#### **Vilnius Declaration**

## Multisectoral care pathways embedding guided self-management, mHealth and air pollution in chronic respiratory diseases

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### I. Chronic respiratory diseases are major chronic diseases across the life cycle

Over 1 billion people suffer from chronic respiratory diseases (CRDs) such as asthma, COPD, rhinitis and rhinosinusitis. CRDs are major non-communicable diseases (NCDs) (1). Asthma and allergic diseases occur along the life cycle from early childhood, affecting 30 million children and adults under 45 years of age in Europe. COPD has an estimated annual death rate of over 4 million people globally. The annual costs due to asthma (direct costs, indirect costs and loss of productivity) in the EU are estimated at 72 b $\in$  (2). Work productivity loss for rhinitis is estimated to be 30-50 b $\in$  annually in the EU (3). Chronic respiratory diseases impact active and healthy ageing (AHA) (4, 5). Asthma in children or adults is a common risk factor for COPD in adults (6-8).

The Polish Presidency of the EU Council (3051<sup>st</sup> Council Conclusions) made the prevention, early diagnosis and treatment of asthma and allergic diseases a priority to reduce health inequalities (9, 10). The 3206<sup>th</sup> Cyprus Council Conclusions (11) recommended that the diagnosis and treatment of chronic diseases should be initiated as early as possible to improve AHA. Several debates at the European Parliament recommended an early diagnosis and management of CRDs in children in order to promote AHA (Cyprus Presidency of the EU Council, 2012) (12), predictive medicine (13) and self-management strategies using mobile technology (14).

The Vilnius EU Summit on the prevention and management of CRDs (Vilnius, Lithuania, 23 March, 2018) follows these recommendations and attempts to provide a road map to prevent and control CRDs using integrated care pathways taking into account the recent advances in mobile technology with a focus on air pollution.

#### II. Protective and risk factors

CRDs and other NCDs often share risk factors (e.g. tobacco, including e-cigarettes, nutrition, indoor and outdoor air pollution and sedentary lifestyle) (1, 15), leading to sustained local and systemic inflammation (16, 17) as well as impaired ageing. Tobacco smoking is the best identified risk factor for many NCDs including CRD. Allergens are of importance in rhinitis and asthma. Indoor and outdoor air pollution is another important risk factor for CRDs of increasing importance (18-21). Moreover, these risk factors can interact to worsen CRDs and induce exacerbations (22).

Pre-natal and early-life events have a major impact on the development of NCDs in adults (23, 24) and older people. A better understanding of these links will make it possible to propose effective novel prevention strategies to promote AHA. The developmental origin of ageing is on the EU political agenda (10, 11, 25, 26).

NCD prevention and control could be considered sequentially before the disease has been identified (i) to prevent its onset (health promotion and primary prevention), and (ii) after its onset, to better control and prevent its short- and long-term consequences (secondary and tertiary prevention and control). It should also be noted that early impairment of lung function is a marker of early all-cause systemic morbidity and mortality (23, 24, 25).

Health promotion and prevention should start at conception and be steadily continued across the life cycle for healthy lungs and active and healthy ageing. They are laid from a political perspective to contribute to the goals of the Europe 2020 strategy of healthy and active ageing (27) and the Sustainalbe Development Goals for 2030 (SDG) and the WHO strategy on NCDs. This strategy was also promoted by the Polish EU priority (9, 10). Multi-sectoral prevention, including policy change, regulation, and market intervention, is of the highest priority.

There is a need to find novel health promotion strategies in CRDs and to promote value creation in order to promote AHA. Particular attention is required for tobacco smoke prevention and mitigation

strategies for air pollution. It should be noted that there is ample evidence on the effectiveness of legislation to restrict smoking and reduce pollution, and that Governments should therefore be pushed.

## III. CRD will be seriously impacted by climate change

Climate change is considered as a major threat for CRDs (28, 29). Heat waves significantly increase morbidity and mortality in patients with chronic lung disease (30). Climate change, mediated by greenhouse gases, causes adverse health effects to vulnerable CRD patients including the elderly, children, and those in a distressed socioeconomic state (31). Reducing greenhouse gas emission and improving air quality represent two global challenges (32).

## IV. Poor adherence to medication: a major factor in CRD-related burden and death

Public health measures play an essential role in improving outcomes, but, for conditions where effective medications are available, such as for non-severe asthma, patients are supported in taking their medication effectively. One important global cause of low adherence is that medications are not accessible or affordable (14), and this must be addressed across Europe, especially in middle income countries. If medications are accessible, adherence is relatively high. This is a known important factor in asthma deaths (15). Unfortunately, the education programmes that have been proposed over the past decades have not increased adherence. Innovative effective educational programmes using mobile technology and guided self-management are crucial to empower patients and therefore increase and support their adherence to medications. Ensuring that practical support strategies are in place also represents an essential strategy for improving outcomes.

## V. Prevention and treatment strategies at a national level

Effective strategies are needed to reduce CRD burden. National programmes (Finnish, Czech, Portuguese Asthma or COPD Programmes) or national partnerships against CRD (Italy, Netherlands, Lithuania, France, Romania, Belgium and Spain) can be cost-effective (33). However, they are insufficiently implemented in many other EU countries, in particular in RIS countries (EIT Regional Innovation Scheme (EIT RIS), https://eit.europa.eu/activities/outreac/eit-regional-innovation-schemeris).

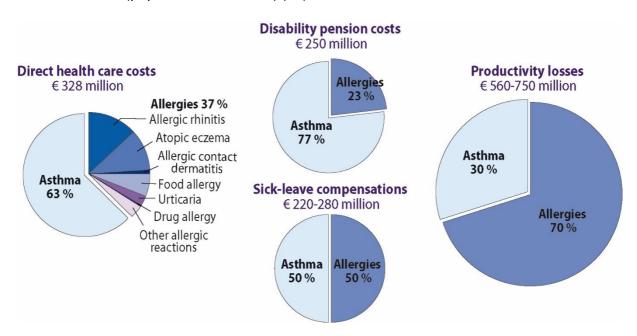
Integrated care pathways (ICPs) exist in some countries, such as in the UK for COPD (QS10) (NICE) (34), France (HAS) and the Netherlands (35), but national ICPs for asthma or asthma and rhinitis comorbidity do not exist. Quality standards for asthma (QS25) have been published by NICE (36). These are specific, concise statements that act as markers of high-quality and cost-effective patient care. Moreover, some initiatives are aimed at also incentivising good practice and improving implementation (i.e. remuneration based on performance indicators). In the UK, the Quality and Outcomes Framework (QOF) has 4 asthma-specific performance indicators which are explicitly linked to the subsequent remuneration of providers (37).

The Finnish asthma and allergy programmes pioneered the field (38, 39) and have been found to be effective (40).

The Finnish Asthma Programme 1994-2004 (41) and Allergy Programme 2008-2018 (38-40) demonstrate why public health problems need public health solutions. The programmes have been based on scientific innovations turned into practical actions. This has been possible in a country where the educational level of citizens is relatively high and where health care is efficiently organized and

mainly funded by public money. Integration of the work of primary and secondary care physicians and nurses, pharmacists and caregivers has been the key for a better flow of information, education and patient care, while patient education and public awareness happened at the same time by organisations representing patients. However, the asthma programme has been successfully deployed in Europe (42) and developing countries (33). The allergy programme was deployed in Norway (43). In asthma, improved detection of disease and recognizing asthma as an inflammatory disorder from the outset has led to early and effective management (60). In the 2016 Pharmacy Barometer Survey, not more than 2.5% of the Finnish asthma patients reported severe symptoms (61). In allergy, the *turning avoidance into tolerance* strategy, focusing on severe forms of disease and emphasizing health rather than mild problems, has encouraged a more rationale use of healthcare resources (3). A nationwide cost analysis was also performed (Figure 1).

Figure 1. In 2013, direct and indirect asthma and allergy costs were €1.3 —1.6 billion in Finland (population 5.5 million) (66).



The Finnish experience calls all European communities to take systematic and coordinated action to improve public health by lessening disability and costs caused by asthma and allergy. Inadequate care of these conditions seems to be a global problem delaying patient management and causing poor outcome (64). Although many actions have already been taken in Europe (65), Lithuania and Baltic countries can speed up implementation and make it relevant to healthcare and society as a whole.

# VI- Multisectoral care pathways embedding guided self-management, mHealth and air pollution in chronic respiratory diseases

ICPs are structured multidisciplinary care plans which detail essential steps in the care of patients (44). They promote the translation of guidelines into local protocols and their subsequent application to clinical practice (45). They empower patients and their carers (health and social). ICPs differ from practice guidelines as they are utilised by a multidisciplinary team and have a focus on the quality and co-ordination of care. Multisectoral care pathways for multimorbid CRDs are needed (46) and should incorporate self-management and aerobiology to allow precision medicine with endotype-driven treatment (47).

A large number of CRD patients do not consult physicians because they think their symptoms are 'normal' and/or trivial. However, CRD including rhinitis and asthma negatively impacts social life, school and work productivity (48). There is a clear role for the pharmacist for AR management in practice, through a guided change management process.

An example of ICP has been proposed for allergic rhinitis (AR). Many rhinitis patients use over-the-counter (OTC) drugs (49) and only a fraction have had a medical consultation. The vast majority of patients who visit GPs or specialists have moderate/severe rhinitis (50-54). GRADE-based guidelines are available for AR and their recommendations are similar (55-57). However, they are based on the assumption that patients regularly use their treatment and are not tested with real-life data. Unfortunately, adherence to treatment is very low and real-life studies do not necessarily accord with all recommendations (58). New-generation guidelines embedding real life data are needed.

Thus, ICPs should consider a multi-disciplinary approach as proposed by AIRWAYS ICPs (Figure 2), self-medication, SDM and new-generation guidelines including messaging for increased adherence and information on aerobiology and air pollution.

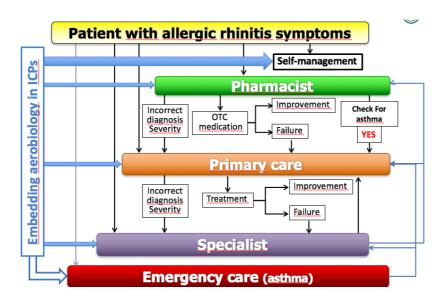


Figure 2: Flow between self-medication and treatment by specialists

#### a. Self-care and shared decision making

Self-care is any necessary human regulatory function which is under individual control, deliberate and self-initiated. CRDs require a long-term approach with emphasis on patient empowerment and appropriate support services stressing the importance of health literacy. In self-care, NCD patients make many day-to-day decisions. Self-management education complements traditional patient education. Self-care is learned, purposeful and continuous, otherwise it is dependent on individual's specific circumstances, resources, beliefs etc. only. Some important targets of self-care include the prevention of COPD exacerbations (59-61) but also the improvement of control of asthma or rhinitis (14, 62).

In shared decision making (SDM), both the patient and the physician contribute to the medical decision-making process, placing the patient at the centre of the decision (63). Physicians explain treatments and alternatives to patients who can then choose the treatment option that best aligns with personal beliefs and goals along with the benefits and risks (64). In contrast to SDM, the traditional medical care system places physicians in a position of authority, with patients playing a passive role in care (65).

#### b. mHealth including messaging

mHealth has evolved from eHealth, the use of information and communication technology (ICT) for health services and information transfer. According to the World Health Organization (WHO) (66), mHealth "has the potential to transform the face of health service delivery across the globe. A powerful combination of factors is driving this change. These include rapid advances in mobile technologies and applications, a rise in new opportunities for the integration of mobile health into existing mHealth services, and the continued growth in coverage of mobile cellular networks." The potential applications and benefits of mHealth are extensive and expanding (67). mHealth may be of great value in self-care and SDM.

The potential for mHealth in CRDs is enormous (68) but implementing ICT innovations may also have adverse consequences. It is therefore important to test applicability in each individual situation (69). Apps may be used to better understand and improve adherence, in particular using messaging, as well as to enable shared decision making and improve self-management of chronic diseases. Patients, who are the final users of these apps, must be included not only in the testing phase, but also in the designing and creation (70)

### VII- The Vilnius Declaration (VD)

#### a- The VD is an essential step for the fight against air pollution in CRD globally

- A first meeting on air pollution in CRD and mHealth was held during the 11<sup>th</sup> GARD meeting in Brussels (November 10, 2017). It paved the way for the VD.
- POLLAR (Impact of Air POLLution on Asthma and Rhinitis) is an EIT health-Horizon 2020
  project to propose strategies to predict and prevent air pollution peaks and CRD morbidity using
  mobile technology (Paris, January 2018).
- The Vilnius meeting (March 2018) will prepare the VD and propose a meeting at the UN to tackle the future risk of air pollution and climate change in chronic respiratory diseases across the life cycle and to propose practical primary and secondary prevention strategies to meet this unprecedented public health challenge and to combat inequities.
- The first ever WHO conference on air pollution and health will be held in Geneva on October 30<sup>th</sup>-November 1<sup>st</sup> 2018, a clear sign that the problem is growing and solutions are needed.
- The 12<sup>th</sup> GARD meeting in Helsinki (August 2018) will refine the VD for the UN High-Level Conferene.
- An ARIA-masterclass (with EUFOREA) will be the first teaching session on the subject focussing on ICPs, self-management and SDM (Brussels, September 12 2018).
- A meeting (HLC) will probably be organized at the UN Assembly (September 27, 2018). The results of the meeting will lead to an action plan for implementing recommendations.
- A consensus meeting will be organized (POLLAR, Paris, December 2018) for improvement in care pathway design to enhance patient participation, health literacy and self-care through technology-assisted 'patient activation' using rhinitis and asthma multimorbidity as a model of non-communicable disease. Pharmacy guidelines will be included in the meeting.
- With the results of POLLAR, a consensus meeting will be organized (POLLAR, Paris, December 2019) to embed aerobiology and air pollution in ICPs.

#### b- The VD

The Vilnius Declaration was developed by the participants of the EU Summit on CRDs (Vilnius, March 23, 2018) under the leadership of EUFOREA (Annex).

#### c- The expected impact of the VD

The VD has a clear strategic relevance with regard to the EU Health Strategy as it will bring added value to the existing public health knowledge:

- To propose a common framework for integrated care pathways in CRDs (and their comorbidities) for the entire EU which can be expanded to Eastern European and other regions and which will allow comparability and trans-national initiatives;
- To help risk stratification in CRD patients with a common strategy;
- To develop cost-effective policies, in particular strengthening those on smoking, including ecigarettes, and environmental exposure;
- To propose a common simulation tool for the entire EU to assist physicians in the segmentation of patients and choice of pathways;
- To develop interoperability of mHealth systems in Europe, including transborder interoperability in Eastern European regions (border between EU member states and associate EU countries);
- To have a significant implication on the health of citizens in the short term (reduction of morbidity, improvement of education in children and of work in adults) and in the long-term (healthy ageing).

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### **ANNEX: The Vilnius Declaration**



## **Vilnius Declaration on Chronic Respiratory Diseases**

## Guided self-management, mHealth and environmental factors in Chronic Respiratory Diseases (CRDs)

#### 23 March 2018

#### A. Introduction

- 1. The European Forum for Research and Education in Allergy and Airway Diseases (EUFOREA) has developed the Vilnius Declaration as a statement to improve the guided self-management of CRDs using mHealth and giving special consideration to the impact of air pollution and climate change.
- 2. The Declaration was elaborated and approved during the EU Summit on CRDs in Vilnius, Lithuania, on March 23, 2018, and addressed to health care personnel, policy makers and most importantly to patients suffering from CRDs.
- 3. Over 1 billion people suffer from chronic respiratory diseases (CRDs) such as asthma, Chronic Obstructive Pulmonary Disease (COPD), rhinitis and rhinosinusitis. CRDs are major non-communicable diseases (NCDs).
- 4. It is the duty of the medical community and health care systems to provide patients with tools to assist them with the most appropriate treatment and self-management of their condition.

## B. Chronic respiratory diseases are major chronic diseases across the life cycle and are affected by environmental risk factors

- 5. CRDs and other NCDs often share environmental risk factors (e.g. tobacco use, including ecigarettes, nutrition, indoor and outdoor air pollution and sedentary lifestyle), leading to sustained local and systemic inflammation as well as impaired ageing.
- 6. Asthma and allergic diseases occur along the life cycle from early childhood, affecting 30 million children and adults under 45 years of age in Europe and more than 600 million people globally. COPD is responsible for an estimated 3 million deaths globally.
- 7. Pre-natal and early-life events have a major impact on the development of NCDs in adults and older people. Early impairment of lung function is a marker of early all-cause systemic morbidity and mortality.

8. Allergens are of importance in rhinitis and asthma. Indoor and outdoor air pollution are other important risk factors for CRDs of increasing importance. Moreover, these risk factors can interact to worsen CRDs and induce exacerbations.

#### C. Prevention, control and self-management of CRDs

- 9. NCD prevention and control could be considered sequentially before the disease has been identified (i) to prevent its onset (health promotion and primary prevention), and (ii) after its onset, to better control and prevent its short- and long-term consequences (secondary and tertiary prevention and control).
- 10. Tobacco smoking is the best identified risk factor for many NCDs including CRDs.
- 11. Health promotion and prevention should start at conception and be steadily continued across the life cycle for healthy lungs and active and healthy ageing.
- 12. A large number of CRD patients do not consult physicians because they think their symptoms are trivial. However, CRDs, including rhinitis and asthma, negatively impact social life, school and work productivity.
- 13. Many rhinitis patients use over-the-counter (OTC) drugs and only a fraction have had a medical consultation. The vast majority of patients who visit General Practitioners or specialists have moderate/severe rhinitis.
- 14. Thus, Integrated Care Pathways should consider a multi-disciplinary approach including physicians, pharmacists and other health care personnel as proposed by AIRWAYS ICPs, using self-medication, shared decisions making (SDM) and new-generation guidelines including messaging for increased adherence and information on aerobiology and air pollution.
- 15. CRDs require a long-term approach with emphasis on patient empowerment and appropriate support services stressing the importance of health literacy.
- 16. Self-care is any necessary human regulatory function which is under individual control, deliberate and self-initiated.
- 17. In shared decision making (SDM), both the patient and the physician contribute to the medical decision-making process, placing the patient at the centre of the decision. Physicians explain treatments and alternatives to patients who can then choose the treatment option that best aligns with personal beliefs and goals along with the benefits and risks.
- 18. The potential for mHealth in CRDs is enormous but implementing Information and Communication Technology (ICT) innovations may also have adverse consequences. It is therefore important to test applicability in each individual situation.
- 19. Mobile Applications (Apps) may be used to better understand and improve adherence, in particular using messaging.

#### D. Health system strengthening and Sustainable Development Goals

The Vilnius Declaration aims to contribute:

- 20. To propose a common framework for integrated care pathways in CRDs (and their comorbidities) for the entire EU which can be expanded to Eastern European and other regions and which will allow comparability and trans-national initiatives.
- 21. To extend the Finnish experience of population management models of long-term state CRD control programmes, especially in low to middle income countries.
- 22. To help risk stratification in CRD patients with a common strategy.
- 23. To develop cost-effective policies, in particular strengthening those on the reduction of smoking, including e-cigarettes, and environmental exposure.
- 24. To propose a common simulation tool for the entire EU to assist physicians in the segmentation of patients and choice of pathways.
- 25. To develop interoperability of mHealth systems in Europe, including transborder interoperability in Eastern European regions (border between EU member states and associate EU countries).
- 26. To have a significant implication on the health of citizens in the short term (reduction of morbidity, improvement of education in children and of work in adults) and in the long-term (healthy ageing).
- 27. To achieve the goals of the Europe 2020 strategy of healthy and active ageing and of the UN Sustainable Development Goals to be reached in 2030.