

# Focusing on outcomes: Making the most of COPD interventions

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**Abstract:** A number of excellent intervention studies related to clinical and psychosocial aspects of chronic obstructive pulmonary disease (COPD) have been undertaken in the recent past. A range of outcomes have been examined including pulmonary function, health care use, quality of life, anxiety and depression, ambulation, exercise capacity, and self-efficacy. The purpose of this narrative review was to a) consider clinical, psychosocial, and educational interventions for people living with COPD in light of the health related outcomes that they have produced, b) identify the type of interventions most associated with outcomes, c) examine work related to COPD interventions as it has evolved regarding theory and models compared to work in asthma, and d) explore implications for future COPD research. Studies reviewed comprised large scale comprehensive reviews including randomized clinical trials and meta-analysis as these forms of investigation engender the greatest confidence in clinicians and health care researchers. Extant research suggests that the most significant improvements in COPD health care utilization have been realized from interventions specifically designed to enhance disease management by patients. A range of interventions have produced modest changes in quality of life. Evidence of impact for other outcomes and for a particular type of intervention is not strong. Research in other chronic diseases, particularly asthma, suggests that interventions grounded in learning theory and models of behavior change can consistently produce desired results for patients and clinicians. Use of a model of self-regulation may enhance COPD interventions. Although the extent to which COPD efforts can benefit from the experience in other conditions is a question, more outcome focused intervention studies using more robust theoretical approaches may enhance COPD results, especially regarding health care use and quality of life.

**Keywords:** COPD, disease management, self-regulation

## Introduction

The trajectory of chronic obstructive pulmonary disease (COPD) can be daunting for both patients and clinicians. ZuWallack<sup>1</sup> described a frequent scenario: sensing breathlessness on exertion patients settle into a sedentary lifestyle that de-conditions their bodies and further aggravates breathlessness and results in further downward adjustments of physical activity. Such decline is often accompanied by significant limitations on functioning and increased anxiety and depression.<sup>2</sup> Indeed, estimates of depression in the COPD population are around 50%<sup>3</sup> or for severe COPD approximately 2.5 times greater than in an age-matched control population.<sup>4</sup> The natural course of the disease produces decline in forced expiratory volume in one second (FEV<sub>1</sub>) accelerating disability and death. Tashkin<sup>5</sup> noted that although lung function is important for diagnosis and classification of severity of COPD, patients and clinicians are very interested in controlling symptoms and maintaining the ability of the patient to function day to day. Modifying these latter outcomes may or may not have an affect on the natural course of the disease<sup>5</sup> and large scale studies (TORCH, UPLIFT) have been undertaken to address this question.<sup>6</sup> Several authors have

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posited that clinical measures such as spirometry are much less important to patients than clinicians. Patients studied appeared to place significantly more value on symptom control, functioning and quality of life including less depression and anxiety<sup>7-9</sup> and they feared exacerbations, hospitalization, and dependency.<sup>10</sup>

Studies to date examining the efficacy of clinical and psychosocial interventions for COPD represent a wide range of efforts (see Table 2) including interventions of varying types and with various emphases to enhance the capacity of individuals to manage their condition on their own with guidance from clinicians. Other types of interventions include community-based management, progressive resistance exercises, pulmonary rehabilitation with and without education, inspiratory muscle training, psychotherapy and psychiatry, psycho-educational interventions, walking and exercise programs. Although many of these efforts are laudable, as a group they reflect a lack of consensus in the field more generally concerning how patients with COPD can best be helped and where emphasis ought to be placed.

Reviews of studies in other diseases, for example asthma<sup>11</sup> have shown that different types of interventions produce different outcomes. It is rare to find an intervention that achieves the full range of results one might wish for a patient with the condition. Further, studies in asthma over a long period of time suggest that bench marks of success have emerged. So many asthma interventions, most particularly those designed to enhance disease management by the patient, have demonstrated reductions in symptoms and health care use, that an intervention that does not produce at least one of these outcomes can be thought to be wanting. Further, asthma studies and those in other conditions (for example heart disease) also have shown that interventions are often effective with subgroups of patients (eg, ones with more severe disease) exhibiting stronger outcomes for these groups of patients than the entire sample of more heterogeneous participants.<sup>12</sup> Studies in medicine and pharmacy regarding variation in response<sup>13</sup> underscore the idea that one size does not fit all patients, that is, what elicits a response from some fails with others. Cost is also an acknowledged concern in management of most long term diseases. When the same desired outcomes are achieved by two interventions of different resource intensity, the less expensive one will be deemed more favorable.

Data are available from studies in COPD regarding a range of outcomes: pulmonary function, health care use, quality of life, anxiety, depression, ambulation, exercise

capacity, self-efficacy (the last of these likely not being a sufficient end point in itself but having been associated with other outcomes such as ambulation and symptoms).<sup>14</sup> The purpose of this narrative review was to a) consider clinical, psychosocial, and educational interventions for people living with COPD in light of the health related outcomes that they have produced, b) identify the type of interventions most associated with outcomes, c) examine work related to COPD interventions as it has evolved regarding theory and models compared to work in asthma, and d) explore implications for future COPD research. Studies reviewed comprised large scale comprehensive reviews including randomized clinical trials and meta-analysis as these forms of investigation engender the greatest confidence in clinicians and health care researchers.

## **Reviews and studies in COPD: clinical, psychosocial, and educational intervention research**

In the recent past, there have been at least ten comprehensive reviews of COPD clinical, psychosocial and educational interventions involving more than 300 articles. These reviews comprise thoughtful and, generally, methodologically sound treatises on the state of evaluation research (see Table 1 for reviews organized by primary outcome). In addition to comprehensive reviews, recent individual studies have also examined various clinical, psychosocial and educational strategies designed to generate benefits for patients with COPD. Table 2 presents these, also organized by the primary outcome. For purposes of our discussion, it seems helpful to consider findings of reviews and individual randomized controlled studies in light of the outcomes assessed.

### **Pulmonary function**

A review by Devine and Percy<sup>15</sup> showed that pulmonary rehabilitation interventions including an educational component improved pulmonary function tests, eg, FEV<sub>1</sub>, for patients with COPD. O'Brien and colleagues<sup>16</sup> reviewed studies of inspiratory muscle training interventions and found that they resulted in increased muscle strength for COPD patients. A study by Watson and colleagues<sup>17</sup> found that patients taking part in an intervention to enhance their disease management skills had changes in behavior but no differences compared to controls on any parameter of lung function. Sassi-Dambrosi and colleagues<sup>18</sup> noted that

instruction and practice in techniques of progressive muscle relaxation and breathing retraining produced positive results on the transition dyspnea index.

## Health care utilization

This outcome has received the most attention in COPD studies. In their review (see Table 1), Adams and colleagues<sup>19</sup> found that interventions including two or more components of the Chronic Care Model (a comprehensive model describing numerous dimensions of health care systems thought to be influential in patient outcomes) produced positive changes in health care utilization among COPD patients. Bourbeau and colleagues<sup>20</sup> reviewed interventions with diverse theoretical bases and areas of emphasis that aimed to enhance disease management by patients. They found that these interventions were likely to improve COPD health care use. A review by Effing and colleagues<sup>21</sup> also found that this type of intervention was associated with fewer hospital admissions for COPD patients.

At least eight groups of investigators confirmed positive health care use outcomes in recent studies of COPD interventions (see Table 2). Boxall and colleagues<sup>22</sup> found that a walking intervention for patients resulted in shorter length of stay for a subsequent hospitalization for COPD. Gallefoss<sup>23</sup> found an intervention providing COPD information delivered by health care professionals resulted in reduced need for GP visits. Rea and colleagues<sup>24</sup> showed that patients assigned to pulmonary rehabilitation had reduced number of annual days in the hospital subsequent to their participation. In a study of the efficacy of a community-based disease management intervention for people with COPD, Hernandez<sup>25</sup> found that specialized care with a nurse coordinator led to lower rates of emergency department visits. Pushparajah and colleagues<sup>26</sup> found that patients with previous hospital admissions were more likely to have a shorter length of stay in a subsequent hospitalization after participating in the intervention.

Sridhar and colleagues<sup>27</sup> found that a nurse-led intervention of pulmonary rehabilitation, enhancement of management skills of patients, and COPD action plans led to reduced need for primary care consultations and a reduction in deaths but had no effect on hospital readmissions. Bourbeau and colleagues<sup>28</sup> found that an intervention to improve management by patients (Living Well with COPD) resulted in declines in health care use and the same group of investigators reported that patients assigned to a similar intervention reduced by almost 40% hospitalizations for COPD. Such magnitude of benefit has not so far been replicated by others. Griffiths and colleagues<sup>29</sup> showed that comprehensive

pulmonary rehabilitation, including enhancement of patient management skills, reduced length of stay in a subsequent hospitalization. Gadoury and colleagues<sup>30</sup> found patients assigned to the Living Well intervention had an overall reduction in hospitalizations and emergency visits.

## Quality of life

Niesink and colleagues<sup>31</sup> reviewed (see Table 1) a variety of interventions, including those to enhance disease management by patients, and concluded that they were in general associated with slight improvements in quality of life. Gallefoss and colleagues<sup>23</sup> (see Table 2) studied a brief informational session given by health care providers and found improvements in quality of life up to 12 months post-intervention. Hermiz and colleagues<sup>32</sup> followed patients assigned to home visits by a nurse and showed that some elements of quality of life were improved for the treatment group. Maa and colleagues<sup>33</sup> looked at acupuncture and acupressure and found that when these were supplements to standard care, quality of life improvements were observed.

## Anxiety and depression

Three recent reviews (see Table 1) assessed interventions to reduce anxiety. Brenes<sup>34</sup> found that psychotherapy, psychopharmacology, and pulmonary rehabilitation including one or both of these forms of treatment reduced anxiety in COPD patients. Rose and colleagues<sup>35</sup> examined diverse interventions and concluded that psychology-based interventions were the least effective among strategies to reduce anxiety while Coventry and Hind<sup>36</sup> determined that reductions in mild to moderate levels of anxiety were achieved in patients with moderate to severe COPD from such interventions. As seen in Table 2, in a study of individually-provided information, home-based walking or exercise self-monitoring, Nguyen and Carrieri-Kohlman<sup>37</sup> found that all three modes reduced depressed mood in patients with moderate to severe COPD.

Emery and colleagues<sup>38</sup> found that in moderate to severe COPD patients comprehensive pulmonary rehabilitation reduced anxiety. In the study by Griffiths and colleagues<sup>29</sup> of comprehensive pulmonary rehabilitation including enhancement of patients' disease management skills, anxiety levels of COPD patients diminished but there was no difference between groups by the three month time period. White and colleagues<sup>39</sup> compared pulmonary rehabilitation with brief advice giving and found no difference in anxiety and depression. Egan and colleagues<sup>40</sup> examined nurse-led case management and found less anxiety at one month but results were not sustained thereafter.

Table 1 Reviews of clinical, psychosocial, and educational interventions and COPD outcomes

Primary outcome and investigators	Type of review	Selection criteria <sup>a</sup>	Studies in review	Results	Implications for practice
<b>Pulmonary function</b>					
Devine and Percy <sup>15</sup>	Meta-analysis (publication dates from 1954–1994)	Provided psycho-educational care to adults with COPD; experimental, quasi-experimental, or pre-post design; minimum 5 participants in each treatment group; all treatment groups from same setting; included outcome measures of physical or psychological well-being, knowledge of psychomotor skills, HCU. Excluded cognitive knowledge as an outcome and effect of inspiratory muscle training.	65	Methodological weaknesses limit confidence in positive findings, eg, only 38% of studies randomized to treatment condition and 15% included a placebo-type control group. Pulmonary rehabilitation (exercise + education + behavioral interventions) had significant positive effects on psychological well-being, endurance, functional status, VO <sub>2</sub> , dyspnea and adherence. Education alone only significantly improved inhaler skills. Relaxation alone significantly improved dyspnea and psychological well-being.	Methodological weaknesses highlight the need for additional randomized controlled studies. Current evidence indicates that multifaceted, comprehensive pulmonary rehabilitation yields improvements in multiple outcomes. Specific outcomes can be benefited by education alone or relaxation interventions.
O'Brien and colleagues <sup>16</sup>	Systematic review (update of Crowe and colleagues <sup>63</sup> ) and meta-analysis	Adult participants with COPD; an IMT intervention; randomized comparison group that received an intervention other than 'sham'.	18	Focused on 2 subgroup analyses. No significance difference in outcomes for IMT compared with exercise (5 studies). Some improvements seen in inspiratory muscle strength and exercise tolerance for COPD patients in combined IMT and exercise compared with exercise alone (3 studies).	More studies are needed to explore the effects of IMT or combined IMT plus other rehabilitation interventions compared to rehabilitation interventions without IMT. Data needed regarding frequency, timing and duration of IMT for maximum benefit.
<b>Health care utilization</b>					
Adams and colleagues <sup>19</sup>	Systematic review (publication dates from 1966–2005)	Enrolled adults with COPD; contained intervention(s) with CCM components; included a comparison group or pre-post measurement; included relevant outcomes. Excluded articles evaluating the impact of specific therapeutic measures considered part of "standard care".	32	20/32 were randomized clinical trials. Methodological issues found in underlying literature. Limited published data evaluating CCM components in COPD. Studies with reduced HCU included CCM components of extensive disease management intervention with individualized action plan, advanced access to care, guideline-based therapy, and a clinical registry system. Studies using disease management component only did not affect QOL or HCU outcomes.	Highlights the need for well-designed studies implementing the CCM components in COPD. Insufficient data to determine optimal combination of components, specific types and duration of interventions. Current evidence suggests that interventions with at least 2 CCM components yielded reduced hospital and ED use.

Bourbeau <sup>4</sup>	Comprehensive review (publication dates from 1966–2003)	Published in peer-reviewed journal; experimental or quasi-experimental design; participant diagnosis of COPD; intervention = disease management specific to care of patients with COPD; outcomes were health status or health care use.	10	Limited number of published prospective controlled trials comparing disease-specific management with usual care for patients with COPD. In this review, only one (Bourbeau and colleagues <sup>28</sup> ) showed effects on both health status and use of health resources, including a 40%–60% reduction in hospitalizations and ED visits in the intervention compared with usual care. Intervention comprised eight weekly sessions of a multi-component educational intervention with action plan and monthly follow-up.	Evidence that a multi-component disease management intervention can have an impact on health status of patients with COPD. Interventions are not a substitute for pulmonary rehabilitation in COPD. Ongoing communication regarding disease management should be provided to patients by trained professionals, including the physician. Further research is needed to identify specific effective intervention components and strategies for long-term care of COPD patients.
Effing and colleagues <sup>21</sup>	Systematic review (publication dates from 1985–2005)	Controlled trials (randomized and nonrandomized) of disease management education in patients with COPD. Excluded studies focusing on pulmonary rehabilitation and studies without a "usual care" control group.	14	Compared to a control group, disease management education significantly reduced the likelihood of at least one hospital admission. QOL significant improvements did not reach clinical significance; small significant reduction in dyspnea observed. No significant effects found in other variables, eg, number of exacerbations, ED visits, lung function, exercise capacity, days lost from work, medication use.	Highlights the need for large RCT with long-term follow-up. Evidence found for disease management education resulting in a reduction in hospital admissions. Data insufficient to develop recommendations for form and content of disease management interventions in COPD.
<b>Quality of life</b>	Systematic Review (publication dates from 1995–2005)	RCT trial with a usual care control group; patients with stable COPD; outpatient integrated care intervention; intervention duration of at least 8 weeks; general or disease-specific QOL measurement. Excluded studies exclusively focused on evaluation of case finding methods, prevention strategies, and provider education or feedback.	10	Limited studies available regarding the effect of chronic disease management interventions on health-related QOL in patients with COPD. Studies in this review did not include all elements of the chronic care model. Substantial variability in quality of studies. Inconclusive whether chronic disease management interventions with different levels of care coordination in people with stable COPD can improve HRQOL.	Highlights the need for further research to identify the most effective methods of integrating the various disciplines in COPD care.

(Continued)



Table 1 (Continued)

Primary outcome and investigators	Type of review	Selection criteria <sup>a</sup>	Studies in review	Results	Implications for practice
<b>Anxiety &amp; depression</b>					
Brenes <sup>34</sup>	Review (publication dates from 1966–2002)	Articles that discuss the prevalence of anxiety among COPD patients, the impact of anxiety on patients with COPD, or the treatment of anxiety in COPD patients.	Not specified	Anxiety disorders occur at higher rates in people with COPD and significantly impact their QOL. Few studies have examined pharmacological, psychotherapeutic, or pulmonary rehabilitation treatments for anxiety in the context of COPD. Some evidence that cognitive-behavioral interventions and multi component pulmonary rehabilitation can reduce anxiety symptoms in people with COPD.	Highlights the need for randomized controlled studies with larger samples and instruments with demonstrated reliability and validity. Need to look at individual components of interventions with multiple components to determine which are most effective.
Coventry and Hind <sup>36</sup>	Systematic review and, et-analysis (all publications through August 2005)	RCT only with standard care control group; participants with clinically stable moderate to severe COPD; outpatient pulmonary rehabilitation interventions of $\geq 4$ weeks that included exercise component or comprehensive interventions; use of validated self-report anxiety and generic or disease-specific HRQOL measures.	6	In patients with moderate to severe COPD, comprehensive pulmonary rehabilitation that included up to 3 sessions/week of supervised exercise along with education and psychosocial support appeared to significantly reduce anxiety and depression compared to standard care.	Further research is needed to determine the most effective interventions for anxiety and depression in people with moderate to severe COPD.
Ofman and colleagues <sup>65</sup>	Systematic review (publication dates from 1987–2001)	Included interventions using a systematic approach and multiple modalities to manage or prevent a chronic disease; addresses a chronic condition affecting at least 1% of population; adult participants; included objective measurement of processes or outcomes; employed experimental or quasi-experimental designs. Excluded risk reduction interventions that did not target a specific chronic disease; evaluations of single treatment modalities; observational studies; studies of hospitalized patients.	102	Six studies addressed COPD. Overall, disease management interventions were associated with improvements in the quality of patient care. Relatively few studies evaluated the effect of disease management interventions on health care utilization and costs. Interventions for patients with depression had the highest percent of comparisons between intervention and control showing significant improvements in patient care, while those for COPD and chronic pain had the least.	Rigorous evaluations of interventions that appear most effective are indicated. Organizations that certify disease management interventions should use formal criteria to evaluate intervention effectiveness.

Rose and colleagues <sup>35</sup>	Systematic review (publication dates from 1985–2001)	RCT of psychologically-based intervention to treat anxiety and/or panic in patients with COPD; participants with diagnosis of COPD based on lung function testing, chronic bronchitis, emphysema. Excluded interventions with exercise or education only; studies that failed to measure anxiety pre/post intervention; studies with patients with asthma or industrial-related COPD.	6	Lack of evidence that psychologically-based interventions reduce anxiety in COPD, perhaps due to methodological problems in reviewed studies.	Highlights the need for more rigorous randomized controlled trials of longer duration; need panic measures specific to the COPD population; screening newly diagnosed COPD patients for anxiety and panic may result in earlier intervention for these conditions.
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**Notes:** <sup>1</sup>In addition to being published in the English language.

**Abbreviations:**

## Ambulation and exercise capacity

Five groups of investigators assessed the efficacy of interventions to achieve these outcomes (see Table 2). Cockcroft and colleagues<sup>41</sup> found an exercise intervention improved ambulation while Behnke and colleagues<sup>42</sup> found a home walking intervention improved walking distance and maintenance for six months. Foy and colleagues<sup>43</sup> found that long-term versus short-term exercise therapy produced greater ambulation scores for men but not women. Ries and colleagues<sup>44</sup> found patients with moderate to severe COPD who took part in a comprehensive intervention including of breathing exercises, postural drainage education and psychosocial support produced greater increases in exercise that diminished after one year. Guell and colleagues<sup>45</sup> found that comprehensive pulmonary rehabilitation resulted in greater functional exercise capacity.

## Self-efficacy

Self-efficacy is generally defined as the level of confidence one feels to perform a given task.<sup>46</sup> Self-efficacy has been linked to other outcomes, although it is a questionable goal if it is the only result of an intervention. Nonetheless, self-efficacy has been studied independently in COPD. Davis and colleagues<sup>14</sup> found that after dyspnea education and home walking coupled with an exercise intervention there were no differences in self-efficacy between the treatment and control groups. Scherer and colleagues<sup>47</sup> showed that subsequent to a pulmonary rehabilitation intervention, self-efficacy scores of participants improved and were maintained up to six months.

## In summary

These reviews and studies suggest that there have been improvements realized from COPD interventions. Using the criteria of number of studies conducted and number illustrating positive, statistically significant results, the most consistent findings appear to be for interventions to enhance disease management skills of patients as they produce health care utilization outcomes. Although not definitive, evidence seems to be somewhat more robust for the ability of these interventions than for other types, to realize service use reductions. Some improvements in quality of life have been noted from a variety of interventions but evidence of success is not strong. For the collective of intervention studies conducted to date questions of significance can be raised. For example, how clinically important are the observed reductions related to anxiety and depression? How important over time are initial results related to pulmonary function? Issues of

**Table 2** Randomized controlled trials of clinical, psychosocial, and educational interventions and COPD outcomes

	<b>Study design</b>		<b>Participants/intervention</b>	<b>Outcomes</b>
	<b>Measurement</b>			<b>Results/discussion</b>
<b>Pulmonary function</b>				
Sassi-Dambros and colleagues <sup>18a</sup>	Six dyspnea measures; 6-minute walk test; Quality of well-being (QWB) scale, Spielberger State-trait Anxiety Inventory (STA); and CES-D. Data collection at baseline, 6 weeks post-treatment and 6 month follow-up		N = 89 with random assignment into treatment or education-control group. Treatment consisted of instruction and practice in techniques for dyspnea management and general education regarding lung disease. Control group received general health education lectures on nonlung disease topics.	No significant differences between groups on any outcome measure were found at the end of the 6-week treatment. At the 6-month follow-up, a significant group difference was found in only one dyspnea variable.
Watson and colleagues <sup>17a,b</sup>	Saint George's Respiratory Questionnaire (SGRQ) Pulmonary function tests Daily diary cards related to respiratory status, medications, health care use Data collection at baseline and 6 months		N = 56 participants with COPD recruited through general practitioners (GPs) completed the 6 month study. Intervention group received a booklet and Action Plan plus a supply of prednisone and antibiotic from their GP. Control group received usual care from their GP	There were significant changes in disease management behavior related to initiating medication use with increasing symptoms in the intervention group compared to controls. Participants in the intervention group did not show any difference in pulmonary function parameters or quality of life scores compared to controls.
<b>Health care use</b>				
Boxall and colleagues <sup>22a</sup>	Hospital admission rates with exacerbation of COPD and average length of stay at readmission; SGRQ; 6-minute walk test; Borg score of perceived breathlessness. Data collection at baseline and 12 weeks follow-up		N = 60 housebound COPD patients older than 60 years. Intervention: 12-week home-based pulmonary rehabilitation intervention consisting of individually tailored walking and arm exercise intervention and multidisciplinary education sessions on COPD and its management. Control group usual care and a 12-week delay before receiving identical intervention.	Compared with the control group, intervention patients demonstrated a significant improvement in 6-minute walk test, Borg score of perceived breathlessness, St. George's Respiratory Questionnaire total score and impact sub score. Intervention group had a significantly shorter average length of stay for hospital readmission at six months follow-up.
Bourbeau and colleagues <sup>28a</sup>	Health care utilization 6-minute walk test Dyspnea after exercise Data collection at baseline, 4 and 12 months		N = 191 patients with COPD and at least 1 hospitalization for exacerbation in the previous year. Intervention group received comprehensive patient education specific to COPD ("Living Well with COPD"). Control group received standard care.	Hospitalizations for exacerbation of COPD were significantly reduced in the intervention group compared to controls, as were hospitalizations for other causes, emergency department visits, and unscheduled physician visits.
Gadoury and colleagues <sup>20</sup> (See Bourbeau and colleagues <sup>28b</sup> )	All-cause hospital admissions All-cause emergency visits Two year follow-up of health insurance usage and hospitalization		N = 191 patients with COPD and at least 1 hospitalization for exacerbation in the previous year with random assignment to intervention or control group. Intervention group received comprehensive patient education specific to COPD ("Living Well with COPD"). Control group received standard care.	Follow-up to clinical trial reported in Bourbeau, J et al 2003 <sup>28</sup> , above. Significant reduction in all-cause hospitalizations and in all-cause emergency visits in intervention group compared to standard care (control) group over 2 years follow-up.



<p>Gallefoss and Bakke<sup>6a</sup></p>	<p>Spirometry; utilization of health resources and absenteeism from work were self reported monthly for 12 months. Hospital dates verified with medical records. SGRQ administered at 12 months follow-up.</p>	<p>N = 78 asthmatics and 62 COPD outpatients assigned to either intervention (2 2-hour group sessions and 1 or 2 individual sessions with providers) or control group.</p>	<p>Patient education in asthmatics and COPD patients reduced the need for GP visits and kept a greater proportion of patients independent of GP. The mean reduction in days off work for the educated was 69%. Patient education significantly increased QOL and FEV1 at 12 months among asthmatic patients but not those with COPD. No difference between rehabilitation and control groups in the number of patients admitted to hospital, but intervention group had significantly fewer hospital days. Rehabilitation group had significantly more primary care office visits and significant improvements in walking ability and quality of life.</p>
<p>Griffiths and colleagues<sup>2a</sup>. (Also ambulation and quality of life results)</p>	<p>SGRQ Hospital Anxiety and Depression Scale; Chronic Respiratory Disease Questionnaire (CRQ), SF- 36 10 m shuttle-walk test Health care use from hospital records Data collected at baseline, 6 weeks, and 1 year follow-up</p>	<p>N = 200 patients randomly assigned to a 6-week comprehensive multidisciplinary rehabilitation intervention (18 visits) or a standard care control group</p>	<p>Mortality and hospital readmissions were similar in both groups. However, at the end of the follow-up period, HH patients had a significantly lower rate of ER visits and improvement in dimensions of quality of life.</p>
<p>Hernandez and colleagues<sup>25a</sup></p>	<p>Hospital admissions, ER visits and outpatient provider visits; SGRQ, SF-12 Data collected at baseline and 8 week follow-up</p>	<p>N = 222 COPD patients randomly assigned to a Home Hospitalization (HH) intervention or conventional care. During HH, integrated care was delivered by a specialized nurse for an 8-week follow-up period. Control group received conventional care.</p>	<p>Overall there was no reduction in length of stay, admission frequency or adjusted total hospitalization days with COPD, but median time interval to next hospitalized exacerbation increased 29% in intervention group. Additional benefits were seen in the more severe patients.</p>
<p>Pushparajah and colleagues<sup>26</sup></p>	<p>Hospitalizations and length of stay compared for one year before and after the intervention</p>	<p>N = 125 patients referred with COPD exacerbations intervention was a community based COPD management intervention led by a respiratory physiotherapist versus control</p>	<p>Mean hospital bed days per patients/year reduced significantly for intervention group, while control group increased. Intervention group also showed an improvement in two dimensions of QOL - fatigue and mastery.</p>
<p>Rea and colleagues<sup>24a</sup></p>	<p>Pre-test/post-test assessments included spirometry, Shuttle Walk Test, SF-36, Chronic Respiratory Disease Questionnaire (CRQ) at baseline and 12 month follow-up</p>	<p>N = 135 moderate to severe COPD patients identified from hospital administration data and general practice records. Assigned either intervention (intensive pulmonary rehabilitation implemented by GP) or conventional care</p>	<p>No significant differences were found in hospital readmission rates. Intervention participants had significantly fewer unscheduled primary care consultations and a significant reduction in deaths due to COPD.</p>
<p>Sridhar and colleagues<sup>27</sup></p>	<p>Hospital readmission rate over 2 years Unscheduled consultations with the general practice (GP) physician over 2 years CRQ at baseline and 3 additional times over two years.</p>	<p>N = 122 patients who had been hospitalized with a primary diagnosis of acute exacerbation of COPD. All participated in a 4 week pulmonary rehabilitation program (8 sessions), received a baseline home visit by a specialist respiratory nurse and a personalized written COPD action plan. Intervention group then received monthly telephone calls and home visits every 3 months for 2 years. Control group received usual care from the GP.</p>	<p>No significant differences were found in hospital readmission rates. Intervention participants had significantly fewer unscheduled primary care consultations and a significant reduction in deaths due to COPD.</p>

(Continued)

Table 2 (Continued)

	Study design		Outcomes	
	Measurement	Participants/intervention	Results/discussion	
<b>Quality of life</b>				
Hermiz and colleagues <sup>32a</sup>	SGRQ Hospitalizations and frequency of MD visits Three-month follow-up after acute care	N = 177 COPD patients assigned to intervention (home visits by community nurse at 1 to 4 weeks after discharge) and control group	Intervention improved patient's knowledge and some aspects of QOL. No differences in admissions to hospital or overall functional status.	
Maa and colleagues <sup>33</sup>	Pre- and post-tests using SGRQ, Dyspnea Visual Analogue Scale, modified Borg Scale, Bronchitis Emphysema Symptom Checklist, Six Minute walk test	N = 41 COPD outpatients, assigned to acupuncture and standard care (N = 11), acupressure (N = 17) and standard care, or standard care alone (N = 13) for 8 week treatment.	SGRQ results of acupuncture and acupressure groups increased significantly compared to the controls. The other variables did not differ significantly between intervention and control groups.	
Monnikhof and colleagues <sup>67a,b</sup>	SGRQ Six Minute Walking test Symptom diary Data collection at baseline, 6 and 12 month follow-up	N = 248 patients with stable moderately severe COPD, no history of asthma, current or former smoker, no exacerbation in month prior Randomized to skill-oriented disease management (five 2-hour group interventions) and fitness intervention or regular care control group	No differences in the SGRQ scores, walking distance, or symptoms found between groups after 1 year.	
<b>Anxiety and depression</b>				
Egan and colleagues <sup>40a,b</sup>	SGRQ; Hospital Anxiety and Depression Scale (HADS); Subjective Well-Being Scale; hospital readmissions Data collection at baseline and 3 month follow-up	N = 66 patients randomized to an intervention or control group. Intervention group received a comprehensive nursing assessment by the CM who also coordinated their care during hospitalization, conducted a case conference as part of discharge planning for intervention patients, and provided follow-up care at 1 week and 6 weeks post-discharge. Control group received normal care.	Intervention group patients reported significantly less anxiety at 1 month post discharge; however, this effect was not sustained.	
Emery and colleagues <sup>38a</sup>	CES-D score; SCL-90-R for depression/anxiety, STAI-State Anxiety and Sickness Impact Profile (SIP) total score; physiological function. Data collection at baseline and 10 weeks follow-up.	N = 79 outpatients with moderate to severe COPD randomized to: a) exercise, education, and stress management; 2) education and stress management; and 3) wait list control. Intervention consisted of Comprehensive Pulmonary Rehabilitation for 10 weeks. Control participants received standard care education, stress management, and psychosocial support	Intervention participants in the comprehensive pulmonary rehabilitation group, compared to the other 2 groups, reported improved endurance, reduced anxiety, and improved cognitive performance (verbal fluency).	
Nguyen and Carrieri-Kohlman <sup>37</sup>	CES-D; CRQ; endurance treadmill test; SF-36 physical and social functions; spirometry Data collection at baseline and 2 month follow-up	N = 100 adults (> 40 years of age) with moderate to severe COPD Randomly assigned to one of three disease management interventions: 1) Dyspnea Self-management Program (DM) and individualized home walking prescription; 2) DM education and 4 tread mill sessions; and 3) DM education and 24 treadmill sessions	All three versions of dyspnea self management significantly improved depressed mood. Patients at high risk of depression at baseline who received 24 sessions had greater reduction in dyspnea.	

White and colleagues <sup>37a,b</sup>	Spirometry; Shuttle walking test; Hospital Anxiety and Depression scale; CRQ, SF-36 Data collection at baseline and 3 month follow-up	N = 103 patients with severe COPD randomized to intervention or control. Intervention was a 6-week (12 sessions) rehabilitation intervention at the hospital. Control participants received a single education session at the hospital and home exercise advice.	At 3 months both groups reported reduced anxiety on the Hospital Anxiety and Depression Scale and dimensions of quality of life, but differences between groups were not significant. Shuttle walking distance increased significantly in the intervention group compared to controls.
<b>Ambulation</b>			
Behnke and colleagues <sup>42, a</sup>	Lung function; 6-minute walk test; Borg and Traditional Dyspnea Index (TDI); and CRQ Data collected in the hospital and 1, 2, 3, and 6 months after discharge	N = 46 patients randomized to an intervention or a control group. The intervention group performed walking training in the hospital, followed by a 6-month intervention of supervised walking training at home. The control group did not have exercise training in the hospital or at home	Six-minute walking distance in the intervention group improved significantly from day 1 to 10 and was maintained over 6 months and their quality of life scores changed significantly over 6 months. The control group showed no significant changes in exercise performance or QOL scores throughout the study period.
Cockcroft and colleagues <sup>41a</sup>	Spirometry; 12-minute walk test; treadmill exercise test; Lorr-McNair Mood Questionnaire scores for tension/anxiety and depression; Eysenck Personality Questionnaire (EPQ) Data collected at baseline, 2, 4, and 8–9 months (after controls completed training).	N = 34 outpatient men with respiratory disability were assigned to intervention or control. Intervention participants received 6 weeks of progressive exercise training. Control participants received standard care for 4 months, followed by the exercise training.	Walking distance improved significantly in the treatment group compared to controls, but no consistent associations between the increase in walking distance and changes in psychological scores were observed. No significant differences between intervention and control groups in anxiety levels or other psychological dimensions were found at follow up.
<b>Exercise capacity</b>			
Foy and colleagues <sup>43</sup>	CRQ Attendance at sessions Heart rate achieved during exercise Measurement at baseline, 3 and 18 month follow-up	N = 140 COPD patients (>50 years if age) randomized to short-term (3 months) and long term (18 months) exercise therapy	Long-term group had significantly more favorable scores than the short-term group on dimensions of CRQ (dyspnea, fatigue, emotional function and mastery). Men in long-term group reported significantly more benefit than those in short-term group; no significant differences were observed for women between short or long term exercise therapy.
Guell and colleagues <sup>45a</sup>	SCL-90-R; 6-minute walk test; CRQ; Million Behavior Health Inventory (MBHI) Data collected at baseline and 16 weeks follow-up	N = 40 outpatients with severe COPD randomized either to a pulmonary rehabilitation group for 16 weeks or to a control group that received standard medical care with drug treatment for respiratory infections and dyspnea	Significant differences in favor of the intervention group were found in dimensions of the MBHI, the SCL-90-R, the dyspnea and mastery domains of the CRQ, and the 6-minute walk test. Pulmonary rehabilitation may decrease psychosocial morbidity in COPD patients even when no specific psychological intervention is performed.

(Continued)

Table 2 (Continued)

	Study design		Outcomes	
	Measurement	Participants/intervention	Results/discussion	
Ries and colleagues <sup>68a</sup>	Pulmonary function tests; treadmill testing; Self-efficacy questionnaire; Quality of Well-Being scale; CES-D score; self-report hospitalization and ED use Data were collected at baseline, after the intervention ended (2 months) and at regular intervals for 6 years	N = 119 outpatients with moderate to severe COPD randomly assigned either to an 8 week comprehensive pulmonary rehabilitation intervention (plus 12 follow up reinforcement sessions for 1 year) or to the control group that received an 8week education intervention.	Rehabilitation produced a significantly greater increase in maximal exercise tolerance. Measures of lung function, depression, general quality of life, and health care use did not differ significantly between groups. Differences tended to diminish after 1 year of follow-up.	
<b>Self-efficacy</b>				
Davis and colleagues <sup>14b</sup>	Self-efficacy for walking and managing shortness of breath; 6-minute walk test with Borg scale; and CRQ Dyspnea subscale. Measured at baseline and after completion of the exercise interventions (8 weeks)	N = 102 participants with moderate to severe COPD Random assignment to one of three disease management interventions: 1) Dyspnea Self-management Program (DM) and individualized home walking prescription; 2) DM education and 4 treadmill sessions; and 3) DM education and 24 treadmill sessions	Education and a home walking intervention significantly improve patients' self-efficacy for walking and for managing shortness of breath. The three intervention groups did not differ in their improvements in self-efficacy.	
Scherer and colleagues <sup>47</sup>	CSES test: Assesses COPD patients' level of confidence in ability to manage or avoid breathing difficulty while participating in certain activities Measurement at baseline, 1- and 6-month follow-up.	N = 59 patients randomized to participate in either the pulmonary rehabilitation intervention (combined education and supervised exercise training) or to a control group receiving an education-only intervention.	Participants' self-efficacy scores improved significantly after the pulmonary rehabilitation intervention and remained improved 6 months later. Education alone was initially effective in significantly improving self-efficacy scores, but scores declined by 6 months.	

**Notes:** <sup>a</sup>Reference is included in a review article; <sup>b</sup>Findings nonsignificant at  $p \leq 0.05$

cost can also be raised. Several interventions have been comprehensive and intensive in terms of provider and patient time and effort and at least one<sup>27</sup> has demonstrated significant cost effectiveness. In general, however, it is not clear how results as produced by more costly interventions stand up against less expensive means of intervention. What are the relative costs of various intervention modes for patients, for clinicians and for the health care system? In addition, questions regarding the capacity of interventions used to date to produce desired outcomes must be raised. How powerful in terms of theory and proven models are the interventions employed? This idea deserves further exploration. As noted, there is consistent evidence that asthma interventions aimed at improving patients' skills of disease management produce symptom and health care use improvements.<sup>48</sup> How has work in the two areas, COPD and asthma, moved forward regarding theoretical approaches and intervention models?

### Improving patient management of COPD

Both reviews and individual studies available in COPD suggest that one of the most studied modes among the range of interventions utilized, those designed to enhance COPD management by patients, can produce changes in health care use. This observation is made recognizing that evidence is not as strong as might be wished. The effect of interventions to enhance disease management by patients on other types of outcomes appears to be weak. Further, there is the odd paradox that although patients fear the need for health care, when need for services is reduced no accompanying improvement in quality of life outcomes has been observed.<sup>21</sup> Nonetheless, such interventions may hold greater promise than currently evident for benefiting people with COPD.

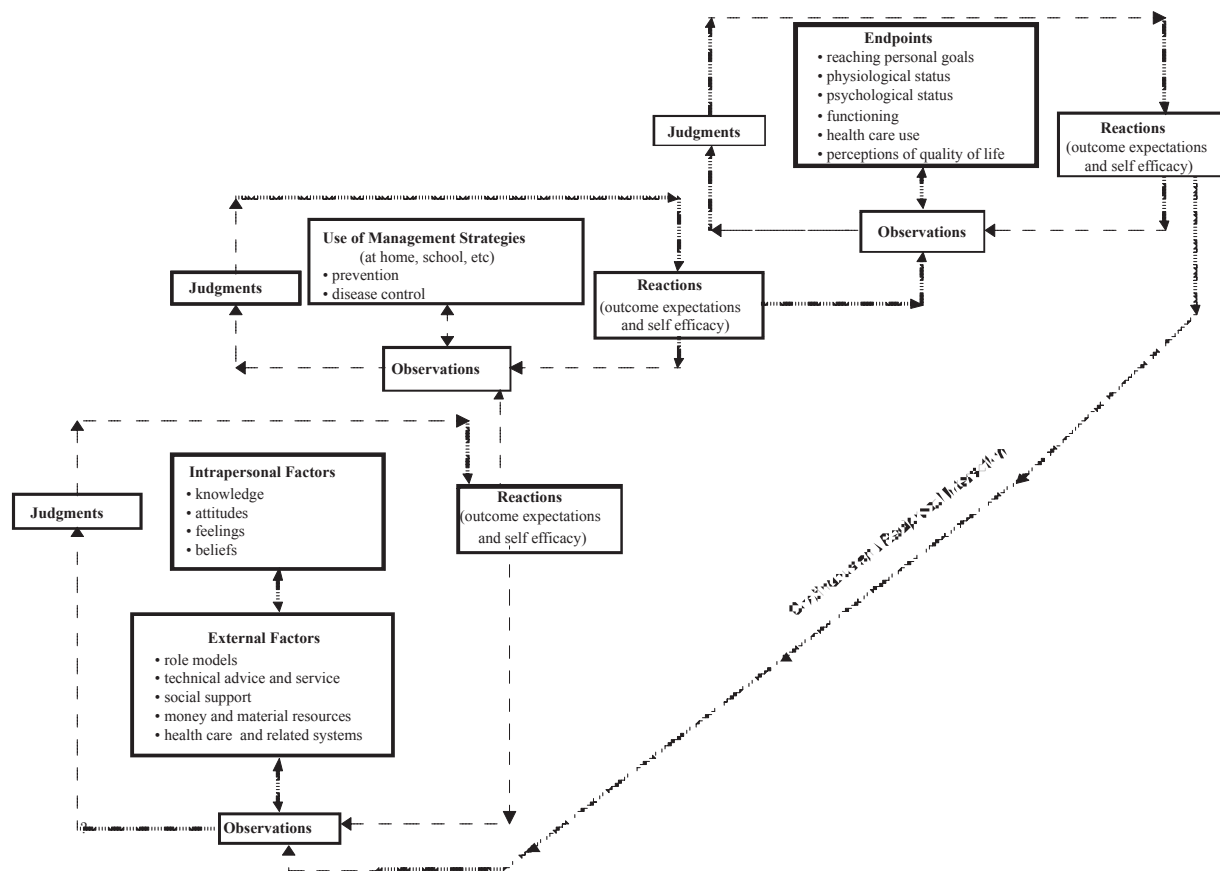
As noted earlier, no one intervention can be expected to produce all the potential desirable results for people with the disease. However, in other conditions the evidence base has increased for interventions focused on developing patients' ability to manage disease on their own with guidance from their clinicians. Research has shown that such interventions have generally produced more than one outcome.<sup>27</sup> Often one of these outcomes suggests a mechanism for the others. For example reduced health care use in asthma resulting from such interventions has usually been accompanied by reductions in symptoms. Often, but not always, enhanced quality of life<sup>49</sup> has been realized along with symptom reduction and/or less health care use. In addition more and more, results of interventions have been shown to benefit sub groups; in the case of asthma, those with more severe disease.

The lack of collective evidence for similar constellations of outcomes in COPD may be attributable to several factors. Perhaps, this is the case because COPD presents a more complicated clinical picture. The umbrella term COPD encompasses patients who might have the predominant pathology affecting their airways or the dominant pathology causing air sac destruction. Furthermore, co-morbidity or even poly-morbidity is so common in this condition that it is difficult to identify a homogenous group for study. The natural history and course of the disease may not allow for management by patients that can be adequately addressed in an intervention, that is, sufficient to result in fewer symptoms, less health care use and/or enhanced quality of life. Perhaps the methods and measures employed to assess outcomes in COPD are insufficiently robust to detect such changes. Another possible contributing factor may be that assessment of constituents of interventions has not been undertaken and is difficult to implement given current science base. Investigators of a single component intervention which might be thought to provide the clearest result regarding cause have produced benefits of such small magnitude that cause is, in fact, not easily attributed. This is in contrast to studies of multi-component interventions which show a greater magnitude of benefit but the casual element is not identifiable. However, COPD interventions to enhance patients' skills may not be as robust as they might be and may, as a group, comprise efforts insufficiently informed by findings in behavioral research in asthma and other chronic conditions. Collectively, they may not adequately reflect a focused approach or principals of learning and behavior change.

Over the past two decades, there has been increased interest in the asthma community in particular and chronic disease field in general in the psychosocial and behavioral factors associated with control of disease.<sup>50</sup> This interest has led to introduction of theories and principles of behavioral science into asthma interventions. For example, one of the most explored has been social cognitive theory. This is a body of work evolved over many years beginning as social learning theory and most recently comprehensively articulated by Bandura.<sup>46</sup> Social cognitive theoretical principles have infused studies in chronic disease generally<sup>51-53</sup> and a model of self-regulation derived from the broader theory has been applied to asthma.<sup>54,55</sup>

Self-regulation is the means by which individuals learn and modify their behavior, eg, managing their COPD. The self-regulation model presented in Figure 1 (adapted from Clark and colleagues<sup>55</sup>) is based on the premise that a continuous and reciprocal interaction of factors external and internal to the individual produces behavior and





**Figure 1** The continuous and reciprocal nature of self-regulation processes in asthma management.

outcomes associated with that behavior. These factors are identified, understood and modified using disease management strategies (including modification of the physical and social environments) to achieve a desired goal. This means his or her ability to observe himself and his social and physical environments, make informed judgments about the observations, try out new behavior and react appropriately (reactions being the belief that the behavior produced a desired result and the confidence to continue the behavior. The latter is referred to as self-efficacy). The model indicates that the most important feature of an intervention is its ability to enhance the self-regulatory process in the participant. As an example, in the case of individuals with moderate to severe COPD, episodes of shortness of breath/difficulty breathing are often a daily occurrence. To manage such episodes, the self-regulation model postulates that individuals observe key factors affecting their current management of the problem. Such factors might include, for example, feelings of fear or panic (intrapersonal factors), living alone (social factors), or difficulty breathing when performing routine housework (role factors). The effectiveness of current

practices for managing episodes are observed and evaluated and new strategies developed for reaching a personal goal, for example, decreasing the occurrence of anxiety associated with breathlessness. In order to reach that goal, strategies might include, for example, using pursed lip breathing as soon as a shortness of breath episode begins. If using home oxygen therapy, one could manage anxiety associated with shortness of breath when performing housekeeping tasks by increasing the oxygen level when engaged in those tasks and/or dividing the tasks into smaller steps and resting between each step. Alternatively, an individual might decide to identify a relative or friend to come in to assist with household tasks. New strategies are linked to the goal, in this case, less anxiety. Skills developed to create new strategies are skills of self-regulation. The model has been used in several successful asthma intervention studies<sup>56-58</sup> and principles from the broader social cognitive theory in others.<sup>59-61</sup> A focus on accepted behavioral science theories of learning and change has resulted in exemplars of robust asthma interventions that are reasonably reliable in producing constellations of desired outcomes.

## Considerations for COPD

It appears that compared to other conditions, eg, asthma, heart disease, and diabetes, there may be less information available in COPD regarding social and behavioral dimensions of management by patients and less use of relevant models to enhance their skills. How much can be extrapolated from these other conditions to COPD comprises a question. Compared to asthma, for example, patients with COPD may experience different or heightened emotional responses. Stigma and guilt may be more prominent in COPD and these patients may be more likely to sense an inevitable downward decline. Perhaps that most COPD patients are older and often more dependent on others attenuates their disease management efforts and the capacity of interventions to enhance them. As a result of these factors, the magnitude of benefits of a COPD intervention may never be as great as in asthma.

Nonetheless, extant studies suggest that the COPD community can make significant progress in developing effective interventions for patients, especially those designed to enhance their management skills, given the excellent work to date and drawing as relevant from the experience in other conditions. Such progress, in part, likely entails a reasonable level of consensus on the most desired outcomes for patients – probably a decision that is best made in collaboration with them. Enhanced quality of life and less health care use likely would be candidates for emphasis. Development and assessment of richer, theory-based interventions that are at the same time affordable and manageable within large health systems seem warranted. This direction for work requires availability of adequate research resources and tools allocated specifically for COPD. Such evaluation research could address a number of important questions including:

- Which social and behavioral science principles and models are most relevant for COPD interventions?
- Which interventions or elements of them are best matched to which patients?
- Can constellations of desired outcomes be realized from more robust interventions directed toward enhancing patient management skills including symptom and health care use reduction and enhanced quality of life?
- What are the specific elements or combination of elements that produce outcomes in interventions designed to help patients manage COPD more effectively?<sup>62</sup>
- Can levels of depression and anxiety be reduced by more efficacious interventions or can more cost effective interventions be found?

Given the extent of current and anticipated levels of COPD in the world's population, more effective interventions that can generate strong, positive results deemed important to both patients and clinicians seem especially important to identify.

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