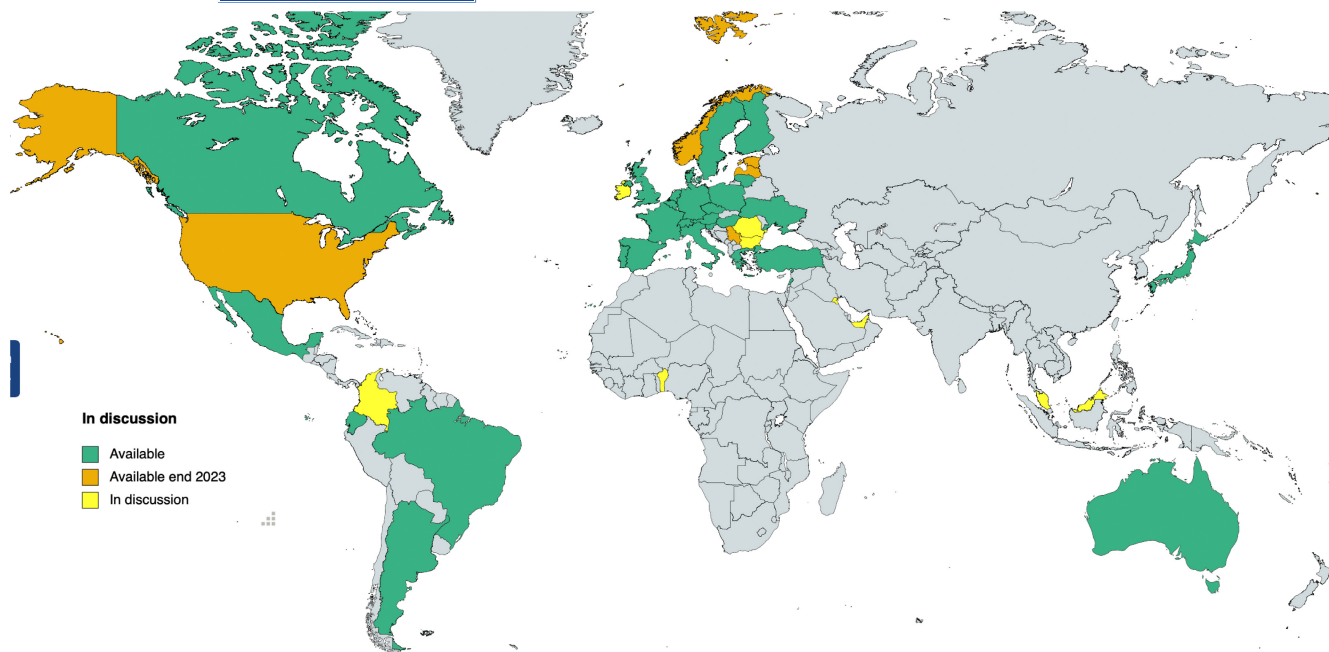


FIGURE 1 Countries where MASK-air® is available in the national language(s).

questionnaire with six Patient-Reported Outcome Measures (visual analogue scales—VASs) for global allergy symptoms, nose, eyes, asthma,^{33,35} work³⁶ (and school)³⁷ and EQ-5D. Moreover, a scroll list of all medications for rhinitis and asthma is available. Additional questionnaires are included: EQ-ED-5L, allowing the assessment of utilities, and CARAT (Control of Allergic Rhinitis and Asthma Test).^{38,39} The maturity level of MASK-air® in rhinitis ranges from Technology Readiness Levels (TRLs) 8 to 9. MASK-air® is combined with the prediction of the allergen season and air quality (pollution) using COPERNICUS data (Finnish Meteorological Institute).⁴⁰ MASK-air includes daily electronic symptom-medication scores for rhinitis⁴¹ and asthma,⁴² allowing a daily follow up (Table S1 in Appendix S3). MASK-air® has been awarded eight EU grants and projects.³³ It is a Best Practice of OECD-DG Santé on *equity-enhancing, digitally-enabled, person-centred care*. MASK-air will soon be available for COPD.

Transferring the data of the app from the patient's phone to the physician's computer usually takes less than a minute (Figure 2). The app follows the GDPR and has been launched in all MASK-air countries. The transferred information includes the self-reported patient's data, the VAS global allergy symptoms and e-DASTHMA. A video demonstrating the transfer will be provided.

The MASK-air app has been translated into Ukrainian and is currently ready to be deployed (Figure 3).

4.2 | CRUSE®

CRUSE® (Chronic Urticaria Self Evaluation) is a new mobile health app that was developed using the MASK-air® model. It was launched in March 2022 for chronic spontaneous urticaria (CSU) patients by the Urticaria Centers of Reference and Excellence (UCARE)

Network under the supervision of Prof. Marcus Maurer (Professor of Dermatology and Allergy at Charité University Hospital). The tool is free of charge and makes disease tracking and monitoring more convenient for urticaria patients. It also improves physician correspondence. It captures the urticaria and angioedema activity scores (UAS and AAS) and the urticaria and angioedema control tests (UCT and AECT), the key and guideline-recommended PROMs (Patient-Reported Outcome Measures) for CSU.⁴³ Similarly to MASK-air®, it includes a visual analogue scale (VAS) regarding overall urticaria symptoms as well as the EQ-5D-5L. CRUSE® is now available in 17 countries (>4000 users, Figure 4)—adapted to the local languages and medications—and also has worldwide English and Ukrainian versions.

5 | IMPLEMENTATION STRATEGY: THE UCRAID 8-STEP MODEL OF CHANGE MANAGEMENT

Change management (CM) aims to prepare and support individuals, teams and organisations in making organisational change. The UCRAID implementation plan and MASK-air/CRUSE action plan will follow the 8-step model of Kotter,⁴⁴ already developed for ARIA.³⁰

5.1 | Establish a sense of urgency

The sense of urgency has identified the threats and associated repercussions by examining the opportunities which can be tapped through effective interventions for Ukrainian citizens and refugees.

TABLE 3 Characteristics of respondents who had seen at least one Ukrainian refugee in the clinical practice and who had experienced difficulties in communicating with those refugees.

	Total (N = 144)	Countries where Russian is not understood (N = 105)	Countries where Russian is understood (N = 39)	p-value
Age—mean (SD)	51.9 (11.7)	53.0 (11.0)	49.2 (13.4)	.116
Males—N (%)	75 (52.1)	61 (58.1)	14 (35.9)	.024
Profession—N (%)				.016
Specialty care physician	111 (77.1)	77 (73.3)	34 (87.2)	
Primary care physician	30 (20.8)	27 (25.7)	3 (7.7)	
Other	3 (2.1)	1 (1.0)	2 (5.1)	
N Ukrainian refugees seen in the clinical practice due to asthma—N (%)				.275
0	25 (17.4)	20 (19.0)	5 (12.8)	
1–10	95 (66.0)	71 (67.6)	24 (61.5)	
11–25	15 (10.4)	9 (8.6)	6 (15.4)	
26–50	5 (3.5)	2 (1.9)	3 (7.7)	
>50	4 (2.8)	3 (2.9)	1 (2.6)	
N Ukrainian refugees seen in the clinical practice due to allergic rhinitis—N (%)				.118
0	25 (17.4)	20 (19.0)	5 (12.8)	
1–10	87 (60.4)	67 (63.8)	20 (51.3)	
11–25	24 (16.7)	13 (12.4)	11 (28.2)	
26–50	4 (2.8)	2 (1.9)	2 (5.1)	
>50	4 (2.8)	3 (2.9)	1 (2.6)	
N Ukrainian refugees seen in the clinical practice due to urticaria—N (%)				.017
0	78 (54.2)	64 (61.0)	14 (35.9)	
1–10	56 (38.9)	34 (32.4)	22 (56.4)	
11–25	6 (4.2)	4 (3.8)	2 (5.1)	
26–50	3 (2.1)	2 (1.9)	1 (2.6)	
>50	1 (0.7)	0	1 (2.6)	
Setting where Ukrainian refugees were seen—N (%)				
Specialty care outpatient consultation	94 (65.3)	62 (59.0)	32 (82.1)	.011
Primary care consultation	41 (28.5)	33 (31.4)	8 (20.5)	.220
Emergency department	17 (11.8)	11 (10.5)	6 (15.4)	.400
Hospitalisation	1 (0.7)	1 (1.0)	0	
Other	10 (6.9)	8 (7.6)	2 (5.1)	
Refugees coming accompanied by a person speaking both Ukrainian and the respondent's language—N (%)				<.001
0%	31 (21.5)	12 (11.4)	21 (53.8)	
1%–10%	34 (23.6)	21 (20.0)	13 (33.3)	
11%–25%	16 (11.1)	12 (11.4)	4 (10.3)	
26%–50%	16 (11.1)	14 (13.3)	2 (5.1)	
>50%	47 (32.6)	45 (42.9)	2 (5.1)	
Difficulties in communicating with refugees coming alone—N (%) ^a				.115
No difficulties	43 (39.1)	24 (32.4)	19 (52.8)	
Some difficulties	50 (45.5)	38 (51.4)	12 (33.3)	

(Continues)

TABLE 3 (Continued)

	Total (N = 144)	Countries where Russian is not understood (N = 105)	Countries where Russian is understood (N = 39)	p-value
Major difficulties	17 (15.5)	12 (16.2)	5 (13.9)	
Difficulties in communicating with refugees coming accompanied by a person speaking both Ukrainian and the respondent's language—N (%) ^b				.211
No difficulties	58 (51.3)	44 (47.8)	14 (66.7)	
Some difficulties	50 (44.2)	44 (47.8)	6 (28.6)	
Major difficulties	5 (4.4)	4 (4.3)	1 (4.8)	
Use of electronic translating tool when communicating with Ukrainian refugees coming alone—N (%) ^a				.199
No	59 (53.6)	36 (34.6)	23 (59.0)	
Yes, and decreased difficulties in communication	44 (40.0)	34 (32.7)	10 (25.6)	
Yes, without decreased difficulties in communication	7 (6.4)	4 (3.8)	3 (7.7)	

^a 34 respondents did not see Ukrainian refugees coming alone.

^b 31 respondents did not see Ukrainian refugees accompanied by a person speaking both Ukrainian and the respondent's native language.



FIGURE 2 Transfer of patient's data to healthcare professional's computer.

5.2 | Create a guiding coalition

The guiding coalition has already been established (Table 4).

The deployment of the UCRAID initiative and the MASK-air/CRUSE action plan has been endorsed by the Ukrainian Ministry of Health and Care that 'recognizes the right of every citizen of Ukraine to health care and ensures its protection. The Ministry supports

measures within the framework of legislation aimed at improving the quality and availability of medical care for the population'.

To implement the proposal, the coalition will initially put forward a pilot study and use existing networks that will later be enhanced by members from scientific societies, patient/citizen's organisations and others. For the full project, we will not be selecting specific physicians. Any physician can volunteer to participate in the project.

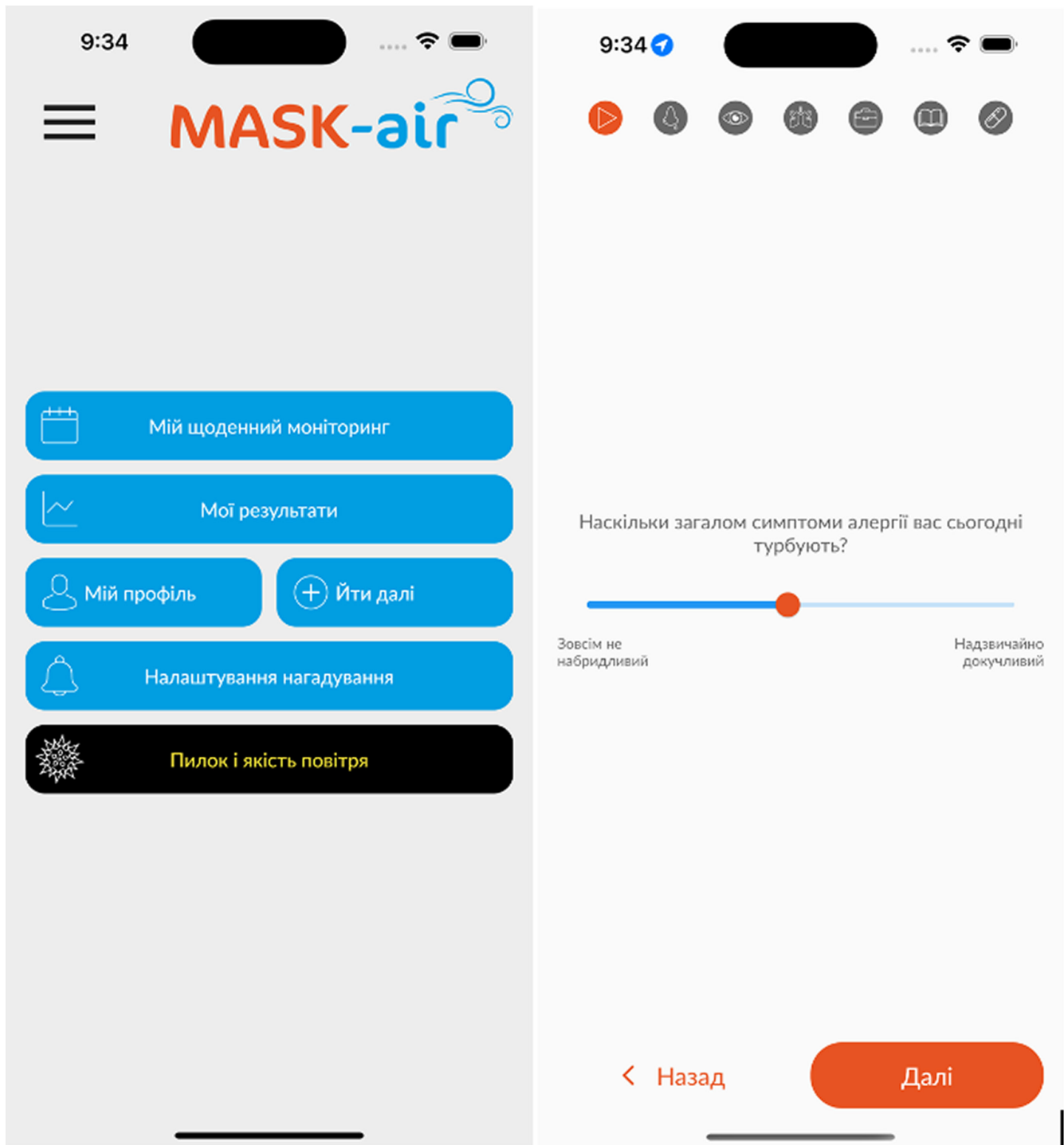


FIGURE 3 MASK-air app in Ukrainian.

Ukrainian groups in Ukraine and in the EU will also join the coalition. The ARIA working group, initiated in 1999, includes over 500 members in 70 countries.⁴⁵ A successful coalition working on CM in the EU has been identified within the group. GA²LEN (Global Allergy and Asthma European Network) was initiated as a European Union FP6 grant.⁴⁶ UCARE, the GA²LEN network of Urticaria Centers of Reference and Excellence, provides excellence in *urticaria* management.⁸

5.3 | Develop a vision and strategy

The vision of the project is to enable Ukrainian citizens and refugees to fill-in—in Ukrainian—the MASK-air® app if they suffer from asthma/rhinitis or the CRUSE® app if they suffer from urticaria. The physicians seeing the Ukrainian patients will have all the content of the app in their own language to facilitate shared decision making.

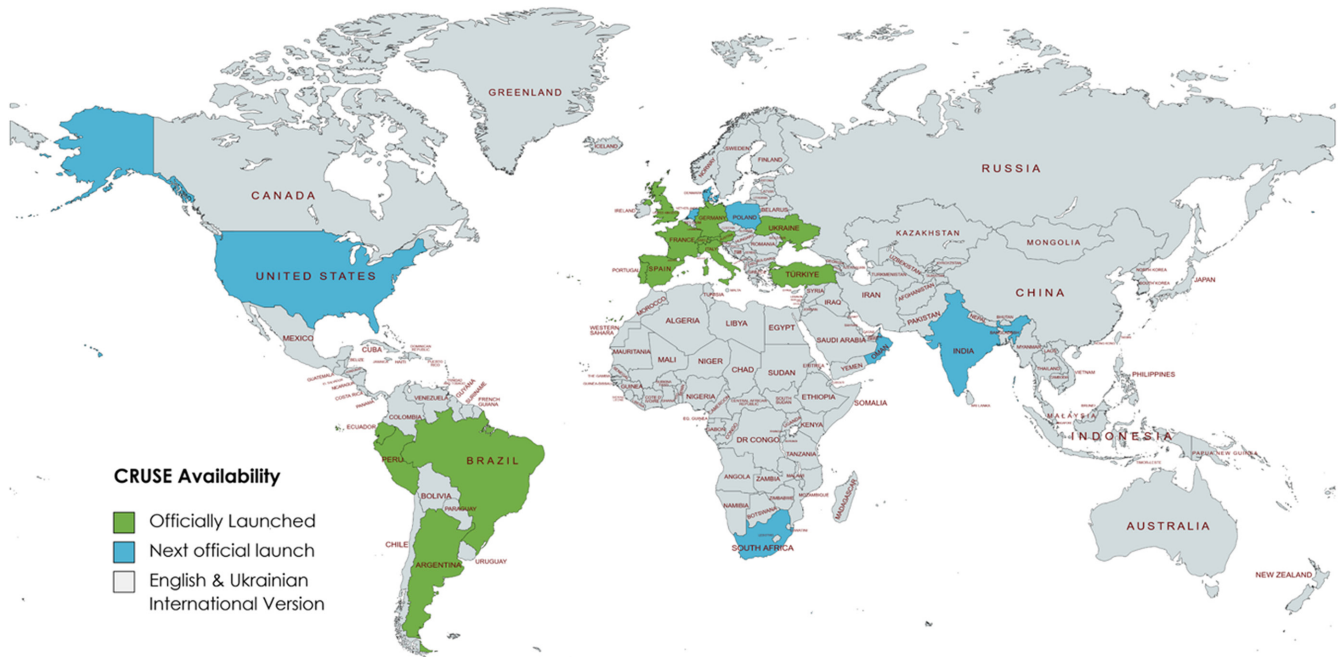


FIGURE 4 Countries where CRUSE® is available in the national language(s).

TABLE 4 Guiding coalition.

Chairs: Jean Bousquet (FR), Boleslaw Samolinski (PL), Igor Kaidashev (Ukraine), Marcus Maurer (DE), Nicolas Roche (FR).

Secretary: Anna Bedbrook (FR).

Coalition:

1. Ukraine: Igor Kaidashev (Ukrainian Society of Specialists for Immunology, Allergology and Immunorehabilitation), Andrii Kurchenko, Roman Stepanenko (Ukrainian Society of Dermatology), Vladyslav Tsaryk, Yuliia Lysanets (Poltava State Medical University)
2. Poland: Maciej Kupczyk, Łukasz Skolimowski (Polish Society of Allergology), Marek Kulus
3. European Academy of Allergy and Clinical Immunology (EAACI): Stefano Del Giacco, Ludger Klimek, Markus Ollert (LUX-DK)
4. European Respiratory Society (ERS): Judith Garcia-Aymerich (SP), Carlos Robalo Cordeiro (PT), Nicolas Roche (FR)
5. European Society for Dermatologic Research (ESDR): Christoph Schlapbach (Switzerland)
6. Fraunhofer ITMP: Torsten Zuberbier (DE)
7. GA²LEN network of urticaria centres of reference and excellence (UCARE): Sophia Neisinger (DE), Aiste Ramanauskaite (DE)
8. GARD (Demonstration project): Arzu Yorgancioglu
9. Think Tank: Josep M Anto (SP), Tari Haahtela (Fi), Bernardo Sousa-Pinto (PT), Rita Amaral (PT), Cristina Bonaglia (IT), Isabelle Wienczyslawa Czarlewski (FR), Rosalba Buquicchio (IT), Demetrios Christou (GR), Galyna Fedoruk (UK), Pietro Fontanesi (IT), Bilun Gemicoglu (TR), Antonio FM Giuliano (IT), Alla Nakonechna (UK), Sophia Neisinger (DE), Ana M Pereira (PT), Aiste Ramanauskaite (LT), Filip Raciborski (PL), Brigita Sitkauskiene (LT), Oksana Sokhatska (PT), Viktor Stepanenko (UA), Katarina Stevanovic (DE), Orysya Syzon (UA), Violeta Kvedariene (LT), Arunas Valiulis (LT), Holger Schünemann (CDN)
10. IT: Govert de Vries (NL), Michiel van Eerd (NL)

The strategy for realising the changes is based on digitally-enabled, person-centred care using IT solutions such as the MASK-air® or CRUSE® apps.

5.4 | Communicate the change vision

Using the experience and strengths of national and international scientific societies, patient/citizen's organisations, ARIA, GA²LEN and UCARE, the change vision will be communicated.

The integration of new paths of understanding health and change is a requirement for the current strategy. The CM model should expand and strengthen the potential for existing models to be adapted to the current situation of Ukrainian patients and contacts in any organisation and institution. It is important to consider the integration of other modes of communication and dissemination. A central issue will be the need to raise the level of understanding of shared decision making and health literacy among refugees. This is a long-term investment in self-care and prevention. A later target audience with a higher level of health literacy will naturally also ensure an easier adoption of subsequent health messages, possibly using ICT.⁴⁷ Similarly, we should consider a wider community-oriented approach to dissemination. This could also cover social media and self-help groups, as some of the later patients would benefit not only from personal previous experience and knowledge about these ailments, but also from a supportive environment, that would be able to better support and help these citizens/friends/family members.

More specifically, and in order to promote the project and change vision, UCRAID will partner with patient organisations, scientific and medical societies, allergy foundations and non-for-profit

organisations such as ECARF (European Centre for Allergy Research Foundation), industry partners and other stakeholders. Specific activities will include joint and broad social media coverage, scientific publications, presentations at national and international congresses, press releases and conferences as well as newsletter coverage by endorsing partners including allergy, respiratory and dermatology societies.

5.5 | Empower others to act on the vision

Organisational processes and initial structures are in place to start the project immediately and are aligned with the overall organisational vision. However, we need to continuously check for the important barriers raised by the project to achieve the best outcomes of treatment. We are acting proactively to remove the obstacles involved in the process of change.

5.6 | Generate short-term wins: pilot study

We propose to create short-term (e.g. 6 months) and medium-term (e.g. 12 months) targets.

To demonstrate the importance and barriers of the project, a pilot study has been initiated in Puglia (Maria Teresa Ventura) and the first Ukrainian patient was enrolled on 20 July 2022. The project is feasible since all MASK-air® tools have been tested in 19 languages and it was found that questions can be understood in all of the languages^{41,48} and by patients of up to 75 years of age.^{49,50}

5.7 | Consolidate gains and produce more change: full deployment

Most of the goals of Kotter's change model step 7⁴⁴ have been met by the ARIA CM strategy³⁰ and will be further developed for UCRAID. The Ukrainian versions of MASK-air® and CRUSE® will then be disseminated in all of the MASK-air®/CRUSE® countries (those in which the apps are available) in order to cover the largest number of Ukrainian refugees. The next steps will be to provide care for urticaria (CRUSE already developed by Peercod) and COPD.

5.8 | Anchor new approaches in the culture and institutionalise the changes

The UCRAID initiative will start but not end with the MASK-air/CRUSE action plan. As its first project, this action plan will provide a roadmap for improving the care of refugee patients with other allergic and skin diseases. This, in turn, will increase the awareness and use of MASK-air/CRUSE in Ukrainian patients and their treating

physicians. The MASK-air/CRUSE action plan may also serve as a model for improving the care of refugees and immigrants from countries other than Ukraine. Future and follow-up projects within the UCRAID initiative, for example a pan-European physician finder, patient education and information activities, will anchor and institutionalise the MASK-air/CRUSE action plan.

6 | ETHICS

1. The download and usage of the apps are free of charge and there are no advertisements. They fall under the French jurisdiction. They follow the General Data Protection Regulation (GDPR) which regulates the processing of personal data in the European Union (EU).⁵¹ Geolocation also follows the GDPR.⁵²
2. MASK-air® was CE1-registered, and this is the app that will be used.
3. However, in the next iteration of MASK-air®, considering the intended use and other information regarding the Software (SW) operation, as defined as part of the section 'purpose', the mentioned SW is 'determined' and will be classified under the MDR 2017/745⁵³ and MDCG 2019–11 guidances.⁵⁴ The SW is considered as an active medical device in line with definitions 1 and 4 (article 2 of the MDR) and step 1 of the MDCG 2019–11 guidance. To further substantiate this position, use has been made of the currently most applicable EU guidance, the MDCG 2019–11 Guidance on Qualification and Classification of Software.⁵⁴ As per Annex VIII, MASK-air® is a class IIa medical device based on rule 11 (UDI MASK-air app: (01)08720165943005(10)3a0808(11)220600).
4. The terms of use of the apps follow the GDPR and have been translated into Ukrainian. The terms of use for Ukraine are also available.
5. The app usage does not require an ethics committee since it is 'a method of recording symptoms and medications taken that does not provide any recommendation concerning treatment or diagnosis' (UK Medicine & Health Products Regulatory Agency, E/2017/0546).

7 | EXPECTED BENEFITS

1. Size of the target population: It is estimated that over 1 million Ukrainian refugees suffer from symptoms of asthma, rhinitis and/or urticaria and that over 100,000 have a severe disease.
2. It is vital to engage with refugees to understand the barriers they face. MASK-air® for respiratory symptoms and CRUSE® for urticaria are prototypes of person-centred care for chronic diseases.
3. *Ukrainian refugees* with asthma, rhinitis and urticaria have *easy-to-use mHealth apps* in their own language to improve symptom control and treatment.

4. Two apps enable *guided self-management*, i.e. they enable the refugees to manage their disease guided by healthcare professionals.
5. Patient-centred, digitally-enabled care supports the *early treatment of symptoms* to improve quality of life and lessen disability.
6. Engagement with healthcare professionals digitally and in person has the potential to reduce *emergency visits and hospitalisations*, especially in asthma. This saves costs.
7. Shared decision making between patients and healthcare providers speeds up *digital transition* in health care. It paves the way to inexpensive mHealth for other symptomatic non-communicable diseases.
8. Propose an inexpensive innovative mHealth model for symptomatic non-communicable diseases.
9. Deploy UCRAID for other diseases (e.g. COPD or cardiovascular diseases).
10. Deploy UCRAID for other refugees. The MASK-air® module exists in 20 languages including Arabic.
11. Facilitate digital transformation in health care, building digital cross-border exchange.
12. The design of UCRAID can be used for patients travelling in different countries to help shared decision making between the patient and the physician speaking different languages.

8 | THE BARI PILOT STUDY

A pilot study will be carried out to test the feasibility of UCRAID. It will involve physicians but also members of the Ukrainian refugee community and a Ukrainian physician. A second step will then include members of the linguistic university of Bona Sforza to better understand cultural and linguistic barriers.

9 | FUTURE DEVELOPMENTS

This project can be a model for improving chronic disease management in the context of language or cultural barriers. This implies that the MASK-air and CRUSE solution (i) can be subsequently expanded to improve care in refugees of other nationalities and (ii) can serve as a role model for other mHealth tools to be used for Ukrainian refugees with other chronic diseases, including COPD and cardiovascular diseases.

AUTHOR CONTRIBUTIONS

Boleslaw Samolinski (PL) proposed the project and led it. Jean Bousquet (FR) co-led the project and wrote the paper. Igor Kaidashev (Ukraine), Marcus Maurer (DE) and Nicolas Roche (FR) were leading the different tasks. Anna Bedbrook (FR) was the secretary of the project. Coalition: Ukraine: Igor Kaidashev (Ukrainian Society of Specialists for Immunology, Allergology and Immunorehabilitation), Andrii Kurchenko, Roman Stepanenko (Ukrainian Society of Dermatology), Vladyslav Tsaryk, Yuliia Lysanets (Poltava State

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CONFLICT OF INTEREST STATEMENT









JB reports personal fees from Cipla, Menarini, Mylan, Novartis, Purina, Sanofi-Aventis, Teva, Uriach, other from KYomed-Innov, other from Mask-air-SAS, outside the submitted work. TH reports personal fees from Orion Pharma, outside the submitted work. MM reports grants from Allakos, personal fees from Alvotech, grants and personal fees from Amgen, personal fees from Aquestive, personal fees from Aralez, grants and personal fees from AstraZeneca, personal fees from Bayer, grants and personal fees from Celldex, personal fees from Celltrion, grants and personal fees from Evommune, grants and personal fees from GSK, personal fees from Ipsen, grants from Kyowa Kirin, grants from Leo Pharma, grants and personal fees from Lilly, personal fees from Menarini, grants and personal fees from Mitsubishi Tanabe Pharma, grants and personal fees from Moxie, grants and personal fees from Noucor, grants and personal fees from Novartis, personal fees from Orion Biotechnology, personal fees from Resonance Medicine, grants and personal fees from Sanofi/Regeneron, personal fees from Septerna, grants and personal fees from Teva, personal fees from Trial Form Support International AB, grants and personal fees from Third HarmonicBio, grants and personal fees from ValenzaBio, grants and personal fees from Yuhan Corporation, personal fees from Zurabio, outside the submitted work. NR reports grants and personal fees from Boehringer Ingelheim, grants and personal fees from Novartis, grants and personal fees from GSK, personal fees from AstraZeneca, personal fees from Chiesi, grants and personal fees from Pfizer, personal fees from Sanofi, personal

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DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this study.

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SUPPORTING INFORMATION

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

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