COPD Disease Management Program

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Abstract

Disease management (DM) is a process evolved from managed care principles. It uses evidence-based medicine, along with practice guidelines to assure patients receive optimal care while providing a favorable return on investment. This paper will explore a proposed DM approach to chronic obstructive pulmonary disease (COPD) DM program. COPD is diagnosed via spirometry and treated with pulmonary rehabilitation. DM proposes to reduce the amount of respiratory flare-ups, shorten hospital stays and increase patient well-being.

COPD Disease Management Program

Chronic Obstructive Pulmonary Disease (COPD) refers to a group of lung diseases that obstruct airflow out of the lungs. Emphysema, chronic bronchitis and chronic asthmatic bronchitis are the main conditions comprising COPD. With COPD, lungs and airways lose the ability to contract. The patient has difficulty expelling air from the lungs. Exchange of oxygen and carbon dioxide is impaired.

COPD is a preventable and treatable disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive. Noxious particles or gases, primarily caused by cigarette smoking, cause abnormal lung inflammation. Although COPD affects the lungs, it also produces significant systemic consequences. (Celli et al., 2004)

COPD is the fourth leading cause of death in the U.S. costing our economy $42.6 billion in health care costs and lost productivity. (*Morbidity and Mortality: 2007 Chart Book on Cardiovascular, Lung and Blood Diseases.*, 2007). COPD is a worthy target for disease management approaches. Among many reasons, it is preventable, predictable and chronic. It is easily amenable to case management approaches, patient compliance issues and provider education. Because of the high-cost and high death tolls, it is desirable to find an approach to reduce the severity of this disease.

For many years, standard medical treatment failed to meet the needs of the chronically ill (Wagner, Austin, & Von Korff, 1996). The concept of integrated care emerged as a solution. In the 1930s, Henry Kaiser, with Sidney Garfield, MD, created the first health maintenance organization (HMO). In the late 1940s Mr. Kaiser helped establish the role of an integrated health system, which offered comprehensive care to patients (Corsello & Tinkelman, 2008). In 1973 under President Richard Nixon's administration, the HMO Act of 1973 was passed (Corsello & Tinkelman, 2008), which proposed to support preventative medicine. In the 1980s, HMOs were established. The HMO philosophy of patient-centered care promised more efficiency, better monitoring of services, evidence-

based medicine and cost-effective use of ancillary services (Mitka, 1998). These ideas later paved the way for disease management programs.

Despite HMOs attempt to use the primary care physician as the gatekeeper, fragmentation of medical care was the norm (Vogt, Elston-Lafata, Tolsma, & Greene, 2004). We needed a better method to approach chronic disease care. Disease management programs began to find a niche by improving upon the methodology introduced by the early HMO trailblazers. Featuring detailed, easily accessible databases, disease specific trained nurse managers, adherence to national guidelines, and coordination of efforts across multiple co-morbid disease states, disease management offered a new, standardized method to handle chronic disease (Krumholz et al., 2006).

This paper focuses on disease management programs in the primary care of COPD. Critical aspects of a COPD disease management program include lifestyle change and exacerbation management. The patient must actively be involved in the treatment plan. The patient must quit smoking, improve inhaler technique, and improve exercise tolerance. Self management will reduce the duration of exacerbations (Chavannes, 2008).

In contrast with most chronic diseases, COPD is associated with one or more co-morbid conditions, which requires a high level of coordinated care. An effective disease management program is valuable for treating of COPD because it will improve patient care, based upon its criteria of heightened physician communication, evidence-based medicine, and adherence to guidelines. It encourages self-management and objectively tracks patient satisfaction (Corsello & Tinkelman, 2008). As a respiratory disease, most treatment focuses on lung function and rehabilitation. The respiratory disease management institute has provided a sound model for COPD disease management.

Respiratory disease management model

The Respiratory Disease Management Institute (RDMI) model for COPD recognizes that because COPD is chronic and progressive, intervention also must be progressive and ongoing.

The model seeks to guide the patients to create positive living patterns through practice and skilled practitioner intervention. RMDI model skillfully proposes the application of theory into the implementation of practice.

The patient must recognize exacerbations, use an inhaler, avoid respiratory irritants and participate in respiratory rehabilitation. It is hypothesized that compliance in these key areas will result in fewer acute attacks, fewer hospitalizations, greater patient well-being and reduced medical costs.

Because COPD is a preventable disease, this model focused on prevention. The agreed upon goal was increased quality of life for participants. Specifically, the goal sought to reduce emergency room visits by 50%. Four outcomes measured program effectiveness:

1. Number of hospital admissions due to acute exacerbations.
2. Total days of hospitalization for acute exacerbations.
3. Spirometry parameters.
4. Quality of Life

(Bisiupiak)

These four outcomes were selected because they best met numerous criteria proposed by The President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. The first three measures are easily measured, quantifiable, evidence based, reproducible, cost-effective, and each can be collected easily and efficiently. (*Establishing Health Care Quality as a National Priority*) The fourth outcome, *quality of life*, will require a specific measurement tool, the SP-36, to put its data in a format measurable on scale with the first three outcomes.

To assure internal consistency when measuring the subjective quality of life, the goal is to assure each value is measured consistently, in order to correlate one with one another. Cronbach's alpha will perform this task adequately for the subjective data of quality of life. The alpha criteria will be measured at 0.7. (Bland & Altman, 1997).

The first two measures, number of hospitalizations and total days in the hospital are simple numbers, requiring no sophisticated measurement tool. The third outcome, spirometry parameters, has been tested clinically for years. Spirometry reliably detects COPD, and more important, tests lung function. (T. L. Petty, 2001). Specifically, spirometry detects FEV1, which is the volume of air expelled forcefully from the lungs in one second. Studies show FEV1 is a reliable indicator of loss of lung function, and therefore progression of COPD. (Rabe et al., 2007)

This effectiveness study will take place in a regular care setting (Toscani & Pizzi), utilizing prospective cohort design. Currently the designers are evaluating the methodology of paired sample *t* testing. Either the patients' previous records will be compared, or an age-matched control group will be selected. Age-matched, severity-matched controls are preferred.

Data generated will be entered into SSPS statistical analysis software for pair wise *t* testing within groups and ANOVA between groups with significance set at p= 0.05. Bonferroni adjustments correct for family wise error rates for the multiple comparisons, if age-matched groupings are used. (Blair & Taylor, 2008) Data generated by SF-36 and spirometrics will be analyzed per written protocol specifics of each respective program.

Patients with another severe chronic disease, who are bedridden, and who have no telephone are ineligible to participate in the study, Tiep (2008).

Intervention Mapping

Intervention mapping asks how we bring theory into practice (Bartholomew).

Theory

An effective COPD model must fully understand the disease. Because almost components of COPD disease progression are improved through treatment, the RMDI model proposes the course of COPD can be improved through prevention, anticipation, and pre-emption. If the patient is trained to keep the airways clear and open, secretions mobilized, exercise, watch for early signs of exacerbations, and use medications placed in the home, the disease can be managed. (Papi, Luppi, Franco, & Fabbri, 2006)

Evidence based guidelines.

Exacerbations are recognized by shortness of breath, a.k.a. dyspnea, and a change in sputum. (B. L. Tiep, 1997) Exacerbations are responsible for most of the health care costs of COPD. (Bourbeau et al., 2006) Although the causes of exacerbations are not clear, respiratory infection and inflammation are known culprits, (Papi et al., 2006) as exacerbations are associated with neutrophilic and eosinophilic inflammation (Leigh et al., 2006). Once a patient develops an infection, dyspnea occurs, resulting in hypoxemia. Hypoxemia, or low oxygen in the blood, results in bacterial infections, which causes damage along the bronchial lining, causing damage and scar tissue. This environment can set the stage for future bacterial infections, causing a

downward spiral in health. As such, an exacerbation must be recognized as soon as possible and rapidly treated. (B. L. Tiep, 1997)

To address the urgency to address the known sequence of exacerbations quickly, the RMDI model provides an arsenal of techniques. Anti-inflammatory medicines, bronchodilators, antibacterials, an exercise program and corticosteroids and pulmonary rehabilitation programs are hallmarks of this model.

The patient and significant others are trained extensively to recognize signs of flare-ups. Exercise is a key tool. Exercise will bring forth the signs of an exacerbation quicker than if one is sedentary. Earlier detection allows the patient to benefit from the arsenal of tools. The patient is prescribed emergency medications, which is stored nearby, and understands how to use them. At the earliest signs of an exacerbation, the patient skillfully takes the medication. If this does not help, a call to the physician will alert the doctor before the condition runs the cycle of infection and lung destruction. (Brian L. Tiep & Barnett, 2008)

This model is promising. One estimate, although lacking strict scientific rigidity, provided data that the RMDI model greatly reduced the hospitalization rate following exacerbations. With RMDI, the hospitalization rate was 3.2%, compared to 27% without. This early data is enough to warrant excitement and further use of disease management to treat COPD.

COPD Standards of Care

Standards of care involve both diagnosis and treatment. Although many standards of care are discussed, one diagnostic method, spirometry, and one treatment modality, pulmonary rehabilitation, will be explained in detail. Practice patterns are interwoven throughout the discussion.

Even though COPD is the fourth leading cause of death in the U.S. costing our economy $42.6 billion in health care costs and lost productivity, (*Morbidity and Mortality: 2007 Chart Book on Cardiovascular, Lung and Blood Diseases.*, 2007) it is under diagnosed, especially in women. Any adult smoker who complains of a daily cough should be screened for COPD. Nearly half of all regular smokers over 60 could have COPD. (Mannino, Homa, Akinbami, Ford, & Redd, 2002) This section will primarily explore spirometry, as well as other necessary tests to detect COPD.

Diagnostic tests - spirometry

Spirometry is a useful preliminary test for pulmonary health conditions. It assesses the effects of contaminants, medications and disease progression (Schribner). The patient exhales forcefully into an instrument several times. The force of the air is measured, which will determine important values such as FVC and FEV1

FVC, or forced vital capacity, is the maximum volume of air forcefully exhaled. It is an indicator of lung size, elasticity, and how well the air passages open and close. FEV1, or forced expiratory volume in one second, is the maximum volume of air exhaled in 1 second. Steady but faster than normal decline in FEV1 over time indicates COPD. The ratio of FEV1 to FVC is standard practice to determine the presence and severity of COPD.

For the clinician, spirometry generates quantifiable data. For a patient with poor lung function, like COPD, it directly assesses the volume and force of air inspired and expired. Spirometry measures post-bronchodilator forced expiratory volume in one second (FEV1)/forced vital capacity (FVC). Spirometry confirms the presence of airflow limitations that are not fully reversible. Spirometry is indicated if a patient is exposed to cigarettes, environmental or occupational pollutants, and presents with cough, sputum and dyspnea. Spirometry usefully predicts, among other things, health status (Ferrer et al., 1997) utilization of healthcare resources

(Friedman et al., 1999), development of exacerbations (Burge et al., 2000) and mortality (Anthonisen, Wright, & Hodgkin, 1986).

Other Diagnostic Tests Representing Standard of Care

As standard practice for all patients, the physician performs a history and physical on the COPD patient. As part of the history, the physician will learn risk factors such as smoking, exercise capacity and exposure to pollutants. Upon physical examination, the physician looks for skin color and chest size. The doctor will listen for chest and lung sounds indicative of COPD symptoms. If the patient can cough, the physician will ask the patient to produce sputum for examination.

Treatment

This section examines the standard treatment for COPD. Pulmonary Rehabilitation will be explained in detail, followed by other treatment modalities.

Pulmonary rehabilitation is a multidisciplinary program of care for patients with chronic respiratory impairment. It is tailored individually and designed to optimize physical and social performance and autonomy (Celli et al., 2004).

The pulmonary rehabilitation program includes exercise training, education, psychosocial/behavioral intervention, nutritional therapy, outcome assessment and promotion of long-term adherence to rehabilitation recommendations. It is conducted by a team of health professionals who provide medical treatments, exercise, breathing retraining, and psychological interventions, when needed. It can be very effective, especially for acute exacerbations.

Pulmonary rehabilitation improves the health status and health care utilization of patients who experiences dyspnea or other respiratory symptoms, reduced exercise tolerance, restricted activities, or impaired health status (Ries, Kaplan, Limberg, & Prewitt, 1995). Positive effects

occur even though rehabilitation does not have much effect on pulmonary function measurements. This result is explained because morbidity from COPD results from treatable secondary conditions. Examples include cardiac deconditioning, peripheral muscle dysfunction, reduction in total and lean body mass, anxiety and poor coping skills. Pulmonary rehabilitation should be incorporated into the care of all patients with COPD.

Other Treatments Representing Standard of Care

Smoking cessation is the primary treatment for COLP, and for slowing its progression. As the main cause of COPD and its decline, smoking takes on critical importance.

Like most chronic conditions, medicines play a large role in the standard treatment modality for COPD patients. A major goal is to prevent acute exacerbations, a cause of lung deteriorization.

The following stepwise approach is recommended ("Chronic obstructive pulmonary disease - Management of chronic obstructive pulmonary disease in adults in primary and secondary care,"):

- Use short-acting bronchodilator (beta agonist or anticholinergic) as required.
- If symptoms persist, use combined therapy of short-acting beta agonist and short-acting anticholinergic.
- If symptoms persist, use long acting bronchodilator (beta agonist or anticholinergic).
- If symptoms persist, consider 4-week trial of combination long acting beta agonist and inhaled corticosteroid. Discontinue if no benefit after 4 weeks.
- If symptoms persist, consider adding theophylline, which can improve FEV_1.

Tiotropium (long-acting antimuscarinic bronchodilator) has been shown to reduce COPD exacerbations and related hospitalizations compared to placebo and ipratropium (Lin, Watkins, Johnson, Rodriguez, & Barton, 2008).

Beta2-agonists and anticholinergics, are the cornerstone of COPD drug therapy. Long-acting beta2-agonists and anticholinergics reduced exacerbation rates by 20% to 25%. Inhaled corticosteroids also reduce exacerbations by up to 25%. This should not be confused with function, as COPD is by definition a progressive disease. Some studies concluded inhalers that combined a long-acting beta2-agonists and a corticosteroid (Advair, Seretide, Symbicort) are more effective than either agent alone -- reducing exacerbations by 30% (Sabroe, Parker, Calverley, Dower, & Whyte, 2008).

Since COPD is progressive, eventually, lung function will worsen, possibly to the point patients requires supplemental oxygen provided through portable or stationary tanks.

The patient should receive enough oxygen to keep the oxygen level at 65 mm/Hg ideally, or at an oxygen saturation level of at least 90%. Upward adjustments may be necessary during sleep or exertion (physical activity). Oxygen therapy does not appear to affect survival.

As chemicals and other lung irritants cause exacerbations, the patient will need instruction regarding infection avoidance. Good hygiene and hand washing techniques are necessary.

Disease managers can be instrumental for teaching home techniques like sanitation, pierced lip breathing and the need for vaccinations, such as Influenza and Pneumococcal vaccine

COPD is now suspected at age 35 or older. People under 35 are not commonly diagnosed with COPD. Women are misdiagnosed as false negatives more often than men. COPD kills more women world wide than breast and lung cancer combined (Mathers & Loncar, 2005).

New research is uncovering evidence that ethnicity may influence the development of chronic obstructive pulmonary disease (COPD) and asthma. One recent study regarding advanced COPD found African-Americans had equally severe disease as white Americans, even though they were younger, started smoking later in life, and smoked fewer tobacco products. The prevailing view is that COPD tends to be more severe in whites (Chatila, Hoffman, Gaughan, Robinswood, & Criner, 2006).

Environmental toxins play a role in COPD. People with COPD, who work where the air is toxic or contain lung irritants are advised to take measures to avoid inhalation. Some may need to find other employment, while others can change positions, or wear protective gear. Lung irritants are suspected to cause exacerbations.

Some studies addressed economic factors, but were confounded with factors such as work environment, access to care and tobacco use.

Factors Influencing Compliance and Barriers

Since COPD is caused primarily from smoking, a voluntary act, compliance and barriers fit nicely into the same category. The barriers to COPD treatment is compliance. Pain is one barrier. Patients are advised to exercise, yet exercise causes pain. Those with COPD are usually in their 50's or 60's. Their lifestyles have persisted for years. Extra considerations may be required to modify behaviors.

Due to the seriousness of chronic disease, the patient likely will have moved away from the precontemplation stage of the Transtheoretical Model, receptive to methods to quit smoking. As the patient understands his/her influence over the environment, Social Cognitive Theory is a possible method to work with lifestyle changes. The Relapse Prevention model will help maintain a smoke free environment.

In addition to smoking cessation, the COPD patient will learn breathing techniques, prevent upper respiratory infections, and avoid lung irritants. The Health Belief Model, Theory of Reasoned Action and Theory of Planned Behavior models provide more tools to accomplish behavioral goals. Each individual is different, therefore an individualized approach is useful to determine which model accomplishes the patient's goals.

In addition to social behavioral models, the disease manager has an arsenal of medical aids, including nicotine replacement devices and antidepressants, such as bupropion (Zyban), available to help the patient quit smoking.

With good patient compliance, coupled with a well-designed COPD disease management program, it is realistic to expect a higher quality of life for those diagnosed with COPD, fewer exacerbations and significantly lower treatment costs.

Risk Analysis

Information on current practices of COPD diagnosis and treatment is needed to identify opportunities for improving care. This paper outlines some clinical characteristics and selected diagnostic evaluations of COPD patients.

Individuals with COPD have obstructed airways and lungs that have lost the ability to contract. Air cannot be expelled easily, which interferes with exchange of oxygen and carbon dioxide.

COPD is the fourth leading cause of death in the U.S. costing our economy $42.6 billion in health care costs and lost productivity. (*Morbidity and Mortality: 2007 Chart Book on Cardiovascular, Lung and Blood Diseases.*, 2007). COPD caused 106,027 reported deaths in 1996, and is the only major chronic illness projected to have an increasing mortality rate over the next decade. (Regueiro, Hamel, Davis, & Desbiens, 1998) The National Health and Nutrition Examination Surveys found evidence of significant airflow obstruction in approximately one of every four adult men. (Coultas, Mapel, Gagnon, & Lydick, 2001). COPD is a major cause of chronic disability and a leading reason for visits to office-based physicians. (Verbrugge & Patrick, 1995)

For the reasons mentioned, *supra,* COPD should be studied for risk management approaches. Although it is prevalent, it is preventable and predictable. It is easily amenable to case management approaches, patient compliance and provider education. Because of the high-cost and high death tolls, it is desirable to find an approach that reduces the severity of this disease, while simultaneously cutting costs.

Most data on COPD utilization comes from studies of hospitalized patients with end-stage disease. (Regueiro et al., 1998) For a proper utilization review, parameters must be established. Spirometry is a useful tool to diagnose, understand and stage COPD. (Author, T, Personal Communication, February 19, 2010). Common identifiers of COPD, such as dyspnea (perceived difficulty breathing), coughing and wheezing, are not unique to COPD. Spirometry is necessary to confirm airflow obstruction. (Murphy, Sethi, & Niederman, 2000) Unfortunately, spirometry often is not utilized by the care providers, which can lead to misdiagnosis. One study reported 14% of the putative COPD subjects had normal spirometry results. (Mapel et al., 2000).

In addition to proper diagnosis, spirometry is useful for many other aspects of the disease, such as early detection and to identification of smokers who are at risk for decreases in lung functioning. (Thomas L. Petty & Weinmann, 1997) Surprisingly, spirometry is not used often by clinicians, while the much more expensive ECGs and chest radiographs were more common utilized. Inexpensive spirometers are available. (Mapel et al., 2000)

Just as spirometry is the most accurate and cost effective means to diagnose and monitor COPD, smoking cessation has the most potential to improve the patient's health. Smoking cessation will slow the rate of respiratory destruction. (Anthonisen et al., 1994) Furthermore, smoking causes a number of comorbid conditions, such as heart disease and cancer. (Mapel et al., 2000) Studies have shown the cost effectiveness of smoking cessations programs. (Curry, Grothaus, McAfee, & Pabiniak, 1998) Smoking cessation is essential for COPD effectiveness, therefore it must me implemented in any viable disease management program.

With the high costs, and the ability of intervene with preventative measures, chronic diseases are candidates for cost saving measures. Studies assessing the utilization of disease management models will provide necessary insight into the best methods to the cost of health care delivery, while providing optimal care.

Limitations

Behavior change variables are very difficult to control and can cause extreme variability in outcomes (Cafiero & Carness, 2001). Because COPD is caused primarily by smoking, it can be helped by focusing on smoking cessation. This also is its most important limitation. Studies show only about 24% of the people who used smoking cessation programs succeeded. (Fiore et al., 1990). This represents a substantial barrier to the effectiveness of a COPD disease management program. Careful analysis must be made in selecting an effective program tailored

for the patient. However, the process of participating in a COPD disease management program may increase the odds of quitting. Some patients, simply by learning the spirometry results showed abnormalities of lung function, had increased motivation to quit smoking, even if they had not yet developed COPD (Selecky, 2008).

Therefore, a specific weakness of this program is that it does not provide specific behavioral intervention programs. Other weaknesses include lack of methods to create shareholder buy in of the process (Eichert, Wong, & Smith) and lack of a method to track participants who are eligible for services. Practice guidelines were discussed, but without specificity (Kelly & Bernard).

Conclusion

COPD is a chronic disease on the rise. It affects men and women of all races, during the retirement years or earlier. COPD patients utilize more doctor visits and cost of care is high. Their quality of life is diminished. Many are stuck to air tanks, with reduced ability to exercise or interact with family. Exacerbations are painful and frightening. A COPD disease management program can reduce exacerbations, reduce hospital stays and increase quality of life, while reducing the cost of the disease.

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