stratified by ulcer healing status. Work productivity loss was captured weekly by the Work Productivity and Activity Impairment (WPAI) Questionnaire [1] specific for VLU. RESULTS: The mean direct medical cost of treating VLU during the study period was estimated to be €1772 per patient for US payers, €1294 for US providers, and £1502 in the UK. The largest direct medical cost component was for professional services, or labor (approximately 70%), followed by dressing, compression bandages, and medications. Patients who had at least one ulcer not healed at the end of study had higher mean costs compared to those patients who had all ulcers healed ($2250 vs. $1012 from the US payer perspective, $1625 vs. $862 from the US provider perspective, and €1770 vs. £965 from the UK NHS perspective). Over the 12-week study duration, more reductions in work productivity loss and activity impairment were found in the healed group vs. the non-healed group. CONCLUSIONS: VLU imposes significant medical costs and work productivity losses. Since the cost of professional services is the main cost driver in the treatment of VLU, new technologies that reduce the professional labor time could significantly reduce the economic burden of venous leg ulcer. [1] Reilly MC, Zbrozek AS, Dukes EM. The validity and reproducibility of work productivity and activity impairment instrument. Pharmacoeconomics 1993;4:353–65.

**PIN43**

DIFFERENCE IN HEALTH CARE UTILIZATION IN EUROPE BETWEEN TREATMENT-NAÏVE PATIENTS WITH CHRONIC HEPATITIS C AND PATIENTS WHO FAILED PRIOR THERAPY

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OBJECTIVES: This study aims to assess if hepatitis C patients who had previously failed to achieve sustained virologic response (SVR) following any hepatitis C treatment demonstrate different patterns of health care utilization versus treatment-naïve patients after peginterferon plus ribavirin (PR) therapy in the European Union. METHODS: A retrospective chart review of hepatitis C patients who received PR was conducted in the UK, Germany, France, Italy, and Spain. Descriptive analyses reported standardized annual rates of hospitalizations, emergency/accident visits (EA), family physician/general practitioner visits (GP), specialist visits (SP), and having ≥5 clinical tests (TESTS). Logistic regression models were applied to assess TF status impact on aforementioned outcomes. RESULTS: 165 physicians collected data for 615 patients (baseline data: mean age 43.7 years, 33% female, 90% Caucasian, 85% genotype-1, 26% viral load >1,000,000 IU/mL, 25% with prior treatment failure [TF]). PR was administered for a median of 9.1 months (interquartile range: 5.3–11.9); median post-treatment follow-up was 6.0 months (interquartile range: 2.0–10.0). Fewer TF patients achieved SVR than treatment-naïve patients (43.3% versus 58.3%). Compared with treatment-naïve patients, TF patients had significantly more annual hospitalizations (1.7 versus 0.3), EA (0.7 versus 0.2), GP (4.3 versus 2.0), SP (4.1 versus 2.3), and TESTS (75% versus 85%) (p < 0.05 for all). When controlling for confounding factors (age, weight, gender, genotype, time between diagnosis and treatment initiation, alcohol intake, past intravenous drug use, pre-treatment liver biopsy, steatosis, pre-viral RNA, and SVR status), TF remained an independent risk factor for significant risk of hospitalization (OR = 4.33, 95% CI = 2.38–7.87), EA (OR = 2.63, 95% CI = 1.49–4.76), GP (OR = 3.45, 95% CI = 2.04–5.63), SP (OR = 2.86, 95% CI = 1.72–4.76) and TESTS (OR = 2.04, 95% CI = 1.14–3.70). Similar results were found in the genotype-1 patients. CONCLUSIONS: Hepatitis C patients who failed prior treatment demonstrate higher health care resource use than treatment-naïve patients after PR therapy, regardless of SVR status.

**PIN44**

IMPACT OF ETARVIRINE ON HOSPITALIZATIONS AND HOSPITAL RELATED COSTS IN BELGIUM: 48-WEEK FINDINGS FROM POOLED DUET TRIALS

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OBJECTIVES: DUET 1&2 are two identically designed, ongoing, randomized, double-blind, placebo-controlled, phase III trials, which have demonstrated superiority of etaravirine (TMC125, ETR) + background regimen (BR) versus placebo + BR in HIV-1-infected, treatment-experienced patients. This analysis estimates the cost of the hospitalizations observed in the DUET studies applied to a Belgian treatment setting. METHODS: Hospitalization events and duration of hospital stay were recorded for each patient in the DUET trials. Differences in hospitalizations and total days hospitalized at 48 weeks were compared between ETR + BR and placebo + BR in the pooled DUET population. Daily hospital costs were collected from the Belgian IMS Hospital Disease database, a longitudinal patient-level retrospective database. A sample of 277 HIV patients with 397 hospitalizations in Belgium were extracted. An average cost per day was calculated in 2007 Euros, which included INAMI (health system cost) and patient contribution costs for medications, procedures, and rooming charges. These costs were applied to the total days observed in the DUET trials to estimate overall hospital costs. RESULTS: A total of 1203 patients were included from the DUET trials: 599 vs. 604 in the ETR vs. placebo groups. Baseline characteristics and average follow-up were comparable between arms. The number (%) of patients hospitalized was 105 (18%) for ETR + BR vs. 139 (23%) for placebo + BR, respectively (p = 0.0006). Total hospital days observed during the 48 week follow-up period were 1702 for ETR + BR vs. 2.747 for placebo + BR. The average cost per patient day was estimated to be €556.39. Over the population, total hospital costs were estimated to be €946,676 for ETR + BR vs. €1,528,403 for placebo + BR. CONCLUSIONS: At Week 48, ETR + BR provided a statistically significant reduction in the number of patients hospitalized vs. placebo + BR. The reductions in the number of hospitalizations and time spent in the hospital represent clinical benefit to the patients and significant savings in hospital-related costs to the health care system.

**INFECTION—Patient-Reported Outcomes Studies**

**PIN45**

IMPACT OF PATIENT-HEALTH CARE PROVIDER COMMUNICATION: THE HIV/AIDS PATIENTS’ PERSPECTIVES

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OBJECTIVES: To assess the impact of communication between physicians and patients living with HIV/AIDS on levels of treatment adherence and patient satisfaction. METHODS: In a previous survey at our teaching hospital in Thailand we found good adherence in 99% of patients, assessed by visual analogue scale. This qualitative study was conducted between November 2007–January 2008. The research comprised direct observations of patient-health care provider encounters at the clinic and in-depth
HEALTH-RELATED QUALITY OF LIFE AMONG PATIENTS WITH VENOUS LEG ULCER

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OBJECTIVES: To assess the health-related quality of life (HRQoL) among patients with venous leg ulcer (VLU) in the US and UK. METHODS: A prospective, observational, multi-center study was conducted among 112 patients with VLU in the US (76 patients) and the UK (36 patients) between 2007 and 2008. Patients completed a generic health status measure, the EuroQol (EQ-5D) Questionnaire and a disease-specific health-related quality of life measure, the Charing Cross Leg Ulcer Questionnaire at study baseline and at the end of the study. Patients were provided routine medical care for their ulcer for a study period of 12 weeks or until all their ulcers healed. Analyses were conducted to assess the change in HRQoL scores over the study period among all patients, among patients with all ulcers healed (healed patients) and among patients with at least one ulcer not healed (non-healed patients). RESULTS: The mean age (SD) of VLU patients was 61.9 (13.7) years in the US and was 70.9 (13.9) years in the UK. A total of 51.3% of VLU patients in the US were males while 36.1% in the UK were males. At baseline, the mean (SD) EQ-5D index score was 0.6628 (0.2402) for US patients and 0.6206 (0.3413) for UK patients. There was a statistically significant improvement in EQ-5D index scores over the study period among the US healed patients (p < 0.01) but not for US non-healed patients or UK patients. Among all patients, the Charing Cross Leg Ulcer Questionnaire showed that patients' social interaction (p < 0.01) and emotional status (p < 0.01) were significantly improved during the study period. CONCLUSIONS: VLU results in a significant negative impact on patients' health status. Treatments for VLU that promote ulcer healing are likely to result in significant improvements in patients' health-related quality of life. EU-08-1532. © 2008 ER. Squibb & Sons, LLC.

VALIDATION OF THE SINONASAL OUTCOME TEST-16 (SNOT-16) IN PATIENTS WITH ACUTE BACTERIAL SINUSITIS

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OBJECTIVES: To document the psychometric properties and estimate a minimal important difference (MID) for the Sinonasal Outcome Test-16 (SNOT-16) in patients with acute bacterial sinusitis. METHODS: Secondary psychometric analysis was undertaken on data from a phase III trial to evaluate the efficacy and safety of moxifloxacin over 5 consecutive days in the treatment of acute bacterial sinusitis (N = 374). Trial patients also completed the RAND SF-36, the Activity Impairment Assessment (AIA) and a global rating of change. The SNOT-16 has 16 items and is scored as a uni-dimensional measure of symptoms of rhinosinusitis. Internal consistency and construct validity (against SF-36 and AIA) were assessed at baseline. Sensitivity and MID were assessed by comparing test of cure data against baseline using statistical methods (effect size (ES), standardised response mean (SRM); and standard error of measurement (SEM) and 1/2 standard deviation (1/2SD)) and anchor methods against the smallest change on the global rating of change. Missing data were imputed using last observation carried forward. RESULTS: Internal consistency (α = 0.874) and construct validity (SF-36 Role Function r = -0.44; Vitality r = 0.45, Social Function r = 0.48, Pain r = 0.51, AIA r = 0.67 all P < 0.001) were confirmed. The SNOT-16 was sensitive (ES = 1.68; SRM = 1.36). The MID estimated by the anchor method was -0.85; but MID was lower by distributional estimates (SEM = 0.21, 1/2SD = 0.29). CONCLUSIONS: The study confirms the good psychometric properties of the SNOT-16 in patients with acute bacterial sinusitis and demonstrates the sensitivity and MID for this measure. The 3 MID estimates were widely separated and the higher anchor based estimate was settled on.

VALIDATION OF THE ACTIVITY IMPAIRMENT ASSESSMENT IN PATIENTS WITH ACUTE BACTERIAL SINUSITIS

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OBJECTIVES: To document the psychometric properties and estimate a minimal important difference (MID) for the Activity Impairment Assessment (AIA) questionnaire in patients with acute bacterial sinusitis. The AIA has previously been validated in people with uncomplicated urinary tract infections. METHODS: Secondary psychometric analysis was undertaken on data from a phase III trial to evaluate the efficacy and safety of moxifloxacin over 5 consecutive days in the treatment of acute bacterial sinusitis (N = 374). Trial patients also completed the RAND SF-36, the Sinonasal Outcomes Test-16 (SNOT-16) and a global rating of change. The AIA has 5 items and is scored as a uni-dimensional measure of the impact of disease on an individual’s work or regular activities. Internal consistency and construct validity (against SF-36 and SNOT-16) were assessed at baseline. Sensitivity and MID were assessed by comparing test of cure data against baseline using statistical methods (effect size (ES), standardised response mean (SRM); and standard error of measure-