University of Alberta

INHALATION DEVICES IN COPD MANAGEMENT

by

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Abstract

Chronic obstructive pulmonary disease (COPD) is expected to become the third most common cause of mortality in the world (GOLD Committee, 2009). COPD management continues to play a large role in everyday medical practice and inhalation therapy will continue to be a mainstay of COPD treatment. Very little is known about how prescribers choose drug-delivery devices for their clients with COPD. This study examined the current practice related to COPD inhalation devices among physicians working in a small rural community hospital. . Results showed that the most frequently prescribed device for patients was a DPI in the community setting and that nebulizers are most commonly prescribed in the emergency department. Physicians reported various factors that they consider when prescribing an inhalation device; ease of use for the patient, disease severity, cost to the patient, and therapeutic response. Physicians expressed that disease severity as the most important factor.

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CHAPTER 1:

INTRODUCTION

In this study I explored aspects of physicians' current management of patients with chronic obstructive pulmonary disease (COPD) in a small rural community hospital. This chapter briefly describes the problem, the purpose of the study, the research questions and summarizes the significance of the study.

Statement of the Problem

COPD is expected to become the third most common cause of mortality in the world (GOLD Committee, 2009). With this rising prevalence, treatment of COPD will continue to play a large role in everyday medical practice. An integral component of COPD management is drug therapy, and guidelines for the treatment of COPD continue to advocate inhaled rather than oral therapy (GOLD Committee, 2009; O'Donnell et al., 2007).

Inhalation treatments come in a variety of devices that disperse medication to the patient. This wide selection of devices can be confusing to the patient and prescriber (Newman, 2005). Device selection is now recognized as a factor that is as important as drug selection to successful clinical outcomes with COPD (Newman, 2005). The problem is that limited information is available to assist practitioners in selecting appropriate devices to deliver medication to their patients. Even less of this information is evidence based (Dolovich et al., 2005; Everard, 2001; Newman, 2005). Understanding the current practice related to device selection can help to find ways to improve the care of people with COPD.

Purpose

The purpose of this study was to add to what we know about ways to improve the care of people with COPD.

Research Questions

1. What is the current pattern of device selection among physicians for patients admitted to a small rural community hospital?
2. What factors influence prescribers' decision making in selecting specific devices for drug therapy for COPD?

I conducted a preliminary study to describe current COPD management in a small rural community hospital. The focus was on existing practice related to inhaler devices, and I explored the factors that guide physicians' decisions on inhaler devices for patients with COPD.

Background of the Problem

Healthcare professionals are becoming increasingly aware that device selection for medication delivery is as important as individual drug selection to ensure successful treatment of COPD (Newman, 2005). Drug therapy for COPD can be delivered by oral, intravenous, and inhaled routes. The inhaled route is preferred for the delivery of medications for therapy for COPD because it minimizes the side effects, and the onset of action is faster than the oral route (Newman, 2005; Thorsson & Geller, 2005; Virchow, 2005).

Various devices such as nebulizers, metered-dose inhalers (MDIs), and dry-powder inhalers (DPIs) are available for the delivery of bronchodilators and corticosteroids. Dolovich et al.'s (2005) recent systematic review of the literature

showed no significant difference among the various devices "in any efficacy outcome, in any patient group for multiple clinical situations, including COPD exacerbations," and the authors concluded that various "devices used for the delivery of bronchodilators and steroids can be equally efficacious" (p. 335). With supporting evidence that all devices have the potential to be equally efficacious, it is left up to the individual medical practitioner to decide which device to use for specific clinical situations.

The proliferation of new inhaler devices has resulted in a confusing number of choices for practitioners, and there is a lack of evidence-based guidelines to aid clinicians in making these choices for their patients (Dolovich et al., 2005). The Canadian Thoracic Society's (CTS's) recommendations for COPD management offer no guidance to clinicians in selecting drug-delivery devices (O'Donnell et al., 2007). The Global Strategy for the Diagnosis and Management and Prevention of COPD (GOLD) report is ambiguous with regard to device selection: "The choice of inhaler device will depend on availability, cost, the prescribing physician, and the skills and ability of the patient" (GOLD Committee, 2009, p. 51). Treatment guidelines clearly lack adequate recommendations on inhaler choice (Virchow, 2005). As well, few researchers have examined the importance of device selection specific to COPD patients (Chapman, Voshaar, & Virchow, 2005; Dolovich et al., 2005; Newman, 2005; Thorsson & Geller, 2005; Virchow, 2005). Other researchers have compared the device selection for asthma patients to that of COPD patients. Nonetheless, applying the recommendations from the research on asthma to

practice with COPD ought to be done with caution because most patients with COPD present with unique characteristics such as advanced age and multiple co-morbidities that determine device selection (Chapman, Voshaar, & Virchow, 2005).

Significance of the Study

Clear practice guidelines support healthcare professionals in their practice, and unambiguous information can aid practitioners in properly selecting an inhalation device for their patients for successful outcomes in COPD management. An important initial step in understanding and improving device selection for COPD patients is identifying what physicians in a rural community currently use to guide their choices. Research on asthma patients has implied that suboptimal device techniques are correlated with poor outcomes, but "less is known about the impact of inhaler choice and inhaler handling on outcomes of patients with chronic obstructive pulmonary disease" (Chapman, Voshaar, & Virchow, 2005, p. 121). COPD management will continue to be a significant part of medical practice because rates of the disease are expected to rise as the population ages and with increased rates of smoking in certain countries (GOLD Committee, 2009). COPD is a chronic disease with an "inherently deteriorating trajectory" (Osman & Hyland, 2005, p. 91), and medication therapy plays a pivotal role in palliating the symptoms and slowing down the disease process. The findings of this study foster a greater understanding of how physicians select certain medication devices and the factors that they consider in prescribing various delivery devices to patients with COPD exacerbations. It is valuable for

health professionals to learn more about the importance of device selection, which is key to the successful treatment of COPD (Newman, 2005).

Implications for Research and Practice

Understanding current practice related to device selection for patients will help to find ways to advance the care of COPD patients. The new information gained from this study will inform local healthcare managers about actual practice related to device selection in their facility. It will also give these leaders insight into how community physicians select devices for their patients. This research focused on physicians and the discipline of medicine, but the findings of this study are expected to benefit the discipline of nursing as well. More often now nurses hold prescriptive authority as nurse practitioners. The health center in this study employs two nurse practitioners who prescribe COPD devices to patients. The findings of this study will inform them about local device-selection practices.

There is a paucity of information on the impact of device selection related to COPD outcomes, including the quality of life and exacerbation rates. Further research is needed in this area. The next step may be to expand future research to evaluate these effects.

CHAPTER 2:

LITERATURE REVIEW

In this chapter I review the applicable research on device selection for COPD patients. The chapter begins with the search strategy that I used to find literature on device selection. Next, I discuss the current understanding of epidemiology, pathophysiology, and COPD management and the pharmacokinetics of drug deposition and caregivers' knowledge of device selection. Finally, I present the literature on drug-delivery devices and device selection.

Search Strategies

I undertook a literature review to explore the available data on device selection for obstructive airway disease. The databases that I explored included All EMB Reviews, Embase, and Medline, and I incorporated the following key words into the search: *inhaler** or *vaporiser** or *vaporizer* or *nebuliser* or *aerosol device*; *chronic obstructive* or *asthma* or *bronchitis* or *emphysema* or *COPD*; and *decision** or *choice** or *choos** or *select** or *prefer**. I also conducted a hand search of key articles. I excluded all non-English publications from this review.

Epidemiology of COPD

The global burden of COPD is growing. In 1990 COPD ranked in sixth place for global cause of death, but experts predict that by 2020 COPD will become the third most common cause of death worldwide, largely because of the aging population, who are living longer (GOLD Committee, 2009). The World Health Organization ([WHO] 2007) estimated that 80 million people have

moderate to severe COPD, and in 2005 three million people worldwide died of the disease. Mortality rates increase sharply for people aged 75 and older. With the increasing numbers of Canadians in the over-65 age group, the mortality rates are expected to continue to increase, and this is especially evident among women (O'Donnell et al., 2007).

COPD is a costly disease to treat. In Canada the costs amount to $1.6 billion per year (Canadian Lung Association [CLA], 2003). The costs related directly to managing exacerbations comprise a significant amount of the total monetary burden of managing COPD. The costs of moderate and severe exacerbations have been estimated at between $646 million and $736 million per annum (Mittmann et al., 2008). Not all costs related to exacerbations are preventable, but a significant amount may be avoided if more attention is given to proper device handling. Ramsey (2000) reported that patients' improper use of inhalers is a type of non-adherence to therapy, which leads to suboptimal COPD management and ultimately increases the cost of COPD care.

Pathophysiology

COPD is defined as a "respiratory disorder largely caused by smoking, and [it] is characterized by progressive, partially reversible airway obstruction and lung hyperinflation, systemic manifestations, and increasing frequency and severity of exacerbations" (O'Donnell et al., 2008, p. 2A). This disease is included under the umbrella of obstructive pulmonary disease, for which cigarette smoking is the "most commonly encountered risk factor" (GOLD Committee, 2009, p. 16). Cigarette smoking is estimated to cause 80% to 90% of the cases

(CLA, 2010a). Other factors seem to play a role, including genetics, occupational air pollution, gender, age, respiratory infections, socioeconomics, nutrition, and co-morbidities.

Generally, people who have COPD notice the symptoms of the disease process, including shortness of breath, wheezing, and coughing, at any time from the age of 40 onward (CLA, 2010b). Cigarette smoke and other irritants are inhaled into the lungs and cause inflammation of lung tissue, which seems to be more evident in patients with COPD, which has led to a theory of genetic predisposition. Exacerbations compound this lung inflammation and increase disease progression (GOLD Committee, 2009).

Patients with COPD manifest typical physiologic changes, including mucous hypersecretion, airflow limitation, air trapping, hyperinflation, gas exchange abnormalities, and cor pulmonale. The inflammatory process in COPD follows a predictable pattern. Inflammatory cells typically include increased numbers of neutrophils, macrophages, CD8 cells, and lymphocytes. Inflammation and airway narrowing cause a decrease in the forced expiratory volume (FEV1). The inflammation seen in COPD differs from that of asthma and ultimately dictates drug selection and response to the treatment (GOLD Committee, 2009). Numerous other co-morbid conditions tend to exist along with COPD, including ischemic heart disease, osteoporosis, cachexia and malnutrition, anemia, peripheral muscle dysfunction, cancer, and metabolic syndrome. Depression and anxiety are also common (O'Donnell et al., 2008).

COPD Treatment

COPD is a chronic lung disease, and as with many other chronic diseases, treatment is aimed at preventing the disease's progression rather than a cure. According to the CTS, the goals of COPD management include measures to (a) prevent disease progression, including smoking cessation; (b) reduce the frequency and severity of exacerbations; (c) alleviate breathlessness and other respiratory symptoms; (d) improve exercise tolerance and daily activity; (e) treat exacerbations and complications of the disease; (f) improve health status; and (g) reduce mortality (O'Donnell et al., 2007, p. 11B).

COPD is treatable at any stage of the disease process. Management involves a comprehensive approach that includes education, smoking cessation, vaccination, pulmonary rehabilitation, oxygen therapy, and pharmacotherapy. Pharmacotherapy plays a major role in the long-term management of COPD, and bronchodilators are the mainstay of therapy throughout all stages (O'Donnell et al., 2007). Inhaled corticosteroids are indicated for the management of moderate and severe disease. The inhaled route, rather than the oral, is preferred because of an increased onset of action, direct localized therapy, and decreased systemic side effects. Therapy is guided by the assessment of the symptomatology, the disease's severity, spirometry, and the frequency of exacerbations (O'Donnell et al., 2008). The severity of the disease is measured according to the Medical Research Council's Dyspnea Scale (Appendix A) and Spirometry (Appendix B).

According to the GOLD Committee (2009), the intention of pharmacological therapy is to "prevent and control symptoms, reduce the frequency and severity of exacerbations, improve health status, and improve exercise tolerance" (p. 49). Pharmacotherapy does not reverse the disease's progression but, rather, helps to control the symptoms and improves the patient's quality of life. Generally, medication treatment tends to be cumulative and long term. The main classes of medication therapy are bronchodilators, including Beta-2 agonists and anticholinergics. Other treatments include glucocorticosteroids and theophylline (GOLD Committee, 2009; O'Donnell et al., 2007). The guidelines emphasize a comprehensive stepwise approach to introducing drug therapy (Appendix C).

Regardless of the type of prescribed medication, instructing patients on how to use the device is essential and a component of the GOLD Committee's (2009) educational recommendations. Inadequate inhaler instruction results in poor technique and is known to be a major cause of poor disease control in asthma patients (Virchow et al., 2008). Previous patient competence in using the device does not predict proper use in the future (Virchow et al., 2008). It is therefore important to regularly review patients' technique.

COPD Treatment: Drug Categories

Bronchodilators are "medications that increase the FEV_1 or change other spirometric variables, usually by altering airway smooth muscle tone" (Calverley, 2003, p. 358). Bronchodilators include two major classes of medication: inhaled Beta-2 agonists and inhaled anticholinergics. Beta-2 agonists relax the airway

smooth muscle by stimulating Beta-2 adrenergic receptors, and anticholinergics block acetylcholine's effect on M3 receptors, which both result in bronchodilation. Long-acting B-2 agonists improve health status, and long-acting anticholinergics reduce the rate of exacerbations. Bronchodilators are effective in the management of exacerbations. Generally, short-acting Beta-2 agonists are the preferred choice for exacerbations, but short-acting anticholinergics may be added if the patient does not respond to Beta-2 agonists. The adverse effects of Beta-2 agonists include tachycardia, arrhythmias, and tremor, and the main side effect of inhaled anticholinergics is a dry mouth (GOLD Committee, 2009).

Glucocorticoids in COPD are not indicated as monotherapy as they are in asthma. There is strong evidence that combination therapy including an inhaled glucocorticoid and a long-acting Beta-2 agonist is more effective in preventing exacerbations and improving lung function and health status than is separating the drugs on their own. Most studies have shown that glucocorticoids alone do not modify long-term decline in lung function, but they have been shown to reduce the frequency of exacerbations and improve health status for patients with an FEV_1 of less than 50% predicted. In an acute exacerbation of COPD, oral glucocorticosteroids are preferred to the inhaled route. The long-term effects of inhaled corticosteroid therapy in COPD patients include oral candidiasis and decreased bone mineral density (GOLD Committee, 2009).

Drug-Delivery Devices for COPD

Inhaled therapy for the treatment of obstructive lung disease was first developed 50 years ago and will continue to be fundamental in the management

of obstructive airway disease (Virchow, 2005). Advances in the technology used in inhaled drug therapy have attempted to address some of the difficulties with inhaled therapy, including improper inhalation technique and the need to replace chlorofluorocarbon (CFC) propellants. This has led to an increased availability of add-on devices, breath-actuated MDIs, DPIs, and non-CFC MDIs (Anderson, 2005). The technology for inhalation delivery systems for the treatment of obstructive diseases continues to evolve at a rapid pace, and many different types of drug/inhaler devices are now available for the prescriber to choose.

A nebulizer is an instrument that converts liquid medication into its aerolized form, which the patient then inhales through either a mask or a mouthpiece. Because the nebulizer creates large particles, most of them are deposited in the large airways or the oropharynx. Nebulizers come in two forms: an ultrasonic system that creates aerolized medication by sound vibrations and a jet nebulizer that uses compressed air to mix with the liquid medication and thereby creates aerolized particles. The disadvantages of nebulizers are that they are bulky, most types need a power source, and they require regular maintenance (Meadows-Oliver & Banasiak, 2005). The largest advantage of nebulizers is that they do not require coordination, and medication can be delivered by simply breathing in and out; therefore, optimum patient cooperation is not required (Dolovich et al., 2005). This can be especially important when the patient is acutely ill and unable to follow complex instructions.

MDIs consist of a canister with an aerosol that contains a propellant and medication. The canister is attached to a plastic sleeve with a mouthpiece. The

advantage of MDIs is their portability; however, many researchers have discovered that patients find it difficult to coordinate the timing of the actuation of the device with inhalation, which causes only a partial dose to reach the lungs (Dolovich et al., 2005). Molimard et al. (2003) found in their observational study of 3,811 patients in a primary care setting that the patients made more errors with MDIs (76%) than with DPIs (49%-55%). Khassawneh et al. (2008) uncovered similar findings: The highest error rate was in the MDI group (74.6%) compared to the DPI, which had the lowest rate of errors at 6.8%. The patients also handled the Turbohaler and Aerolizer incorrectly 43.2% of the time. The most common mistakes that the patients made were failing to trigger the device and simultaneously breathe in (67.4%) and omitting the step of shaking the canister device (42.5%; Khassawneh et al., 2008). Spacer devices, which fit onto the mouthpiece of an MDI, have been created to deal with the difficulty of coordinating the actuation of the device with inhalation. Although spacers increase the proportion of medication that reaches the lungs (Meadows-Oliver & Banasiak, 2005), the addition of a spacer device on the MDI makes the treatment more expensive and less portable than using the MDI alone (Dolovich et al., 2005).

DPIs are *breath actuated*, which means that they provide a drug in a dry micronized powder only when the patient triggers the mechanism by inhaling. The primary advantage of this system is that it avoids the actuation-breath coordination required for MDIs, but the patient is required to have a moderate to high inspiratory flow for actuation of the DPI, which can be a limitation for some

patients. Dolovich et al. (2005). The Turbohaler and diskus have inherently different resistances to inspiratory flow. The Turbohaler requires an optimal inspiratory flow rate of 60L/min, and the discus, 30L/min (Amirav, Newhouse, & Mansour, 2005; Turner & Jensen, 2008). This is an important consideration, especially with elderly patients Janssens et al. (2008) found that 30% of elderly patients, regardless or whether or not they had COPD, were not able to generate sufficient respiratory flow rates with a Turbohaler. I have adapted a comprehensive list of the advantages and disadvantages of various devices from Dolovich et al. (2005) with permission (Appendix D).

Pharmacokinetics: Drug Deposition in the Lung

Understanding the pharmacokinetics of relative drug deposition from different delivery devices is valuable to the practitioner. Urinary pharmacokinetic methods have been used to determine post-inhalation lung deposition for different delivery devices used in COPD treatment. Urinary excretion of salbutamol in the first 30 minutes is a useful marker of bioavailability of drug in the lungs, and 24-hour urinary excretion of salbutamol and its metabolite is an indicator of total systemic delivery (Hindle, Parry-Billings, & Chrystyn, 1997; Mazhar, Ismail, Newton, & Chrystyn, 2008).

Mazhar et al. (2008) compared the lung deposition of 100 mcg of salbutamol inhaled from an MDI and spacer (MDI+SP) and 5mg of salbutamol inhaled from a jet nebulizer (NEB) and found similar lung deposition between the two devices. Urine excretion of salbutamol was 13.1mcg and 14.4mcg for the MDI+SP and NEB, respectively (Mazhar et al., 2008). Silkstone, Corlett, and

Chrystyn (2002) have also observed differences in the pharmacokinetics of inhaled salbutamol with an MDI, MDI+SP, and NEB. The 30-minute excretion of urinary salbutamol was 12.6 ±3.5 for the MDI, 27.1±6.0 for the MDI+SP, and 16.1±4.6 for the NEB. The 24-hour urine excretion of salbutamol and indicator of systemic absorption was 287mcg±46.5 for the MDI, 198.1mcg±34.7 for the MDI+SP, and 253.4mcg±138.3 for the NEB. This indicates that the MDI+SP delivered more drug to the lungs and less to the systemic circulation than the MDI alone or the NEB did.

Borgstrom (1998) compared lung deposition of salbutamol by various devices. Healthy patients who were 'good coordinators' were able to achieve 18.6% of drug deposition from an MDI compared to only 7.2% for patients who were 'poor coordinators.' This researcher did not explicitly define poor coordinators in the experiment, but they were patients whom Borgstrom determined before the experiment used an insufficient inhalation technique. Two other devices that were compared, the diskhaler and the Turbohaler, achieved 12.4% and 23.2%, respectively (Borgstrom, 1998). In this study the Turbohaler achieved the highest concentrations of lung deposition.

Selection of Drug-Delivery Device

Newman (2005) recognized that device selection is as important as drug selection for the effective treatment of COPD. Physicians are responsible for selecting not only the correct drugs for their patients based on their clinical situation, but also the most appropriate device. The events of the influenza pandemic urgently brought the relevance of this to our attention.

Infection-control awareness, practices, and responses have been amplified in response to the recent worldwide pandemic of influenza. Locally, Alberta Health Services (AHS) has issued a memorandum advising that "all inhaled medications should be ordered by MDI rather than by nebulizer wherever possible" (P. Lynkowski, personal communication, November 6, 2009). The reason for the switch to MDIs includes minimization of the risk of transmission of pathogens, which has been important in the recent influenza outbreak. Similar actions to those of AHS have been evidenced in Hong Kong, where medical staff used the MDI+SP instead of the nebulizer during an outbreak of severe acute respiratory syndrome (Khoo, Tan, Said, & Lim, 2009). Now more than ever, hospital administrators, physicians, and allied healthcare staff are analyzing the selection of devices.

Many studies and systematic reviews have shown that all devices can be equivocal (Dolovich et al., 2005). This may lead prescribers to conclude that the appropriate selection of a device ought not to matter. Many clinical trials that compare treatments include only subjects who are highly trained in the particular device used in the study or exclude subjects who use a suboptimal technique (Molimard et al., 2003). This does not provide physicians with 'real-world' evidence that they can apply to their patients (Molimard et al., 2003). Relatively little is known about how practitioners select inhalers, but "anecdotal evidence suggests that many practitioners choose to become familiar with a single type of inhaler and prescribe it exclusively" (Chapman, Voshaar, & Virchow, 2005,

p. 119). They then "delegate the task of monitoring inhaler technique to others" (p. 119).

Few guidelines contain useful information to assist prescribers in selecting devices for patients with COPD. Chapman, Voshaar, and Virchow (2005) cautioned physicians about the practice of extrapolating information from asthma guidelines and applying it to patients with COPD. The CTS's guidelines for COPD include relatively clear recommendations for drug selection, but the information on device selection is nebulous (O'Donnell et al., 2007). The GOLD guidelines offer limited direction in relation to device selection:

> The choice of inhaler device will depend on availability, cost, the prescribing physician, and the skills and the ability of the patient. . . . COPD patients may have more problems in effective coordination and find it harder to use a simple metered dose inhaler (MDI) than do healthy volunteers or younger asthmatics. (GOLD Committee, 2009, p. 51)

The GOLD report does not recommend wet nebulizers for regular treatment because they are more expensive and require "appropriate maintenance" (p. 51). Although this offers some guidance, it still leaves prescribers without practical advice on which device/drug combinations would best suit their individual patients. Appendix E contains a list of maintenance and appropriate techniques for various devices.

The most comprehensive guideline for device selection is that from the American College of Chest Physicians and the American College of Asthma, Allergy, and Immunology (ACCP/ACAAI) (Dolovich et al., 2005). The guideline includes a systematic review and a comparison of the efficacy of various devices across a wide variety of clinical settings for both asthma and COPD.

Dolovich et al. (2005) reviewed seven studies to determine the differences among the device outcomes for B-2 agonists and anticholinergics in the outpatient setting. A pooled analysis of these studies revealed no differences among the nebulizer, MDI, and MDI+SP. In the inpatient setting they also found no difference between a nebulizer and an MDI+SP. However, few studies in this meta-analysis included patients with COPD. Dolovich et al. also stated that the data on combination products, steroid preparations, and delivery systems that administer long-acting bronchodilators are very limited; therefore they offered no recommendations for their use.

Dolovich et al.'s (2005) review offers clinicians some practical advice in prescribing COPD medications. The results of this review are not to be interpreted to mean that device selection is insignificant; rather, they simply mean that all devices can work equally well for patients who can use them appropriately. The guideline does not favour one device over another, but asks clinicians to consider the following in prescribing medication:

1. In what devices is the desired drug available?
2. What device is the patient likely to be able to use properly, given the patient's age and the clinical setting?
3. For which device and drug combination is reimbursement available?
4. Which devices are the least costly?
5. Can all types of inhaled asthma/COPD drugs that are prescribed for the patient (e.g., Short-acting B-agonist, corticosteroid, anticholinergic, and long-acting B-agonist) be delivered with the same types of device (e.g., Nebulizer, manually actuated MDI, MDI with spacer/holding chamber, or breath-actuated device [i.e., automatically activated MDI or DPI]? Using the same type of device for all inhaled drugs may facilitate patient teaching and decrease the chance for confusion among devices that require different inhalation techniques.
6. Which devices are the most convenient for the patient, family (outpatient use), or medical staff (acute care setting) to use, given the

time required for drug administration and device cleaning, and the portability of the device?
7. How durable is the device?
8. Does the patient or clinician have any specific device preferences? (p. 367)

Chapman, Voshaar, and Virchow (2005) expanded on the ACCP/ACAAI's guideline by suggesting an algorithmic approach that includes all of the steps that the ACCP/ACAAI proposed. Chapman, Voshaar, and Virchow also recommended the assessment of the following: patients' inspiratory flow with an inhalation monitoring device, ability to coordinate actuation and inspiration, and ability to prepare the device and take other steps such as shaking the canister and holding the breath for 10 seconds.

Patients' correct use of a device is well known to be suboptimal (Brennan, Osman, Graham, Critchlow, & Everard, 2005; Coady, Davies, & Barnes, 1976). The most commonly recognized error in device handling is in coordinating the device's actuation and inhalation (Coady et al., 1976). Prescribers need to consider the patient's ability to use a device correctly, the patient's preference, and the likelihood of compliance (Chapman, Voshaar, & Virchow, 2005; Dolovich et al., 2005; Newman, 2005; Osman & Hyland, 2005). COPD patients have special considerations compared to asthmatic patients in that they tend to be older and have more co-morbidities such as arthritis, which will affect their ability to actuate an MDI device. Also, patients with COPD tend to have diminished inspiratory flow rates, and the most serious error with DPIs occurs when they are unable to generate a sufficient inspiratory flow rate because it diminishes the drug deposition to the lower airway (Chapman, Voshaar, & Virchow, 2005).

Patient preference is an important factor in device selection. COPD patients show loyalty to particular devices even when they are not fully competent in using the device (Osman & Hyland, 2005). Evidence has revealed that if patients prefer a particular device, they are more likely to adhere to that device (Lenney, Innes, & Crompton, 2000).

According to Dolovich et al. (2005), cost ought to be a factor in selecting aerosol delivery devices. The current cost of salbutamol outpatient treatment at regular doses of one to two puffs QID without a spacer is $19 dollars per month, compared to $94/month for ventolin nebules (Turner & Jensen, 2008). Various studies have compared the in-hospital cost difference between an MDI+SP combination and a wet nebulization and have found that the cost of the MDI+SP is considerably less than that of a wet nebulization (Bowton, Goldsmith, & Haponik, 1992; Japer, Mohsenifar, Kahan, Goldberg, & Koerner, 1987; Numata, Bourbeau, Ernst, Duquette, & Schwartzman, 2002; Turner, Gafni, Swan, & Fitzgerald, 1996). The savings are related primarily to the increased cost of staff time to administer wet nebulizations. Numata et al. determined the amount of teaching time required for patients to utilize MDI+SP devices and reported that the total median time required for initial instruction was 6.5 minutes. They considered this time well within the capacity of their emergency room staff.

The costs of tiotropium and ipratropium are $82 and $26-$32 per month, respectively (Turner & Jensen, 2008); tiotropium is significantly more expensive than ipratropium. Oostenbrink, Rutten Van Molken, Al, Van Noord, and Vincken (2004) compared the costs and took into account the differences among the

groups in their study with regard to hospital admissions, hospital days, and unscheduled visits to healthcare providers and found that the cost of tiotropium was partly offset by improved health outcomes. A list of various drug and device costs is located in Appendix F.

The GOLD Committee (2009) has set COPD guidelines for pharmacotherapy that is known to decrease the number of exacerbations and hospitalizations and delay the time of first or next hospitalization. These include long-acting bronchodilators, inhaled glucocorticoids, and combination inhalers. Reducing the number of hospitalizations decreases the cost of COPD management. Recently, the Therapeutic Research Center's (2010) Understanding Potential Long-Term Impacts on Function With Tiotropium study showed that tiotropium decreased the mean number of exacerbations and the risk of exacerbation-related hospitalizations by 14% compared to a placebo. A subsequent meta-analysis showed that tiotropium is "associated with a decreased risk of all-cause mortality, cardiovascular mortality, and cardiovascular events compared to placebo" (p. 2).

Caregivers' Knowledge of Inhalers

Unfortunately, studies have shown that medical professionals are uninformed on correct device techniques (Hanania, Wittman, Kesten, & Chapman, 1994; Owayed, Al-Ateeqi, & Behbehani, 2006). Hanania et al. studied the knowledge and ability of various medical professionals, including physicians, respiratory therapists, and registered nurses, to use three common inhalation devices. They found that many medical professionals lack "rudimentary skills"

(p. 111) to use the devices and that nurses and physicians rarely receive formal training in the correct use of inhalation devices. Although this study is several years old, the results from Owayed et al.'s recent study of pediatricians are similar. They found that 35.2% of pediatricians who were evaluated for the proper use of MDIs performed at least five steps incorrectly.

Medical practitioners receive very little in the way of training on device use. Jackevicius and Chapman (1999) compared the effectiveness of different types of device training that pharmacists receive. In this randomized control trial they placed pharmacists into two groups; one group received more intensive training that included a 'hands-on' component, and the other received written materials. Jackevicius and Chapman found that the individual, hands-on approach resulted in greater knowledge attainment than did the written materials, but that this difference was temporary, and that there was less difference between the two groups when they were evaluated three months later.

Summary of Key Points

COPD is a growing health concern and a costly disease to treat. Its characteristics differ from those of other obstructive lung diseases, including asthma. The two diseases differ in pathophysiology and are not treated in the same manner. They also affect differing cohorts: COPD patients tend to be older and have increased rates of co-morbidity. Because of these differences, it is undesirable to apply what we know about inhaler device selection for asthma patients to those with COPD.

The mainstay of COPD management includes inhaled anticholinergics, Beta-2 agonists, and steroids. Medication management can reduce the number of exacerbations and potentially leads to decreased costs and improved quality of life. A vast selection of device/drug combinations is available for prescribers to choose, but, unfortunately, research has shown that healthcare providers' knowledge of inhaler devices is poor. Patients are also known to demonstrate suboptimal device-handling techniques.

Drug deposition studies have revealed that various devices can alter the amount of drug that reaches the lungs, which indicates that the device selection is critical in COPD therapy. Yet guidelines offer few practical steps to support physicians in their task of prescribing inhaler devices. Minimal research is available on how physicians make these choices. Dolovich et al. (2005) suggested a stepwise approach to device selection that includes considerations such as the availability of drugs/device combinations, the durability of the device, the likelihood of its proper use, and the cost. Others have expanded on these factors to include patients' inspiratory flow and their ability to prepare and actuate their devices with the required amount of coordination. In this study I addressed some of the gaps in the research on device selection, and I will present some preliminary information on the methods that physicians use to decide which devices to prescribe for their patients.

CHAPTER 3:

METHODS AND PROCEDURES

In this chapter I present the design of the study, the population, and the sample and measurement strategies, including the development of a questionnaire. I also discuss the characteristics of the sample, the data collection, and the process of reviewing charts.

Study Design

This study was guided by two research questions: What is the current pattern of device selection among physicians for patients admitted to a small rural community hospital? And what factors influence prescribers' decision making in selecting specific devices for drug therapy for COPD? I used a descriptive design to answer the study questions. To answer the first study question I collected data from a retrospective chart review, and to answer the second question I conducted a survey of physicians.

Study Setting

I conducted the study in a small rural community hospital and physician offices in the local area. The facility holds 72 beds: 20 acute care beds, 2 maternity suites, and 50 continuing care beds (E. Billay, personal communication, January 7, 2009. The hospital offers multiple services, including acute care, continuing care, and 24-hour emergency services.

Chart Review to Identify Current Practice:

Sample, Instrument, and Procedure

I reviewed the charts at the small rural community hospital. The hospital is located in the local area of Edmonton, Alberta. In the health center's Medical Records Department I accessed inpatient charts dated from January 2008 to June 2008 (six months) and analyzed all charts with a COPD diagnosis, either primary or secondary. I planned to recruit a sample size of 100 charts. The information in the health center charts included patients' demographics, admitting diagnoses, secondary diagnoses, and any co-morbidities. I included only charts that met the criteria for admission into the study.

I used a data-collection tool (Appendix G) to guide data collection from the chart review including: the specific drug/device combinations for preadmission, in the emergency room, during admission, and at the time of discharge, as well as the details on any changes made to the patients' inhalation therapy and the reasons for changes. I also noted the patients' education on the use of the device. Other information that I gathered included patients' primary/ secondary diagnoses which also included co-morbidities, length of hospital stay, and lists of other medications (by drug class) that the patients were prescribed. However, I collected no information that could be used to identify any of the patients; I used numeric codes to identify the cases. I entered all of this information into an Excel data file to eliminate the use of paper copies of the data extraction tool. As the principal investigator in this research, I collected all aspects of the chart data and conducted the chart analysis in the medical records

department of the health center. I tasked the medical records clerks with pulling the charts (with permission from the site director of the health center).

Administration of a Questionnaire to Identify Physicians' Selection Strategies: Sample

The target population for this study was general practitioner physicians who were practicing in the hospital and the local area, including office settings in the two towns nearby. I used convenience sampling and obtained a list of practicing physicians by contacting the physician liaison person in the health center. The inclusion criteria for this study were general practitioner physicians who worked either in the health center or in clinics in the local area, including the two towns nearby and who were providing care to patients with COPD. I expected a sample size of 40 physicians and a response rate of 60%, based on similar research. (Tein, Dorfman, Kastner, & Bauchner, 2001). I sent each physician in the sample a questionnaire and asked any physicians who did not wish to participate or who were not providing care to COPD patients to return the survey to indicate that they did not wish to participate.

Data-Collection Tool

After an extensive literature review I found no prior data-collection tools or self-report physician surveys related to the prescribing factors with COPD. Tein et al. (2001) administered a self-reported questionnaire to determine emergency room physicians' misconceptions about the advantages and disadvantages of an MDI+SP for children with acute asthma exacerbations. I obtained the survey questions from Dr. Tein via e-mail, along with permission to

adapt the questionnaire to this study, and I reconstructed some of the questions to reflect the needs of the current inquiry. I piloted the survey with a pulmonologist and two respiratory therapists from the health center. I then considered the recommendations from this pilot and revised the questionnaire before I sent it to the physicians. A short description of the study and a copy of the questionnaire are included in Appendixes H and I, respectively.

Procedures

Upon receipt of ethics approval from the Ethic Review Board and official agency approval, I asked the hospital administrators' support staff to notify the physicians about the upcoming study electronically. In addition, I posted notices about the study in key sites (Appendix J). I sent an electronic copy of the survey to all physicians who were practicing in the study settings using the software Survey Monkey to allow the electronic return of the completed questionnaires. I also placed a paper copy of the survey in the mailboxes of all physicians who were practicing in the health center and asked them to submit the survey either electronically or in the provided envelope as a hard copy to my mailbox, located in the hospital physicians' lounge. The remainder of the physicians who practiced in the community also received a paper copy of the survey, which I dropped off at the various clinics. I asked the physicians to return the completed surveys via Canada Post; I included a self-addressed envelope for their convenience. Three weeks after the first mailing, I again sent out both the electronic and the paper survey, which both included a short description of the study.

Data Analysis

The data analysis was largely descriptive in nature, and I analyzed both the chart review and the survey data. For the chart review I tabulated the frequencies for the demographic data, the primary admission diagnosis, and the secondary admission diagnosis and noted the means and standard deviations of the demographics. I then calculated the percentages of the various devices that the patients used prior to admission, in the emergency room, during admission, and upon discharge. I determined the number of patients on the various drug types, which included short-acting bronchodilators (SABAs), long-acting bronchodilators (LABAs), short-acting anticholinergics, long-acting anticholinergics, combination products, steroid inhalers, oral steroids, and theophylline. I then calculated the response rates for the questionnaire. Subsequently, I tabulated the frequencies for all of the data from the questionnaire, along with the means and ranges of the demographic data.

Ethics Review

I obtained approval for this study from the University of Alberta ethics review board and Alberta Health Services ethics review committee. I gave the potential respondents to the survey the option of not participating by indicating so in the box on the front page of the document and returning the survey uncompleted. All of the physicians' responses were anonymous because I did not record any identifying data on the questionnaire; furthermore, Survey Monkey, an intermediary software program, collected the responses electronically and did not at any time identify the participants' names. Only I conducted the chart review in

the medical records department of the health center. At no point did I remove any of the charts from the medical records area for the purposes of this study. The patients remain anonymous, identified only by a numerical code. After I received ethics approval, I sent out the questionnaires and began the chart review.

CHAPTER 4:

FINDINGS

In this chapter I present a profile of the sample from both the chart review and the physician survey. I also present the results and statistical analysis of the chart review and physician survey.

Chart Review

Sample

I reviewed a total of 65 hospital-admission charts over the six-month period of January 1 to June 30, 2008. One patient was admitted to the health center on four separate occasions during this period, and another patient was admitted twice. In summary, 59 patients had a single admission and 2 had multiple admissions. Although a total of 97 admissions occurred during the six-month period, 32 charts were not available from the Medical Records Department for review. All of these chart records were for patients who had deceased.

Sample Characteristics: Age, Sex, and Length of Stay

The mean age of the patients in the study was 75 years (SD = 10.7), and the ages ranged from 50 to 98 years. The chart admissions were for 35 (54%) females and 30 (46%) males (Table 1). The average length of stay was 8 days (SD = 11), and the range was from 1 to 64 days.

Reason for Admission

The most common primary diagnosis documented for hospital admissions for patients with COPD in this study was pneumonia (n = 26; 40%). The second most common primary diagnosis was categorized as *other* (n = 21; 32%), which

Table 1

Sample Characteristics

Characteristics	n	%
Age in years: M (SD)	10.7	75.8
Female	35	54%
Male	30	46%

included diagnoses of dementia, falls, acute myocardial infarct, cellulites, gout, hip arthroplasty, gastro-intestinal bleeds, transient ischemic attack, compression fracture, C-difficile colitis, and sciatica. The primary diagnosis for 23% of the admissions was COPD exacerbation and for 9% of the 65 admissions, heart failure (Table 2).

Table 2

Clinical Characteristics

Characteristic	Response count	%
Smoking status		
Current	18	30
Quit	35	57
Missing data	8	13
Length of stay in days: M (SD)	11.8	8.3
Primary diagnosis		
Pneumonia	26	40
Other	21	32
COPD exacerbation	15	23
Heart failure	6	9
Secondary diagnosis		
COPD	50	77
Renal failure	28	43
Coronary artery disease	25	38
Hypertension	23	35

(table continues)

Characteristic	Response count	%
Number of co-morbidities		
0	0	0
1	7	11
2	12	18
3	23	35
4	13	20
5	9	14
6	1	2

In the sample of charts, most (89%) recorded ≥2 co-morbid conditions, and all recorded at least one additional secondary diagnosis. The secondary diagnosis included either a second reason for admission or co-morbidity with which the patient had been previously diagnosed. The most frequent secondary diagnosis other than COPD (n = 50; 77%) was renal failure (n = 28; 43%). Other major diagnoses included coronary artery disease (n = 25; 38%) and hypertension (n = 23; 35%).

Devices and Pharmacotherapy

The chart review revealed that 26% of the patients had either two or three different home devices that they used to treat their COPD; 29% did not use any devices at home (Table 3). The most commonly prescribed medications for home were a combined long-acting B_2 agonist and inhaled corticosteroid (LABA/ICS; n = 21; 32%) and SABD (n=21; 32%). LAAC were also frequently prescribed (n=20; 31%). See Table 4.

Once the patients presented to the emergency room, they were most commonly prescribed a short-acting bronchodilator (SABD; n = 46; 71%). Systemic corticosteroids were also frequently administered (n = 20; 31%). Once

Table 3

Number of Devices

Number of devices	Response count	%
0	19	29
1	24	37
2	16	25
3	1	1
Missing	5	8

Table 4

Pharmacotherapy

	Home		Emergency		Hospital		Discharge	
Pharmacotherapy	n	%	n	%	n	%	n	%
No therapy	19	29	8	12	6	9	8	12
SABD	21	32	46	71	50	77	31	48
LABA	5	8	5	8	6	9	4	6
ICS	3	5	16	25	8	12	4	6
LAAC	20	31	5	8	23	35	35	54
LABA/ICS	21	32	6	9	19	29	26	40
Systemic corticosteroid	1	2	20	31	20	31	5	8
Theophyline	4	6	4	6	4	6	4	6
Missing data	3	5	2	3	0	0	11	17

Note. SABD: Short-acting bronchodilator (Ipratropim, Salbutamol); LABA: Long-acting beta-2 agonist (Serevent); ICS: Inhaled corticosteroid (Flovent, Pulmicort); LAAC: Long-acting anticholinergic (Tiotropium); LABA/ICS: Long-acting beta-2 agonist/inhaled corticosteroid (Advair, Symbicort).

the patients were admitted, the most common respiratory drug prescribed was again a SABD (n = 50; 77%). The most commonly prescribed medications for discharge from hospital were a LAAC (n = 35; 54%) and a SABD (n = 31; 48%; Table 4).

The most commonly prescribed device for patients in the home setting was the DPI (n=36; 55%). In the emergency room the most frequently prescribed device was a nebulizer (n=45; 69%). During the hospital admission the nebulizer device was also prescribed most commonly (n=45; 69%). At time of discharge most patients were placed back on a DPI (n=45; 69%). See Table 5.

Table 5

Devices

	Home		Emergency		Hospital		Discharge	
Device	n	%	n	%	n	%	n	%
No device	19	29	8	12	6	9	7	11
MDI	18	28	3	5	5	8	19	29
MDI with spacer	1	2	0	0	1	2	11	17
DPI	36	55	13	20	38	58	45	69
Nebulizer	4	6	45	69	45	69	4	6
Missing data	5	8	2	3	0	0	11	17

Physician Survey

Sample

I invited a total of 38 physicians from the local area of the health center to participate in the COPD survey, and 24 (63%) responded to the survey. Many respondents had practiced as physicians for more than 20 years (n = 7; 30.4%) and spent an average of 4 to 8 hours per week treating patients with COPD (n = 8; 36.4%). Most physicians named the office setting as their primary area of practice (n = 16; 69.6%). The majority of the physicians (n = 16; 88.9%) held certification

in family medicine. Most (n=19; 82.6%) had no additional training in COPD management (Table 6).

Table 6

Characteristics of Physicians

Characteristics	Response count	Percentage
Years spent practicing as a physician		
<5 years	3	13
5-10 years	7	30.4
10-20 years	6	26.1
>20 years	7	30.4
Missing	1	4
Average number of clinical hours spent treating COPD patients/week		
1-4 hours	13	59.1
4-8 hours	8	36.4
8-12 hours	0	0
More than 12 hours	1	4.5
Missing data	2	8
Primary practice setting		
Emergency room	6	26.1
Office setting	16	69.6
Other	1	4.3
Missing	1	4
Board certification		
Family medicine	16	88.9
Emergency medicine	6	33.3
Missing	6	25
Additional training in COPD management		
No	19	82.6
Yes	4	17.4
CME	3	75
Advanced course	1	25
Missing	1	4

Although 73% of the respondents did not use a specific guideline for device selection, some (n = 11; 47.8%) reported that they had general knowledge on device selection, and 10 (43.5%) reported that they were fully aware of the guidelines for device selection (Table 7).

Table 7

Physicians' Knowledge of COPD

Questions on physicians' knowledge	Response count	Percentage
Do physicians use a guideline for device?		
Yes	6	26.1
CTS guideline	3	50
TOP guideline	2	33
Pharmaceutical industry	1	17
No	17	73.9
Missing	1	4
How knowledgeable/comfortable do you feel about device selection?		
Fully aware of guidelines and research	10	43.5
Have general knowledge, but still have some questions	11	47.8
Do not feel up-to-date	2	8.7
Missing	1	4

Factors That Influence Device Selection

The physicians were asked an open-ended question about the various factors that they consider when they prescribe inhalation devices for their clients. Their responses are summarized in Table 8. The most frequent factor that they cited was ease of use for the patient (n = 10; 42%). Other popular responses included disease severity or severity of symptoms (n = 9; 38%), cost to the patient (n = 7; 29%), and therapeutic response or clinical efficacy (n = 6; 25%). The

physicians considered disease severity (n = 6; 25%) the most important factor that ought to be considered.

Table 8

Factors That Determine Physicians' Selection of a Device

Factors that determine device selection	Response count	Percentage
What factors do physicians consider when prescribing a drug/device combination?		
Cost to the patient	7	29
Therapeutic response/clinical efficacy	6	25
Ease of use	10	42
Patient co-morbidities	3	13
Severity of disease or symptoms	9	38
Pt adherence	4	17
Availability of samples	1	4
Consideration for other devices in use	4	17
CTS guidelines	3	13
Pt age	3	13
Ability to adjust medication easily	2	8
Pt cognition	1	4
Limited adverse reactions	2	8
What is the most important factor physicians' consider when prescribing a drug/device combination?		
Efficacy	5	21
Cost	1	4
Disease severity	6	25
Patient ability to use device correctly	1	4
Deposition	2	8
Spirometry	1	4
Simplicity of use	2	8
What is the most common device physicians' prescribe for COPD exacerbations?		
Nebulizer	6	26.1
Metered dose inhaler	3	13.0
Metered dose inhaler with spacer device	10	43.5
Dry powder inhaler	3	13.0
Other	1	4.3
Missing	1	4

For COPD exacerbations, the prevailing device that physicians prescribed was the MDI/spacer device (n = 10; 43.5%). The physicians were asked to identify factors that assist them in making decisions regarding the selection of devices for both COPD maintenance therapy and COPD exacerbations (Table 9). For COPD maintenance therapy, ease and simplicity of use was the physicians' most common answer (33%). For COPD exacerbations the answers were more diverse in that 17% of the respondents identified cost, severity/clinical condition, and the usual use of MDIs or DPIs as factors in their selection of devices for patients with a COPD exacerbation. Other reasons (n = 4; 17%) included consideration for medication titration, onset of action of the drug, other medications in use, and whether the patient was in hospital or was being treated as an outpatient.

Table 9

Factors That Determine Physicians' Device/Medication Delivery for COPD Maintenance and COPD Exacerbations

Factors that determine device/medication delivery	COPD maintenance		COPD exacerbations	
	Response count	%	Response count	%
Cost	4	17	4	17
Ease/simplicity of use	8	33	2	8
Previous therapy	2	8	1	4
Guidelines	2	8	2	8
Usually use MDI or DPI	4	17	4	17
Based on assessment of inspiratory flow	2	8	0	
Severity/clinical condition	0		4	17
Use a nebulizer	0		2	8
Other	1	4	4	17
Missing	1	4	1	4

The physicians used a 5-point Likert-type scale (from *not a consideration* to *extremely important*) to rate the importance of different factors that they consider in prescribing a device for patients with COPD (Table 10). Of the physicians who responded to this item, a large proportion (n = 8; 47%) reported that it was extremely important that their patients be able to perform the correct technique for the device that they had prescribed. Other factors that the physicians rated as at least being important included assessment of the patient's co-morbidities (n = 12; 63.1%), ability to assess the patient's inspiratory flow (n = 13; 72.2%), acknowledgement of the patient's preference (n = 10; 62.5%), cost to the patient (n = 13; 68.4%), personal familiarity with the drug (n = 11; 68.8%) or device (n = 12; 70.6%), and device portability (n = 12; 70.6%). The factors that the physicians rated not important include cost to the facility (n = 5; 23.8%), but seven (33.3%) reported that, although the cost to the facility is important, it is not essential.

COPD Education

Physicians were instructed to use a Likert-type scale to indicate how often (from *never* to *always*) they used different methods of educating patients with COPD (Table 11). Thirty-three percent reported that they usually do their own teaching on devices while treating a patient, and only 11% stated that they always teach patients about devices during a visit. Fifty-eight percent of the respondents stated that they rarely review the device if the patient has used it in the past. Many physicians (50%) also responded that they rarely use a COPD action plan.

Table 10

Physicians' Rating of Importance of Selected Factors in Considering COPD Drug/Device Combinations

Factors	Not a consideration	Not important	Important but not essential	Important	Extremely important	Rating average	Response count
Patient co-morbidities (e.g., arthritis)	0 (0.0%)	0 (5.3%)	6 (31.6%)	**7 (36.8%)**	5 (26.3%)	3.84	19
Ability to assess patient's inspiratory flow	0 (0.0%)	0 (0.0%)	5 (27.8%)	**8 (44.4%)**	5 (27.8%)	4.00	18
Patient preference	0 (0.0%)	1 (6.3%)	5 (31.3%)	**10 (62.5%)**	0 (0.0%)	3.56	16
Cost to the patient	0 (0.0%)	2 (10.5%)	4 (21.1%)	**10 (52.6%)**	3 (15.8%)	3.74	19
Cost to the facility	5 (23.8%)	5 (23.8%)	**7 (33.3%)**	3 (14.3%)	1 (4.8%)	2.52	21
Personal familiarity with the drug	1 (6.3%)	0 (0.0%)	4 (25.0%)	**8 (50.0%)**	3 (18.8%)	3.75	16
Personal familiarity with the device	0 (0.0%)	1 (5.9%)	4 (23.5%)	**8 (47.1%)**	4 (23.5%)	3.88	17
Ensuring the patient is able to perform the correct technique	0 (0.0%)	0 (0.0%)	2 (11.8%)	7 (41.2%)	**8 (47.1%)**	4.35	17
Device portability	0 (0.0%)	2 (11.8%)	3 (17.6%)	**10 (58.8%)**	2 (11.8%)	3.71	17
Consideration of infection control	0 (0.0%)	4 (20.0%)	**7 (35.0%)**	4 (20.0%)	5 (25.0%)	3.50	20
Answered question							23
Skipped question							1

Table 11

Frequency With Which COPD Patients Receive Educational Information After Discharge From the ER or Office

Educational information	Never (0%)	Rarely (1%-10%)	Sometimes (115-50%)	Usually (515-90%)	Always (905-100%)	Rating average	Response count
COPD educational pamphlets	5 (29.4%)	**7 (41.2%)**	3 (17.6%)	0 (0.0%)	2 (11.8%)	2.24	17
Device teaching provided by yourself	3 (16.7%)	3 (16.7%)	4 (22.2%)	**6 (33.3%)**	2 (11.1%)	3.06	18
Device teaching provided by a pharmacist	**5 (26.3%)**	**5 (26.3%)**	**5 (26.3%)**	3 (15.8%)	1 (5.3%)	2.47	19
Device teaching provided by a respiratory therapist	2 (10.5%)	5 (26.3%)	**8 (42.1%)**	3 (15.8%)	1 (5.3%)	2.79	19
Device teaching provided by a nurse	2 (11.8%)	**9 (52.9%)**	4 (23.5%)	1 (5.9%)	1 (5.9%)	2.41	17
Regular review of device use if the patient has used the device in the past	1 (5.9%)	**10 (58.8%)**	2 (11.8%)	3 (17.6%)	1 (5.9%)	2.59	17
Provided with a written Action Plan* for sick days	4 (20.0%)	**10 (50.0%)**	5 (25.0%)	0 (0.0%)	1 (5.0%)	2.20	20
Referred to a pulmonary rehabilitation program	1 (4.8%)	7 (33.3%)	**8 (38.1%)**	5 (23.8%)	0 (0.0%)	2.81	21
Answered question							23
Skipped question							1

*A written plan that outlines what patients should do if they become ill or their COPD is exacerbated.

CHAPTER 5:

DISCUSSION

In this chapter I discuss the major findings from the chart review and physician survey. I will discuss the findings as they relate to current research. I will then review the similarities between the chart review and the physician survey and present the limitations of the study, the implications for nursing practice, and recommendations for further research.

I explored two research questions:

1. What is the current pattern of device selection for patients admitted to a small rural community hospital?
2. What factors influence prescribers' decision making in selecting specific devices for drug therapy for COPD?

Major Findings: Chart Review

A total of 97 admissions met the inclusion criteria for this study. I excluded 32 admissions because the charts of those patients with COPD were not available from the medical records department at the health center; they had been archived at another site because these patients were now deceased. The precise cause of death for those hospitalized with a diagnosis of COPD during the six-month period was undetermined. However, the mortality rate of 33% is consistent with the findings of current studies on COPD patient mortality rates. Gunen et al. (2005) found that mortality rates for patients hospitalized with COPD exacerbations were high. In his study patients hospitalized for acute exacerbations of COPD had poor short- and long-term survival rates; the overall six-month

mortality rate was 24%. The one-, two-, and three-year mortality rates were 33%, 39%, and 49%, respectively (Gunen et al., 2005).

The Pattern of Device Selection for Patients Admitted to a Small Rural Community Hospital

In this study I found that the most frequently prescribed device for home use upon admission and upon discharge was the DPI. There are no known studies that have reported the various types of devices prescribed at different stages of a patient's admission. In fact, very few studies have compared different devices and their relative efficacy to one another (Dolovich et al., 2005). The availability of certain medications might explain the frequent use of DPIs. For instance, the CTS's COPD guidelines recommend that all patients (mild to severe disease) be on a LAAC (O'Donnell et al., 2007). Because the single LAAC tiotropium is available only as a DPI, it is reasonable to suggest that this might explain the frequency of DPI use.

The DPI has many advantages, including that they are portable, less patient coordination is required, the treatment time is short, and it is breath actuated rather than hand actuated. The disadvantages are that DPIs require moderate to high inspiratory flow, they have high pharyngeal deposition, and not all medications are available in the DPI form (Dolovich et al., 2005). The ACCP/ACAAI guidelines for device selection suggest that the MDI (with/without spacer), the nebulizer, and the DPI are "all appropriate for the delivery of inhaled B_2-agonist and anti-cholinergic agents" (p. 359) to treat COPD patients in the outpatient setting. The ACCP/ACAAI does, however, recommend that the

following be assessed: the patient's ability to use the device correctly, the patient's preference, the availability of a drug/device combination, the cost of therapy, and the availability of education on the device (Dolovich et al., 2005). From the chart review alone it is difficult to assess whether the physicians' device selection concurred with the current guidelines because all devices are deemed appropriate. The process of selection is more of an intellectual process and is not expected to be documented on a patient's chart.

It is interesting that this study revealed that 19 (29%) of the COPD patients were not on any type of drug/device combination in the preadmission setting. There may be several reasons for this, such as the hospital staff's neglect to chart on the patient's record. A common mistake in emergency room nurses' charting is omission ("What You Document," 2006), which personal observations confirm. Patients often do not report medications delivered through inhalation devices or herbal therapy or over-the-counter medications unless they are specifically asked about them. However, these patients may truly have had no inhaler-delivered therapy. Zoia et al. (2005) reported that about 33% of the initial diagnoses of COPD are made when people visit an emergency department and are hospitalized with acute respiratory failure.

In the emergency department the overwhelming treatment of choice was the nebulizer. Tein et al. (2001) reported similar results in her survey of physicians' treatment of asthmatic patients who present to the emergency room for an acute exacerbation of asthma. Data on the management of COPD is limited compared to the data on asthma; only seven studies met the ACCP/ACAAI

guidelines on device selection (Dolovich et al., 2005). Dolovich et al. mentioned that nebulized albuterol increases patients' heart rate more than an MDI does but also recognized that nebulizers are often used for "sicker and less cooperative patients" (p. 359).

When patients transitioned from the emergency room and were admitted as in-patients, the nebulizer again was the preferred delivery device. The use of DPIs also increased tremendously once the patients were admitted compared to usage in the emergency department. From my observations during the chart review, the most common DPI that was added to the SABA on admission was tiotropium or a LABA/corticosteroid combination. Again, on discharge the most commonly prescribed device was the DPI. This may reflect the fact that patients need a more portable device rather than a less portable device such as a nebulizer.

Pharmacotherapy

The chart review revealed that approximately one third of the patients in the home setting were on a SABD (32%), one third on a LAAC (31%), and one third on a LABA/ICS (32%). The prescribing practices of the physicians in the sample seem to meet current practice guidelines. The CTS's guidelines recommend the combination of a LAAC, plus a LABA/ICS and a SABA is needed for persistent disability of patients with moderate COPD and for those with severe COPD (O'Donnell et al., 2007). One patient was on theophyline, which the CTS recommends for patients with severe COPD and persistent disability despite triple therapy (O'Donnell et al., 2007). The guidelines also recommend the use of tiotripium, a LAAC, because of evidence that tiotropium

delays the time to the first experienced COPD exacerbation. In the UPLIFT trial tiotropium delayed the time to first exacerbation (16.7 months vs. 12.5 months) and also reduced the mortality rate: 14.9% for the tiotropium patients versus 16.5% for the placebo group (HR 0.89, 95% CI 0.79 to 1.02; Tashkin et al., 2008).

In the emergency room and during hospital admission the use of SABDs was common; the rates were 71% and 77%, respectively. This finding is expected because the CTS guidelines recommend "combined short-acting Beta-2 agonist and anticholinergic inhaled therapy" (O'Donnell et al., 2007, p. 18B) in the acute situation. The patients also used a systemic corticosteroid fairly frequently; the rates in the emergency room and in hospital were both 31%. The guidelines recommend the use of systemic corticosteroids for most patients with COPD exacerbations (O'Donnell et al., 2007). Upon discharge, fewer patients remained on a short-acting anti-cholinergic compared to in hospital and were placed back on LAACs . LABA/ICS were common and many patients remained on a SABD.

Device Education

Educating patients and their families on proper inhalation device use before discharge is essential but not easily achieved. In the chart review I found little evidence of device education from either respiratory therapists or nurses. Only 12.5% of the patient charts had documented device education. There may be many reasons for this. Both nurse and allied health professionals' charting techniques are narrative and therefore require that the health professionals recall all aspects of clients' assessment, which can result in charting omissions. The

literature also suggested that healthcare professionals are not entirely competent in device technique (Hanania et al., 1994; Owayed et al., 2006), and this may be reflected in the lack of education that they pass on to their patients.

Other: Smoking Status

A review of the smoking status of the patients in this study revealed that most had quit smoking (n = 35; 57%), and 18 (30%) were current smokers. The data was missing for 8 patients. In Gunen et al.'s (2005) study, of 205 patients, 95 (46%) were current smokers, and 83 (41%) had quit. Smoking was not a risk factor in the mortality of the COPD patients in this study. Neither smoking status nor smoking load by pack year history had a statistically significant impact on survival rate. Smoking cessation remains important for COPD patients because of the well-known benefit of decreased rates of smoking-related heart attacks, decreased rates of lung cancer, and decreased effects of second-hand smoke (CLA, 2010a).

Major Findings: Physicians' Survey

Physicians' Responses: Device Selection

The reported factors that guide physicians' prescribing practices around devices for their COPD patients varied widely. The more prevalent guiding factors were ease of use (42%), severity of disease or symptoms (38%), cost to the patient (29%), and therapeutic response/clinical efficacy (25%). Both cost and ease of use are factors that the ACCP/ACAAI recommended in its guidelines (Dolovich et al., 2005), but the physicians who responded to this survey identified many more factors that are not included in the guideline: severity of

disease/symptoms, therapeutic response/clinical efficacy, patient co-morbidities, availability of samples, ability to adjust medication easily, patient cognition, and limited adverse reactions. This demonstrates that physicians are adhering to some extent to the ACCP/ACAAI guidelines (Dolovich et al., 2005), even though many did not report using a guideline for device selection. Physicians reported that the most important factor they consider when they prescribe a drug/device combination was disease severity (25%).

The most common device that this sample of physicians reported prescribing for patients with COPD exacerbations was the MDI/spacer. This response is not surprising because the CTS guidelines advise the use of short-acting Beta-$_2$ agonists and short-acting anti-cholinergics for COPD exacerbations (O'Donnell et al., 2007). Both are delivered only through an MDI or a nebulizer. The chart review revealed that most patients were treated with a nebulizer solution for COPD exacerbations. This discrepancy in the responses can be explained by the fact that many COPD exacerbations can be treated on an outpatient basis. Furthermore, the majority of the physicians practice in an office setting, and this might explain the high selection of MDI/spacer as the most common device prescribed to patients. The chart review revealed that the most common device that the physicians use is the nebulizer, which is easier to use and more readily available in a hospital setting.

Physicians' Knowledge of COPD

Physicians were asked about their knowledge on device selection, and many stated that they were fully aware of the guidelines and research (43.5%);

only 8.7% felt that their knowledge was not up to date. However, previous studies have shown that the knowledge of healthcare professionals is limited with regard to device use and techniques (Hanania, Wittman, Kesten, & Chapman, 1994; Owayed, Al-Ateeqi, & Behbehani, 2006).

When asked about a specific guidelines for device selection, most physicians (74%) responded that they do not use a guideline. This finding is not surprising because few guidelines are available on the selection of devices. The ACCP/ACAAI have specific guidelines for device selection (Dolovich et al., 2005), but although both the CTS's (O'Donnell et al., 2007) and the GOLD Committee's (2009) guidelines for COPD are helpful in drug selection, they offer little guidance on device selection. Of the physicians who responded that they use a guideline (26%) , half (50%) cited the CTS guideline, and approximately one third (33%) reported that they use the Alberta Medical Association's (2009) "Towards Optimized Practice" (TOP) guidelines.

Physicians' Responses to the Frequency of COPD Education

Physicians recognize the importance of COPD education. Yet only 34% of the respondents stated that they usually do their own device teaching after patients are discharged from the emergency room or their office. Chapman, Voshaar, and Virchow (2005) referred to the barriers that physicians face, including the brevity of patient visits: "A five or ten minute encounter could encompass diagnosis, assessment of control, review of medication usage, physical examination, measurement of lung function, prescription and education" (p. 117). Physicians might also consider educating patients who present to emergency rooms of low

priority because they are increasingly overwhelmed with high patient flow. Many physicians also reported that they rarely review device use if the patient has used it in the past (59%), nurses rarely teach patients about devices (53%), physicians rarely provide a written action plan for sick days (50%), and patients rarely receive educational pamphlets (41%). These findings are consistent with the research of Chapman, Boulet, and Rea (2004), who found in a primary practice audit of asthma management that 28% of patients had never demonstrated their inhaler technique to a healthcare professional. Patient outcomes are affected by incorrect inhaler use, which is a type of non-adherence to treatment that leads to suboptimal management and may "adversely affect patient outcomes and increase the cost of care" (Ramsey, 2000, p. 35S).

Study Limitations

I used convenience sampling to select patient charts for review in this study, which is a limitation because the results cannot be generalized to all COPD patients. The physicians were from the local area surrounding the small rural hospital, and the sample size was small. This limits generalization to all physician groups.

I reviewed the charts over a six-month period (January 1 to June 30, 2008), and the physicians completed the survey in June 2010. Comparisons between the chart review and the survey are difficult because of the two-year time lapse since they were completed. Major events, including the H1N1 influenza pandemic, have occurred. The chart-review time period did not include this event, but it might have influenced the physicians' responses to the survey because

healthcare professionals discussed device selection more during the pandemic, especially in terms of infection control.

I developed the physicians' survey and modified only a few questions from Tein et al.'s (2001) questionnaire; therefore, this survey had not been used in any other previous study. Tein et al.'s questionnaire had not been tested for reliability and validity, which could be a limitation in this study because I did not test the tool on any other population to determine its reliability and validity. However, some of my findings were similar to those of Tein et al.; specifically, the high use of nebulizer therapy in the emergency room for acute asthma exacerbations.

Implications for Practice

In light of the growing numbers of COPD patients and its increasing complexity of care for elderly patients, health professionals need to be aware of the complexity of prescribing inhalation devices, to monitor their effectiveness, to review the devices regularly with patients, and to educate them on their use. This research was intended to increase our understanding about current practice related to device selection for this patient population.

In recent years there has been a proliferation of inhaler devices to manage COPD (Dolovich et al., 2005). In this study over a quarter of the sample were using two or more different inhalation devices, and each device requires a specific set of sequential steps to be performed for the drug to be deposited into the lungs. Patients of advanced age are more likely to have more co-morbid medical conditions, and cognitive and executive function impairment increases with

advanced age. In addition, physical impairments such as arthritis are well-known determinants of whether patients are able to take medications correctly. Simple tools such as Minimental or EXIT25 tests are useful in identifying patients who do not have the necessary functioning to use their inhalers correctly. A Minimental score of less that 24/30 and an EXIT25 score of greater than 14/25 both predict that patients will likely not take their medications correctly (Allen, 2005). Also, minimizing the different types of inhalation devices will increase patients' ability to learn the complex steps required to use them.

Lack of documentation of education provided to patients with COPD is an important finding of this research. As the demands on health care providers increase, they have less time to devote to patient education. Documentation of the care that health care workers provide is critical and methods to streamline the process should be considered. A standardized form would perhaps simplify the process.

It is important to encourage patients to ensure that they receive high levels of care because suboptimal management of COPD can contribute to poorer long term outcomes and increase costs of care (Ramsey, 2000). Care provided to patients with COPD should continue to be provided by multidisciplinary teams. Multidisciplinary teams are increasingly caring for older, more complex patients. Kuzma et al. (2008) showed that the management of patients with COPD by multidisciplinary teams, including nurses, exercise specialists, social workers, dieticians, and physicians, results in high-quality medical care and that the team members' roles complement each other.

Recommendations for Further Research

I recommend that this study be replicated with another group of physicians and chart review in a different geographical area to compare the findings. The findings could then be generalized to a wider population. I also recommend reliability and validity testing of the physicians' questionnaire and chart review in future studies. More research is needed for the selection of COPD devices. Specifically, there is a need to determine the impact of inhaler choices on actual clinical outcomes and to test the value of a checklist to help prescribers to select devices for COPD patients. A sample checklist is included in Appendix K.

Summary

In this study I examined the patterns of device selection for patients diagnosed with COPD in a small rural community hospital. Results show that the most frequently prescribed device for patients was a DPI in the community setting and that nebulizers are most commonly prescribed in the emergency department. As patients transitioned from the emergency room and hospital ward to discharge the frequency of nebulizer use decreased. This suggests that there is a belief that nebulizers are more effective in the acute setting. This is contrary to the ACCP/ACAAI guidelines which state that all devices can be "equally efficacious" (Dolovich et al., 2005, p.335). Few studies have compared different devices and their relative efficacy to one another (Dolovich et al., 2005) and there are no known studies that have examined how device selection affects clinical outcomes.

The physicians who responded to this survey identified many factors that they consider when prescribing inhalation devices to their patients diagnosed with

COPD. They reported ease of use, severity of disease or symptoms, cost to the patients, therapeutic response/clinical efficacy, co-morbidities, availability of samples, patient cognition, limited adverse reactions and the ability to adjust medication easily. They also reported that the most important factor that they consider when prescribing an inhalation device is disease severity. By the responses of physicians in the sample, it would seem that physicians meet current practice guidelines for device selection as identified by the ACCP/ACAAI guidelines.

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APPENDIX A:

MEDICAL RESEARCH COUNCIL DYSPNEA SCALE

Grade	Description
1	Not troubled by breathlessness except with strenuous exercise
2	Troubled by shortness of breath when hurrying on the level or walking up a slight hill
3	Walks slower than people of the same age on the level because of breathlessness or has to stop for breath when walking at own pace on the level
4	Stops for breath after walking about 100 yards (90m) or after a few minutes on the level
5	Too breathless to leave the house or breathless when dressing or undressing

(O'Donnell et al., 2007, p. 9B)

APPENDIX B:

SPIROMETRY CLASSIFICATION BY IMPAIRMENT OF LUNG FUNCTION

COPD stage	Spirometry (postbronchodilator)
Mild	$FEV_1 \geq 80\%$ predicted, $FEV_1/FVC < 0.7$
Moderate	$50\% \leq FEV_1 < 80\%$ predicted, $FEV_1/FVC < 0.7$
Severe	$30\% \leq FEV_1 < 50\%$ predicted, $FEV_1/FVC < 0.7$
Very severe	$FEV_1 < 30\%$ predicted, $FEV_1/FVC < 0.7$

FVC: Forced vital capacity; FEV_1: Forced vital capacity in 1 second
(O'Donnell et al., 2007, p. 10B)

APPENDIX C:

STEPWISE APPROACH TO DRUG THERAPY IN COPD

Increasing disability and lung function impairment →→→		
Mild	Moderate	Severe
SABD as needed	LAAC or LABA + SABA as needed	LAAC + ICS/LABA + SABA as needed
if persistent disability	if persistent disability	If persistent disability
LAAC + SABA as needed	LAAC +LABA + SABA as needed	LAAC + ICS/LABA + SABA as needed
LABA + SABD as needed	LAAC + ICS/LABA + SABA as needed	± theophylline

SABD: Short-acting bronchodilator; LAAC: Long-acting anti-cholinergic; SABA: Short-acting Beta-2 agonist; LABA: Long-acting Beta-2 agonist (O'Donnell et al., 2007, p. 14B)

APPENDIX D:

ADVANTAGES AND DISADVANTAGES OF

DIFFERENT AEROSOL DEVICES

Device type	Advantages	Disadvantages
Small volume jet nebulizer	Patient cooperation is not required Effective with tidal breathing High dose possible Dose modification possible No CFC release Can be used with supplemental oxygen Can deliver combination therapies if compatible	Lack of portability Pressurized gas source required Lengthy treatment time Device cleaning required Contamination possible Not all medication available in solution form Does not aerosolize suspensions well Device preparation required Performance variability Expensive when compressor added in
Ultrasonic nebulizer	Patient cooperation is not required High dose possible Dose modification possible No CFC release Small dead volume Quiet Newer designs small and portable Faster delivery then jet nebulizer No drug loss during exhalation (breath actuated devices)	Expensive Need for electrical power source Contamination possible Not all medication available in solution form Device preparation required Does not nebulize suspensions well Possible drug degradation Potential for airway irritation with some drugs

(table continues)

Device type	Advantages	Disadvantages
Pressurized MDI	Portable and compact	Coordination of breathing actuation needed
	Treatment time is short	Device actuation required
	No drug preparation required	High pharyngeal deposition
	No contamination of contents	Upper limit to unit dose content
	Dose-dose reproducibility high	Remaining doses difficult to determine
	Some can be used with breath-actuated mouthpiece	Potential for abuse
		Not all medications available
		Many use CFC propellants in United States
Holding chamber, reverse flow spacer, or spacer	Reduces need for patient coordination	Inhalation may be more complex for some patients
	Reduces pharyngeal deposition	Can reduce dose available if not used properly
		More expensive than MDI alone
		Less portable than MDI alone
		Integral actuator devices may alter aerosol properties compared to native actuator
DPI	Breath-actuated	Requires moderate to high inspiratory flow
	Less patient coordination required	Some units are single dose
	Propellant not required	Can result in high pharyngeal deposition
	Short treatment time	Not all medications are available
	Dose counters in most newer designs	

(Dolovich et al., 2005, p. 337) reproduced with permission of author

APPENDIX D:

LETTER (EMAIL) OF PERMISSION TO USE COPYRIGHT MATERIAL

January 25, 2009

Hello Kathy,
You have my permission to use the table for your research publication.
All the best.

Regards,
Myrna Dolovich

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APPENDIX E:

APPROPRIATE DEVICE USE AND MAINTENANCE

Device type	Appropriate technique	Maintenance
Metered dose inhaler (MDI)	1. Remove cap. 2. Shake well 3. Breathe normally and slowly through the mouth 3. Breathe out 4. Tilt head slightly backwards 5. Open mouth: hold the inhaler 2-5cm from your mouth. Keep mouth wide open or Closed mouth: Place the mouthpiece in your mouth between your teeth and close your mouth around it 6. Begin to breathe in and push down on the canister once. Continue to breathe in slowly and deeply through the mouth until the breath is complete 7. Hold your breath for 5-10 seconds 8. Breathe out slowly 9. Replace cap	1. Once a week, remove the medication canister from the plastic casing and wash the casing in warm, soapy water. When the casing is dry, replace the medication canister in the casing and put the cap on the mouthpiece. 2. Ensure the hole is clear.
Metered dose inhaler with spacer (MDI-S)	Wait 30 seconds before taking another dose. 1. Remove the cap and shake the MDI 2. Remove the cap on the spacer and insert the mouthpiece of the MDI into the opening at the end of the spacer. 3. Place the spacer mouthpiece in mouth between your teeth and close your lips around the mouthpiece, making sure there are no air leaks. Check that the small holes on the each side of the mouthpiece are not covered with the lips. Exhale. 4. Push down on the MDI canister to allow the medication to enter the spacer. Breathe in slowly and deeply for 3-5 seconds. Hold breathe as long as possible. If you have trouble breathing deeply and holding your breath, breathe in and out more normally into the spacer 3-4 times 5. If you need more than once dose wait 30 seconds before taking it. 6. Replace cap on the spacer and MDI	1. Clean the spacer once a week. Immerse in warm, mildly soapy water and agitate. 2. Shake off excess water and leave overnight to dry.

(table continues

Device type	Appropriate technique	Maintenance
Turbohaler	1. Unscrew and remove cap. 2. Hold Turbohaler in upright position and turn the coloured base as far as possible in one direction, then turn back until a "click" is heard. 3. Breathe out away from the Turbohaler. 4. Place the mouthpiece between your teeth and close your lips around it. 5. Breathe in quickly and deeply through the mouth. Remove Turbohaler from mouth and hold breathe for 10 seconds, then breathe out. 6. Repeat steps if further inhalations are required. 7. Replace the cap	1. Clean mouthpiece using a dry tissue or cloth. 2. Check the number of doses that are left in the dose window.
Diskus	1. Open by holding the outer case in one hand and put the thumb of the other hand on the thumb grip 2. Push the thumb as far as it will go until a click is hear 3. Slide the lever as far as it will go until a click is heard. 4. Hold the diskus inhaler away from the mouth and breathe out completely. 5. With the mouthpiece to the lips, breathe in quickly and deeply. 6. Remove the diskus inhaler. 7. Hold your breath for about 10 seconds, then breathe out slowly. 8. Close: slide the thumb grip as far as it will go until a click is heard.	1. Store the device in a dry place. 2. Diskus is to be closed when not in use. 3. Keep away from direct frost, heat or sunlight and from high temperatures. 4. Check the number in the dose window counter.
Nebulizer (compressed gas)	1. Ensure the compressor is plugged in and functioning. 2. Attach the nebulizer tubing to the compressor air outlet. 3. Unscrew the medication chamber and fill with the appropriate amount of medication. Hold upright. 4. Screw the top back on and attach to a mouthpiece or mask. 5. Turn the compressor on.	1. Wash mask and nebulizer medication chamber in warm, soapy water. 2. Rinse well and allow them to air-dry before reuse.

(Manitoba Lung Association and the Lung Association of Saskatchewan, n.d)

APPENDIX F:

INHALED PHARMACOTHERAPY IN COPD

Drug name (generic)	Drug name (trade)	Dosage form and strength	Usual dose	Cost per 30 days
Short-acting β² agonists				
Salbutamol				
	Ventolin	100mcg MDI	1-2 puff QID prn	$19
	Ventolin	5mg/mL inhalation solution	2.5mg/neb QID prn	$49
	Ventolin nebules	1.25, 2.5, 5 mg/ 2.5mL		$94
Terbutaline	Bricanyl Turbohaler	500mcg	QID prn	$18
Long-acting β² agonists				
Formoterol	Foradil	12 mcg capsules for inhalation; 6mcg, 12mcg turbohaler	12mcg BID	$63
Formoterol/ Budesonide	Oxeze	6, 12mcg Turbohaler	6-12 mcg BID	$46-$59
Salmeterol	Symbicort	6mcg/100mcg, 6mcg-200mcg Turbohaler	2 puff BID	$79-$100 $72
Salmeterol/Fluticisone	Serevent	50mcg discus	50 mcg BID	$99-$115
	Advair diskus	50mcg/100, 50/250, 50//500mcg diskus	1 puff BID 2 puff BID	$115-$165
	Advair HFA	25mcg/125mcg, 25/250mcg MDI		

(table continues)

Drug name (generic)	Drug name (trade)	Dosage form and strength	Usual dose	Cost per 30 days
Anticholinergics				
Ipratropium bromide	Atrovent	20mcg MDI	2puff TID – QID	$26-$32
	Atrovent	250mcg/2mL, 500mcg/2mL nebules	250mcg TID	$88
	Atrovent	Inhalation solution	250mcg TID	$66
Tiotropium	Spiriva Handihaler	18mcg Handihaler	18mcg OD	$82
Corticosteroids				
Beclomethasone	Qvar	50mcg, 100mcg MDI	50-100mcg puff BID	$27-$48
Budesonide	Pulmicort	100mcg/200mcg/ 400mcg Turbohaler	100-200-400mcg BID	$18-$29-$46
	Pulmicort	0.25mg, 0.5mg, 1mg/2mL nebules	1mg BID	$125
Fluticasone	Flovent HFA	50mcg. 125mcg, 250mcg MDI	1 puff BID	$35-$55-$99
	Flovent diskus	50mcg, 100mcg, 250mcg, 500mcg discus	250mcg-500mcg BID	$55-$99

(Turner & Jenson, 2008)

APPENDIX G:

DATA EXTRACTION TOOL FOR CHART REVIEW

1. Case numerical (code- 001 through 500)

2. Patient Age in Years

3. Patient Sex: 1 = female; 2 = male

4. Length of stay in days

5. Primary Diagnosis: 1 = COPD; 2 = Heart Failure; 3 = pneumonia; 4 = diabetes; 5 = Renal Failure; 6 = other

6. Secondary Diagnosis (Circle all that apply) : 1 = COPD; 2 = Heart Failure; 3 = pneumonia; 4 = diabetes; 5 = depression ; 6 = Asthma; 7 = Atrial fibrillation; 8 = Osteoporosis; 9 = Osteoarthritis; 10 = Coronary artery disease; 11 = Renal Failure; 12 = Hypertension; Other- Specify

7. Medications for COPD (home) (Circle all that apply): 0 = none; 1 = Salbutamol; 2 = Ipratropium bromide; 3 = Fluticasone; 4 = Salmeterol; 5 = Salmeterol/Fluticasone; 6 = Formoterol/budesonide; 7 = Tiotropium; 8 = Prednisone; 9 = Theophyline; 10 = Budesonide; 11 = unknown

8. Medications for COPD (Emergency Room) (Circle all that apply): 0 = none; 1 = Salbutamol; 2 = Ipratropium bromide; 3 = Fluticasone; 4 = Salmeterol; 5 = Salmeterol/Fluticasone; 6 = Formoterol/budesonide; 7 = Tiotropium; 8 = Prednisone; 9 = Theophyline; 10 = Budesonide; 11 = unknown

9. Medications for COPD (during admission(Circle all that apply) : 0 = none; 1 = Salbutamol; 2 = Ipratropium bromide; 3 = Fluticasone; 4 = Salmeterol; 5 = Salmeterol/Fluticasone; 6 = Formoterol/budesonide; 7 = Tiotropium; 8 = Prednisone; 9 = Theophyline; 10 = Budesonide; 11 = unknown

10. Medications for COPD (upon discharge) (Circle all that apply) : 0 = none; 1 = Salbutamol; 2 = Ipratropium bromide; 3 = Fluticasone; 4 = Salmeterol; 5 = Salmeterol/Fluticasone; 6 = Formoterol/budesonide; 7 = Tiotropium; 8 = Prednisone; 9 = Theophyline; 10 = Budesonide; 11 = unknown

11. Device used at home (Circle all that apply): 0 = None; 1 = MDI; 2 = MDI/ spacer; 3 = DPI; 4 = Nebulizer; 5 = Unknown

12. Device used in Emergency Room (Circle all that apply): 0 = None; 1 = MDI; 2 = MDI/spacer; 3 = DPI; 4 = Nebulizer; 5 = Unknown

13. Devise prescribed during hospital admission(Circle all that apply) :
    0 = None; 1 = MDI; 2 = MDI/spacer; 3 = DPI; 4 = Nebulizer; 5 = Unknown

14. Device prescribed at discharge : (Circle all that apply) 1 = Nebulizer ;
    2 = MDI; 3 = MDI/Spacer; 4 = DPI

15. Device Education documented 1 = yes; 2 = no

16. Currently smoking 1 = yes; 2 = no; 3 = Unknown

17. Prednisone prescribed 1 = yes; 2 = no

APPENDIX H:

DESCRIPTION OF THE STUDY

INHALATION DEVICES IN COPD MANAGEMENT:

A RESEARCH PROJECT

Kathy Romaniuk Verge, NP

and MN student

Principal Investigator:

University of Alberta

Faculty of Nursing

Committee Members: Dr. Carolyn Ross Supervisor, Faculty of Nursing,
Dr. Beverly Williams, Faculty of Nursing
Dr. Eric Wong, Faculty of Medicine (Pulmonary Division)

COPD is fast becoming the third most common cause of mortality in the world (World Health Organization). With its rising prevalence, COPD will continue to play a necessary role in everyday medical practice. An integral part of COPD management is inhaled drug therapy. Inhalation therapy continues to be the mainstay of COPD treatment, as therapy can be targeted directly to the lung tissue where it is most effective and has the least amount of systemic absorption. There are known to be numerous drug/device combinations on the market today and this can be problematic for both the patient and the prescriber.

Recently, there has been an increasing interest in COPD device selection as it has been deemed to be as important as drug selection in the successful management of COPD. Very little is known of about how physicians determine which device to select for various COPD patients. This study will explore current practice in admitted patients at the health center and investigate the various factors physicians take into consideration when prescribing a drug/device combination for their patients.

APPENDIX I:

PHYSICIAN SURVEY: FACTORS RELATED TO CHOICE OF INHALER DELIVERY DEVICE IN COPD PATIENTS

This survey asks questions about your current practice pattern of device selection for inhalation therapy in COPD patients.

Please respond as appropriate for your primary practice setting if you work in more than one area. The survey should take approximately **10 minutes** to complete. Your participation in this survey is voluntary. Information collected is anonymous. Not information that could link an individual to data will be collected. Data collection will be kept confidential and destroyed after five years.

☐ I do not wish to participate in this survey

☐ I do not treat COPD patients in my practice

PLEASE NOTE THERE ARE *TWO FORMATS* OF THIS SURVEY (ELECTRONIC AND PAPER). IF YOU HAVE COMPLETED THE OTHER FORMAT PLEASE DISREGARD THIS COPY

Please return survey in envelope provided in my mail box at the hospital (Located in the physicians lounge) or by Canada Post Mail in the self addressed envelope

Kathy Romaniuk Verge MN student
University of Alberta

Box 66 Site 10 RR#1
Calahoo, AB
T0G 0J0

Email: kromaniu@ulberta.ca

COPD Device Selection Survey

1. What is the average number of clinical hours that you spend treating COPD patients per week?

   a. 0 hours
   b. 1-4 hours
   c. 4-8 hours
   d. 8-12 hours
   e. More than 12 hours

2. How many years have you practiced as a physician?

   a. <5 years
   b. 5-10 years
   c. 10-20 years
   d. > 20 years

3. Are you board eligible or certified in (check all that apply):

   Emergency Medicine _____
   Family Medicine _____

4. Do you have any additional training in COPD management? If so, please list.

   a. No
   b. Yes

   _____

   _____

   _____

   _____

5. What is your primary practice setting?

   a. Emergency Room
   b. Office Setting
   c. Other: Please list _____

6. Do you have a guideline for inhalation device selection in your practice setting? If yes, who developed it?.

   a. No
   b. Yes _____

7. What are the factor(s) that you consider when prescribing a drug/device combination for your COPD patients?

   _____

   _____

   _____

   _____

8. What is the **most important** factor that you consider when prescribing a drug/device combination for your COPD patients?

   _____

   _____

10. What is the most common device that you prescribe for your COPD patient when they are experiencing an **exacerbation**?

    a. Nebulizer
    b. Metered Dose Inhaler (MDI)
    c. Metered Dose Inhaler (MDI) with spacer device
    d. Dry powder inhaler (DPI)
    e. Other – please list _____

11. How do you decide on which device or method of medication delivery you use for any particular COPD patient?

    a. For COPD maintenance therapy

    _____

    _____

    _____

    b. For COPD exacerbations

    _____

    _____

    _____

12. How knowledgeable/comfortable do you feel about device selection for inhalation therapy in COPD patients?

    a. I am fully aware of the various guidelines and research regarding device selection in COPD patients
    b. I have general knowledge, but still have some questions about device selection
    c. I do not feel that I am up-to-date on device selection
    d. Other: Please list _____

13. How often do your patients' receive the following educational information upon discharge from the emergency room or from your office setting?

	Never (0%)	Rarely (1-10%)	Sometimes (11-50%)	Usually (51-90%)	Always (91-100%)
COPD educational pamphlets					
Device Teaching provided by yourself					
Device Teaching provided by a pharmacist					
Device Teaching provided by Respiratory therapist					
Device Teaching provided by a nurse					
Regular review of device use if the patient has used the device in the past					
Provided with a written Action Plan∗ for Sick days					
Referred to a pulmonary rehabilitation program					

∗An action plan is a written plan that outlines what patients should do if they become ill or their COPD is exacerbated.

The following question asks you how important certain factors are to your decision-making when you consider specific device/drug combinations for your COPD patient.

Scale:

5 – Extremely important
4 – Important
3 – Important but not essential
2 – Not important
1 – Not a consideration

14. How important are the following factors?

	5 Extremely important	4 Important	3 Important but not essential	2 Not important	1 Not a consideration
Patient co-morbidities; e.g., arthritis					
Ability to assess patients' inspiratory flow					
Patient preference					
Cost to the patient					
Cost to the facility					
Personal familiarity with the drug					
Personal familiarity with the device					
Ensuring the patient is able to perform the correct technique					
Device portability					
Consideration of infection control					

APPENDIX I:

LETTER (EMAIL) OF PERMISSION TO USE COPYRIGHT MATERIAL

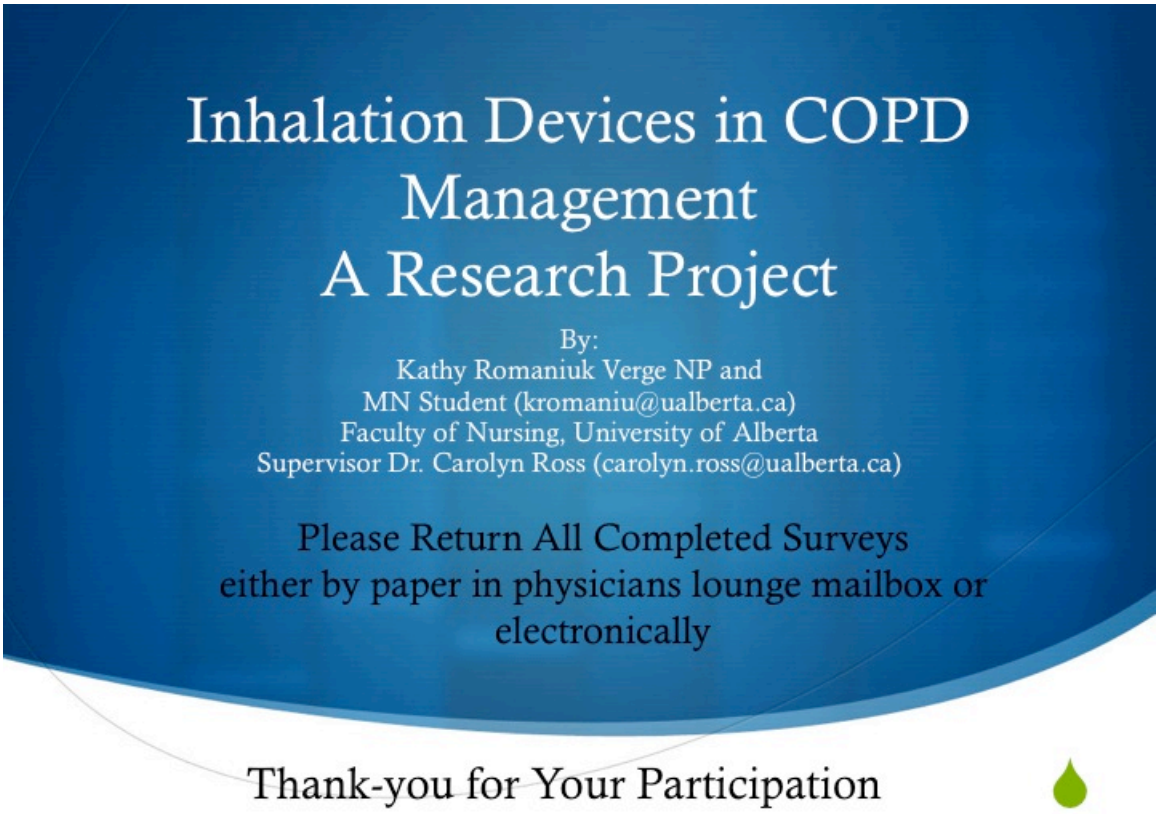
December 27, 2009

Hi, Kathy-
Attached is a copy of the survey we used in our study. Sorry it took so long for us to connect, but hopefully this is helpful.
Good luck and Happy New Year!

Irene

APPENDIX J:

POSTER TO NOTIFY PHYSICIANS OF THE INVESTIGATION



APPENDIX K:

SAMPLE CHECK LIST OF FACTORS TO CONSIDER WHEN PRESCRIBING INHALATION THERAPY

PRESCRIBER CHECKLIST	
	Ease/Simplicity of Use
	Patient is Able to Perform Correct Technique
	Cost to Patient
	Cost to the Facility
	Personal Familiarity with Drug/Device
	Device Portability
	Check Patient's Inspiratory Flow
	Patient Preference for a Device
	Patient Co-Morbidities
	Patient Cognition
	Previous Therapy
	Severity of Clinical Condition
	Patient Adherence
	Other Devices in Use