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Self-reported inhaler use in patients with chronic obstructive pulmonary disease

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Summary
COPD is a common disease which is increasing in prevalence. The proportion of patients who vary their inhaler use from what is prescribed and the reasons for variance are largely unknown. The objective of this study was to determine the extent of and reported reasons for patient-reported variance in the use of inhalers prescribed for COPD. A 17-item survey was mailed to 600 ambulatory patients with spirometry-defined COPD. The survey included questions about inhaler use and reasons for using inhalers differently than prescribed. Survey responses were compared between patients reporting no variance vs. variance from prescribed instructions. Logistic regression was used to determine predictors for variance. The response rate was 45.8% (48.7% male; mean age: 73 ± 8 years). Forty percent of respondents were not using inhalers as prescribed. The most common reasons were: feeling the inhalers did not help breathing (20%), forgetting to use inhalers (19%) and cost (15%). Higher education level, home oxygen use and prescriptions for ipratropium were predictors for inhaler variance. The impact of inhaler variance on morbidity of COPD should be evaluated.

Chronic obstructive pulmonary disease (COPD) is a disease characterized by airflow limitation.[1] The incidence of COPD is increasing and is the fourth leading cause of death in the United States.[2] By 2020, COPD is expected to become the third most common cause of death worldwide.[3]

The goals of treating COPD are to prevent disease progression, relieve symptoms, improve exercise tolerance, prevent complications, exacerbations and infections, and reduce mortality. Other than smoking cessation, no clinical interventions have been shown to modify the long-term

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decline in lung function that is the hallmark of COPD, although both supplemental oxygen and the influenza vaccination may prolong survival.[1] The Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines provide recommendations for diagnosing and classifying disease severity and strategies for treating and monitoring disease progression.[1] Despite the publication of these guidelines, a significant treatment gap exists in that the disease remains under-diagnosed and under-treated.[4–7]

Few studies have evaluated reasons for the treatment gap, but physician-, health care system-, and patient-related factors likely all contribute. With regard to patient-related factors, studies suggest that up to 50% of COPD patients are non-adherent (i.e., vary inhaler use) to prescribed therapy.[8–14] Non-adherence is defined as the extent to which a person's behaviour corresponds with agreed recommendations from a health care provider.[15] Patients may underuse, overuse, or misuse medications. Underuse is a reduction (whereas overuse is an increase) of the daily use of medication indicated for the treatment or prevention of a disease or condition,[16] whereas use of an ineffective, not indicated, or duplicate drug is defined as misuse.[16] Patients may also self-manage their COPD based on their symptoms.[12,13] There are limited data on the extent of patient-reported variance in inhaler use and reasons for variance.[13] The purpose of this study was to determine the extent of patient-reported variance to prescribed inhaler regimens and the reported reasons for this variance in patients with spirometry-defined COPD.

Materials and methods

Study design and patient population

This was a cross-sectional survey mailed to ambulatory patients with spirometry-defined COPD at Kaiser Permanente Colorado (KPCO). KPCO is a group-model, closed-panel, non-profit health maintenance organization that provides integrated health care services to over 470,000 members at 17 medical offices in the Denver–Boulder metropolitan area. Medical and pharmacy records were reviewed for pertinent study-related data for all patients who responded to the survey. Study approval was obtained from the KPCO Institutional Review Board.

Patients were identified for study inclusion using a KPCO database that houses validated patients with spirometry-defined COPD. This database is populated administratively using ICD-9 diagnoses codes with patients who have had at least two encounters with a COPD diagnosis at clinic visits, emergency department visits, or hospitalizations separated by at least 30 days. Spirometry-data are then manually abstracted from medical records for each patient and classified by severity (mild, moderate, severe and very severe) based on GOLD guidelines.[1] Patients with spirometry-defined COPD per the GOLD guidelines were eligible for inclusion.[1]

Survey development and administration

Invitation letters, the survey instrument, and an addressed, postage-paid envelope were mailed to eligible patients. The invitation letter contained required elements of informed consent to allow access to the patients' medical and pharmacy records. Reminder postcards were sent to non-respondents 30 days after the original mailing. In order to protect patient confidentiality, surveys were mailed, collected, and analyzed by a local, independent research firm. Responses were collated and entered into a database that identified patients only by a unique identifier which was then linked back to medical record numbers by the researchers.

Searches of the medical literature using the MEDLINE database (1966 through November 2006) were conducted in order to retrieve any current literature in which a survey appropriate for our needs had already been published. Reference lists of studies were also manually reviewed to identify any additional relevant studies. Through this process, one study was identified. Although the survey used in this study was not validated for construct, it did undergo a process for face and content validity.[13] A 3-page, 17-item survey (Appendix I) was developed to assess self-reported inhaler use, patient beliefs about COPD, and demographic characteristics. The initial survey items were developed by the study investigators. Initial drafts of the survey were independently reviewed by five clinical pharmacy specialists and two primary care physicians with extensive experience in developing patient adherence surveys who were not active participants on the study team. The survey was revised based upon these comments. The survey was revised based on the content experts' feedback.

Patients reported the number of times they used each inhaler per day on the first section of the survey, we did not use other types of adherence scales (such as Medication Adherence Scale or Inhaler Adherence Scale) to limit the length of the survey. Patients reported reasons for varying inhalers by selecting responses from a list of possible reasons or adding reasons in an open-ended fashion. Patient-reported inhaler use that varied from the prescribed regimen was ascertained by the question: ''Do you use all your inhalers exactly as they have been prescribed by your physician?'' (Answer options were yes or no). A Likert-type scale (1 = strongly disagree, 5 = strongly agree) was used to quantify the responses to questions regarding patient beliefs and understanding about COPD and its treatment. Responses were dichotomized and compared by strongly disagree/disagree/neutral vs. agree/strongly agree.

Sample size

No formal sample size was determined for this study because the primary outcome was descriptive. A convenience sample of 600 patients with spirometry-defined COPD was surveyed. After surveying was complete, an analysis for potential non-response bias was conducted by comparing administratively available demographic characteristics (age, sex, COPD severity) of respondents to non-respondents.

Statistical analysis

The primary outcome measure was to describe the proportion of patients who self-reported varying their inhaler use compared to how it was prescribed. Secondary