**FULL PROTOCOL TITLE**

*Knowledge, perceptions and limitations of the use Patient Reported Outcomes Measures (PROMs) by physicians in allergic diseases.*

**Study Chairman or Principal Investigator:**

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***Steering Committee:***
*Dr. Marcus Maurer (Germany)*
*Dr. Torsten Zuberbier (Germany)*
*Dr. Jean Bousquet (France)*
*Dr. Ivan Cherrez-Ojeda (Ecuador)*

**Supported by:**

*Universidad Espíritu Santo*

*(Any modification to the protocol should be annotated on the coversheet or in an appendix)*

**Version 2**
**November 21st, 2021**

## 1. BACKGROUND AND RATIONALE

Patient Reported Outcome Measures (PROMs) are validated questionnaires that take into account opinions, feelings and experiences of patients in order to assess their health status and the medical care received, as well as the disease course and response to treatment. There is increasing recognition of the importance of patient's perceptions of disease and their assessments of healthcare processes (1).

The prevalence of allergic diseases is increasing around the world. Many allergic diseases, including asthma, allergic rhinitis, allergic conjunctivitis, urticaria/angioedema and atopic dermatitis, share similar risk factors. In 2017, the incidence of asthma was 43.12 million new cases / year (0.56%), while in that same year the prevalence and mortality included 272.68 million cases (3.57%) and 0.49 million deaths (0.006%), respectively (2). It is estimated that by 2025, another 100 million are likely to be affected (3). Worldwide, allergic rhinitis (AR) affects between 10% and 30% of the adult population, children and adolescents, as well as young adults, were the age groups most affected by AR with asthma comorbidities, sinusitis, conjunctivitis and nasal polyposis (4).

Allergic diseases affect people of all ages and imposes a substantial loss both for the patient and for their environment, as well as for society and public health. Inadequate control of these diseases can lead to increased severity and less adherence to treatment. In addition, it can lead to limitations in activities of daily living, decreased productivity in the workplace and altered functional capacity, reduced quality of life, and various socioeconomic limitations.

The importance of collecting data on PROMs during routine clinical encounters has been advocated by leading global health institutions, including the World Health Organization (WHO), the United States Food and Drug Administration (FDA), and the European Medicines Agency (EMEA) (5). PROMs are more sensitive in estimating the burden of disease and capturing the impact of interventions that is why the aim of this study is to identify clinicians' perspectives regarding the use of PROMs in clinical contexts (1,6,7).

To achieve the proposed objectives, a cross-sectional, anonymous study will be carried out using a survey-type questionnaire that will be sent in electronic format to the participating physicians.

## 2. OBJECTIVES

**Primary Objectives:**

To describe the knowledge, perceptions and limitations of the use Patient Reported Outcomes Measures (PROMs) by physicians in allergic diseases in order to increase engagement and uptake of these tools in clinical practice.

**Secondary objectives:**

1. To develop a questionnaire that evaluates knowledge, perceptions and limitations of physicians in the use of patient-reported outcome measures (PROMs) in urticaria, angioedema, allergic rhinitis, allergic conjunctivitis, atopic dermatitis, rhinosinusitis and asthma.
2. To describe the factors that influence PROs data interpretation or use in clinical practice.
3. To identify what PROs have the most utility for healthcare professionals during their daily clinical practice according to the specific disease studied.

*Description of hypotheses to be tested (PICO format)*

| | |
|---|---|
| ***Patients*** | *Physicians,* |
| ***Intervention*** | *PROM-USE Questionnaire* |
| ***Comparison / Control*** | *None* |
| ***Outcomes*** | *To describe the knowledge, perceptions and limitations of the use Patient Reported Outcomes Measures (PROMs) by physicians in allergic diseases.* |

## 3. METHODS

**Study design:** This is an observational analytical cross-sectional international multicenter study in physician who meet the inclusion criteria.

Enrollment: 3000 participants
Target Follow-up Duration: 3 months

**Study Center(s):**

- Respiralab Research Group
- UCARE Network - Urticaria Centers of Reference and Excellence
- ADCARE Network – Atopic Dermatitis Centers of Reference and Excellence
- ACARE Network - Angioedema Centers of Reference and Excellence
- Other Allergy, Dermatology and Pulmonology Centers that accept our invitation to the project.

**Study personnel:**

- **Steering Committee:**
  - Dr. Marcus Maurer
  - Dr. Zuberbier
  - Dr. Jean Bousquet
  - Dr. Ivan Cherrez-Ojeda
- **Principal Investigator:** Dr. Ivan Cherrez-Ojeda
- **Development of PROMUSE questionnaire:**
  - Ivan Cherrez-Ojeda
  - Marcus Maurer
  - Jean Bousquet
  - Karla Robles-Velasco
  - Romina Hinostroza
  - Carolina Crespo
  - Miguel Felix Romero

- **Diffusion of online PROMUSE survey:**
    - Respiralab
    - UCARE Center
    - ACARE Center

**Patients/Participants:**
**Recruitment strategy:**
We will send an invitation to the UCARE and ACARE and Latin-American allergic centers to our project "PROM-USE Study". The doctors who kindly accept to participate will receive the survey in electronic format will be sent through a link. Each doctor will have a different link. They will be in charge of surveying physicians related to the management of allergic diseases. The information will be automatically saved in the general database.

**Eligibility (Inclusion and exclusion criteria)**

**Inclusion criteria:**

- Physicians who attend any allergic disease related to: urticaria, angioedema, allergic rhinitis, allergic conjunctivitis, atopic dermatitis, rhinosinusitis and asthma.
- Able to answer a survey in an electronic device.
- Willing to complete a self-administered questionnaire

**Exclusion criteria:**

- Physicians who are not interested in participating, in whom informed consent is not obtained or who revoke their consent.

**Study protocol**

1. Send the invitation to the doctors for participating in our project "PROM-USE Study" to the UCARE, ACARE and Latin-America Allergy Societies members.
2. Once the doctor have accepted the invitation, they will receive an own link that will redirect them to the PROMUSE survey, they must answer the survey and at the same time disseminate it to other physicians who are related to the management of allergic diseases.
3. The information will be automatically collected in the database through the Qualtrics platform.
4. The collection of information will be for 3 months from November 1, 2021 to January 31, 2022.
5. Once the data collection is completed, the information will be refined, tabulated and statistically analyzed.
6. The results will be presented.

7. The publication article will be written, which will follow specific authorship criteria that will be detailed later.

**Instruments:**

- PROMUSE Survey
- Qualtrics Platform
- Gmail
- UCARE Office for communication and announcements
- ACARE Office for communication and announcements

**Statistical plan**

**Sampling Method:**
Non-Probability Sample: Our sample will be composed by all participants who accept the invitation to volunteer and answer our questionnaires.

**Statistical Analysis:**
After data collection, descriptive analysis will be used for all questions in the questionnaire: mean and standard deviation for quantitative variables, frequency and percentage for categorical variables. The ANOVA test (analysis of variance) will be used to verify the quality of the hypothesis of equality of the different means. The Chi-Square test will allow evaluating comparisons between groups, as well as crude and adjusted logistic regression analysis. A p-value of 0.05 will be considered significant for all tests.

**Ethical considerations:**

We have the approval of the Ethics Committee for Research in Human Beings (CEISH) with acceptance letter No. HCK-CEISH-21-002.
In no case will the material obtained be used for purposes other than scientific research, in accordance with current legislation on health (see Constitution of the Republic, art. 66 nos. 19 and 20; and, in general, on the prohibition of any form of experimentation that violates fundamental rights, article 66 number 3 lit. d); Organic Health Law, arts. 7, lit. l), 208, 211 and other secondary regulations). Regarding the rights of confidentiality, a letter of commitment to confidentiality and information security will be attached by each of the authors individually, where the subscriber of the letter agrees to maintain confidentiality in relation to all documentation and information. obtained in the process of collecting, analyzing and presenting data from any participant who is part of the project, and who therefore agrees with:

- Not disclose to third parties or institutions the content of any documentation or information, as part or result of the process of preparing the project
- Do not allow third parties to handle documentation resulting from the accreditation process that they may have in their possession
- Do not exploit and take advantage of for their own benefit, or allow the use by others, of the information obtained or knowledge acquired during the development of the project
- Do not keep documentation or allow unauthorized copies of this information to be made.

## 4. SCHEDULE

| | | | First Year | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Activity** | **Jun** | **Jul** | **Aug** | **Sept** | **Oct** | **Nov** | **Dec** | **Jan** | **Feb** | **Mar** | **Apr** | **May** | **Jun** | **Jul** | **Aug** | **Sept** |
| Review the literature | X | X | X | X | | | | | | | | | | | | |
| Assign doctors who will disseminate PROMUSE survey | | | | | X | X | | | | | | | | | | |
| Include patients | | | | | | | X | X | X | X | | | | | | |
| Data processing and analysis | | | | | | | | | | X | X | | | | | |
| Presentation of results | | | | | | | | | | | X | X | | | | |
| Manuscript writing | | | | | | | | | | | | | X | X | X | |
| Final report to funding agency | | | | | | | | | | | | | | | | X |

## 5. AUTHORSHIP CRITERIA

*The authorship of this study will follow the following criteria:*

1. The first author of the article will be the principal investigator Dr. Ivan Cherrez-Ojeda.
2. The members of the steering committee will also appear as co-authors of the article.
3. The researcher who gets 150 surveys will be recognized as co-author and could include 3 authors in the article.
4. The researcher who gets 100 surveys will be recognized as co-author and could include 2 authors in the article.
5. The researcher who gets 50 surveys will be recognized as co-author and could include 1 author in the article.
6. The other doctors who get less than 50 surveys will be recognized in the collaborators segment at the end of the article alphabetically.

## 6. SPONSORS

Universidad Espíritu Santo

## 7. CONTACTS, LOCATIONS, AND INVESTIGATOR INFORMATION

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## 8. APPENDICES

*PROMUSE SURVEY*