their untreated female partners. Measures of efficacy included the Treatment Satisfaction Scale (TSS). The analysis was performed in patients (partners) valid for intent-to-treat plus having a baseline and post-baseline measurement, followed by subgroup analysis regarding ED pre-treatment status. Separate analyses of co-variance adjusting for baseline values and study effects were conducted to investigate the change in treatment satisfaction in patients and their partners using the TSS. RESULTS: At baseline, TSS domain scores (least square means; LS means) were similar for vardenafil and placebo groups. Vardenafil significantly (p < 0.0001) improved the treatment satisfaction for all domains compared to placebo (LOCF; absolute difference in LS means for patients and partners): ease of erection (23.4 and 24.9), erectile function satisfaction (36.7 and 32.9), pleasure from sexual activity (23.0 and 23.7), satisfaction with orgasm (27.6 and 21.8), confidence to complete sexual activity (28.2 and 32.5), satisfaction with medication (37.4 and 35.6). The effect of vardenafil on treatment satisfaction in patients who had received previous treatment with PDE5 inhibitors was even higher for all domains (absolute difference in LS means between vardenafil and placebo groups for patients): ease of erection (25.2), erectile function satisfaction (39.5), pleasure from sexual activity (25.6), satisfaction with orgasm (29.8), confidence to complete sexual activity (30.4), satisfaction with medication (41.3). CONCLUSIONS: Vardenafil significantly improved (p < 0.0001) treatment satisfaction in men with ED and their partners. The treatment effect was even higher in patients who had previously been treated with PDE5 inhibitors.

RESPIRATORY DISORDERS

**PREVALENCE AND TREATMENT OF COPD IN GERMANY**


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**OBJECTIVES:** Data on prevalence, treatment, and stages of COPD for Germany are limited. This study aims at investigating into prevalence and treatment of COPD as well as the distribution of COPD stages, frequency of comorbidity, and exacerbations. METHODS: Claims data from a German sickness fund were used to perform a retrospective cohort study. For the period of 2001 to 2003 beneficiaries 45 years of age or older were identified as COPD patients if they had a diagnosis of emphysema and/or other chronic obstructive pulmonary diseases (ICD-10 codes J43*, J44*) and/or at least one prescription for a drug for obstructive airway diseases (ATC R03A*). Comorbidity and exacerbations were identified according to related diagnoses and prescriptions. Patients were allocated to COPD stages by detection of drug prescription patterns as defined by the GOLD guideline (Pauwels et al., Am J Respir Crit Care Med 2001;163:1256–76). RESULTS: Among 499,530 beneficiaries 45 years of age or older 41,100 were identified as COPD patients corresponding to a three-year prevalence rate of 8.2%, with rates of 8.5% in men and 7.9% in women, respectively. Prevalence rates of 9.3% in total, 9.6% in men, and 9.3% in women, respectively, were estimated for the German resident population 45 years of age or older. For many of the COPD patients only few specific drug prescriptions were detected within the three-year observation period. Sixty-eight percent of patients were allocated to GOLD stages 0 and 1 (at risk or mild COPD). Exacerbations were found in 14,513 (35.4%), and comorbidity (mostly cardiovascular disease) in 63% of patients. CONCLUSION: The observed COPD prevalence rates are within the range of results reported in former studies. The low level of treatment with COPD-related drugs may be an indicator for a low awareness of COPD among patients as well as among physicians.

**PRF2**

**EFFECT OF DRG IMPLEMENTATION IN GERMANY—ANALYSIS OF LENGTH OF HOSPITAL STAY OF IN-PATIENTS SUFFERING FROM COMMUNITY-ACQUIRED PNEUMONIA**

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**OBJECTIVES:** In-patient treatment of community-acquired pneumonia (CAP) is a generally non-invasive therapy with financial burden depending on length of hospitalization. In 2004, the concept of diagnosis-related groups (DRG) was implemented in Germany. Objective of this study was to analyse the effect of DRG implementation on length of hospital stay. METHODS: Open, prospective observational study conducted in German hospitals before and during DRG-implementation. Between October 2002 and July 2003 patients with CAP were enrolled (cohort A). Between January and October 2005 a second investigation was conducted (cohort B). No intervention in physicians’ treatment decisions was taken. Diagnostic measures, drug application, non-medical therapy, nursing time and length of hospital stay were documented by the treating physicians. RESULTS: In cohort A 319 patients were documented in 9 hospitals, in cohort B 322 patients in 14 hospitals. Cohort A and B showed no significant differences in demographic data, clinical condition and severity of CAP classified according to Fine et al. 88.7% (A) and 92.9% (B) of patients were discharged from hospital due to successful treatment. 11.3% (A) and 7.1% (B) of patients died. Average length of stay was 10.67 (A) and 10.05 days (B) in peripheral ward (p = 0.229), and 0.79 (A) and 0.73 days (B) in ICU (p = 0.847). Overall length of stay was 11.46 (A) and 10.80 days (B) (p = 0.162). CONCLUSIONS: In this study the effect of DRG-implementation, measured by length of hospital stay, was marginal. Between 1994 and 2000 a dramatic reduction of both length of stay and number of hospital beds were observed because of a number of new laws aiming at cost reduction. Therefore, the DRG concept for CAP patients has not yet led to a significantly reduction of length of stay in the hospital sector.

**COST-EFFECTIVENESS OF ROFLUMILAST IN THE UK:A 1-YEAR STUDY IN PATIENTS WITH SEVERE TO VERY SEVERE COPD**

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**OBJECTIVE:** Roflumilast is an oral, once-daily PDE 4 inhibitor under investigation for COPD and asthma therapy. This study investigated the cost-effectiveness of Roflumilast in patients with severe to very severe COPD, including the financial impact on the UK health care system. METHODS: The analysis was conducted alongside a randomised, placebo-controlled, multinational trial (M2-112) evaluating the efficacy of roflumilast in terms of lung function and the frequency of moderate and severe (mod/sev) exacerbations in severe and very severe COPD patients. COPD-related health care use and absence from work were recorded. Differences in costs were related to differences in number of mod/sev exacerbations. Trial wide resource use was
multiplied with 2004 UK unit cost. A total of 1505 COPD patients with post FEV1% pred < = 50% were included (roflumilast 755, placebo 750). 62% were taking inhaled corticosteroids. RESULTS: In the total group, COPD-related costs from a societal perspective were €1635 (roflumilast) and €1400 (placebo). From a payer's perspective this was €1385 and €1253, respectively. The overall rate of mod/seg COPD exacerbations in the trial was low and no differences existed between roflumilast (0.96) and placebo (1.06). In a subgroup of patients with very severe COPD (n = 223), placebo was associated with a higher exacerbation rate (1.7 exacerbations/patient/year) and roflumilast was associated with 35% fewer exacerbations. This lower exacerbation rate was associated with €1001 lower COPD-related treatment costs. In the subgroup of patients with high health care resource use prior to the study (n = 549) the roflumilast group showed 0.41 fewer exacerbations per patient year, which translated into an ICER of €804 per mod/seg exacerbation avoided. CONCLUSION: These data suggest that roflumilast, like many newly introduced therapies, increases the overall cost of therapy for COPD; however, this increase was partly offset by savings. Furthermore, in this study, roflumilast was found to be cost saving in very severe patients.

THE COST-EFFECTIVENESS OF DRUG THERAPY IN COMMUNITY-ACQUIRED PNEUMONIA AND THE IMPACT OF ANTIMICROBIAL RESISTANCE IN GERMANY

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OBJECTIVE: The incidence of community-acquired pneumonia (CAP) caused by drug resistance has increased dramatically in recent years. The aim of this analysis was to analyse the impact of antimicrobial resistance on the cost-effectiveness of different antibiotic classes (beta-lactams, macrolides, fluoroquinolones) in patients with CAP in Germany. METHODS: A decision analytic model was developed for mild-to-moderate CAP outpatient treatment. Treatment algorithms incorporated follow-up after treatment failure due to resistance or other reasons. First-line treatment included moxifloxacin (MXF), beta-lactams (AMX), or macrolides (ROX); second-line treatment used a different antimicrobial class. In contrast to existing cost-effectiveness models in CAP class-specific resistance profiles were included in the model. This allows for the analysis of the impact of antimicrobial resistance on the cost-effectiveness in addition to standard outcomes like clinical failure, hospitalisation rates and total costs. Input data were derived from surveillance studies, from literature and expert opinion. Total costs were estimated using standard sources and a third-party payer perspective in Germany. RESULTS: Total cost were €240.60 (MXF), €250.59 (ROX), and €268.91 (AMX). First-line clinical failure, second-line treatment, and hospitalisation rates were lower for MXF as compared to the other treatment options. First-line MXF treatment dominated all other treatments. Antimicrobial resistance accounted for 53% (AMX), 72% (ROX) and 2% (MXF) of all clinical failures and 37% (AMX), 56% (ROX) and 1% (MXF) of all hospitalisations. CONCLUSIONS: Antimicrobial resistance has a significant impact on the cost-effectiveness of empirical treatment of CAP. The first-line use of moxifloxacin in CAP is a dominant strategy even in a country with a low level of resistance like Germany.

COSTS OF COPD EXACERBATIONS IN POLAND (RESULTS OF THE PILOT STUDY)

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OBJECTIVES: Exacerbations are the key drivers of the costs of chronic obstructive pulmonary disease (COPD). This was the pilot study of patients with COPD aimed at evaluating direct and indirect cost of exacerbations under usual clinical practice in primary and secondary care form societal perspective. METHOD: It was observational, multicenter study with participation of 73 subjects with moderate or severe COPD, defined according to the current GOLD criteria. Patients presenting at the selected health care centres were included into the study in the sequential manner, if they fulfilled the inclusion criteria. Exacerbations were divided into three different severity types according to Anthonisen N.R. classification. The management of exacerbations followed the usual clinical practice. RESULTS: The average monthly cost of maintenance therapy of COPD was ca. PLN 180. The average direct health care cost per exacerbation was PLN 4002 (95% CI = 3537; 4503) and PLN 438 (95% CI = 326; 570) in secondary and primary care respectively. In secondary care, the drug acquisition and oxygen therapy cost represented 18.3% of total direct costs, diagnostic tests costs accounted for 14.5%, the other hospital care and post-discharge follow-up visit costs 67%. Costs varied considerably with the severity of the exacerbation as well as the duration of COPD. In primary care the cost structure was as follows: diagnostic tests and medical devices 47.5%, drug acquisition costs 41% and doctors visits 11.4%. The average indirect costs per exacerbation were PLN 232 and PLN 141, in secondary and primary respectively. (EUR 1 = PLN 3.85; year 2006). The average reported number of COPD exacerbations in previous year was 3. CONCLUSION: Exacerbations of COPD are costly. Cost of exacerbation managed in secondary care is 9-fold higher than in primary care. Prevention of moderate-to-severe exacerbations, requiring hospitalization could be very cost-effective strategy.

CONSEQUENCES FOR DRG-IMPLEMENTATION IN GERMANY: EFFECT ON DIRECT COSTS OF IN-PATIENTS WITH COMMUNITY-ACQUIRED PNEUMONIA FROM HOSPITAL'S PERSPECTIVE

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OBJECTIVES: In 2004, diagnosis-related groups (DRGs) had been implemented for the reimbursement of hospitals instead of daily lump sum. We analysed the effect of DRG-implementation on direct costs of hospitals on the basis of in-patient treatment of community-acquired pneumonia (CAP). METHODS: This open, prospective observational study was divided into two parts. First part was performed between October 2002 and July 2003, the second in 2005. In-patients suffering from CAP were enrolled. The perspective of hospital management was applied for calculation of costs for drug acquisition, non-medical therapy, diagnostic procedures, hotel and staff. The quantity aspect of treatment was documented by the physicians. Information on the costs per measure was provided by the hospital controller. RESULTS: In 2002/2003, 319 patients (cohort A) were documented in 9 hospitals. In 2005, 322 patients (cohort