

Disease Management for Chronic Obstructive Pulmonary Disease

A Clinical Strategy

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Abstract

Chronic obstructive pulmonary disease (COPD) is a progressive chronic disease that is subject to acute exacerbations. Ideally, a patient with such a chronic disease should be provided with medical care that addresses these issues while empowering the patient to initiate rapid and definitive treatments to counter exacerbations. To do this, disease management for COPD must recognize that, as this disease is chronic and progressive, any intervention must be ongoing and progressive. As timely recognition of, and rapid intervention for, exacerbations is crucial, COPD disease management must be patient centered.

The care offered to patients with COPD should include smoking cessation, regular vaccinations for influenza and pneumonia, and instruction on avoidance of respiratory irritants, as well as medications such as bronchodilators and corticosteroids. Daily exercise is essential and pulmonary rehabilitative tools should be employed. Patients with end-stage disease should be assisted in creating advance directives and should be provided with palliative care. The training of patients in the self-management skills of medication self-administration, secretion clearance, pursed lips breathing, walking exercise, and recognition and rapid treatment of exacerbations is integral to a successful COPD disease management program. Doctor's therapeutic office visits guide and practice patients in performance of their daily routines to hone their skills, create habits, and develop positive living patterns. With practice, patients improve these skills over time – counter to the natural disease progression. Outcomes monitoring is necessary in order to evaluate the impact of the intervention, and to improve its efficacy.

The Respiratory Disease Management Institute (RDMI) model for COPD is based on the aforementioned considerations. In a total of 1981 doctor's therapeutic office visits over 6 years of this program, 744 exacerbations were identified, with a hospitalization rate of 3.2%. These results compare favorably with those of a previous study.

COPD disease management is a systematic approach to the treatment of this chronic disease. When exacerbations are detected in their early stages, they are highly reversible and hospitalization may be avoided. The available data from the RDMI suggest that it is time for a multicenter study to evaluate this model of healthcare delivery for COPD.

Disease management is often administered in parallel with usual medical care. It is commonly driven by both a clinical incentive to improve patient care and an economic incentive to lower the cost of healthcare. Accordingly, the most intensive intervention is offered to those patients who are in the more severe stages of the disease, have frequent exacerbations, and require higher levels of healthcare.^[1] This article offers an alternative perspective with respect to disease management for patients with

chronic obstructive pulmonary disease (COPD). A chronic condition such as COPD is one that is always there, usually gets worse over time, and may be subject to acute exacerbations. Ideally, a patient with a chronic condition should be provided with medical care that addresses these issues while empowering the patient to initiate rapid and definitive treatments to counter the acute exacerbations. As such, patient self-management becomes the core of care and acute flare-ups are anticipated, detected early, and man-

aged rapidly and effectively.^[2,3] The healthcare team must ensure that this process of care is fully functional, sustained, intensifies, and is remodeled over the life of the patient so that it continues to address patient needs and desires. Optimally and practically, this process develops skills, habits, routines, and collaboration to promote quality health and health outcomes for the patient throughout their lifespan.

Within this article, we will explore COPD as it runs its natural (poorly adaptive) course in regard to the limitations imposed by the disease, its systemic effects, aging, co-morbidities, and general deconditioning. We will then consider how the course of COPD can be redirected so that the disease can be brought under sustained control and enable a rich quality of life. Accordingly, the design of a mainstream approach to caring for these patients will be presented in a way that addresses the foregoing issues and meets goals set forth in this introduction. We will weigh methods to evaluate and improve the disease management approach. While this system of care may have economic advantages, both in delivery and outcomes, its design focuses on the needs of the patient: the patient's ability to recognize health changes and react in a timely and direct manner to effectively manage the process. Ultimately, all stakeholders in disease management and the optimization of health will have to be aligned with the needs of the patient and their family to realize maximal outcomes. While this latter topic is beyond the scope of this article, we acknowledge that all stakeholders must embrace this vision and that the right incentives for each entity must exist.

1. Chronic Obstructive Pulmonary Disease (COPD): a Chronic and Progressive Illness

COPD is a multi-component integration of chronic and progressive illnesses characterized by airway obstruction, inflammation, hyperinflation, and acute-on-chronic exacerbations. Included under this heading are chronic bronchitis, emphysema, and partially reversible asthmatic bronchitis. Bronchiectasis has also recently been included.^[4,5]

The clinician, having identified one component, is obligated to identify and treat the other lung pathologies. While COPD may start out as an organ-specific illness of the lung, every region of the body eventually feels the impact of the disease. Physiological deficits lead to self-imposed avoidance of activity, which results in deconditioning, which in turn further amplifies dyspnea on exertion. All of these factors contribute to disability and combine to impair quality of life. The natural course of COPD typically follows a stepwise path of increased dyspnea, functional decline, loss of independence, decreased self-efficacy, increased medical intervention, respiratory failure, and death.^[6] Towards end-stage

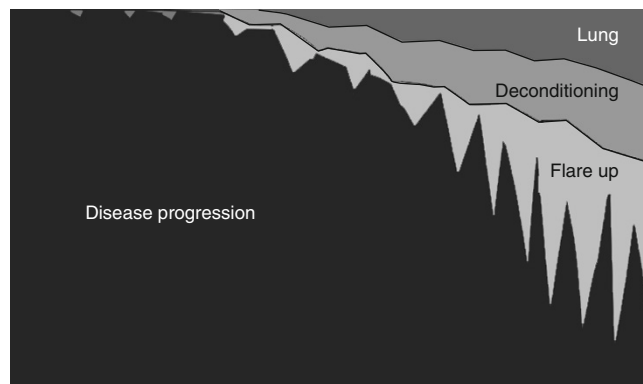


Fig. 1. Disease progression. The three-layered loss of function seen in chronic obstructive pulmonary disease. The top layer represents lung function decline. The middle layer represents the progressive impact of deconditioning due to increased dyspnea and avoidance of activity. The bottom layer represents the impact of repeating acute exacerbations. The impact of co-morbid conditions is not included in this diagram but affects all three layers.

disease, the patient is beset by exacerbations of accelerating frequency and intensity.^[7,8] Concurrently, co-morbid conditions assume a greater presence and magnify the clinical impact of the disease. The loss of ability to function is depicted in figure 1.

Until recently, much of the attention drawn by COPD has focused on airway obstruction. However, several developments have modified this focus. It appears that patients are substantially limited by hyperinflation of the lungs, particularly during exertion. Inflammation and oxidative metabolism play prominent roles in the pathophysiology of COPD, particularly during exacerbations.^[7] While new medications are being developed to target these pathologic processes, enough is known to affect treatment strategies. For example, hyperinflation during exertion is driven by breath rate. Exercise training enables patients to exercise at a given work rate while ventilating at a lower breath frequency, thereby minimizing dynamic hyperinflation.^[9] Adjunctive measures to exercise training in patients with COPD, including bronchodilators, oxygen, and pursed lips breathing, can magnify that benefit.^[7] This information is constructive in the development of a functional disease management program.

1.1 Clinical Staging of COPD

The progression of COPD has been tracked by measuring loss of lung function – particularly decline in the forced expiratory volume in 1 second (FEV₁). Various guidelines, including the Global Initiative on Obstructive Lung Disease (GOLD) guidelines,^[10] have described disease progression in this manner. However, the FEV₁ is only a part of the story, as the clinical impact of the disease varies widely with respect to the FEV₁,^[8] albeit the direction of deterioration is clear. A more practical approach is to

directly track the clinical presentation of the disease (figure 2).^[8] The clinical benchmarks are as follows: ‘at risk’ (not yet symptomatic), ‘symptomatic’ (not yet experiencing exacerbations), ‘exacerbations’ (not yet in respiratory failure), and ‘respiratory failure.’ This approach is simplistic but direct. While it has received little scientific investigation, each stage is highly recognizable. It is known that a previous exacerbation is associated with a higher risk of having another. This is useful information in the design of a clinical strategy for disease management.

Exacerbations are the acute-on-chronic events characterized by increasing dyspnea, particularly on exertion, and a change in sputum.^[7] These episodes are responsible for a significant share of the healthcare costs associated with COPD.^[11] The cause of an exacerbation in an individual case may be unknown; however, respiratory infection and inflammation play prominent roles.^[12] Actually, several possible contributing factors that vary chronologically in their appearance include infection, inflammation, bronchospasm, environmental irritants, gastroesophageal reflux, hypersedation, cor pulmonale, and right heart failure.^[12] Many of these factors conspire to promote mucus stasis, airway damage, and remodeling.

An exacerbation is a dynamic process; this has substantial implications as to how it is best managed. In general, exacerbations are associated with increased neutrophilic and eosinophilic inflammation.^[8] One scenario of exacerbation dynamics is that the patient develops an upper respiratory infection, which is usually viral. This is followed by inflammation as manifested by bronchial edema, bronchoconstriction, mucus hypersecretion, and mucus stasis. These factors obstruct the airways: dyspnea is increased because of hyperinflation and increased work of breathing, and

ventilation/perfusion mismatching increases, causing hypoxemia and sometimes CO₂ retention. At some point, a bacterial infection may take on a prominent role. Infection promotes and intensifies damage along the bronchial lining, which may heal by laying down scar tissue – leading to airway remodeling. This disruption of the bronchial lining may create endobronchial havoc and set up an environment for future bacterial infections and exacerbations. The overall implication of this scenario is that an exacerbation must be recognized in its earliest stages, and then rapidly and effectively treated.^[7]

Fortunately, we have a therapeutic arsenal that includes anti-inflammatory medications, bronchodilators, antibacterials, and airway clearance techniques. Importantly, living an active life, maintaining a daily exercise program, and regular use of long-acting bronchodilators and inhaled corticosteroids within a self-management protocol may prevent many exacerbations.^[8] Unfortunately, we are lacking a globally accepted system of care that consistently strives to prevent or reverse exacerbations by empowering timely and focused interventions led by the physician and disease management team. Early recognition and rapid response yields major therapeutic returns.

1.2 Recognizing Acute Exacerbations

A common question that comes up when experts get together and discuss exacerbations is, ‘How do we define exacerbation?’ The definition according to the American Thoracic Society/European Respiratory Society (ATS/ERS) COPD guidelines is: “An exacerbation of COPD is an event in the natural course of the disease characterized by a change in the patient’s baseline dyspnea, cough and/or sputum beyond day-to-day variability sufficient to warrant a change in management.”^[8] The implication of this definition is that an exacerbation must be sufficiently discernible so that it can not be ignored by the patient. The patient then calls for help from the physician. The physician must then make the determination that a change of management has become necessary. Since an exacerbation is a dynamic and destructive process, the delay in intervention implied in this scenario would be intolerably long and require more intensive care for reversal. Thus, if patients and their families are empowered and educated in exacerbation interventions and uniquely prescribed methodologies are formulated to the individual patient, optimization of health may be realized. Protocol interventions performed by the patient are done so at the direction of the physician.

Patients with a sedentary lifestyle may be living with an exacerbation in progress for days before it gets to the point of the patient calling for medical help. However, if the patient is active every day, the limitation imposed by an exacerbation will likely be

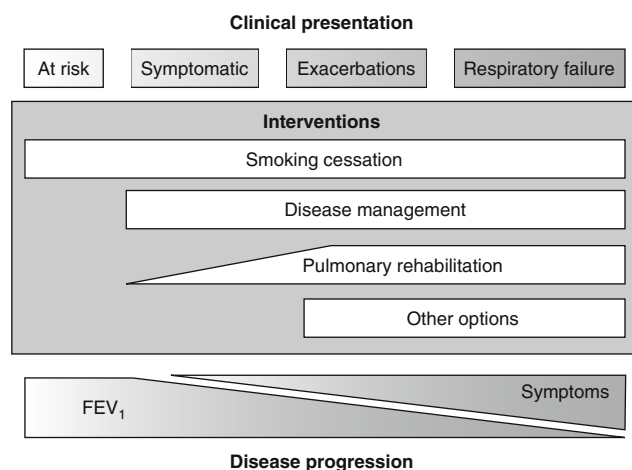


Fig. 2. Disease management diagram (reproduced from the American Thoracic Society/European Respiratory Society chronic obstructive pulmonary disease guidelines,^[8] with permission. © American Thoracic Society). FEV₁ = forced expiratory volume in 1 second.

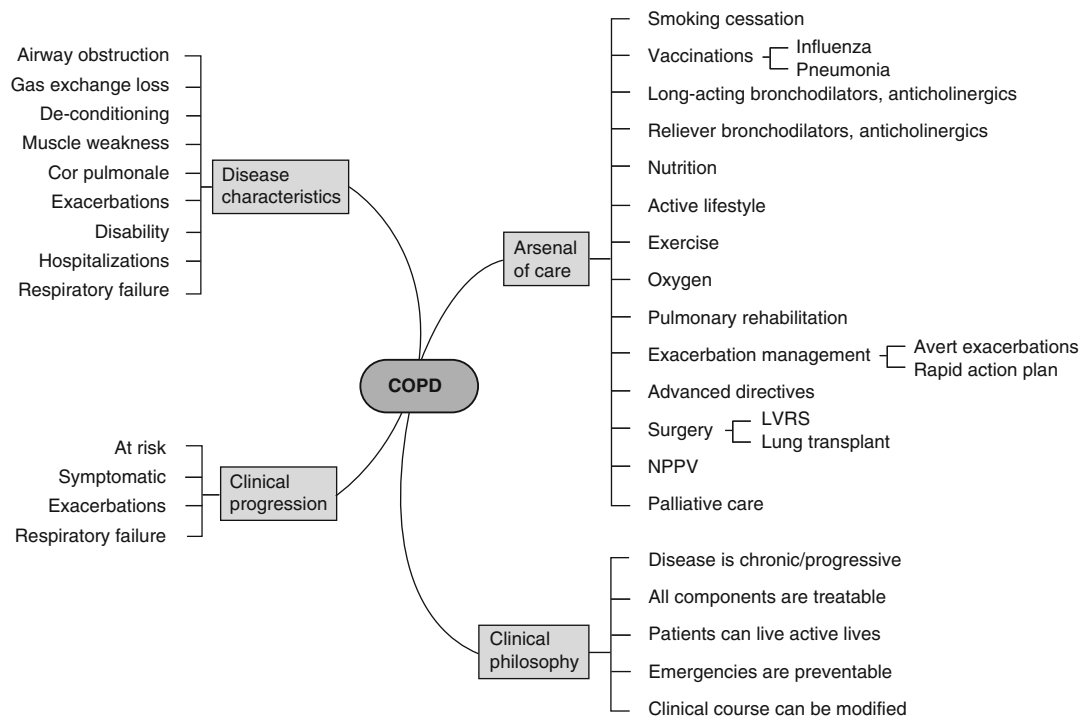


Fig. 3. An overview of chronic obstructive pulmonary disease (COPD). **LVRS** = lung volume reduction surgery; **NPPV** = non-invasive positive pressure ventilation.

detected as soon as he/she exerts him/herself and will often present as increased dyspnea. This is especially true if the patient's daily routine includes exercise. This lower threshold of detection could lead to earlier exacerbation management and obviate the requirement for emergency care. If emergency care is required, it is not only costly but a higher level of care may become necessary.

2. Disease Management: Developing the Clinical Strategy

2.1 Background: Pulmonary Rehabilitation

The background for the development of this methodology is our experience with pulmonary rehabilitation.^[7] These programs have a remarkable ability to positively alter the course of this illness – for a while. The impact of the pulmonary rehabilitation affects pulmonary physiology, behavior, and ability to live an active life complete with pre-illness quality. Unfortunately, pulmonary rehabilitation is designed to last for a short period with little or no long-term reinforcement. Also, the availability of pulmonary rehabilitation is relatively low. Millions of patients need it and only thousands receive it.^[13] The problem is that it is a definitive program running parallel to standard care. What is needed is for the tools of pulmonary rehabilitation to be integrated into standard care.

2.2 The Philosophy

The key to designing a care model for COPD is to profoundly comprehend the disease; both its characteristics, and its behavior as shown in figure 3. All components of the disease, including the co-morbidities, are treatable to some degree. Armed with that understanding, it is possible to redirect its course by creating a process of care through prevention, anticipation, and pre-emption. As the disease is progressive and chronic, so must be the intervention. The center of management must be the patient. The patient must keep the airways clear and open, secretions mobilized, maintain an optimal level of fitness, be highly vigilant for early signs of an exacerbation, and be equipped to respond in a timely and definitive manner. As the disease is systemic, a higher level of general health is required to combat inflammation and oxidative destruction.^[12]

2.3 Arsenal of Care

Preventive measures include smoking cessation, avoidance of respiratory irritants, and regular vaccinations against influenza and pneumonia;^[8] all of these tend to slow disease progression. If the patient is presently smoking, the first order of clinical business is smoking cessation (see Huber and Mahajan^[14] later in this issue for more detail). Smoking is considered a primary disorder, and newer and more effective interventions are available to assist the

clinician and patient in cessation. Long-acting medications, including anticholinergics and bronchodilators, help to keep the airways open and patent. Inhaled corticosteroids may prevent or reverse exacerbations. Daily exercise builds strength, endurance, and stamina, mobilizes secretions, and lowers the threshold for detecting exacerbations. Antibacterials are essential in treating the infectious components of exacerbations. Rapid exacerbation recognition and intervention prevent hospitalizations and disability.^[3,7]

Pulmonary rehabilitation restores the patient to the best level of function and can work interactively with a comprehensive program of care. Pulmonary rehabilitative tools provide the basis for disease management and chronic care programs.^[7] Breathing retraining techniques, specifically pursed lips breathing, are provided to reduce/control dyspnea, minimize exercise dynamic hyperinflation, and increase arterial oxygenation. Surgical options that improve lung function are becoming more available and appropriate in specific patients.

Advance directives enable patients to express their end-of-life instructions before they lack the ability to make decisions for themselves. Palliative care enables patients to be more comfortable as they reach the end of life.^[15,16]

2.4 Disease Management Strategy

When faced with the challenges of a chronic and progressive illness with acute exacerbation episodes, we must expand our

vision of the practice of medicine to encompass active prevention combined with anticipation and pre-emption of acute exacerbations – all integrated within the mainstream of medical care (see figure 4). Disease management in this setting is a method, process, or strategy of care that maximizes the patients’ ability to care for themselves, perform routine daily maintenance, and prevent or rapidly reverse an exacerbation in conjunction with the timely response and guidance of the healthcare team. It entails a practical understanding of the disease and its clinical course, and simplifies care to its lowest common denominator.^[17] Otherwise stated, patients are trained to do a basic set of daily tasks proficiently. They are guided and reinforced during their regular visits. They are provided, trained, and regularly reinforced in early recognition of exacerbations and in implementing their rapid action plan. They are prescribed medications to have on-hand and ready to go. At the very first sign of an exacerbation, they get started on their rapid action plan (see table I).

Successful management of chronic illness is highly dependent upon the patients’ ability to manage their care at home and to recognize and pre-empt an exacerbation at its earliest stage collaboratively with the healthcare team. Disease management programs require a lifetime commitment from both the patient and healthcare team, with regular reminders and reinforcement.

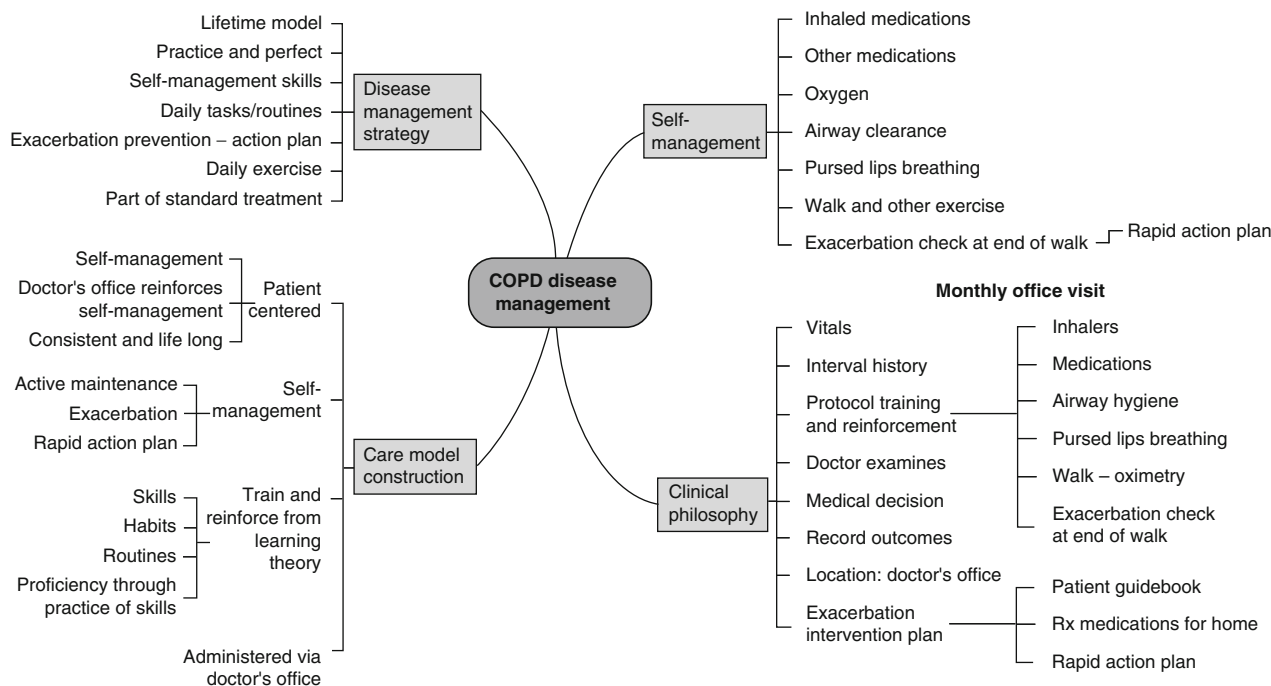


Fig. 4. Chronic obstructive pulmonary disease (COPD) disease management. Rx = prescription.

Table I. Exacerbation interventions and rapid action plan

Exacerbation recognition signs and symptoms	Early intense intervention rapid action plan
Increased exercise intolerance	Call doctor
Increased dyspnea	40 mg prednisone daily (usually 5 days)
Change in secretions	Antibacterial
Wheezing/tightness	Bronchodilators
Weight increase (2 lb [0.91 kg] in 1 day)	Hot fluids
Fever (rare)	Pursed lips breathing
	Increase oxygen

2.5 Self-Management Training

Essential skills include the self-administration of inhaled medication, secretion clearance, pursed lips breathing, walking exercise, and early recognition of exacerbations and rapid intervention when they occur.^[3] These skills provide the therapeutic core of self-management training. Rather than simply prescribing or advising self-management tasks, the therapist trains and reinforces skills that, over time, will become a routine integral part of the patient's life.^[18] These skills are perfected through regular reinforcement. Patients may be provided with a simple patient guide, which guides them through their daily routine. The skills are practiced at home, navigated by a written patient self-management guide, and reinforced and improved upon in the doctor's office during the doctor's therapeutic office visit.

2.6 Doctor's Therapeutic Office Visit

In the doctor's therapeutic office visit, the patient goes through their daily routine to hone their skills. It is crucial to heighten the patient's sense of observation about changes in physical status indicative of exacerbation, as well as their comprehension of the importance of a rapid response. If an early intervention is set in place prior to the onset of airway destruction, the patient can respond rapidly and definitively. Corticosteroids, bronchodilators, and antibacterials form the pharmacological core of the rapid action plan. Positive feedback for all of the aforementioned skills and interventions is an important component of training and behavior modification. The atmosphere of the office visit should be light, upbeat, and therapeutically reinforcing.

2.7 Learning Theory

An essential goal of any COPD disease management program is to modify human behavior over time and instill the observational skills necessary to recognize and respond to an impending exacerbation early in its course.^[3,18] Education alone does not accomplish this. Rather, education helps the patient and family understand and

accept the disease and how it must be managed. Beyond that, the patient must be trained in enhancing their proficiency in self-management. Skills training derived from learning theory is required to effectively administer aerosolized medications, accomplish excellent secretion clearance, and recognize and adequately stem the course of an exacerbation.^[3,7] Skill training is not a healthcare specialty, yet it should be. The modification of human behavior to bring about adherence to a life-long program of daily health maintenance originates from the science of learning theory. Learning theory is utilized to great success in the field of advertising, and now we are incorporating it into the management of chronic illness.

2.8 Outcome Monitoring

A reasonable expectation of any clinical intervention is that it must be effective. It is not adequate to simply apply treatment without monitoring the outcomes – both positive and negative.^[19] Decisions to utilize a methodology must be weighed based upon both clinician and patient expectation. Since no therapeutic intervention plays out as predicted, expectations must be continually adjusted as influenced by a continual supply of therapeutic information. Outcomes monitoring describes the therapeutic benefits of a specific intervention, in a specific clinical setting, in a somewhat formal manner. Outcome monitoring is used to document health outcomes and improve methodology through therapeutic experience. It is essential when attempting to convince health plans that the new methodology/practice/intervention justifies reimbursement.

When evaluating a new intervention, it is not always clear what parameters provide the best indications of efficacy. In disease management of COPD, exacerbations that require hospitalization or an emergency room visit would be an obvious choice, as these outcomes indicate that the disease is not well controlled, and we have reason to believe that many such hospitalizations are preventable.^[2,3] Hospitalizations are the most costly feature of COPD. Preventing hospitalizations could be accomplished via an alteration of the patient's lifestyle, adherence to medications and oxygen, and exacerbation management.^[2,3] Previous studies have shown that earlier response to exacerbations yields better disease control.^[2,3]

Another indicator of success of disease management is the rate of disease progression. By monitoring the FEV₁ or airway hyperinflation over time, the rate of disease progression can be documented and evaluated. Quality of life, disease impact, and functional measures are being perfected and are available to monitor patients and populations of patients with chronic illness. However,

the clinical utility for each instrument deserves further consideration, especially as applied to disease management processes.

3. Scientific Evidence Supporting Disease Management

3.1 Randomized Controlled Trials

Outcome monitoring does not take the place of rigorous scientific studies. In healthcare, a randomized control trial (RCT) provides the most credible scientific evidence. This is because randomization minimizes the bias effect of confounding factors both known and unknown, by evenly distributing them between treatment groups. RCT recruits a population of subjects having common demographics and disease severity. Patients may also be matched on a number of characteristics, thereby improving on the power of the experimental design. Patients are randomized to receive the intervention in question versus standard care. Most studies start with a 'null hypothesis' (no effect of treatment) and an alternative hypothesis (treatment works). Analysis at the end of the trial will scientifically determine whether the null hypothesis can be safely rejected and that the intervention is effective beyond the likelihood of chance.^[19]

In determining the effectiveness of a program of care, a meta-analysis of trials is often useful. All data from all available studies that meet the stringent meta-analysis criteria have combined in order to get a maximum amount of statistical information and to assess the weight of evidence. It is important that both studies that support and studies that refute the intervention are included. In the most recent Cochrane review of 20 studies of shared care, interventions for chronic disease management were identified.^[20] The results were equivocal. It was therefore concluded that there was insufficient data to draw a positive or negative conclusion and that additional data using well defined interventions with consistent outcomes data have required. One of the main difficulties is that disease management approaches vary widely. In spite of that, more recent Cochrane reviews have been more encouraging.^[21] Chronic care approaches are often not considered.

3.2 Bayesian Evaluation

Another approach that enjoys a lower level of acceptance in the scientific community is to rigorously monitor physiological and behavioral responses as the intervention progresses. The effect of the intervention is determined by computer analysis using pattern recognition or Bayesian analysis.^[22] Both approaches are useful when applied appropriately. An advantage of an RCT is that it is highly controlled, the rules are set, and we know the exact intervention. The disadvantages are that they require a long-term study,

Table II. Principles of Respiratory Disease Management Institute (RDMI) model

Education for understanding and acceptance
Knowledge of lungs and concepts of ventilation
Knowledge of disease impact
Understand importance of intervention components
Reinforce understanding through practice
Daily maintenance
Training skills
Creating habits
Establishing routines
Prevention of exacerbations
Practice and reinforce methodology
Exacerbation management
Early detection and rapid action
Availability of medications at home
24-hour, 7-day physician/therapist support and collaboration
Reinforce exacerbation management skills through practice and feedback

the answer is years away, and there is not much room for observation. It is also very expensive. An advantage of the continuous evaluation approach is that it enables the ongoing evaluation of the intervention and rapid response to improve the methodology – yet this too changes the overall merit of the approach. As we evaluate and continuously develop the methodology, this approach deals with many uncertainties. Ideally, both approaches will be utilized in the evaluation of disease management processes. Major differences materialize in how different components of programs are administered and to what extent they impact the outcome. Bayesian analysis is useful in an idealized practice of medicine where continuous evaluation and improvement in practice skills are possible. Well designed studies with adequate research populations may answer major questions as to whether a program or specific intervention works.

3.3 Outcomes of the Respiratory Disease Management Institute Model

The chronic care management model of the Respiratory Disease Management Institute is designed based on the aforementioned considerations (see table II). It is patient centered and administered from the doctor's office. Patients are trained and reinforced in a simple non-branching flow model during their monthly doctor's therapeutic office visit. The approach is lifelong and takes the place of a standard doctor's office visit. It is also billed as a standard doctor's office visit. However, it has been reconfigured to attend to the needs of chronic and progressively ill

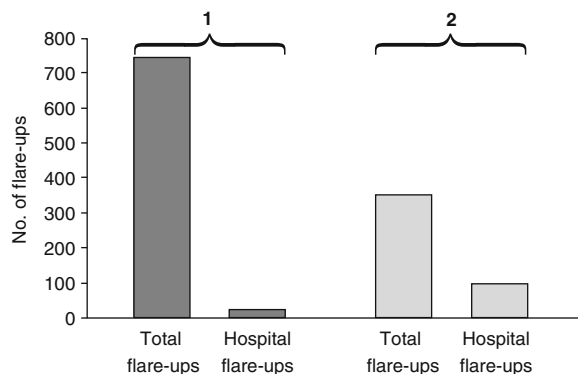


Fig. 5. Outcome data from the Respiratory Disease Management Institute (RDMI) program: total number of exacerbation (flare-ups) and those leading to hospitalization. **1** RDMI (unpublished data); **2** Cote et al.^[23]

COPD patients with chronic lung disease who are subject to acute exacerbations. A database has been established and data collected since the start of the present model (2001), incorporating nearly 2000 patient visits (as of 2008). Exacerbations are recorded, along with patient adherence to the rapid action plan methodology. In training, patients are taught the signs and symptoms of an early exacerbation and the benefits of immediate intervention. They are strongly encouraged to monitor for early signs of exacerbations at the end of their daily walk and to begin all aspects of the rapid action plan immediately, if such signs are detected. This includes calling the physician, who monitors and directs the protocol via telephone. Experience informs us that some symptomatic relief is often felt within the first day.

3.4 Hospitalization for Exacerbation

Of 1981 doctor's therapeutic office visits from the RDMI program monitored over a 6-year period, 744 exacerbations were identified, with some patients experiencing more than one exacerbation. From that population, there were 24 hospitalizations for exacerbation – a hospitalization rate of 3.2%. Four of the hospitalizations were end of life. None of the patients required long-term ventilator management (unpublished data). In a recent study, for other purposes, Cote et al.^[23] investigated 352 exacerbations from which there were 95 hospitalizations – a hospitalization rate of 27% (figure 5). While the two groups of patients may not be entirely comparable, our experience suggests that hospitalization for exacerbations should not be a common event.

4. Conclusions

COPD is a chronic and progressive disease with episodic acute exacerbations. The clinical impact of COPD encompasses heightened dyspnea, reversible airway obstruction, pulmonary hyperinflation, deleterious consequences of a sedentary lifestyle, systemic

manifestations, and ongoing acute exacerbations. Medical and rehabilitative interventions minimize the impact of COPD on functionality and lifestyle, and prevent/pre-empt exacerbations. Disease management is a systematic approach to the long-term management of chronic illnesses. When detected in their early stages, exacerbations are highly reversible and hospitalizations may be avoided. Given the available outcome data from the RDMI model, in which the therapeutic doctor's office visit supplants the standard doctor's office visit, it is time for a multicenter trial to evaluate this model of healthcare delivery and to document outcomes, costs, and medical efficacy at several levels.

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