

The Shifting Paradigm in COPD Management

Expert Report on COPD
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Initiated and developed by Takeda, with
contributions from the European Federation of
Allergy and Airways Diseases Patients' Association



Expert Report on Chronic Obstructive
Pulmonary Disease and its Management

declaration

The expert Report on COPD has been initiated and developed by Takeda Pharmaceuticals International GmbH and includes contributions from key experts within the field of respiratory and the European Federation of Allergy and Airways Diseases Patients' Association (EFA). The views expressed are those of the authors and may not necessarily reflect those of Takeda.



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Foreword

This expert Report on COPD was initiated and developed by Takeda Pharmaceuticals International GmbH and includes contributions from international opinion leaders in respiratory care, other healthcare professionals and the European Federation of Allergy and Airways Diseases Patients' Association (EFA). Its primary aim is to help healthcare professionals gain a better understanding of a changing view on chronic obstructive pulmonary disease (COPD). It can also be helpful in providing a better understanding of this sometimes debilitating health problem to patients, their families, policy makers and, through medical journalists, even to the general public.

As a Board Member of the European Federation of Allergy and Airways Diseases Patients' Association, a non-profit network of allergy, asthma and COPD patients organisations, representing 34 national associations in 22 countries and over 400,000 patients, I believe that patient-centered projects are of increasing importance and that patients have a right to the best quality of care, to safe environments, to live uncompromised lives and to be actively involved in all decisions regarding their health. Patient-centered activities are also a way to ensure that policy makers are more aware of the unmet needs of COPD patients.

There is an ongoing need for continuous education of COPD patients about risk prevention and management of the disease. Patients who know more about their disease are more likely to better comply with treatment, which leads to a better outcome. Because COPD is potentially a preventable disease, there is also an urgent need for better education of the lay public about COPD prevention. While in the past the majority of COPD patients were male, currently more and

more females suffer from COPD. Though irreversible, COPD is both a preventable and treatable disease, making it imperative that it is recognised and marked as an issue that must be addressed not only by healthcare professionals but also by policy makers and legislators.

COPD has a clear negative socio-economic impact. COPD accounts for more time off work than any other respiratory illness,¹ and a COPD exacerbation is one of the most common reasons for admission to hospital.² The total annual financial burden of lung disease in Europe amounts to nearly 102 billion euros.¹ COPD accounts for almost half of this figure.¹ Health economic data suggest that in Europe 28.5 billion euros are lost each year due to reduced productivity of COPD patients.¹

There is an ongoing need for continuous education of COPD patients about risk prevention and management of the disease.



EFA's recommendations to decrease the economic and socioeconomic burden and increase quality of life for people with COPD focus on:

1. Prevention

Further limitation of occupational and passive exposure to risk factors, smoking cessation and tobacco labeling, better education of the lay public about COPD risk factors and problems.

2. Early diagnosis

Access to spirometry testing for all those at risk, better co-operation between healthcare professionals working in primary care and specialists.

3. Disease management

Preventing and early recognition of costly and disease deteriorating exacerbations, individual tailoring of COPD medication and auxiliary care.

4. Access to good quality rehabilitation programmes and to oxygen supplementation

Provision of this for all in need would increase their chances of staying employed.

5. Best practices

Need to facilitate the dissemination of lessons learned from best practice programmes, such as the 10-year Finnish COPD Programme.

6. Employment

Employers need to be motivated to adopt flexible approaches to allow their staff with COPD to remain in the work force. This approach might be promoted by policy makers.

7. Registration

To establish a register for COPD patients to support evidence based policy making.

8. Research

Not only aimed at new drug development but also addressing reduction of the risk of exacerbations, improvement of cooperation within a multidisciplinary team, real life studies to complement randomised controlled trials, problems of co-morbidities, such as depression or cardiovascular disease and their interdependencies.

I believe that this expert Report can be seen as one of the tools to realise this ambitious but absolutely necessary list of activities. It is also a delight for me to see important statements of sufferers, the COPD patients themselves, included within this expert Report.

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Executive Summary

Chronic obstructive pulmonary disease (COPD), a leading cause of morbidity and mortality, is set to be the third largest killer in the world by 2030. Affecting about 210 million people worldwide, it is associated with significant psychosocial and economic burden.

“Mortality at 12 months following hospitalisation for an acute COPD exacerbation, at between 20 percent and 40 percent, is actually much worse than the mortality observed following hospital admission with an acute myocardial infarction.”

According to the European Federation of Allergy and Airways Diseases Patients' Association (EFA), continuous education of COPD patients about prevention and management of the disease will result in better informed patients who are more likely to comply with treatment, leading to better outcomes. The urgent need for education about COPD risk prevention extends to the general public, as well as policy makers and legislators.

The latest thinking on COPD management represents a shifting paradigm to recognise risk reduction as being of equal and complementary importance to symptom control. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) management strategy now emphasises the need for an individualised assessment of current symptoms and future risk. This two-fold management approach, commonplace in other diseases notably in cardiovascular medicine, needs to become the norm in COPD.

Risk reduction involves preventing disease progression, preventing and treating exacerbations, and reducing mortality.

COPD exacerbations lead to considerable morbidity, hospital admission and readmission, and

mortality. They are the most important determinants of health status in COPD, with frequent exacerbators at greater risk of poor health status, faster disease progression and mortality.

COPD patients often do not report exacerbations for treatment or do not self-manage the event themselves. As such they may have a reduced quality of life, with longer exacerbations, and are more likely to be admitted to hospital with an increased risk of another exacerbation during the eight weeks following.

With regard to reducing mortality, there is much we can learn from the cardiovascular disease arena (CVD) and adopt in COPD management. Mortality at 12 months following hospitalisation for an acute COPD exacerbation, at between 20 percent and 40 percent, is actually much worse than the mortality observed following hospital admission with an acute myocardial infarction (MI).

There are significant tools to address future risk in COPD, but they are frequently underused. Lessons must be learned from the success seen in organised systematic preventative management of CVD in order to make a long term difference to COPD.



Patients should be offered treatment with combinations of inhaled corticosteroids, vaccinations, long-acting beta agonists and long-acting muscarinic agonists which have been shown to reduce the risk of future exacerbations, with the phosphodiesterase 4 inhibitor roflumilast further reducing exacerbations when added in those suffering from the symptoms of chronic bronchitis.

Adherence to lifestyle and medications that allow prevention of outcomes in COPD must be encouraged, even when they do not acutely improve symptoms and may induce some side effects. If preventative treatments in COPD are recommended and adhered to, they will lead to reductions in further COPD exacerbations and mortality.

Good communication between physician and patient is essential for effective disease management. It is important that the term exacerbation is clearly defined and standardised to promote mutual understanding by patients and physicians.

Talking about flare ups or lung attacks with patients may help reinforce that an exacerbation is not a temporary inconvenience. Patients often prefer simpler terms such as a chest infection, crisis or attack.

They may underestimate the impact of exacerbations on their daily lives and overestimate disease control, as evidenced by them still suffering from a high number of exacerbations.

Patients' illness-related behaviour assumes greater significance with the new focus on risk reduction in COPD. They need to understand the value in adhering to treatments that may not have an immediate impact on their symptoms but may help to prevent future exacerbations and to reduce disease progression. Patient-centred communication strategies and other interventions enhancing patient-physician communications in COPD may help and should be adopted.

Lessons must be learned from the success seen in organised systematic preventative management of CVD in order to make a long term difference to COPD.

“ It is important that the term exacerbation is clearly defined and standardised to promote mutual understanding by patients and physicians. ”



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COPD in Focus: Setting the Scene

Chronic obstructive pulmonary disease (COPD) affects more than 210 million people worldwide¹ and is a major health care burden.² Its prevalence increases with age and, among individuals reaching the age of 80, more than a quarter may be given a diagnosis of COPD.³ Globally, COPD is associated with significant mortality; it has become the third leading cause of death in the United States⁴ and will be the third leading cause of death in the world in coming decades.

“Smoking accounts for only 40-70 percent of the attributable risk for COPD.”

One of the major reasons for the increasing prevalence of COPD is the worldwide epidemic of cigarette smoking. However, smoking accounts for only 40-70 percent of the attributable risk for COPD.⁵ Other exposures, including air pollution and biomass fuel use, are also major causes. In addition, COPD can develop in non-smokers with no known exposures. Thus, COPD is expected to be a major public health problem for the foreseeable future.

COPD is characterised by airflow limitation that is not fully reversible. In most cases the disease is progressive. However, COPD generally advances very slowly, over decades.^{6,7} As a consequence, patients with COPD frequently adjust their behaviour and their expectations to their declining physiologic status. This leads to both under-diagnosis and under-treatment of COPD.

The most common symptom of COPD is probably dyspnoea. It is currently thought that dyspnoea occurs from the

dynamic hyperinflation that results when a patient with expiratory airflow limitation increases respiratory rate, e.g. with exertion.⁸ As a result, dyspnoea with COPD is characteristically present on exertion or at other times when respiratory rate is increased. Similarly, COPD patients often tend to minimise exertion, perhaps as a strategy to avoid dyspnoea. This results in a severely sedentary lifestyle together that leads to marked de-training.

COPD is also extremely heterogeneous.⁹ Airflow limitation can result from either disease of the airways or from the alveolar destruction that results from emphysema. While both mechanisms for airflow limitation can result in dyspnoea, airways disease can also lead to cough and sputum production, the other two characteristic symptoms of COPD.

COPD is also associated with systemic manifestations. These include cardiac disease, depression, osteoporosis, metabolic syndrome, muscle weakness, decreased activity levels, lung cancer and

an increased risk for thrombotic disorders.¹⁰ These extrapulmonary manifestations are present variably among COPD patients, further adding to both the heterogeneity of COPD patients and the complexity of their management.

Exacerbations are a feature of COPD that become increasingly common as disease progresses.^{11,12} These are acute events that generally last from a few days to a few weeks during which symptoms of cough, sputum, dyspnoea and fatigue increase beyond the usual day-to-day variability. Infections with viruses and/or bacteria are common causes, but exacerbations may also occur without obvious infection. Both emphysema and airways disease are associated with exacerbations, and these may differ in their clinical features including response to therapy.^{13,14} Exacerbations are major drivers of healthcare costs, as they result in unscheduled visits and hospitalisations. Concurrent depression may worsen these problems.¹⁵ They are also associated with increased mortality, more rapid loss of lung function and worse overall health status.

Appropriate diagnosis and management of COPD patients is essential. First line therapy is bronchodilators.¹ While these agents cannot restore lung function to normal, they can improve airflow. This reduces dynamic hyperinflation and can improve functional status. Most patients with COPD have low activity levels and will benefit from an organised programme of rehabilitation that includes exercise training. Several therapies have been developed that can reduce exacerbation risk. As disease progresses, many patients will develop hypoxemia, which is associated with worse survival. For these individuals long term oxygen therapy prolongs life. Finally, for selected individuals, volume reduction surgery may be an option.

Current management of COPD requires that patients be assessed for their level of function as well as their symptoms. This has led to the specific recommendations that airflow, exacerbation frequency and health status or dyspnoea should all be considered when planning patient management programmes.¹



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The Importance of Future Risk Prevention in COPD: A Two-Fold Management Approach

For the first time, the newly revised Global Initiative for Chronic Obstructive Lung Disease (GOLD) strategy document emphasises that an individualised assessment of current symptoms and future risk is necessary for effective management of chronic obstructive pulmonary disease (COPD).¹

“In COPD, risk reduction involves preventing disease progression, preventing and treating exacerbations, and reducing mortality.”

This two-fold management approach, commonplace in other diseases notably in cardiovascular medicine and closer to home with asthma, needs to become the norm in COPD.

Relying fully on the results of spirometry is the standard for COPD diagnosis but is not dynamic enough to reflect the day-to-day needs of individual patients or assist in pragmatic management in office practice. Further characterisation can be done simply by the bedside.

Complementing FEV₁ from diagnostic spirometry with assessment of quality of life, either using the mMRC dyspnoea scale or a new CAT score, which can be completed by patients in your office, is helpful particularly to assess current symptoms and control. It is also crucial to assess future risk by enquiring about exacerbations or lung attacks in the previous year, i.e. admitted to hospital, attended the emergency department or had a course of oral steroids and/or antibiotics for an acute exacerbation.¹

When assessing a patient's disease history, it is important to identify those individuals that have daily cough and sputum i.e. who have chronic bronchitis (for a period of three months, for two consecutive years) as they are prone to recurrent exacerbations, which increase in frequency and severity as the disease advances.^{2,3}

The GOLD strategy categorises COPD patients into groups A, B, C and D, of increasing severity and risk of exacerbations, with group D being at greatest risk, having significant impairment of FEV₁, increased mMRC, increased CAT scores and frequent exacerbations ≥ 2 /year.¹

In COPD, risk reduction involves preventing disease progression, preventing and treating exacerbations, and reducing mortality. The focus of patient management continues to emphasise both non-pharmacological and pharmacological methods. Patient education leaflets on COPD, achieving

smoking cessation and maintenance of a smoke free environment are paramount. Weight normalisation and increased activity are also extremely beneficial.^{1,4}

Pharmacological interventions have focused on relief of dyspnoea and improvement of current symptoms with short and long acting bronchodilator agents, with or without the use of inhaled corticosteroids.^{1,3}

The recent ECLIPSE trial identified a specific exacerbation phenotype of patients who, in spite of receiving current optimal treatment with bronchodilators and inhaled steroids, were noted to have two or more exacerbations in the first year of the study and then went on to have two or more exacerbations in the second and third years of follow up.⁵ It is therefore important to assess adjunctive or additional treatment with the objective to further reduce exacerbation risk in these patients.

Exacerbations are feared by patients. Although traditional acute exacerbations of COPD are treated with five days of antibiotics, seven days of hospitalisation and ten days of oral steroids, it can take six weeks or more for symptoms to fully abate. It is important to realise therefore those COPD patients with frequent exacerbations occurring at Halloween, Christmas and Easter in western climates, can result in patients having six months of chronic ill health. Prevention of future risk should be of equal and complementary importance to a COPD patient as the immediate impact of treating symptoms.

A key target of COPD management is to reduce the significant increase in mortality, hospitalisation and

healthcare utilisation associated with exacerbations. The phosphodiesterase 4 inhibitor roflumilast has a different mode of action to bronchodilators and inhaled corticosteroids, and may provide additional benefits when added to these treatments in frequent exacerbators.⁶ Furthermore, a post-hoc pooled analysis of two 1-year studies demonstrated that roflumilast significantly reduced the rate of hospitalisations (21.6 percent $p=0.0439$) resulting from severe exacerbations versus placebo.⁷

In a further study, Professor Leo Fabbri investigated the benefits of roflumilast when added to tiotropium in highly symptomatic COPD patients, in keeping with the new GOLD recommendations. In this post-hoc subgroup analysis of 395 patients with a baseline mMRC ≥ 2 participating in a 24 week study M2-128,⁸ roflumilast reduced the mean rate of moderate/severe exacerbation per patient, per year, by 45.5 percent $p=0.034$ versus placebo.⁹

Diagnosis and risk stratification of COPD patients can commence with spirometry but can be easily complemented by asking about symptoms of cough and sputum (chronic bronchitis) or dyspnoea (emphysema) along with assessment of an mMRC dyspnoea scale or CAT score and a history of exacerbations over the previous year.

With this information, we can put together a management plan in keeping with the new GOLD strategy, to not only improve the dyspnoea and daily function of our patients but also to reduce future risk in terms of reducing the frequency and severity of exacerbations and healthcare utilisation of our patients.

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What Can We Learn From the Cardiovascular (CV) Arena and Adopt in COPD Management?

Crushing retrosternal chest pain with radiation to the left arm is recognised by every medical student as a medical emergency, with a real risk of mortality to the person suffering from an acute myocardial infarct (MI); systems rapidly mobilise to ensure a good outcome. Once stabilised, our patient is discharged on a cocktail of secondary prevention, as further ischemia will cause additional loss of cardiac function and increase risk of mortality. It would be considered bad medicine to not review smoking cessation, prescribe aspirin, beta blockers, statins and ACE inhibitors.

Let us compare the risk of future events and mortality for a patient suffering from an acute exacerbation of COPD (AECOPD) to that of an acute MI. Data from several studies show that mortality at 12 months following hospitalisation for an AECOPD is between 20 percent and 40 percent.^{1,2,3,4} This is actually much worse than the mortality observed following hospital admission with an acute MI, even when patients received acute reperfusion therapy.^{5,6}

That being said, are we doing as good a job in recognising and preventing an AECOPD or “lung attack”?

We now look at future risk⁸ as an important part of COPD management outcomes in addition to treatment of current disability. What is in our toolkit to reduce future risk in COPD?

This concept of secondary prevention following an exacerbation needs to be introduced and accepted more widely. Patients should be offered treatment with combinations of drugs which have been shown to reduce the risk of future exacerbations (i.e., combinations⁹ of inhaled corticosteroids (ICS),¹⁰ long-acting inhaled beta₂-agonists (LABA)¹¹ and long-acting muscarinic antagonists (LAMA)¹²). The addition of the novel anti-inflammatory agent, roflumilast, a phosphodiesterase 4 inhibitor, can further reduce COPD exacerbations in those suffering from symptoms of chronic cough and sputum and frequent exacerbations.¹³

The most common prospective cause of death in COPD is AECOPD,¹⁴ but mortality is also frequently mediated

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3 Eriksen N, et al. Chronic obstructive pulmonary disease. Admission, course and prognosis. *Ugeskr Laeger.* 2003;165:3499–3502.

4 Groenewegen KH, et al. Mortality and mortality-related factors after hospitalization for acute exacerbation of COPD. *Chest* 2003;124:459–467.



through vascular events, meaning we should pay attention to CV protection for our COPD patients as well. COPD patients should be encouraged to address lifestyle factors such as smoking cessation weight optimisation and exercise; they should undertake pulmonary rehabilitation (PR) when indicated. We must encourage adherence to lifestyle and medications that allow prevention of outcomes in COPD, even when they do not treat symptoms. Just as aspirin and statins in CV disease, metformin in diabetes, do not acutely improve symptoms and may induce some side effects, preventative treatments in COPD such as roflumilast, ICS, and vaccinations providing benefit over time must be recommended and adhered to. Treatments providing reductions in COPD exacerbations may in the long

term reduce COPD mortality, mirroring the significant slowing of CV mortality seen over the last few decades.

In summary, we have significant tools to reduce future risk in COPD, but they are frequently underused and we must learn lessons from the organised systematic preventative management of CV disease and copy their success in order to make a long term difference to COPD patients.

We have significant tools to reduce future risk in COPD, but they are frequently underused and we must learn lessons from the management of CV disease.

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Clarifying and Recognising COPD Exacerbations

Exacerbations of chronic obstructive pulmonary disease (COPD) are episodes of respiratory symptom worsening especially dyspnoea, cough, increased sputum purulence and volume and are usually associated with infective triggers especially respiratory virus infections.¹

Many exacerbations have evidence of both viral and bacterial infection.^{2,3} COPD exacerbations are associated with variable amounts of airway and systemic inflammation with exacerbations triggered by colds or respiratory viruses showing more inflammation.^{4,5} COPD exacerbations lead to considerable morbidity, hospital admission and readmission and mortality. COPD exacerbations are the most important determinants of health status in COPD⁶ and are important targets for therapies both from the point of view of treating the event and prevention.

Following COPD exacerbations not all symptoms and lung function impairment will return to usual stable levels⁷ and it is now recognised from a number of studies that COPD exacerbations of different severities affect disease progression^{8,9} and have an effect on accelerating FEV₁ decline independent of tobacco smoking. It has been estimated that 25 percent of the lung function decline may be due to the effect of exacerbations.⁸ Over time exacerbations are associated with more sputum production and this suggests that with more progressive disease exacerbations have an increased inflammatory load.¹⁰

Some patients with COPD across disease severities are particularly susceptible to exacerbations and are known as frequent exacerbators^{6,11} and these patients are at greater risk of poor health status, faster disease progression and mortality.

A history of frequent exacerbations is also associated with bronchitis (cough and sputum production).⁶ Patients with a history of frequent exacerbations are more likely to suffer a myocardial infarction and risk seems to be higher early in the time course of the exacerbation especially when the systemic inflammatory response is at its highest.¹² Frequent exacerbators also have a higher risk of psychological co-morbidity with more depression and anxiety¹³ and show a faster fall in their exercise capacity over time.¹⁴

Thus patients with a history of exacerbations are important to target for therapies to reduce the number and severity of exacerbations.

COPD patients often do not report exacerbations for treatment with antibiotics and/or oral corticosteroids or do not self-manage the event themselves.⁶

- 1 Wedzicha JA and Seemungal TAR. COPD exacerbations: defining their cause and prevention. *Lancet* 2007;370:786-96.
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The best predictor of a subsequent exacerbation and hospital admission is a history of previous COPD exacerbations and thus risk from exacerbations can be determined from the clinical history.^{6,11}

With specific questioning COPD patients can recognise their previous exacerbation history quite accurately and this can be used to determine exacerbation risk.¹⁵ To date there is no biomarker that can reliably be used to confirm the occurrence of an exacerbation.

COPD exacerbations are episodes of symptom worsening that patients need to understand, but it has been shown that COPD patients often do not report exacerbations for treatment with antibiotics and/or oral corticosteroids⁶ or do not self-manage the event themselves. Patients who often do not report exacerbations have worse quality of life and are more likely to be admitted to hospital.¹⁶ Furthermore patients who delay presentation with exacerbation symptoms will have longer exacerbations and more likely to be admitted to hospital. Thus patients need to recognise exacerbations and present for review as soon as possible from onset so that appropriate exacerbation therapy can be started.

When a COPD patient develops an exacerbation, they are at increased risk of another exacerbation for the next eight weeks and this is known as exacerbation clustering.¹⁷ A recent study has shown that the occurrence of every new severe exacerbation requiring hospitalisation worsens the course of the disease and increases the risk of a subsequent exacerbation, with patients 25 times more likely to be readmitted after their tenth COPD hospitalisation than after their first.¹⁸ Thus if a patient

does not fully recover after an initial exacerbation, further review and follow up is essential.

Recent data suggest that COPD exacerbations have different patterns – some exacerbations have fast onset and recovery but some exacerbations have slower onsets and take longer to recover.¹⁸

Exacerbations with slower onset are more likely to be associated with colds or viruses and thus will have more inflammatory processes. However they may be more insidious and thus patients need to understand the importance of recognising and treating exacerbations early especially those associated with viral infections. Co-morbidities may also impact on the time course of exacerbations and exacerbations associated with heart failure have a more prolonged time course.¹⁹

As COPD exacerbations are associated with increased airway and systemic inflammation, anti-inflammatory therapy is important and oral phosphodiesterase E4 inhibitors (roflumilast) are useful as they target both airway and systemic inflammation and may also reduce the chance of associated cardiovascular risk.²⁰ Roflumilast has been shown to reduce the risk of exacerbations^{21,22} in severe COPD patients with a history of past exacerbations and symptoms of chronic bronchitis.

COPD exacerbations have different patterns – some exacerbations have fast onset and recovery but some exacerbations have slower onsets and take longer to recover.

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Prof Robert Horne

Professor of Behavioural Medicine, UCL School of Pharmacy, University College London, UK

Enhancing Patient-Physician Communication in COPD

Chronic obstructive pulmonary disease (COPD) has a significant impact on patients' lives. In particular prevention of exacerbations, episodes of worsening of patients' symptoms, and prompt diagnosis and engagement with treatment is now a key target for patients and physicians as part of a COPD risk reduction strategy.¹

1.6%
of patients understood the term 'exacerbation'

In common with most chronic illnesses, optimal patient self-management of COPD can improve outcomes. Patients' perceptions of their illness and its treatment are an important determinant of illness-related behaviour, for example whether they seek and subsequently adhere to treatment.

People rarely blindly follow medical advice, even when it comes from trusted clinicians. Rather they evaluate whether following the advice makes 'common-sense' in the light of their own perceptions of the illness and prescribed treatment. Behaviours such as patient delay or non-adherence, from the medical perspective, may seem nonsensical. However, when viewed from the patients' perspective, they often represent a common-sense response to the condition as perceived and experienced by the patient.² For example, delay to seek treatment may be the result of logical (yet misplaced) perceptions of the condition³ or a response to fear of the consequences of a diagnosis or treatment.² Similarly, studies across long term conditions including asthma³ have shown that adherence to prescribed treatment is influenced by patients' common-sense evaluations of treatment; in particular how they judge their personal need for treatment relative to concerns about potential adverse effects.

Efforts to support optimal patient self-management are likely to be more effective when they are based on an understanding

of the patient's perspectives and tailored to address both perceptual factors (e.g. beliefs and feelings) about the illness and treatment as well as practical factors (e.g. capacity and resources) influencing self-management.⁵

Good communication begins with eliciting the patient's perspectives, needs and wants in relation to the illness and treatment, and taking account of these in clinical decisions. Medical terminology can be a barrier. The widespread medical use of the term exacerbation is fraught with difficulties. While exacerbation is favoured by physicians, in a study of 125 patients with moderate to very severe COPD, only 1.6% of patients understood the term. Patients preferred to use simpler terms such as a chest infection, crisis or attack.⁶ Terms such as flare ups or lung attacks may be a more accessible alternative to exacerbation.⁷

While physicians strive to define COPD exacerbations and the impact they have on objective clinical outcomes, patients' own understanding, experience and recognition of these events have been largely ignored. Clinical experience suggests that patients may underestimate the impact of exacerbations on their daily lives and, conversely, may overestimate disease control.⁶

Patients with severe breathlessness may often describe their condition as being only

1 From the Global Strategy for the Diagnosis, Management and Prevention of COPD, Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2011. Available from: www.goldcopd.org.

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5 Horne R. Compliance, adherence, and concordance: implications for asthma treatment. *Chest* 2006; 130:65-72.

mild or moderate in severity, and many patients fail to report their exacerbations to their physicians.⁶ For example, two thirds of patients responding to The Hidden Depths of COPD Survey thought that their COPD was well-controlled, yet this was inconsistent with the high number of exacerbations they suffered.⁸

In COPD, as in asthma, a key challenge for healthcare professionals is to help patients to engage in self-management behaviours with optimal adherence to appropriate treatment, by achieving a greater understanding of the patient's perspective.⁹ This assumes greater significance with the new focus on risk reduction in COPD, as patients need to understand the value in adhering to treatments that may not have an immediate impact on their symptoms but may help to prevent future exacerbations and reduce disease progression. Patients are more likely to adhere to treatment

when they believe it will improve disease management or control, or anticipate serious consequences related to non-adherence.¹⁰

Simple strategies such as encouraging patients to give their perspective of the condition¹¹ and express concerns¹² are a good starting point. Such improvements in physician-patient communications should go hand-in-hand with enhanced awareness of symptoms and warning signs, the psychological impact and long term physical effects of repeated exacerbations on patients, and the specific actions that individual patients need to take at the onset of an exacerbation.⁶ Interventions enhancing patient-physician communications in COPD may improve identification of patients at risk of suffering from exacerbations, and may also improve adherence to the lifestyle changes and daily therapy needed in order to reduce future risk.

- 6 Kessler R, et al. Patient understanding, detection and experience of COPD exacerbations: an observational, interview-based study. *Chest* 2006; 130:133-142.
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- 8 Nycomed Hidden Depths of COPD Survey. September 2010. Data on file.
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Establishing a Strong Patient-Physician Relationship

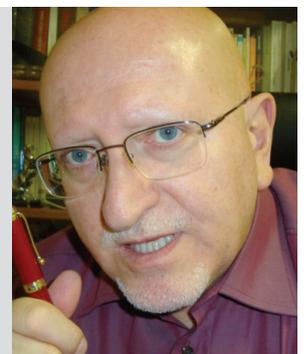
Professor Giacomo Mangiaracina is an internist and professor at the Sapienza University of Rome, and founder of the scientific society of "tabaccologia" in 1999.

As with most physicians, Prof Mangiaracina has had numerous challenges in encouraging his COPD patients to understand the seriousness of their disease and more importantly understand the necessity for them to quit smoking.

Prof Mangiaracina explains: "What I still often find difficult with my patients is encouraging them to change their attitude and more importantly, their tobacco addiction. This is a challenge, and one that requires hard work, great patience and professional expertise. Empathy plays a key role in developing the relationship

between doctors and patients and it is important to take into account that once a patient closes themselves off, it is a doctor's responsibility to help that patient open up to talk about their concerns and worries about their disease.

"One of the key factors in helping my patients is to ensure that I develop an open, honest and supportive relationship with them, to help avoid feelings of abandonment and ensure they are able to openly talk to me when they need to. It's important that I provide them with the support they need to better address their disease. I also use the social network sites to stay in touch with my patients and this helps to keep a strong relationship with them."



Prof Giacomo Mangiaracina
University of Rome



Dr Ondrej Rybnicek
EFA Board Member and
Treasurer, Czech Initiative
for Asthma – Member of the
Executive Board and Lecturer

The Patient Story – My Life Living with COPD

When a chronic disease is diagnosed, who or what is most important? The physician, the patient, caregivers, the quality of treatment, adherence, reimbursement...? I believe that all of these factors and people are vital in the management of COPD, but that the key focus should be very much on the patient. Therefore, we at EFA welcome this section to the expert Report on COPD, 'The Patient Story', which provides a brief insight – from the patient – into life with COPD.

The main causative factor for the development of COPD is cigarette smoking. Many of those who live with COPD state that they were not warned about the risk of smoking and its consequences when first taking up the habit and even following diagnosis of COPD.

The epidemiology of COPD has been changing in the last few decades - more than half of the sample answers come from females. About the same percentage of respondents are still within the age of employment (less than 65 years of age).

COPD means an enormous burden to patients. Words such as frustration, invalidity, disability, immobility, loss of freedom, dependence on others, resignation, renunciation, anxiety and depression are often used to describe patients' feelings. This is shocking and more importantly not necessary since COPD is both treatable and controllable, but only if the diagnosis is made early enough and physicians and patients communicate with each other in a clear and comprehensive way.

Most of the patients interviewed would like to improve dialogue with their physicians. Many also wished for a better understanding of the disease from their primary care physicians.

The understanding of what exacerbations are is worryingly low among patients. Even more disconcerting is that many patients only tend to report exacerbations or flare-ups to their physicians after they have tried to treat and control it themselves. This demonstrates a lack of understanding among patients of the impact exacerbations can have upon further disease progression and the potential damage they are causing by leaving their exacerbations untreated.

Patient organisations such as EFA can have a positive impact upon the level of knowledge among individual patients. Our aim is to help patients through peer-to-peer communication increase their knowledge and understand the day-to-day steps they can take to help them live more positively with their disease.

**What can we learn from COPD patients?
I invite you to read these patient stories.**

“ Frustration, invalidity, disability, immobility, loss of freedom, dependence on others, resignation, renunciation, anxiety and depression are often used to describe patients' feelings. ”

Lucky enough to enjoy a good quality of life – unfortunately my case is rare

Mrs Elizabeth (Betty) Sutton is 70 years old and lives in County Wicklow, Ireland with her husband of 50 years, surrounded by a large family: seven children, 15 grandchildren and three great-grandchildren.

In 2004, at the age of 62, Betty was diagnosed with emphysema. Like the vast majority of COPD patients, she was diagnosed late, despite several symptoms pointing in the direction of COPD for quite some time. Surprisingly, many primary care professionals, who are in fact the first contact point for patients, fail to take the COPD symptoms – shortness of breath, wheeze, phlegm and/or recurrent respiratory infections – as a reason to test their patients for COPD.

Betty was left for four years without diagnosis, suffering numerous chest infections and was put on antibiotics by her doctor and just told to go home and rest. “I honestly thought I had lung cancer,” she explained, “but it wasn’t until I started seeing one of the new practice managers that it was then I was diagnosed correctly and put onto treatment – which helped to manage my symptoms.”

Like many patients, Betty was given minimal counsel by her primary care physician, and it was actually her pharmacist who gave her the much needed advice and information on her disease and treatment when she collected her inhaler prescription.

Betty had been a smoker since she was 14-years old and when she was diagnosed was smoking up to 60 cigarettes a day, but quit as soon as she was diagnosed. She is now on 6 litres of oxygen a day, which she uses during exertion. “Yes of course I regret smoking but you can’t live regretting your life. Now I just do all I can to stay active,” she says.

Despite a positive outlook, Betty’s COPD affects every aspect of her life from morning to night. Betty explains: “Personal hygiene is particularly difficult, just having a shower and trying to wash my hair to drying myself – it’s always just the simple things that are the most difficult. I feel the impact on every aspect of my life. Certain smells are sometimes too strong for me too from paint to perfume; it hits the back of throat making it hurt to breathe.”

However, when Betty was diagnosed it soon became apparent that there was no support available to her following her initial eight-week rehabilitation programme. So she started up her own rehabilitation exercise support group. She started with three people out of her original group and now has up to 56 people attending the group each month, which has now been running for 3½ years.

“Whilst COPD is a pain, I am lucky enough to enjoy a good quality of life, since I have a therapy and staying-active programme tailored to my own needs – unfortunately, my case is rare.”



Mrs Elizabeth Sutton

“I now understand that an exacerbation is a severe chest infection. However I found this out through my specialist and not my doctor. GPs don’t really have the time to sit and talk to people in detail about their condition, so it’s not until you get to the specialist that there is the time to talk it through.”

Elizabeth Sutton



Mr Dario Beretta

Benefiting from a deeper, more open relationship with my physician

Four years ago, at 74 years old, Mr Dario Beretta received the diagnosis that he was living with COPD.

Dario is now retired and lives in the province of Sondrio in the beautiful Valtellina, Italy with his beloved wife Anna. He was a heavy smoker, although he quit a few years before he was diagnosed, but unfortunately this was too little too late and smoking was probably the unique cause of his illness.

Dario knew nothing about COPD when he received his diagnosis and has a normal relationship with his doctor, but

like many other COPD patients, feels as though he would benefit from a deeper, more open relationship, with his doctor. Dario uses the internet to gather information about his illness, but feels as though he needs something more. He would like to have the chance to get in touch with people like him, who share the same thoughts, symptoms and worries due to COPD, underlying the importance of a strong support network for those living with COPD, not only from primary and secondary healthcare physicians, but also from others living with COPD.

“I wish I had a deeper relationship not only with my doctor, but also with other patients affected by COPD.”

Dario Beretta

The Patient Voice

Many patients involved in a survey conducted for this expert report are convinced that if they were provided with more information and support upon diagnosis, this would have been of real help to them. Some said they had little or no trust in their primary care practitioners, due to their perceived limited expertise in respiratory and in particular COPD. A number of patients said they were not told of the importance in identifying and treating exacerbations in order to prevent disease progression. In a few cases, exacerbations were still going unreported, due to a lack of knowledge of the impact of them.

The Physician Voice

While many care gaps do exist in the management of our patients with COPD, we can work as a team to support patients and help them manage their condition and lessen their associated emotional burden.¹ Both the family physician and respiratory consultant need to help them deal with helplessness and low affect, particularly when there is limited social support from family and social networks - factors negatively associated with managing illness.² Together we can help our patients deal with quite real fears, including terrifying things like dying of breathlessness or suffocation.³

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- 3 Gardiner C, et al. Living with advanced chronic obstructive pulmonary disease: patients concerns regarding death and dying. *Palliat Med* 2009; 23(8):691-7. <http://dx.doi.org/10.1177/0269216309107003>.

About the European Federation of Allergy and Airways Diseases Patients' Association (EFA)

EFA is a European community of patient organisations that share the responsibilities for substantially reducing the frequency and severity of allergies, asthma and COPD, minimising their societal

implications, improving health related quality of life and ensuring full citizenship of people with these conditions, and pursue equal health opportunities in the field of allergy and airways in Europe.



Final Word

As COPD historically has been perceived as an incurable, continuously progressive disease, it has been associated with a therapeutic nihilism amongst both patients and healthcare providers. The attitude has been that, except from smoking cessation, there is not much we can do to stop disease progression. Thus clinicians and patients have primarily focused on short term 'here-and-now' goals, targeting immediate patient benefit such as symptom relief. Also COPD exacerbations have traditionally been treated as and when they happen with a primary focus to relieve symptoms of the acute attack.

In managing CV disease clinicians and patients have since long been focusing on long term risk prevention goals. Risk factors such as hypertension and hypercholesterolaemia have been identified and treated in the context of preventing the long term risk independently of any acute effects on current symptoms. Also in the case of the CV equivalent to a COPD exacerbation, the acute myocardial infarction (MI), initial management is much more rapid and aggressive, and risk stratification and risk reducing actions such as increased preventative medications (lowering blood pressure and serum cholesterol) and rehabilitation programmes (including exercise and diet) are routine when patients are discharged.

During the last decade our knowledge on risk factors for poorer outcomes in COPD has increased and data now exists on positive effects of pharmacological interventions and rehabilitation. It is now time to move COPD management from a pure reactive mode (i.e. focusing on relieving symptoms) to a more preventative mode. Here we can learn from the CV area by:

1. Implementing routine risk stratification when assessing COPD patients

Recently specific risk factors that can be easily assessed in routine clinical practice

have been identified, such as a previous history of exacerbations and symptoms of chronic bronchitis.

2. More rapid and aggressive management of COPD exacerbations as they happen

COPD exacerbations are extremely frightening events for patients and COPD patients with severe exacerbations report quality of life scores that are worse than death. Survival rates after a COPD hospitalisation is at the same or even worse magnitude as a MI.

3. An increased focus on preventative actions to reduce future risk subsequent to the event

New data support a positive impact on long term disease progression by currently available inhaled therapies, and the oral anti-inflammatory roflumilast has been shown to reduce exacerbations in patients with a history of exacerbations and chronic bronchitis. Flu vaccination and rehabilitation programmes including exercise and diet are also important.

Finally, and importantly, healthcare professionals need to adopt patient-centred strategies that are individualised and holistic, and can help to improve adherence to preventative therapies and improve the outcomes of people with COPD.

Expert Biographies



Prof Rob Horne

Rob Horne is Professor of Behavioural Medicine and Head of the Department of Practice and Policy at the University College London (UCL) School of Pharmacy. He is also Director of the Centre for Behavioural Medicine.

A qualified pharmacist with a PhD in health psychology from Kings College, London, Prof Horne combines an initial decade in clinical pharmacy and medicines management within the NHS, with a 15-year programme of research in behavioural medicine. He was designated a Fellow of the Royal Pharmaceutical Society of Great Britain in 2010.

Prof Horne's research focuses on the role of psychological and behavioural factors in explaining variation in response to treatment. His particular focus is on patients' adherence to medication and this work translates into a portfolio of theory-based, pragmatic approaches to help patients get the best from treatments. Studies are on-going in a range of long term conditions including asthma and COPD.



Dr Alan Kaplan

Alan Kaplan is the Chairperson of the Family Physician Airways Group of Canada and a family physician practicing in Richmond Hill, Ontario.

A Chairperson of the Respiratory Section of the College of Family Physicians of Canada, Dr Kaplan graduated with a medical degree from the University of Toronto. He is a board member of the International Primary Care Respiratory Group (IPCRG) and was President of the 2010 IPCRG 5th bi-annual world scientific meeting, "Making Every Breath Count," in Toronto.

Dr Kaplan is a member of the Canadian Consensus Guidelines for Asthma, Chronic Obstructive Pulmonary Disease and Sinusitis. He is also a board member of the Canadian Network of Asthma Care, a member of the Chronic Respiratory Disease Surveillance Advisory Committee (Public Health Agency of Canada) and the International Editor for the International Primary Care Respiratory Journal.



Prof Andrew McIvor

Andrew McIvor is Professor of Medicine at McMaster University and a Staff Respiriologist at Firestone Institute for Respiratory Health, St Joseph's Healthcare, Ontario, Canada.

Prof McIvor qualified with an Honour's degree in Medicine from Queen's University, Belfast and continued to train in Respiratory Medicine at the University of Toronto. He obtained an MRC grant to study in Clinical Epidemiology at McMaster University, where he spent time working in the field of obstructive lung disease.

His major clinical and research interests are in "Knowledge Translation" in asthma and COPD. He has authored over 100 scientific papers and has recently completed a 5-year term as Chairman of the Asthma Committee of the Canadian Thoracic Society and as an examiner in Respiriology for the Royal College of Physicians and Surgeons Canada.



Dr Stephen Rennard

Stephen Rennard is Larson Professor of Medicine in the Division of Pulmonary, Critical Care, Sleep and Allergy, University of Nebraska Medical Centre.

Dr Rennard completed internal medicine training at Barnes Hospital, Washington University, Missouri, and trained in Pulmonary Diseases at the National Institute of Health. He currently serves on the Board of Directors of the COPD Foundation and the Alpha-1 Foundation and is a member of the National Heart Lung Education Program Executive Committee.

Dr Rennard maintains an active programme of clinical investigation in COPD and smoking cessation and a programme of basic research in the mechanisms of lung tissue repair and remodelling. He is also academic chair of the COPD Biomarkers Qualification Consortium and an external advisor to the Thomas Petty Aspen Lung Conference and the University of California-Davis Pulmonary Training Grant.



Dr Ondrej Rybnicek

Ondrej Rybnicek is a paediatrician specialising in allergy and clinical immunology, pneumology and aerobiology. He is also a Board Member of the European Federation of Allergy and Airways Diseases Patients' Association (EFA).

Dr Rybnicek holds a particular interest in COPD, allergies and asthma and has consequently participated in a number of patient awareness campaigns. He has also authored and co-authored numerous scientific and educational articles on allergical, immunological, pneumological and aerobiological disease areas.

He is a long time member and lecturer of the patient organisation, The Czech Initiative for Asthma, where he also acts as a Head of the Czech Pollen Information service. In 2008 he was elected a Board Member of EFA, moving to Vice-President in 2009 and currently sits as Treasurer of EFA.



Prof Wisia Wedzicha

Wisla Wedzicha is Professor of Respiratory Medicine at the University College London (UCL) Medical School.

Prof Wedzicha received her qualifications from Somerville College, Oxford University and St Bartholomew's Hospital Medical College, London University. The causes, mechanisms and impact of COPD exacerbations and the role of bacterial and viral infections are of major interest to Prof Wedzicha. She directs an active research group into COPD exacerbations and has published extensively on this topic.

As a key member of the Guideline Development Group, Prof Wedzicha played a key role in the revision of the NICE COPD guidelines and was Editor in Chief of Thorax until June 2010. She currently chairs the DoH Home Oxygen Clinical User group and is a member of the Programme Board for the COPD National Clinical Strategy. Prof Wedzicha's expertise makes her a valued member of the BMJ, BioMed Central and AJRCCM advisory boards and on the editorial board of a number of international journals.

