

Patient Advisory Board for Chronic Rhinosinusitis – A EUFOREA initiative*

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Abstract

Despite the high prevalence of chronic rhinosinusitis (CRS) and its impact on patients' quality of life, no European patient organization that advocates for patients with CRS currently exists. To fill this gap and give a voice to CRS patients, EUFOREA has created a patient advisory board, whose goal is to better understand the real-life needs of patients, to raise awareness at political level and to involve patients in the development of novel integrated solutions to accelerate access to accurate diagnosis and treatments. This report summarizes the key discussion points from the kick-off meeting of the board on the 8th June 2018 and provides an outline of the key objectives for the future.

Key words: chronic rhinosinusitis, asthma, nasal polyps, patients, advisory board

Introduction

Chronic rhinosinusitis (CRS) is an inflammatory disease of the nose and paranasal sinuses, characterized by sinonasal symptoms persisting for more than 12 weeks ⁽¹⁾. The symptoms can comprise nasal blockage, secretions, postnasal discharge, facial pain or pressure, and decreased sense of smell and taste. The overall prevalence of CRS is 10.9% in Europe with differences between countries ranging from 6.9-27.1% ⁽²⁾. CRS patients suffer from a significant decline in Quality of Life (QoL) as they experience a wide range of symptoms which usually last for

years or decades, while aggravating over time. Compared to other chronic diseases, it is estimated that the impact of CRS on patients' QoL is similar to conditions such as congestive heart failure, COPD, angina and back pain ⁽³⁾. Not surprisingly, CRS is associated with significant impaired performance at work, school or daily life activities ^(4,5). As a result, this widespread disease generates a large economic burden to health care systems around the globe, via both direct and indirect costs ^(2,6). Despite the socio-economic burden, research on CRS is still underrepresented in the medical literature compared to other

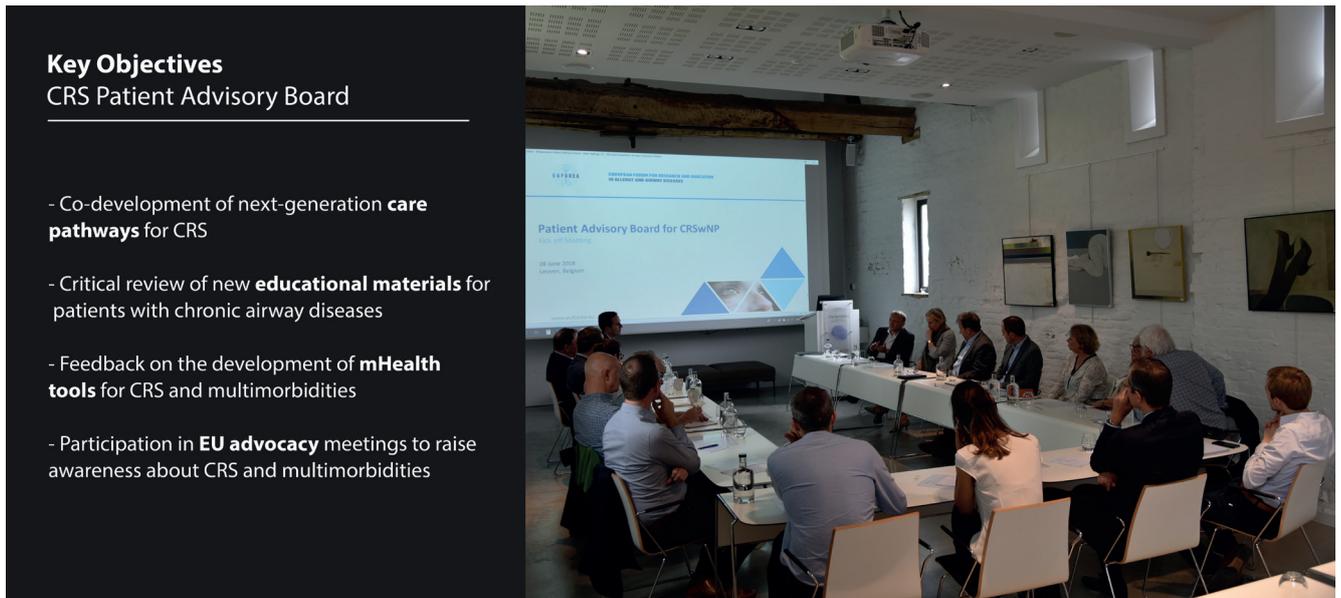


Figure 1. Key objectives of the Patient Advisory Board. Picture taken during the kick-off meeting, 8th June 2018, Leuven, Belgium.

chronic illnesses⁽⁷⁾, and various unmet needs in the management of CRS have been identified.

Unmet needs in CRS management

Compared to other diseases, the integrated management of CRS is somewhat lagging behind, with a slow evolution of optimization of care delivery and few concrete solutions proposed to patients:

- Unpublished data suggest delayed diagnosis in a significant proportion of patients with CRS. Late diagnosis and start of adequate treatment in CRS may lead to uncontrolled disease and higher prevalence of comorbidities^(8,9).
- From a therapeutic perspective, limited options are currently available for both CRS with (CRSwNP) and without (CRSsNP) nasal polyps. Guidelines recommend anti-inflammatory treatment (mainly topical corticosteroids) supplemented by sinus surgery in case of failure of medical treatment⁽¹⁰⁾. In that context, a significant proportion of CRS patients remain uncontrolled despite maximal treatment, and a high recurrence rate is observed after medical therapy and endoscopic sinus surgery^(11,12). Biological therapies, which will likely be available from 2020 onwards for well-defined patients with CRSwNP, might represent an attractive strategy for patients who have reached a therapeutic impasse⁽¹⁰⁻¹⁵⁾.
- In regards to the availability of reliable information about the disease, patients' primary source of information is the Internet, which often contains non-validated, biased information. As a result, in an attempt to alleviate their symptoms, many patients self-manage and frequently self-adjust their treatment regimen⁽¹⁶⁾. Unbiased information is therefore highly needed to empower patients to self-manage their diseases, a

key step towards Precision Medicine⁽¹⁷⁾.

- Finally, CRS patients lack a global patient organization that will represent their interests during the development of new care strategy, novel drugs, or health policy decisions. The EU-FOREA patient advisory board was created to fulfill that gap.

Role of Patient Organizations

The purpose of a Patient Advisory Board is to provide the unique perspective of patients on clinical management, treatment options and patients' real-life experiences on care delivery. Engagement of patients and advocacy group stakeholders brings awareness and invaluable knowledge and is considered crucial to meaningful outcomes research. Advisory boards are usually composed of patients, family members of patients and healthcare providers. All members meet to discuss aspects of the patient's experience, input and concerns. During these meetings, there is an open exchange of ideas about different ways to facilitate and improve patient-centered care practices and to increase the general awareness of the general public⁽¹⁸⁾. Until now, no European Patient Advisory Board was founded for patients suffering from CRS.

Launch of the CRS Patient Advisory Board

The CRS Patient Advisory Board was launched with a kick-off meeting on the 8th June 2018 (Figures 1,2). The board consists of voluntary patients from different European countries, willing to brainstorm about the unmet needs in CRS care, and to help the health community with the development of innovative integrated solutions for other patients. Most patients present during the kick-off meeting suffer from CRS with comorbid asthma. Approval by the local institutional review board was obtained



Figure 2. Group picture of the Patient Advisory Board.

for the creation of this organization.

The kick off meeting started with an introductory lecture by Dr. Maria Mavris from the European Medicines Agency (EMA), who emphasized the importance of collaboration with patients. EMA is a decentralized agency of the European Union, established in 1995, which aims at evaluating new medicines for use in humans and animals. It is a network of over 4000 scientific experts, who evaluate the medicines from early stages of development, through marketing authorization to the safety monitoring once they are on the market. EMA is now actively collaborating with patients through the life cycle of medicines, with 167 patients and consumers involved in EMA activities in 2008, to up to 925 in 2017. Partnering with patients is essential to bring the everyday aspects of living with a disease into the scientific discussions, to help bridge the gap between clinical trial data and real-world data. Engaging with patients is also important to improve transparency and trust and increases the general awareness of the public.

The kick-off meeting was subsequently divided into various brainstorming sessions to define and agree on the unmet needs for patients.

Empowering CRS patients through education

Lack of reliable online information about CRS is an issue acknowledged by all patients from the board. Improving patients' knowledge about their disease and treatment options is essential to reach better self-management and higher adherence to treatment. Patients from the board believed that a dedicated website developed by medical experts, with trusted and unbiased information about the newest developments in the field, best practices, risks and side effects of all treatments, and additional tips and tricks to better manage their diseases would be highly recommended. Patients are especially eager to learn about preventive measures to better control their symptoms (e.g. How air-conditioning, air pollution, or a certain type of food

can affect their diseases?). With that goal in mind, EUFOREA has launched an awareness platform for patients with chronic respiratory diseases (chronic rhinosinusitis, allergic rhinitis, and asthma: <https://www.euforea.eu/patient-platform>). Finally, an online forum where patients can connect with each other, share their experience and ideas about the diseases would be valued by them (e.g. in regards to lifestyle and nutrition).

Raising public awareness through advocacy

Patients also believe that creating awareness about the impact of CRS and asthma on work and social life is highly important. This is required to create a more empathic environment for them, with family, employers, and social circles more aware of the burden they have to deal with. Better awareness would also bring the disease higher on the political agenda of the EU, and national and local governments. In turns, additional funding for research could be allocated to this field and a deeper understanding of the pathophysiological mechanisms of CRS and asthma could be envisaged ⁽¹⁹⁾.

Patients also express the necessity to have homogenization of treatments across Europe, with the different medicines available in each European country. Indeed, currently some patients must travel to other countries to purchase the medication they need. Harmonization of care delivery for patients with CRDs in Europe is one of EUFOREA's objectives.

Impact of CRS on work & quality of life – A lifelong disease

In accordance with previous reports ⁽²⁰⁾, the negative impact of the disease on work productivity was acknowledged by all patients from the board.

Specific CRS and asthma symptoms were further discussed with patients to better understand how each of them impacts their daily life. Patients often report social embarrassment and limitations due to constant smell disturbances, rhinorrhea, purulent discharge, sneezing, or vocal congestion:

- Patients' inability to smell or taste greatly impact their quality of life. To picture the situation, a patient used the following metaphor: "Living with no sense of taste and smell is like watching the TV in black & white in the 21st century". Smelling and tasting is an important part of what makes life enjoyable, colorful, and sharing a meal or a drink with family, friends, and colleagues is socially fulfilling. Not surprisingly, the lack of olfactory sense in CRS patients has been correlated with depression ⁽²¹⁾. This impairment can also lead to dangerous situations at home or work. In case of gas leakage or if high levels of toxic chemicals are present in the air (e.g. acetone, ammoniak, etc.), patients might not notice it quickly and would remain for prolonged periods of time in the toxic surrounding. Patients with olfactory dysfunction experience anxiety over their inability to protect themselves and family members from such hazards ⁽²²⁾.

- Shortness of breath is another problematic symptom in CRS & asthma, as the incapacity to perform daily physical activities impact every moment of patient's life and can even lead to terrifying situations with sensations of suffocation.
- Nasal blockage also greatly impacts their quality of life because of chronic sleep impairment resulting in lack of energy, depressing feeling, but also with regards to their social life. Indeed, patients are often perceived in a distorted way by the social circle. To others, a person with constant nasal blockage may sound and look sick, giving the impression of a weak or even contagious person.
- In addition, patients often report social embarrassment and limitations due to constant rhinorrhea smell disturbances, sneezing, purulent discharge, or vocal congestion.

Need for better solutions & treatments

For the patients composing the board, joining the advisory group represents a novel way to help others with their disease journey. By supporting the experts who study or develop new treatments and solutions, patients aim at accelerating the access to accurate diagnosis and treatments for all patients around the world. The following comments are already worth mentioning: A more integrated care was suggested by patients, with better communication among healthcare professionals to facilitate referrals. Pharmacists and general practitioners should be better informed and involved in the care. Specialists, such as ENT doctors and pulmonologists, should discuss and align on the best therapeutic approach. Indeed, CRS and asthma comorbidity is frequent and often linked by similar mechanism of inflammation, the concept of united airway diseases⁽²³⁾.

Digital tools such as mySinusitisCoach might help implementing these changes⁽²⁴⁾. The patient advisory board is uniquely positioned to provide recommendations to the mySinusitisCoach development team in regards to new functionalities of the mobile app in the short- and mid-terms; thereby ensuring the development of a relevant tool for patients and doctors.

Finally, patients are highly enthusiastic about the arrival of new biological drugs for the treatment of CRS and asthma. Between the risks of long-term usage of oral steroids^(25,26), and the high probability of recurrent surgeries⁽²⁷⁾, patients cherish the idea of

a more optimal approach.

Key objectives & future perspectives

In conclusion, the creation of the patient advisory board represents an important milestone in CRS and asthma. Not only will experts learn from patients' experiences, but patients from the board have also expressed their high interest in being active actors in the field. The Patient Advisory Board will be involved in multiple key activities including (but not limited to):

- Co-development of next-generation care pathways for CRS
- Critical review of new educational material for patients with chronic airway diseases (online and printed)
- Feedback on the development of mHealth tools for CRS and multimorbidities
- Participation in EU advocacy meetings to raise awareness about CRS and multimorbidities.

Patients from the advisory board have already been involved in various EUFOREA meetings, such as a round table entitled "Framework for better patient awareness" (15th September 2018, Paris, France), the 2017 and 2018 edition of the Rhinology Future Debates (www.rhinology-future.com)^(10,22), and during the consensus expert board meeting on novel biological treatments for CRSwNP and asthma (30th November 2018, Brussels, Belgium). Their valuable opinion has proven to be essential to shape the future of CRS care.

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Authorship contribution

BP, LD, PWH, SFS conceived and designed the manuscript; BP, LD, PWH, SFS wrote the manuscript; All authors critically reviewed and revised the manuscript. All authors read and approved the final manuscript.

Conflict of interest

The authors disclose no conflict of interest related to this manuscript.

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