Improvement in COPD management by access to asthma/COPD clinics in primary care: Data from the observational PATHOS study

Karin Lisspers a,*, Gunnar Johansson a, Christer Jansson b, Kjell Larsson c, Georgios Stratelis d, Morten Hedegaard e,1, Björn Ställberg a

a Department of Public Health and Caring Sciences, Family Medicine and Preventive Medicine, Uppsala University, BMC, Box 564, SE-751 22 Uppsala, Sweden
b Department of Medical Sciences, Respiratory Medicine and Allergology, Uppsala University, Akademiska sjukhuset, SE-751 85 Uppsala, Sweden
c Unit of Lung and Allergy Research, National Institute of Environmental Medicine, Karolinska Institutet, Box 210, SE-171 77 Stockholm, Sweden
d AstraZeneca Nordic-Baltic, SE-151 85 Södertälje, Sweden
e Formerly AstraZeneca Nordic-Baltic, DK-2300 Copenhagen S, Denmark

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Summary
Background: Chronic obstructive pulmonary disease (COPD) guidelines emphasize the importance of patient education to improve quality of life and avoid exacerbations. Longitudinal evaluations of structured management of COPD in primary care are lacking.
Aim: To evaluate the impact of primary care asthma/COPD clinics on exacerbations, hospitalizations, and associated costs in COPD.
Methods: This population-based, retrospective, observational study, linking primary care medical records data to mandatory Swedish national registries, included patients with COPD from 76 primary healthcare centers (1999–2009). A questionnaire on access to an asthma/COPD clinic was retrospectively answered. Propensity score matching was performed at index (COPD diagnosis) by center type (with and without an asthma/COPD clinic). Poisson regression was used to compare the yearly rate of exacerbations (hospitalization, emergency visits, or prescription for oral steroids or antibiotics) and COPD-related prescriptions at the centers. An
Introduction

Due to exposure to risk factors and an ageing population, the prevalence of chronic obstructive pulmonary disease (COPD) is increasing worldwide. [1] The disease is an important challenge for public health and healthcare systems [2], imposing substantial healthcare and societal costs [1]. Many patients remain undiagnosed, and many diagnosed patients are not treated in accordance with international guidelines [3]. Current guidelines emphasize the importance of patient education to improve disease knowledge and eliminate risk factors, and also provide recommendations for treatment options with the overall goal of improving quality of life and reducing exacerbations. If left untreated or inadequately treated, exacerbations and poor quality of life contribute to a permanent deterioration in health status and drive costs [1,4]. To face these challenges, there is a need for an efficient and proactive primary healthcare structure to enable optimal management and symptom relief [5–7].

The Swedish healthcare system is organized into primary healthcare centers, each responsible for a defined population. With primary care as the base for patient healthcare, structured COPD management in an asthma/COPD clinic, integrated at the primary healthcare center, facilitates routine diagnosis, education about the disease and regular follow-up. The main criteria for an asthma/COPD clinic are that it should be led by a disease-specialist primary care nurse, who works part-time at the clinic, and have a specifically appointed general practitioner as the responsible physician. The main tasks of the asthma/COPD nurse are to perform diagnostic lung function tests, offer smoking cessation programs, support patient education and self-management but also follow-up, especially of patients with poor disease control [8]. However, every general practitioner is responsible for the management, i.e diagnosis, treatment and follow-up of his/her patients with COPD, often in cooperation with the nurse. In addition, the general practitioner always has the opportunity to refer to a pulmonologist/respiratory specialist if there is a need of care that is not available at the primary healthcare center, or if the general practitioner is uncertain of the diagnosis or treatment. There are no limits regarding referrals. Many patients, especially with severe COPD, are managed in collaboration with the general practitioner and pulmonologist/respiratory specialist.

During the past 15 years, these integrated nurse-based asthma/COPD clinics have gradually developed in primary care in response to increasing patient demands, and in concordance with established national criteria [8,9]. In a survey conducted in western Sweden, 80% of primary healthcare centers reported having an asthma/COPD clinic on site. [10] However, there is a lack of knowledge of the effectiveness of asthma/COPD clinics, and well-designed studies are scarce [11]. In one Swedish study, the frequency of acute exacerbations was lower for patients with COPD managed at primary healthcare centers with an asthma/COPD nurse [12], and another showed that quality of care was dependent upon time allocated for the nurse—patient interaction [13].

Asthma/COPD clinics in primary care, including training and employment of specialized nurses, may represent an additional cost to the healthcare system. Costs may also increase if better-structured care leads to increased resource utilization with respect to maintenance pharmacological treatment. Conversely, costs may decrease if improved maintenance therapy and patient management reduces the rate of exacerbations and the need for costly acute treatments. There is a lack of data evaluating asthma/COPD clinics and educational programs in primary care, particularly with regard to health-economic outcomes in patients with COPD [11,14].

This is the first large, retrospective, epidemiological study that links data from medical records and mandatory national healthcare registers in patients with COPD. The aim was to describe the development of COPD healthcare structure in primary care and evaluate the effectiveness of asthma/COPD clinics in primary care, with respect to patient exacerbations, hospitalizations, resource utilization, and treatment costs.

Materials and methods

Study design

The population-based, retrospective, observational PATHOS study was conducted by linking data from primary care
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electronic medical records with data from mandatory Swedish national registries from 1999 to 2009. The linkage of data was performed by the Swedish National Board of Health and Welfare, and the database was managed by the Department of Public Health and Caring Sciences, Uppsala University, Uppsala, Sweden. The personal identification number used to identify patients with respect to all contacts with healthcare professionals was replaced by a study identification number prior to further data processing.

The study protocol was approved by the regional ethics committee in Uppsala, Sweden (reference number 2010/040) and registered at www.clinicaltrials.gov (NCT01146392). The AstraZeneca study code was NIS-RSE-DUM-2010/1. Several analyses of data from this study have previously been published [15–17].

Study population

The baseline population included patients with physician-diagnosed COPD (J44, according to the International Classification of Diseases, 10th Revision, Clinical Modification [ICD-10-CM]). The index date was defined as the date of first COPD diagnosis. Starting from 1 January 1999, patients were followed to 31 December 2009, emigration, or death. Patients eligible for matching were classified according to the type of center at index (with asthma/COPD clinic vs. without asthma/COPD clinic). No exclusion criteria were predefined.

Primary healthcare centers

No formal stratification of primary healthcare centers was performed, but effort was made to ensure that the included centers covered a representative sample of rural and urban areas, public and private providers, and center size. A total of 76 centers were included, with a catchment area of ~800,000 individuals corresponding to 8% of the Swedish population.

Access to an asthma/COPD clinic was defined as availability of a disease-specialist primary care nurse.

Data sources

Data from primary care electronic medical records (e.g., date of birth, sex, diagnoses [ICD-10-CM], number of contacts, lung function assessments, and drug prescriptions) were extracted using an established software system (Pygargus Customized eXtraction Program, CXP; Pygargus AB, Stockholm, Sweden) [18]. Data were also extracted from mandatory Swedish national registries: the National Patient Register (inpatient hospital care [admission and discharge dates, diagnoses] and outpatient hospital care [contacts, diagnoses]), the Cause of Death register (date and cause[s] of death), and the Swedish Prescribed Drug Register.

In 2010, all primary healthcare centers in the study responded to a questionnaire regarding the number of listed patients and the structure of the center during the study period. Questions focused on access to an asthma/COPD nurse, responsible general practitioner, spirometry, and smoking cessation programs. Centers were classified according to the availability of an asthma/COPD nurse. If unknown, centers were classified as having no asthma/COPD nurse. Each center with an asthma/COPD nurse reported the number of allocated nurse-hours per week per 1000 listed patients for 2009.

Outcome measures and variable definitions

COPD exacerbation definition

Exacerbations were defined as COPD-related hospitalizations (ICD-10-CM code J44 as primary diagnosis or J44.0/J44.1 as secondary diagnosis), emergency visits (ICD-10 J44.0/J44.1 in outpatient hospital care), collection of oral steroids (Anatomical Therapeutic Classification [ATC] System code H02AB) or antibiotics (ATC codes J01AA, J01CA). Exacerbations occurring within 14 days were defined as a single event.

Prescription event

Dispensed prescriptions of inhaled drugs used in obstructive pulmonary diseases were defined using ATC codes: inhaled corticosteroids (ICS, R03BA), long-acting β2-agonists (LABAs; R03AC12 and R03AC13), short-acting β2-agonists (SABAs; R03AC), tiotropium bromide (R03BB04), and fixed ICS/LABA combinations (R03AK06 and R03AK07).

Medication utilization

Drug usage after index was calculated for each year for all eligible patients in a given year. The end date of drug usage was calculated from the prescribed dose.

Contacts

Defined as any patient visit, telephone contact, or prescription contact.

Referrals

Defined as any referral to specialist care (out-patient hospital visit) independent of type and reason.

Comorbidities

Diagnosed comorbidities were classified according to ICD-10-CM.

Health-economic analysis

The economic analysis was based on the clinical outcomes for the matched patient populations, and the annual cost per patient for each of the two center types was calculated. The incremental cost-effectiveness ratio was calculated by dividing the difference in costs between the two types of centers with the difference in effect, to determine the additional cost per exacerbation avoided by having an asthma/COPD clinic compared with no clinic. The analysis took a Swedish healthcare perspective and did not consider productivity losses or other indirect costs. Direct costs included general practitioner and nurse contacts, hospitalizations, emergency visits, and exacerbation- and COPD-related medication. The mean annual cost of treatment was calculated by applying Swedish unit costs to the estimated average annual resource use per patient. All unit
costs were 2011 values, except medication costs, which were collected in 2012 and were not indexed. Costs were not discounted due to the 1-year time horizon of the analysis.

The cost of a hospitalization day was based on Diagnose Related Group (DRG) data (average cost per hospitalization day for DRG 088, diagnosis J44.0–44.1) [19]. The costs of emergency and specialist visits were based on the official price list [20]. Costs of general practitioner and nurse contacts were estimated from official cost databases [21,22]. Pharmaceutical costs were based on the official pharmacy retail price [23] of the most frequent prescription for each type of therapy (including any patient co-payment, excluding value-added tax, and parallel imports). Costs were converted to Euros (€) using the average 2011 exchange rate [24].

Statistical analysis

The yearly rate of healthcare utilization events (exacerbations or prescriptions) was calculated using Poisson regression with “events” as the dependent variable and “time on center type” (with or without asthma/COPD clinic) as the offset variable. If a center changed from not having an asthma/COPD clinic, or vice versa, the patient was regarded as having switched from one center type to the other. Robustness analysis included the calendar year at index date as a covariate in the Poisson regression.

Propensity score matching was used to compensate concerns related to the non-random assignment of patients to centers with or without an asthma/COPD clinic [25], reducing potential confounding caused by unbalanced covariates [26]. Patients belonging to either center type were pair-wise matched (1:1), with propensity scores calculated using a number of criteria during the 2 years prior to and at the index date including: age; sex; available lung function measurements; number of prescriptions for antibiotics, oral steroids, tiotropium, ipratropium, ICS, SABAs, LABAs, angiotensin receptor blockers, β-blockers, statins, calcium antagonists, and thiazides; diagnosis of diabetes, asthma, cancer, rheumatoid arthritis, heart failure, hypertension, and stroke; and number of previous hospitalizations.

Results are mean values (standard deviation [SD]), unless otherwise stated. Data management and statistical analyses were performed using SAS version 9.2 (SAS Institute Inc, Cary, NC, USA).

Results

Patient population and healthcare structure

Overall, 21,361 patients with a recorded COPD diagnosis were identified at 76 primary healthcare centers, and formed the study baseline population (Table 1). Of these, 53% were female, the mean age was 68.0 years, and 57% were smokers (smoking status was available for one-third of the study population).

The availability of asthma/COPD clinics increased during the 11-year study period from 34% in 1999 to 85% in 2009 (Fig. 1). In 2009, 89% of the centers with asthma/COPD clinics reported that a nurse was available for 0.95 (0.70) hours per week per 1000 listed patients. The availability of the responsible asthma/COPD general practitioner increased during the study period from 32% in 1999 to 80% in 2009. Likewise, the availability of spirometers and smoking cessation programs increased from 41% and 24% in 1999 to 93% and 80% in 2009, respectively (Fig. 1). Before matching, 11,846 patients were managed at primary healthcare centers with an asthma/COPD clinic at the time of diagnosis, and the remaining 9515 patients were managed at centers without an asthma/COPD clinic (Table 1). Complete lung function data at index were available from only one county and a limited number of patients: 15.2% (n = 1800) at primary healthcare centers with an asthma/COPD clinic and 7.5% (n = 717) without an asthma/COPD clinic. Post-bronchodilator forced expiratory volume in 1 s/forced vital capacity-ratio was similar in the two groups (Table 1).

All 21,361 patients were eligible for matching. Prior to matching, the two populations (with or without an asthma/COPD clinic) differed somewhat (Table 1). Following 1:1 pairwise propensity score matching, two cohorts of 8202 patients each were obtained. The cohorts were similar on the majority of variables examined, but differed with respect to all inhaled therapies with the exception of SABAs (Table 1).

Patients attending a primary healthcare center with an asthma/COPD clinic had both significantly fewer total physician contacts (8.12 [3.35] vs. 16.0 [10.7] per patient/year; mean [SD]) and fewer referrals to specialist care (1.37 [0.51] vs. 1.98 [1.44] per patient/year) (Fig. 2). Patients attending primary healthcare centers with an asthma/COPD clinic were younger at COPD diagnosis than patients at centers without an asthma/COPD clinic (67.4 [11.4] vs. 68.7 [11.2] years, respectively).

Exacerbation-related outcomes

Significant differences between the two propensity score-matched populations were observed with respect to the mean yearly rate of exacerbations and related outcomes (Table 2). Patients managed at primary healthcare centers with an asthma/COPD clinic experienced fewer COPD exacerbations and hospitalizations annually than patients managed at centers without an asthma/COPD clinic (0.71 vs. 0.98, and 0.36 vs. 0.58; 27% and 37% difference, number needed to treat 3.7 and 4.7 respectively; p < 0.0001). In addition, the number of days per year spent in the hospital due to COPD was 35% lower for patients attending a center with an asthma/COPD clinic than those without a clinic (2.40 vs. 3.71 days, respectively; p < 0.0001). The yearly number of emergency visits and collections of prescribed antibiotics showed a similar difference (Table 2), whereas prescription of oral steroids did not differ between the groups (p = 0.817). These results were unchanged after applying the calendar year as a covariate.

Health-economic analysis

The total annual cost per patient was SEK 33,902 (€3754) and SEK 53,546 (€5930) for primary healthcare centers with and without an asthma/COPD clinic, respectively (Table 3).
Having an asthma/COPD clinic was associated with a reduction in both the annual cost of medication and the cost of healthcare contacts (Fig. 3). The total annual cost per patient was reduced by SEK 19,644 (V2175) in centers with an asthma/COPD clinic compared with centers without a clinic. As patients at primary healthcare centers with an asthma/COPD clinic experienced fewer exacerbations (Table 2), the presence of such a clinic was the dominant treatment strategy from a cost-effectiveness perspective (i.e. more effective at lower costs).

Discussion

Main findings

This large, retrospective, propensity score-matched cohort study evaluated the effectiveness of COPD management in primary care, and demonstrated that patients managed at primary care centers with nurse-based asthma/COPD clinics experienced fewer COPD-related exacerbations and hospitalizations. Moreover, structured management of patients with COPD increased in Sweden during the 11-year study period, and access to asthma/COPD clinics at primary healthcare centers considerably reduced treatment costs.

Strengths and limitations of this study

This study has several important strengths, not least the primary care setting, with no restrictions with respect to...
age, medication use, comorbidities, or healthcare insurance. This unbiased data extraction from electronic medical records linked to mandatory national healthcare registers provides high-quality coverage and the opportunity to follow a patient’s management over time using personal identification numbers. The real-world design and large population studied provide data that are increasingly more demanded in respiratory disease research and have a high level of applicability to the general population [27,28].

Propensity score matching ensured that all patients were matched on a number of parameters to minimize bias and the influence of confounding factors. The differences found following matching likely reflects a difference in the overall quality of care, better patient management, and treatment with inhaled therapies at well-organized centers.

Further, possible unknown confounding factors may still reside in the data. The completeness and accuracy of the COPD diagnoses could not be fully verified by spirometry in all cases, due to lack of structured reporting in medical records. This does not mean that spirometry was not performed when establishing the COPD diagnosis. Furthermore, characterization of primary healthcare centers by the presence or absence of an asthma/COPD clinic was performed retrospectively and may be subject to recall bias. Other limitations were lack of available information on the educational level of the nurse in the respiratory field or the specific management used at the asthma/COPD clinics, and smoking status for all included patients.

**Interpretation of findings in relation to previously published work**

The main findings of this study support those of other studies [12,29,30]. However, research evaluating different management programs for COPD has yielded conflicting results. Integrated disease management improved quality of life for patients with COPD in primary care compared with standard care [31], as did an action plan that included the ongoing support of a case manager, which decreased the impact of exacerbations on health status [32]. Conversely, other studies that compared a variety of management programs with standard care found no difference in quality of life, efficacy, hospitalization, or death rates between groups [33–35]. Nevertheless, there are few large studies evaluating the association between asthma/COPD clinics in primary care and exacerbations, hospitalizations, and treatment costs.

One of the reasons for the positive effects in this study could be that centers with well-organized COPD care generally provide a higher quality of care. One indicator of this is that the primary healthcare centers with an asthma/COPD clinic had fewer referrals to secondary care for any reason, as well as fewer all-cause physician contacts, implying a more structured form of patient care. The earlier diagnosis of COPD at primary healthcare centers with an asthma/COPD clinic also reflects improved patient management, and is of importance for disease prognosis [36].

The health-economic analysis showed that overall treatment costs were reduced for patients with COPD treated at a primary healthcare center with an asthma/COPD clinic, which is consistent with previous findings [37]. Ideally, such analyses should include all costs and effects related to treatment. Investments to improve diagnosis were not taken into account in the present study. Moreover, the cost of training of nurses should also be considered. However, given the substantial savings per patient per year, it is likely that such investments would be recouped quickly. The effect of improved care on quality of life, if included in the study, would likely have added to the demonstrated cost effectiveness of the asthma/COPD clinics.
Implications for future research, policy and practice

Data from observational studies of propensity score-matched cohorts provide an alternative to minimize bias and confounding when randomization is not possible, providing complimentary real-life data and alleviating some of the limitations of controlled clinical trials [38]. This study highlights the importance of structured care to improve patient management, clinical outcomes, and reduce treatment costs associated with COPD care. Furthermore, there is a need for more primary care studies to determine asthma/COPD clinic parameters that influence patient outcomes and related costs.

Conclusions

In summary, this observational study linking primary care records to mandatory national registries demonstrates that primary healthcare centers with an asthma/COPD clinic
Table 2  Yearly occurrence of events among pairwise (1:1) propensity score-matched populations of COPD patients treated at primary healthcare centres with or without asthma/COPD clinic, yearly rate of events and yearly number of days.

<table>
<thead>
<tr>
<th>Variable</th>
<th>PHCC with clinic</th>
<th>PHCC without clinic</th>
<th>Rate ratio (95% CI)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exacerbations</td>
<td>0.71 (0.69, 0.73)</td>
<td>0.98 (0.95, 1.01)</td>
<td>0.74 (0.70, 0.75)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Oral steroid prescriptions</td>
<td>0.82 (0.78, 0.86)</td>
<td>0.81 (0.77, 0.86)</td>
<td>1.01 (0.94, 1.08)</td>
<td>0.8107</td>
</tr>
<tr>
<td>Hospitalisations</td>
<td>0.36 (0.35, 0.38)</td>
<td>0.58 (0.55, 0.60)</td>
<td>0.63 (0.59, 0.67)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Number of days at hospital</td>
<td>2.40 (2.26, 2.54)</td>
<td>3.71 (3.49, 3.94)</td>
<td>0.65 (0.60, 0.70)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Antibiotic prescriptions</td>
<td>0.38 (0.37, 0.39)</td>
<td>0.52 (0.50, 0.54)</td>
<td>0.74 (0.71, 0.77)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Emergency visits</td>
<td>0.18 (0.17, 0.19)</td>
<td>0.26 (0.24, 0.29)</td>
<td>0.68 (0.61, 0.76)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

CI, confidence interval; COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroids; LABA, long-acting β2-agonist; OCS, oral corticosteroids; PHCC, primary healthcare centre; SABA, short-acting β2-agonist.

Table 3  Unit costs (SEK 2011) and yearly cost per patient per year in centres with or without asthma/COPD clinic and ICER per exacerbation avoided per patient per year among patients with COPD.

<table>
<thead>
<tr>
<th>Resource</th>
<th>Unit cost (SEK)</th>
<th>PHCC with clinic</th>
<th>PHCC without clinic</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hospitalisation, days</td>
<td>5978</td>
<td>14,347</td>
<td>22,178</td>
<td>–7831</td>
</tr>
<tr>
<td>Emergency, visits</td>
<td>2567</td>
<td>462</td>
<td>667</td>
<td>–205</td>
</tr>
<tr>
<td>Non-emergency outpatient visits</td>
<td>3243</td>
<td>492</td>
<td>654</td>
<td>–162</td>
</tr>
<tr>
<td>General practitioner, consultations</td>
<td>1254</td>
<td>10,182</td>
<td>20,064</td>
<td>–9881</td>
</tr>
<tr>
<td>Nurse, consultations</td>
<td>459</td>
<td>2911</td>
<td>4422</td>
<td>–1511</td>
</tr>
<tr>
<td>Total contact costs</td>
<td>28,394</td>
<td>47,984</td>
<td>19,590</td>
<td></td>
</tr>
<tr>
<td>Total contact costs, €</td>
<td>3144</td>
<td>5314</td>
<td>–2169</td>
<td></td>
</tr>
<tr>
<td>Prescription costs</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fixed ICS/LABA combination prescriptions</td>
<td>1802</td>
<td>2414</td>
<td>2252</td>
<td>162</td>
</tr>
<tr>
<td>Tiotropium prescriptions</td>
<td>1243</td>
<td>1702</td>
<td>1653</td>
<td>50</td>
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<tr>
<td>LABA prescriptions</td>
<td>755</td>
<td>506</td>
<td>589</td>
<td>–83</td>
</tr>
<tr>
<td>Ipratropium prescriptions</td>
<td>182</td>
<td>149</td>
<td>176</td>
<td>–27</td>
</tr>
<tr>
<td>SABA prescriptions</td>
<td>161</td>
<td>197</td>
<td>236</td>
<td>–39</td>
</tr>
<tr>
<td>Total medication costs</td>
<td>5508</td>
<td>5562</td>
<td>–54</td>
<td></td>
</tr>
<tr>
<td>Total medication costs, €</td>
<td>610</td>
<td>616</td>
<td>–6</td>
<td></td>
</tr>
<tr>
<td>Total costs</td>
<td>33,902</td>
<td>53,546</td>
<td>–19,644</td>
<td></td>
</tr>
<tr>
<td>Total costs, €</td>
<td>3754</td>
<td>5930</td>
<td>–2175</td>
<td></td>
</tr>
<tr>
<td>ICER</td>
<td></td>
<td></td>
<td></td>
<td>Dominant</td>
</tr>
</tbody>
</table>

Data are presented as yearly costs per patient in SEK, unless otherwise stated.

COPD, chronic obstructive pulmonary disease; ICER, incremental cost-effectiveness ratio; ICS, inhaled corticosteroids; LABA, long acting β2-agonist; PHCC, primary healthcare centre; SABA, short-acting β2-agonist.

Figure 3  Yearly treatment costs per patient in primary healthcare centers with and without an asthma/COPD clinic. COPD: chronic obstructive pulmonary disease.
were associated with benefits in patient outcomes and overall cost of care, emphasizing the importance of access to structured COPD care.

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