Disease Management Programs for Patients With COPD in Germany: A Longitudinal Evaluation of Routinely Collected Patient Records

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INTRODUCTION: The primary aim of the disease management program (DMP) for patients with COPD is to improve health outcomes and thereby to reduce overall costs. Six years after its introduction in Germany, no consensus has yet been reached as to whether the DMP has been effective in reaching these goals. The objective of the study was an evaluation of the DMP for COPD in Bavaria using routinely collected subject medical records. METHODS: A longitudinal population-based study, comparing the total DMP population of up to 86,560 patients with a stable cohort of 17,549 subjects over a period of 5 years. The effect of subject dropout in the cohort is further estimated by means of inverse probability weighting. RESULTS: The proportion of subjects in the total population who were prescribed and received treatment with oral corticosteroids declined at a constant rate of 1.0% per year ($P < .001$). The proportion of subjects who were given a prescription for theophylline decreased at a constant rate of 2.0% per year ($P < .001$). By 2012, 15.6% of the total population and 26% of the cohort had undergone self-management education. While the proportion of smokers in the total population remained constant because of the effect of newly enrolled subjects, the proportion of smokers decreased significantly even after dropout adjustment, from 29% to 21%. The occurrence of exacerbations decreased steadily at a rate of 0.9% (total population) or 0.7% (cohort) per year. While the occurrence of emergency hospital admissions decreased in the total population, an increase was observed within the cohort. CONCLUSIONS: Summarizing all results leads to the suggestion that the German DMP for COPD has been effective in enhancing the quality of care in regard to an improved adherence to guidelines, pharmacotherapy, exacerbations, and self-management education. However, the DMP was not able to prevent an increase in emergency hospital admissions for the stable population in the cohort. *Key words: active patient participation;* COPD*; disease management program; general practice;; exacerbations; pharmacotherapy; guideline adherence; emergency admission.* [Respir Care 2014;59(7):1123–1132. © 2014 Daedalus Enterprises]

Introduction

The German disease management programs (DMP) were introduced in 2003. Currently, more than 6 million statutorily insured patients in Germany are enrolled in one of the 6 DMPs.[1] At present, programs have been introduced for patients with breast cancer, type 1 and type 2 diabetes, coronary heart disease, asthma, and COPD.

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Dr Schneider received grants from the German Ministry of Health as an external expert for the development of the disease management programs for asthma and COPD and received grants for disease management program lectures. Mr Donnachie and Dr Hofmann are employees of The Association of Statutory Health Insurance Physicians in Bavaria (Kassenärztliche Vereinigung Bayerns [KVB]). This Association is a statutory public corporation and therefore a nonprofit organization. As a contract partner to the Bavarian Disease Management Programs, the KVB represents the interests of the participating physicians. It is responsible for the distribution of remuneration, retaining a percentage of this to cover administrative costs. The other authors have disclosed no conflicts of interest.

Various studies suggest that the German DMPs have improved the quality of care for patients with diabetes,[2-4] coronary artery disease,[5] and asthma.[6] Furthermore several systematic reviews confirm positive effects on the quality of care across a number of chronic diseases.[7-11]

As yet, however, the German DMP for COPD patients has not been broadly evaluated. Studies investigating the utility of such programs for COPD have come to varying conclusions, and the authors of several meta-analyses[12,13] have argued that larger randomized controlled trials are needed. A randomized controlled study conducted by Rice et al[14] showed that a relatively simple DMP reduced hospitalizations and emergency department visits for patients with COPD. Similar findings including an improvement in health care were reported in the Netherlands by Steuten et al,[15] who followed up on 317 patients after 1 y of participation in a DMP. The generalizability of this result is questionable, having been conducted in a small group of general practices with nurse practitioners trained for caring for COPD patients. In contrast, Ofman et al[7] reviewed 102 studies to conclude that disease management has fewer benefits for patients with COPD than for those with other conditions. Monninkhof et al[16] demonstrated that self-management education in patients with COPD did not improve the number of hospitalizations and emergency department visits or lung function. A Cochrane review[17] examined whether action plans with limited COPD education assist in the recognition of and reaction to an exacerbation, thus speeding the initiation of an appropriate treatment. However, they found no evidence that the utilization of health care resources had decreased or that health-related quality of life had improved. For this reason, they were unable to recommend the use of an action plan and limited self-management education where this is not part of a multifaceted approach or ongoing case management. The efficacy of DMPs for COPD patients is thus still a matter of discussion, especially for population-scale interventions such as those in Germany.

The present investigation aims to assess whether key indicators of quality improved during the first 5 y of the Bavarian DMP for patients with COPD. Building upon the authors' previous study of the DMP for asthma,[6] the present evaluation investigates the effectiveness of the German DMP for COPD based on similar routinely collected patient records.

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QUICK LOOK

Current knowledge

The primary aim of a disease management program is to improve health outcomes and to reduce overall costs. Disease management programs for COPD have been introduced to prevent exacerbations and to maximize quality of life.

What this paper contributes to our knowledge

A German disease management program for COPD was effective in enhancing the quality of care with regard to an improved adherence to guidelines, pharmacotherapy, exacerbations, and self-management education. However, emergency admissions for stable population in the cohort were increased.

Methods

The German DMP for COPD

In 2001, a committee of experts reporting to the German Federal Ministry of Health criticized the overuse, underuse, and misuse of treatment in the care of chronically ill patients, including those with COPD. A DMP was suggested as a quality program to facilitate the continuous improvement in the care of chronically ill patients.[18,19] As a result, the DMP for COPD was developed by the Federal Joint Committee (Gemeinsamer Bundesausschuss) and introduced in Bavaria in April 2006. The aim was to improve care by establishing standards for diagnosis, treatment, documentation, quality assurance, and referral, while enhancing active patient participation. In parallel to the introduction of DMP, the national COPD guideline[20] was developed, taking the Global Initiative for Chronic Obstructive Lung Disease and the National Institute for Health and Clinical Excellence guidelines as its basis. Released in February 2006, it serves as the primary guideline for the German health care system. The main characteristics of the German DMP are as follows:

- Coordination of care is provided by a general practitioner (GP);
- Care is based on evidence guidelines;
- Patient education and active involvement of patients;
- Regular standardized documentation;
- Benchmarking of both process and outcome quality;
- Minimum standards of structural quality for participating physicians;

- Voluntary participation from physicians and patients; and
- Incentives for participation for physicians and patients.

To enroll a patient into the DMP COPD, the diagnosis must first be confirmed and documented by the coordinating GP according to the guidelines. In addition to a typical COPD medical history and an FEV_1 measurement of $< 80\%$ of the predicted value, at least one of the following 3 criteria must be met: (1) $FEV_1/VC \leq 70\%$ and an increase in FEV_1 of $< 15\%$ and/or < 200 mL under β_2-agonist or anticholinergic reversibility testing; (2) $FEV_1/VC \leq 70\%$ and an increase in FEV_1 of $< 15\%$ and/or < 200 mL under glucocorticoid reversibility testing; and (3) if FEV_1/VC was $> 70\%$, the exclusion of other lung diseases by means of x-ray and a diagnosis of increased airway resistance, lung hyperinflation, or impaired gas exchange.[20]

Participating patients receive a check-up at their coordinating general practice either quarterly or half-yearly. The check-up interval is decided by the physician based on symptom severity and overall patient health. A reminder system for patients and practices helps to ensure that these regular consultations are not overlooked. Health insurance companies support their patients by supplying information to assist self-management, and by providing monetary and other incentives (eg, waiving the quarterly consultation fee of €10 that was usually payable when visiting a GP).

Patients must be treated according to evidence-based guidelines. A standardized medical record is created at each check-up and submitted to various official agencies for quality assurance purposes. This includes height, weight, smoking history, FEV_1 measurements, COPD-related medication, participation in patient education courses, exacerbations, emergency hospital admissions due to COPD, and referrals to a specialist pulmonologist. Physicians receive monetary compensation for submitting the data, but there are no sanctions or direct incentives attached to the contractually defined performance targets (eg, pay-for-performance).

The DMP was underpinned by the introduction of additional quality improvement measures. GPs receive half-yearly feedback reports to benchmark their performance on the basis of quality indicators (eg, emergency hospital admissions, exacerbation rates, utilization of self-management education, and pharmacotherapy). Additionally, participating GPs are obliged to complete COPD-specific continuing medical education at least once every 3 years. These are provided by various commercial and nonprofit organizations, including the National Association of Statutory Health Insurance Physicians of Bavaria (Kassenärztliche Vereinigung Bayerns [KVB]). Finally, the KVB utilizes continuing medical education events and its members' journal to engage coordinating physicians in the process of continuous quality improvement.

In July 2008, a revised version of the patient record was introduced to simplify the documentation process and increase data quality. The most significant changes were that oral and inhaled corticosteroids and theophylline were no longer classified as controller or reliever medication, instead being listed as options under "additional COPD-specific medication." Additionally, the new record asks for the number of exacerbations since the previous record, whereas the initial version asked for the number of emergency treatments received as an out-patient. A direct comparison of, for example, the proportion of patients receiving theophylline in 2007 and in 2012 is thus misleading.

Study Data and Methods

The KVB analyzed 86,560 DMP records of anonymous COPD subjects, with each subject identified by a unique pseudonym. To assess the impact of an evolving study population, the total study population is first compared and contrasted with a cohort of subjects enrolled in the first year of the DMP. The cohort removes the influence of newly enrolled and possibly less severely ill subjects, although both groups are affected by subject dropout. In the second part of the analysis, the dropout process is modeled. Analysis of the cohort with correction for dropout enables the development of the disease to be observed, and not simply changes in the makeup of the DMP population.

The cohort was composed of participants enrolled before July 2007 and were observed until June 2012. It included only those participants with a plausible FEV_1 value in the first year of the program. As sex (required to calculate the FEV_1 as percentage of predicted) was not recorded in the first version of the documentation, this criterion implicitly requires that the members of the cohort did not drop out before this point. Participants were considered implausible and therefore were excluded from the study if ≥ 2 documented FEV_1 values were present that were higher than the expected value for a healthy adult, or if identical values were given in 3 consecutive records. We thus consider the cohort to be a more controlled collective than the total population, containing fewer subjects with borderline or undifferentiated diagnoses.

Regression Analysis

Regression analysis was used both to measure the trend over time and to model the discontinuity induced by the revised subject record. The standard regression model applied was of the form $y = \alpha + \beta_T t + \varepsilon$, where y is the proportion being observed, t is the time (y) from July 2006, and ε is an independent normally distributed error term. The coefficient β_T may then be interpreted as the

Table 1. Subjects and Distribution of Age and Sex Between 2007 and 2012 in the DMP for COPD in Bavaria

Variables	Year of participation					
	2007	2008	2009	2010	2011	2012
Subjects enrolled (*n*)	29,006	46,722	61,009	71,448	79,712	86,560
Age						
18–40	2.1	2.3	2.4	2.3	2.1	2.0
41–60	25.9	25.4	25.2	24.6	24.5	24.2
61–80	62.3	61.	61.1	61.1	60.9	60.7
> 80	9.7	10.5	11.3	12.0	12.6	13.2
Mean	66.6	66.7	66.9	67.2	67.4	67.6
SD	11.4	11.6	11.8	11.9	11.8	11.8
Sex						
Female	38.2	41.6	44.1	44.2	44.7	45.3
Male	48.1	51.7	54.0	53.9	53.6	53.3
Unknown	13.7	6.7	2.0	1.8	1.6	1.4

Data are %, unless otherwise indicated.

average annual increase in the proportion *y*. Discontinuities due to the change in the subject record were modeled by adding to the regression models a binary term (β_D), which was removed if nonsignificant. Exacerbations and emergency hospital admissions exhibit a seasonal trend, modeled by including a term (β_S) to differentiate the first and second half of the year. The increase in the proportion of subjects with completed self-management education was found to be nonlinear and best modeled by including time on a logarithmic scale.

Dropout Analysis

An initial assessment of subject dropout is obtained by grouping the subjects according to their observation time and comparing the development of the different dropout groups with the group that was observed throughout. Differences between these groups enable the presence and direction of any attrition bias to be identified. This simple diagnostic procedure does not measure the extent to which dropout influences the inference of the basic regression models, but does provide a useful sanity check for more complex procedures.

A quantitative estimate of the effect of dropout is obtained using the statistical method of inverse probability weighting (IPW) as described in Robins et al.[21] The idea behind IPW is to weight the subjects available at *t* to compensate for those not present due to dropout.[22,23] It is assumed that the dropout mechanism can be modeled adequately using the available data, such that the probability of dropout at *t* is largely dependent on data collected at $t - 1$. In the first stage, the probability of a subject being present is estimated using logistic regression, and the inverse probability is calculated. In the second stage, weighted regression models (generalized estimating equations) are used to obtain an unbiased estimate in the sense that, under the stated assumption, the effect of dropout due to measured variables is removed. The resulting models may thus be interpreted as the predicted outcome of a closed system, with both the influence of newly enrolled subjects and dropouts being removed by the cohort and IPW, respectively.

The study was approved by the Medical Ethics Committee of the University Hospital Klinikum rechts der Isar (approval no. 5121/11). Statistical analysis was conducted using the R environment for statistical computing.[24]

Results

The results of the study are summarized in Tables 1, 2, and 3, with data aggregated by half-year. Both for reasons of clarity and to highlight the long-term trend, each year is represented in the tables by the result from the first half-year (ie, January to June). The regression models include data from both halves of each year.

Table 1 shows that since the introduction of the DMP the number of participating subjects has increased steadily. A total of 30,445 subjects were enrolled between July 2006 and July 2007, the first year of the program, with a subject record available for 29,006 of these subjects in the first half of 2007. By 2012, > 85,000 subjects were participating in the program. The distributions of age and sex remained largely unchanged over the observation period. The number of participating physicians increased from 5,293 in 2006 to 8,218 in 2012. These doctors are predominantly GPs (96–97%), followed by pulmonologists (1–2%) and other specialists (1–2%) in private practice.

Table 2. Comparison of the Total Population and Cohort for Variables Other Than Medication

Variables	Group	First Record		Revised Record				Time Effect		Seasonal Effect	
		2007	2008	2009	2010	2011	2012	β_T	*P*	β_S	*P*
Subjects enrolled (*n*)	Total	29,006	46,722	61,009	71,448	79,712	86,560				
	Cohort	17,109	16,341	15,589	14,244	12,841	10,916				
Mean FEV_1 (% predicted)	Total	75.3	75.7	77.5	78.2	78.0	77.5	0.6	< .001	NA	
	Cohort	63.9	62.8	62.8	62.2	62.3	62.4	−0.4	.002	NA	
	IPW	62.3	61.7	61.1	60.5	59.9	59.2	−0.3	< .001	NA	
Emergency hospital admission (%)	Total	3.7	3.6	3.2	2.8	2.9	2.7	−0.2	< .001	−0.5	< .001
	Cohort	3.5	3.9	4.3	4.0	4.3	3.4	0.1	.04	−0.7	.001
	IPW	3.7	3.8	4.6	4.7	4.9	5.0	0.01	.05	−0.2	< .001
Emergency department treatment/ exacerbation (%)*	Total	2.7	5.8	9.9	9.1	9.0	8.2	−0.9	< .001	−1.5	< .001
	Cohort	2.4	7.2	13.3	11.8	12.1	11.1	−0.7	.007	−2.0	.002
	IPW	16.2	15.6	15.1	14.6	14.0	13.5	−0.02	< .001	−0.2	< .001
Patient self-management education (%)	Total	3.9	9.5	11.8	14.2	14.7	15.6	NA		NA	
	Cohort	8.0	16.8	20.3	23.1	24.4	26.0	NA		NA	
	IPW	9.5	15.6	19.6	22.6	25.0	27.1	NA		NA	
Smoking status (%)	Total	26.9	26.8	26.7	27.8	28.7	29.3	0.4	.004	NA	
	Cohort	28.3	25.5	23.5	22.8	21.9	21.6	1.4	< .001	NA	
	IPW	27.3	26.1	24.5	23.0	21.6	20.2	−0.04	< .001	NA	

For each parameter, the total population is compared with the cohort. IPW estimates are given for the cohort, whereby the parameter estimates (time and discontinuity effect) result from a different model and are thus not comparable.

* Regression model considers only exacerbations, recorded from July 2008 onwards. The IPW estimation extrapolates to make predictions for 2007 and 2008.

IPW = inverse probability weighting

NA = not applicable

β_T = average annual increase in the proportion *y* (the proportion being observed)

β_S = term for differentiating the first and second half of the year

Table 3. Comparison of the Total Population and Cohort for Medication

Variables	Group	First Record		Revised Record				Time Effect		Discontinuity Effect	
		2007	2008	2009	2010	2011	2012	β_T	*P*	β_T	*P*
Short-acting β_2 agonists or short-acting anticholinergics (%)	Total	59.8	57.8	60.0	60.2	59.7	59.6	0.1	.47	NA	
	Cohort	62.5	63.1	65.9	66.4	66.4	66.7	0.64	< .001	1.3	.003
	IPW	62.7	63.4	65.3	66.0	66.7	67.3	0.01	< .001	0.04	.001
Long-acting β_2 agonists (%)	Total	57.0	56.0	58.9	60.0	60.3	60.2	0.5	.01	1.8	.01
	Cohort	60.5	62.2	65.6	68.0	68.5	69.1	1.2	< .001	2.7	< .001
	IPW	60.5	62.0	65.5	66.9	68.3	69.6	0.03	< .001	0.09	< .001
Long-acting anticholinergics (%)	Total	37.6	37.1	33.8	38.3	39.4	39.8	0.7	.08	NA	
	Cohort	41.1	42.7	44.3	47.2	48.0	48.8	1.7	< .001	NA	
	IPW	41.1	42.9	44.7	46.6	48.4	50.3	0.03	< .001	NA	
Oral corticosteroids (%)	Total	19.5	17.8	9.1	8.0	7.4	6.6	−1.0	< .001	−8.0	< .001
	Cohort	20.0	20.9	12.8	12.3	11.7	10.7	−0.6	< .001	−6.6	< .001
	IPW	20.6	20.0	13.2	12.8	12.4	12.0	−0.02	< .001	−0.46	< .001
Inhaled corticosteroids (%)	Total	56.0	53.2	39.8	38.9	37.5	36.5	−1.3	< .001	−12.6	< .001
	Cohort	58.3	58.9	46.5	47.3	47.6	47.4	0.2	.155	−11.8	< .001
	IPW	58.3	58.5	47.4	47.5	47.7	47.8	0.0	.69	−0.45	< .001
Theophylline (%)	Total	24.9	21.2	14.3	12.4	10.7	9.1	−2.0	< .001	−5.9	< .001
	Cohort	25.9	25.2	19.1	18.3	16.8	15.6	−1.2	< .001	−4.7	< .001
	IPW	56.3	25.1	19.6	18.7	17.8	17.0	−0.03	< .001	−0.24	< .001

NA = not applicable

IPW = inverse probability weighting

β_T = average annual increase in the proportion *y* (the proportion being observed)

Total DMP Population

The mean FEV_1 in the total population rose marginally from 75.3% in 2007 to 77.5% in 2012 ($P < .001$; see Table 2). Emergency hospital admissions fell from 3.7% to 2.7% in the same interval ($P < .001$). The occurrence of exacerbations fell significantly from 9.9% in 2009 to 8.2% in 2012 ($P < .001$); the rate of ambulatory emergency hospital admissions, as recorded until July 2008, is seen not to be comparable with the rate of exacerbations. Both emergency hospital admissions and exacerbations exhibit clear seasonal trends, with the proportion of subjects experiencing such events reduced by 0.5% and 1.5%, respectively, in the second half of the year ($P < .001$). Whereas in 2007 only 3.6% of the subjects had taken part in an educational program, this number had increased to 15.6% by 2012, with a sharp increase in the first years of the DMP. The proportion of smokers in the total DMP population increased from 26.9% to 29.3% ($P = .004$).

Analysis of the prescribed medication in the total DMP population reveals a number of distinct findings (Table 3). The most demonstrative result is a clear declining trend in the prescription of oral corticosteroids, inhaled corticosteroids, and theophylline. Despite large discontinuities due to the revised subject record, the data and fitted regression models show significant decreases both before and after this discontinuity. The prescription of oral corticosteroids in the total population declined at a rate of 1.0% ($P < .001$) per year, prescription of inhaled corticosteroids declined at a rate of 1.3% ($P < .001$), and prescription of theophylline declined at a rate of 2.0% ($P < .001$). The proportion of subjects who received prescriptions for short-acting β_2 agonists and short-acting anticholinergic bronchodilators remained stable at just under 60%. The proportion of subjects who received prescriptions for long-acting β_2 agonists and long-acting anticholinergics increased by 3.2% and 2.2%, respectively.

Cohort

The cohort analysis observed a total of 17,549 participants who were enrolled in the study before July 2007, of whom 17,109 had a subject record in the first half of 2007 (see Table 2). The mean FEV_1 of the cohort decreased slightly from 63.9% in 2007 to 62.4% in 2012 ($P = .002$; see Table 2). The increase in FEV_1 by 0.6 per year ($P < .001$) in the total population contrasts with the decrease observed in the cohort. Emergency hospital admissions within in the cohort rose by ~0.1% per year in the same interval ($P = .04$). This again contrasts with the decreasing trend of 0.2% per year ($P < .001$) seen in the total population. The occurrence of exacerbations in the cohort fell significantly from 13.3% in 2009 to 11.1% in 2012 ($P = .007$). As in the total population, emergency hospital admissions and exacerbations in the cohort exhibit clear seasonal trends, with the proportion of subjects experiencing such events reduced by 0.7% and 2.0%, respectively, in the second half of the year ($P < .002$). The proportion of subjects receiving self-management education by 2012 was 26%. The proportion of smokers in the cohort decreased from 28.3% to 21.6% ($P < .001$). As with the total population, the prescription of theophylline and oral corticosteroids was reduced significantly (Table 3). Unlike in the population as a whole, the use of short-acting β_2 agonists, long-acting β_2 agonists, and long-acting anticholinergics saw substantial increases of 0.6%, 1.2%, and 1.7% per year, respectively. Prescriptions for inhaled corticosteroids saw no change, other than a discontinuity with the introduction of the new subject record.

Dropout Analysis

Figure 1 reveals differences between subjects observed until the end of the observation period and those withdrawing from the program after 3, 4, or 5 y. The plots of short-acting medication, long-acting β_2 agonists, long-acting anticholinergics, and oral corticosteroids show that dropouts are more likely to receive these drugs. The effect of dropout is therefore to reduce the number of subjects in the cohort with prescription of the drug; the observed rate of increase may therefore be an underestimate of the underlying rate of new prescriptions. Dropouts are also more likely to receive theophylline, suggesting this as a contributing factor in the observed decline in prescription. The data for inhaled corticosteroids is inconclusive but is consistent with an unchanged level of prescription. Likewise, the utilization of patient self-management education appears to be independent of the number of dropouts. Finally, dropouts are more likely to be smokers, have low FEV_1 values, and to experience exacerbations and emergency hospital admissions. In interpreting these plots, it is important to consider both the scale of the Y axis and the fact that most subjects are contained within the continuous line of completers. Seemingly large differences do not automatically translate into large biases.

The observations from Figure 1 are quantified by the IPW model and visualized in Figure 2. The points in Figure 2 show the observed development of the variables in the cohort. The dashed lines represent the estimate obtained by simple linear or logistic regression without consideration of subject dropout. The continuous lines represent the estimate from the equivalent generalized estimating equation model with IPW, as displayed in Tables 2 and 3. The most notable difference between the 2 models is seen with emergency hospital admissions, where the dropout correction reveals a much clearer deterioration over time. Likewise, the weighting reduces the rate of decline in exacerbations and the prescription of oral corticosteroids.

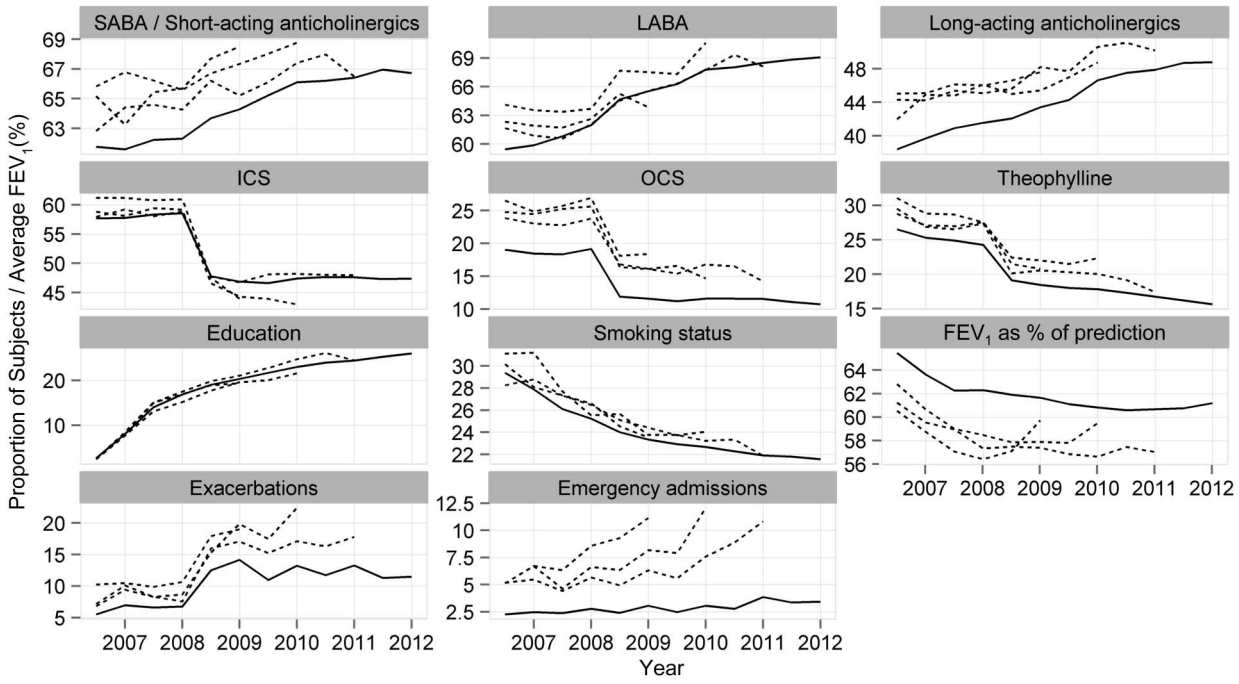

Fig. 1. Pharmacotherapy, hospitalization, exacerbation, and smoking status within the cohort between 2007 and 2011. Subjects are grouped according to the year of dropout, creating 3 dropout groups (dashed lines represent the dropout groups with respect to their last recording in 2009, 2010, and 2011) and one group with complete observation (continuous lines). SABA = short-acting β_2-agonists. LABA = long-acting β_2-agonists. ICS = inhaled corticosteroid. OCS = oral corticosteroid.

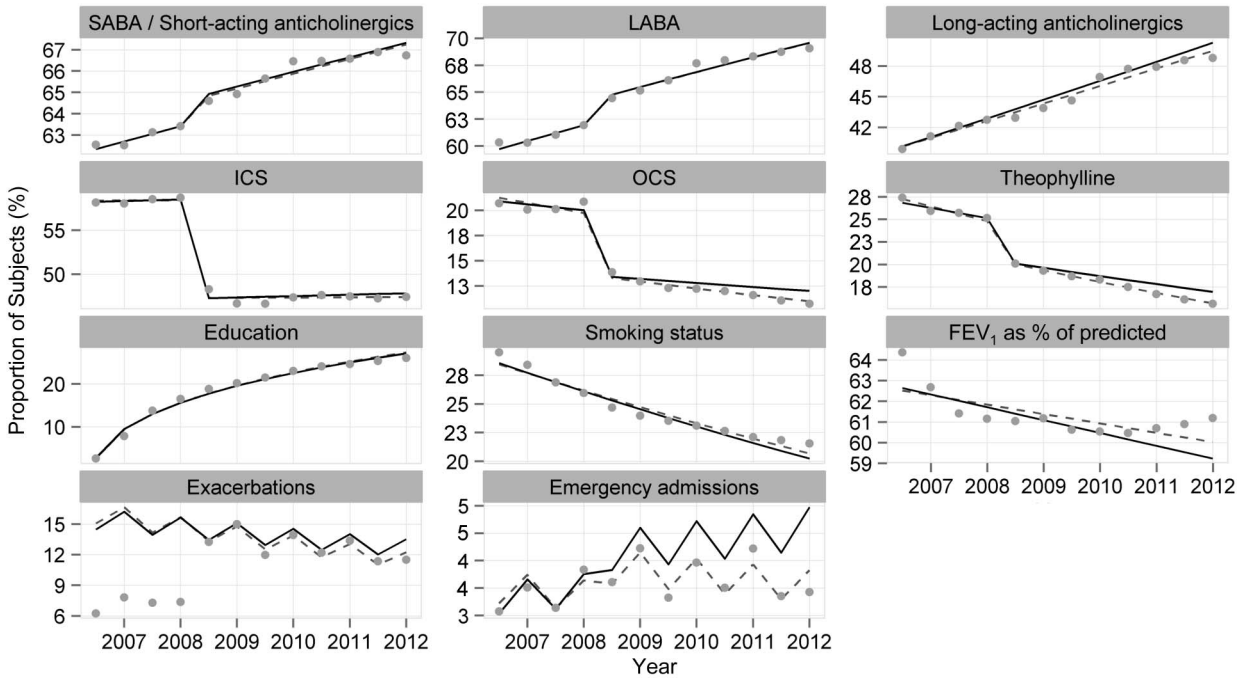

Fig. 2. Development of the cohort over time with dropout analysis. The points represent the observed data. Dotted lines represent simple linear regression models without dropout correction. Continuous lines include a correction for dropout based on the inverse probability weighting model. SABA = short-acting β_2-agonists. LABA = long-acting β_2-agonists. ICS = inhaled corticosteroid. OCS = oral corticosteroid.

Otherwise, the IPW adjustment leads to only a negligible change in the observed rates.

Discussion

To our knowledge, the present study is the first systematic evaluation of a German DMP for COPD to be conducted independently of any one health insurance company. A particular strength of the study is the explicit modeling of attrition bias and a comparison of a cohort with the total population. Our main results are a reduced prescription of theophylline and oral corticosteroids together with an increased utilization of patient education and smoking cessation programs, and a significant reduction in the occurrence of exacerbations. Within the cohort, disease progression is reflected in an increased prescription of short-acting β_2 agonists, long-acting β_2 agonists, and anticholinergics, and an increase in emergency hospital admissions. This occurs alongside a decreased rate of exacerbations, which was significant after adjustment for dropout. However, the DMP was unable to prevent an increase in emergency hospital admissions as the disease severity in the cohort progressed.

Our findings are to some extent consistent with results from other studies. Steuten et al[15] found that the implementation of a DMP for COPD led to improvements in self-care behavior such as smoking status, physical activity, and compliance with a medication regimen. However, this was demonstrated in a selection of general practices where, among other conditions, a specialist respiratory nurse performed diagnostic and therapeutic activities to enhance patient education and self-management. Nevertheless, our results show that guideline adherence improved continuously throughout the period of observation, with evolving pharmacotherapy regimens and a major increase in the proportion of patients with self-management education.

The comparison of the total DMP population with a more stable cohort of subjects has proved to be a useful tool in understanding the development of the program. The increased prescription of short-acting medication, long-acting β_2 agonists, and anticholinergics was found in both collectives. Both the influx of new subjects and, to a lesser degree, the dropout of existing subjects have the effect of slowing the perceived increase in the prescription of these medications. For example, with long-acting β_2 agonists and anticholinergics, the rate of increase in the cohort is roughly twice that in the total population. A different picture is seen with theophylline and oral corticosteroids, where these factors explain some of the observed decrease in the overall prescription rates. It may be that physicians are reluctant to withdraw such medications from patients already receiving them, with patients having new diagnoses being more likely to receive a drug treatment that conforms to modern guidelines. Such observations are of interest when seeking ways of improving the quality of care.

The increased prescription of long-acting β_2 agonists and long-acting anticholinergics, combined with the decline in prescriptions of inhaled corticosteroids, demonstrate that pharmacotherapy was optimized according to evidence-based guidelines.[20] Of particular interest is the reduced prescription of theophylline, which is considered to be a third-line treatment due to its small therapeutic ratio and the potential risk of adverse events.

Our pharmacotherapy results are comparable to those from a recent investigation[6] of equivalent routinely collected subject records from patients within a DMP for asthma. Despite the requirement of a clear diagnosis before study enrollment, an overlap between asthma and COPD patients cannot be excluded. The relatively high and increasing FEV_1 measurements in the DMP population, together with the result that ~37% of subjects are prescribed inhaled corticosteroids, may support this hypothesis. The imprecise distinction between asthma and COPD may reflect diagnostic uncertainty in general practice.

The specification underlying the German DMP strongly emphasizes the need for the coordinating physician to continually motivate smokers to quit. Whereas the proportion of smokers in the total population remained constant, the proportion of smokers in the cohort, after dropout adjustment, decreased over time. This is plausible, with the enrollment of newly diagnosed smokers masking the effect of smoking cessation in the total population. This result confirms the previous findings of Steuten et al,[15] where the proportion of smokers in a DMP was seen to decrease from 40% to 36% over a 12-month period. Au et al[25] showed within a cohort study of 23,971 current and past smokers that smoking cessation was associated with a reduced risk of exacerbations. Reimbursing the costs of smoking cessation therapy has been shown to be both efficacious[26] and cost-effective.[27]

Exacerbations are important determinants of prognosis in patients with COPD, and are associated with economic costs,[28] health status,[29,30] lung function,[31] and mortality.[32] Prodromal symptoms of an exacerbation commonly occur up to a week before a discernible reduction in lung function,[33] and about one-half of patients who seek treatment in an emergency department report having had characteristic symptoms for at least 4 days.[34] The early treatment of exacerbations has been shown to reduce morbidity and to have an effect on quality of life.[35] Niewoehner et al[36] show that the duration of the COPD disease predicts a higher risk of exacerbations. This is in line with our observation that the proportion of subjects experiencing exacerbation decreased to a lesser extent in the cohort, with exacerbations more likely to occur in the year before dropout. The

reduced rate of exacerbation of the present observation across different analyses confirms previous findings from Rice et al.[14] Additionally, Rice et al[14] demonstrated within a large multicenter randomized controlled trial that a relatively simple DMP for patients with severe COPD reduced the composite frequency of COPD-related hospitalizations and emergency department visits by 41%.

A meta-analysis by Lemmens et al[37] found evidence that multiple interventions led to a significant reduction in hospitalization in comparison with routine care. A reduction in hospitalization may in turn save costs.[15] A recent published study from Moullec et al[38] detected within a randomized cohort study a significant reduction in the incidence of COPD-related hospitalizations after a 1-y intervention. Women in particular appear to have benefited from the intervention, with the reduction in the risk of hospital admission being 2.6 times greater than that for men. Our result of a clear declining rate of emergency hospital admissions in the total population of $>$ 80,000 DMP subjects would appear to support these positive findings. However, after further investigation this declining trend cannot be observed in the cohort and IPW analyses. This contradiction leads to the suggestion that the decrease in emergency hospital admissions was caused by the enrollment of less severely ill subjects and by the dropout of more severely ill subjects. The simultaneous decline in oral corticosteroid prescriptions and in the occurrence of exacerbations may suggest that subjects were recognized and treated at an earlier stage, and that the guideline adherence improved, thus preventing emergency department visits and hospital admissions in the long term. Unfortunately, the available data and lack of a suitable control group do not facilitate the detailed investigation of such questions.

Observation of the total population is of primary interest because it summarizes the subjects enrolled in the DMP and shows how the population is changing. However, the influence of incoming subjects and attrition due to death and other causes make the total population unsuitable for inferences regarding many questions of interest. After accounting for these factors in the cohort, the progressive nature of the disease is clearly seen in the development of pharmacotherapy and the number of emergency hospital admissions. While the IPW methodology used does have a number of beneficial properties, alternative methods could provide additional insight into more specific questions of interest.[21-23]

The main limitation of the present evaluation is the absence of a suitable control group with which to compare the effectiveness of DMP COPD with standard care. A selection bias may reasonably be assumed, whereby more motivated and possibly healthier subjects are more likely to be enrolled into the program. The lack of a randomized control design thus represents an inherent limitation when assessing the effectiveness of the German DMPs, which were introduced on an almost universal basis in each German federal state.[39] Indeed, given the large numbers of participating subjects, it may almost be stated that a DMP is the standard care model for COPD patients in Germany. Our results cannot therefore prove the efficacy of the DMP intervention but do demonstrate how the quality of care has improved under the influence of DMPs, with their accompanying guideline implementation, feedback strategies, and financial incentives. In this context, the discontinuities introduced by the modified subject record highlight the need to conduct data collection in a consistent manner. Careful consideration is required in such cases to ensure that seemingly innocuous changes do not adversely affect the evaluation of the program.

We conclude that since the implementation of the DMP for COPD in Bavaria in 2006, the quality of care has improved together with an improved adherence to guidelines and pharmacotherapy. In the cohort, both the proportion of smokers and the rate of exacerbations have fallen. The decreasing occurrence of emergency hospital admissions in the total DMP population may be attributed to the enrollment of less severely ill subjects and by the dropout of more severely ill subjects. Our findings also reveal a potential for further improvement, particularly in efforts to promote smoking cessation and increase the proportion of patients with self-management education.

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