1 General information

DFG-reference num- ber	STA 1311/3-1 und SCHR 1260/3-1
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Topic	Health-Economic Evaluation of the Disease Management Program for Chronic Obstructive Pulmonary Disease in Germany
Period covered by	
the report /	Grant approval: 07.06.2015
Overall funding period	Funding period: 01.02.2016 – 31.07.2017

- List of the most important publication resulting from the project
 - a) Articles which at the time of proposal submission have been published or officially accepted by publication outlets with scientific quality assurance
 - Achelrod D, Welte T, Schreyögg J, Stargardt T (2016): Costs and Outcomes of the German Disease Management Programme (DMP) for Chronic Obstructive Pulmonary Disease (COPD) - A large population-based cohort study, Health Policy, 120(9): 1029-39.

b) Other publications: N/A

c) patents: N/A

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2 Final progress report

2.1 Research question / objectives

Chronic Obstructive Pulmonary Disease (COPD) is characterised by a not fully reversible airflow limitation. Risk factors appear to be smoking (de Marco et al. 2004), occupational dust exposure (Trupin et al. 2003), and higher age (Maciewicz et al. 2009). With a two-year mortality of up to 49% after hospitalization for an acute exacerbation (Connors et al. 2009, Groenewegen et al. 2003, Gudmundsson et al. 2006), COPD casts an extensive burden on patients and health systems. For patients, the main burden of COPD is its impact on their daily lives (Rodriquez et al. 2009). Impairment in social activities, mental disorders and physical disability stemming from exercise-induced dyspnoea, muscular deconditioning, and other factors have a major influence on the self-perceived quality of life (QoL) of patients (Ng et al. 2007, Kuhl et al. 2008).

Over the last decade, the management of COPD in Germany has gradually changed. Disease management programs (DMP) have been a proposed and implemented solution to improve management of disease, prevention of complications, and outcomes in patients with COPD. The aim of these programmes was to modify treatment patterns, thereby improving outcomes of care whilst increasing the efficient use of scarce health care resources, or even generating cost savings.

Internationally, a number of studies evaluated interventions that follow the disease management approach for the management of COPD. However, the design of these interventions is highly heterogeneous. While some offered patient self-management modules only, others provided advanced access to medical care, enhanced decision support or a combination of these. Hence, most interventions did not correspond to the abovementioned definition of the classical 'German' DMP COPD. While there have been numerous studies evaluating DMP type 2 Diabetes in Germany, including four studies gathering retrospective claims data from sickness funds, one from physicians' records, two patient surveys and one using prospective data from ambulatory care,²⁹ little evidence was available for all other German DMPs, including DMP COPD at the time of the grant application.

Being the first study of its kind in the German healthcare context, it was the primary aim is to compare the cost-effectiveness of DMP COPD with standard care for COPD over a time period of 3 years. Effectiveness was measured in terms of mortality, number of (emergency) hospital visits and ability to work. In addition and as a secondary aim, we examined sociodemographic and clinical parameters that may drive patients decisions to enrol in a structured care program. Data from the BARMER/GEK, a large German sickness fund with 8.6 million insured was used.

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2.2 Project developments

The project followed the work plan as laid down in the proposal. For data analysis, improvement in matching / balancing methods lead to an improvement in the methods that were applied:

- 1) Data collection / data mining: At first, data was collected directly at the sickness fund. This means that patients with COPD were identified in the sickness funds data bases according to the inclusion criteria. Subsequently, information 3 years before and after inclusion of patients was linked together from different inpatient and outpatient data bases.
- 2) **Transfer of data / assessment of data quality**: In a second step, the dataset was remotely worked on the server of the sickness fund including assessment for data quality.
- 3) **Data analysis:** Third, data was analysed. Instead of using a combination of propensity score matching and regression models, one of the successors of propensity matching, entropy balancing, was used in combination with DiD-regressions. As planned, preliminary results were presented on a national and an international conference.

As questions arose on potential selection bias of the intervention group during the publication process, we carefully analysed parameters that (a) affected a patient's decision to enrol in a structured care program and (b) that made patients to drop out of structured care programs. In addition to the abovementioned data on DMP COPD, we also included similar data for a telemonitoring program for patients with COPD in the analyses.

4) **Writing of publication:** Finally, a manuscript was drafted and successfully submitted to Health Policy.

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2.3 Presentation of results and discussion

Main results were published as

'Achelrod D, Welte T, Schreyögg J, Stargardt T (2016): Costs and Outcomes of the German Disease Management Programme (DMP) for Chronic Obstructive Pulmonary Disease (COPD) - A large population-based cohort study, Health Policy, 120(9): 1029-39.' (see Appendix).

Please find a short abstract of the publication below; the full publication was uploaded as appendix:

Introduction: To curb costs and improve health outcomes in chronic obstructive pulmonary disease (COPD), a nationwide disease management programme (DMP) was introduced in Germany in 2005. Yet, its effectiveness has not been comprehensively evaluated.

Objective: To examine the effects of the German COPD DMP over three years on costs and health resource utilisation from the payer perspective, process quality, morbidity and mortality.

Methods: A retrospective, population-based cohort study design is applied, using administrative data. After eliminating differences in observable characteristics between the DMP and the control group with entropy balancing, difference-in-difference estimators were computed to account for time-invariant unobservable heterogeneity.

Results: 215,104 individuals were included into the analysis of whom 25,269 were enrolled in the DMP. DMP patients had a reduced mortality hazard ratio (0.89, 95%CI: 0.84-0.94) but incurred excess costs of €553 per year. DMP enrolees reveal higher healthcare utilisation with larger shares of individuals being hospitalised (3.14%), consulting an outpatient clinic due to exacerbations (11.13%) and pharmaceutical prescriptions (2.78). However, average length of hospitalisation due to COPD fell by 0.49 days, adherence to medication guidelines as well as indicators for morbidity improved.

Conclusion: The German COPD DMP achieved significant improvements in mortality, morbidity and process quality, but at higher costs. Given the low ICER per life year gained, DMP COPD may constitute a cost-effective option to promote COPD population health.

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With regard to the (secondary) analyses on enrolment into and drop-outs from structured care programs, please find a short summary as well as tables on results below:

Background: Chronic obstructive pulmonary disease (COPD) affects approximately 10 – 15 percent of people in Germany above the age of 40. Previous studies suggest that structured care programs are effective to reduce hospitalizations due to COPD and to subsequently achieve savings. Enrolment in structured care programs is voluntary, thus patients must be willing to participate. Once they are enrolled their continuation is crucial for the program's success.

Objective: To examine sociodemographic and clinical parameters that may drive patients decision to enrol in a structured care program. Two different types of care programs for COPD, which are initiated by different players of the German health care market, are analysed. A telemonitoring and a disease management program.

Methods: The study is conducted using routine data of two German statutory sickness funds. First a binary logit model is used to determine which parameters affect a patient's decision to enrol in a structured care program. A survival model using Cox regression then examines what circumstances may cause a drop out. To avoid endogeneity only data regarding the time frame prior to the enrolment or start of the program is used.

Results: Patients with an inpatient contact no longer than 6 months ago are more likely to enrol in a structured care program. Prior enrolment in a DMP is a predictor for enrolment in a telemonitoring program (p < 0.001). Patients with a higher Charlson score and those older than 70 years are less likely to enter a care program (p < 0.01). A high number of outpatient contacts within the first 12 months of the intervention increases risk of drop out (p < 0.001), as does a high Charlson score prior to enrolment (p < 0.05).

Discussion & Conclusion: Previous studies showed DMPs and telemonitoring intervention to be (cost-) effective. Patient's willingness to enrol and to continue their participation in a telemonitoring program may be influenced by different factors, especially outpatient contacts. After enrolment, sickness funds would need to monitor patients with a high number of outpatient contacts to prevent them from dropping out.

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Results for logistic regression on enrolment

-	log (willing to participate)	odds ratios	95% CI (Oc	lds)
sociodemographic parameters				
Age group				
< 40	-1.298 ***	0.273 ***	0.208	0.359
40 - 50	-0.4543 ***	0.635 ***	0.549	0.735
50 - 60	-0.0966	0.908	0.819	1.007
60 - 70	reference	reference		
70 - 80	-0.1636 **	0.849 **	0.763	0.945
>80	-0.4702 ***	0.625 ***	0.531	0.735
Gender (1 = female)	-0.1246 **	0.883 **	0.816	0.955
Health care consumption				
Time since last outpatient contact (within last 12 months)			
COPD related				
None	reference	reference		
<3	1.2136 ***	3.366 ***	3.054	3.709
3 - 6	0.1886 *	1.208 *	1.087	1.342
>6	-0.4647 ***	0.628 ***	0.552	0.716
Not COPD related				
None	reference	reference		
<3	0.2246	1.252	0.975	1.607
3 - 6	0.2351	1.265	0.958	1.67
>6	-0.3381 *	0.713 *	0.513	0.991
Time since last inpatient contact (within last 12 months)				
COPD related				
None	reference	reference		
<3	1.8769 ***	6.533 ***	5.235	8.152
3 - 6	1.3332 ***	3.793 ***	3.137	4.587
>6	0.6022 ***	1.826 ***	1.587	2.102
Not COPD related				
Morbidity				
Charlson score	-0.1313 ***	0.877 ***	0.858	0.897
GOLD stage				
GOLD I	reference	reference		
GOLD II	0.4631 ***	1.589 ***	1.294	1.952
GOLD III	0.6727 ***	1.96 ***	1.541	2.492
GOLD IV	0.2165	1.242	0.971	1.588
Na	0.3573 ***	1.429 ***	1.199	1.704

^{*} p ≤ 0.05 ** p ≤ 0.01 *** p ≤ 0.001

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Results for logistic regression on drop-outs

	cox estimate	hazard ratio
sociodemographic parameters		
Age group		
< 40	0.48106	1.618
40 - 50	0.699 **	2.012
50 - 60	0.31188	1.366
60 - 70	reference	reference
70 - 80	-0.04073	0.96
> 80	-0.45226	0.636
Gender (1 = female)	0.26077 **	1.298
Health care consumption		
Number of outpatient contacts within first 12 months of interventi	on	
COPD related	-0.36068 ***	0.697
Not COPD related	-0.06884 ***	0.933
Number of hospital days within first 12 months of intervention		
COPD related	-0.02761	0.973
Not COPD related	-0.01235	0.988
Morbidity		
Charlson score before start of program	0.08199 *	1.085
Change of charlson score within first 12 months of intervention	-0.01002	0.99
GOLD stage		
GOLD I		
GOLD II	0.21497	1.24
GOLD III	0.47837	1.613
GOLD IV	-0.00887	0.991
Na	0.05448	1.056

2.4 Statement on whether the results of the project are economically valuable and whether exploitation is already taking place or may be anticipated

No further exploitation of results besides publication is planned. The main results have been published.

The results on the secondary analyses conducted to further understand selection into the intervention group and drop-outs from the intervention group are currently considered to be too project specific and not worth publishing.

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2.5 Other contributors

- Co-authors of the published paper:
 - Prof. Dr. Tobias Welte, Hannover Medical School, Carl-Neuberg-Str. 1, 30625 Hannover (Co-author).
 - Dr. Dmitrij Achelrod, Hamburg Center for Health Economics, Universität Hamburg

2.6 Qualification of young researchers in the context of the

- Student fellows that worked on the project:
 - Anna Weller
 - Mathias Baumann
 - Tim Sonnenschein
 - Nele Eckert
 - Christina Berner
- Master thesis related to the project
 - Mirko von Hein, M.Sc. Health Economics & Health Care Management, topic: 'Systematischer Review über die Auswirkung von COPD DMP-Programmen auf Leistungsausgaben der Krankenversicherung und Gesundheit/Lebensqualität der Patienten'
 - Theresa Gattert, M.Sc. Health Economics & Health Care Management, topic: 'Kosten-Effektivität von Disease Management Programmen für COPD-Patienten - ein systematischer Review'
- Part of PhD-works
 - Dr. rer. oec. Dmitrij Achelrod, Measuring the Value of Healthcare Innovation Through Economic Evaluation.
 - Dr. rer. oec. (cand.) Florian Hofer, Cost-Effectiveness of Care Programs for COPD.

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