

gender, ethnicity, marital status, educational attainment, household income, employment status, insurance possession, body mass index, exercise and smoking habits, alcohol use, and HIV/AIDS and hepatitis B status as predictors. **RESULTS:** Mean age was similar between hepatitis C patients who had ever initiated treatment (51.3 yrs, SD=11.39) and those who had not (52.0 yrs, SD=11.50). Patients who were married (OR=1.43, p=.004), in possession of insurance (OR=1.56, p=.003), or diagnosed with AIDS or HIV (OR=1.60, p=.05) were more likely to have initiated treatment than patients without those characteristics. No other significant differences were found. **CONCLUSIONS:** The current findings indicate that lack of insurance and lack of support from a partner are associated with lower odds of initiating treatment for hepatitis C. While speculative, this suggests that lack of social support and insurance may be barriers to treatment. Patients treated for hepatitis C may be more informed about their HIV/AIDS status, although conversely, patients with HIV/AIDS may be more likely to initiate therapy to avoid liver-related immunodeficiency complications. Further investigation is needed to help determine the direction of causation.

PGI5

COMPARISON OF HEALTH CARE UTILIZATIONS BETWEEN PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE WHO SWITCHED FROM A BRANDED PROTON PUMP INHIBITOR TO A GENERIC PROTON PUMP INHIBITOR AND VICE VERSA

Xie L, Baser E, Wang L, Baser O
STATinMED Research, Ann Arbor, MI, USA

OBJECTIVES: To compare health care utilizations between patients who switched from a branded proton pump inhibitor (PPI) to a generic PPI and vice versa. **METHODS:** We conducted a retrospective database analysis using commercial enrollees from a large US health plan from February 2008 to March 2010. Continuously eligible adult patients who had gastroesophageal reflux disease (GERD) or GERD-related conditions, and evidence of PPI use during February 2009 to September 2009 were included. The index PPI was defined as the first PPI prescribed during the identification period. Patients who switched from a generic PPI to a branded index PPI and patients who switched from a branded index PPI to a generic index PPI were included as the two cohorts in this study. Risk adjustment was performed using propensity score matching. We controlled for age, gender, region, GERD severity, plan, pre-index Quan-Charlson comorbidity score (CCI), baseline DACON, and baseline costs and utilization. **RESULTS:** A total of 9881 patients from each cohort were matched after propensity score matching. During the six months after the switch, there were no significant differences in office visits, emergency room visits, and inpatient admission rates between the two groups of switchers. Patients who switched from a branded PPI to a generic PPI had a slightly lower rate of outpatient visits compared to patients who switched from a generic PPI to a branded PPI (54.67% vs. 56.23%, p=0.0275). **CONCLUSIONS:** Although outpatient visit rates were slightly lower for patients who switched from a branded to a generic PPI, there were no significant differences in other health care utilizations such as office visits, emergency room visits, and inpatient admissions.

Gastrointestinal Disorders – Cost Studies

PGI6

THE ECONOMIC BURDEN OF ADVANCED LIVER DISEASE AMONG PATIENTS WITH HEPATITIS C VIRUS: A STATE MEDICAID PERSPECTIVE

Menzin J¹, White LA¹, Nichols C¹, Deniz B²
¹Boston Health Economics, Inc., Waltham, MA, USA, ²Vertex Pharmaceuticals Incorporated, Cambridge, MA, USA

OBJECTIVES: Untreated chronic hepatitis C (HCV) may progress to advanced liver disease (ALD), including decompensated cirrhosis (DC) and/or hepatocellular carcinoma (HCC). ALD can lead to significant clinical and economic consequences, including liver transplantation. There are limited data on ALD-associated healthcare costs among HCV-infected patients in a Medicaid program. **METHODS:** Using Florida Medicaid administrative claims data, we identified cases with HCV diagnosis on an inpatient or outpatient claim, or prescription HCV therapy, with an incident ALD-related diagnosis ("index event") between 7/1/1999 and 6/30/2007. ALD-related conditions included DC, HCC, or liver transplant procedure or history. Patients were included if they had ≥ 11 months continuous Medicaid eligibility pre- and post-index, and no enrollment in Medicare or an HMO. A one-to-one matched control cohort of HCV cases without ALD was generated using age, sex, and race. 2009 USD per-patient-per-month (PPPM) costs were reported and compared between cases and controls using Wilcoxon rank sum tests. **RESULTS:** The final study group included 1,193 cases and 1,193 matched controls (mean age: 49 years; 45% female; 54% white, 23% black, 23% other). The majority of ALD-related diagnoses were DC (92%), followed by HCC (6%) and liver transplant (2%). Cases with ALD had greater comorbidity (mean Charlson score: 3.1 vs. 2.3 among controls, P<.001). All-cause inpatient resource use in the one year follow-up from incident ALD diagnosis was significantly greater among cases than controls (74% vs. 27%, P<.001). Mean all-cause PPPM costs (including inpatient, outpatient, pharmacy, and others) were ~3 times greater among cases with ALD than controls (\$4,937 vs \$1,730, P<.001). **CONCLUSIONS:** HCV patients with ALD had a 2.9-fold higher economic burden in Florida Medicaid from 7/99 to 6/07 than the controls in the first year following ALD development. Preventing or delaying ALD onset in HCV patients could potentially help reduce this economic burden. Further study is necessary.

PGI7

THE ECONOMIC BURDEN OF REFRACTORY GERD: A RESTROSPECTIVE CLAIMS DATABASE STUDY

Gerson LB¹, Bonafede M², Princic N³, Gregory C⁴, Farr A⁴, Chu BC⁵, Balu S⁶

¹Stanford University, Palo Alto, CA, USA, ²Thomson Reuters, Andover, MA, USA, ³Thomson Reuters, Cambridge, MA, USA, ⁴Thomson Reuters, Washington, DC, USA, ⁵Thomson Reuters, Santa Barbara, CA, USA, ⁶Eisai, Inc., Woodcliff Lake, NJ, USA

OBJECTIVES: Gastroesophageal reflux disease (GERD) is a common disease affecting 10-20% of the US adult population. The objective of this study was to estimate the prevalence of refractory GERD and associated direct medical costs using real-world data. **METHODS:** Adult patients with GERD initiating a GERD medication were identified using the MarketScan Research Databases (2004-2009) and evaluated in the twelve months before and after GERD medication initiation. Refractory GERD was evaluated using an eight point scale where one point was given for each of the following: doubling GERD medication dose (including BID), adding another GERD medication, switching GERD medications, GERD-related procedure receipt, GERD-related surgery receipt, excess GI-related outpatient visits (>2), excess GERD-related office visits (>2), or GI-related ER visits. Patients were determined to have refractory GERD if they had 2 or more points. Annual unadjusted and multivariate adjusted GERD-related costs (i.e., claims with a GERD diagnosis) and all-cause costs were reported in 2009 dollars for patients with and without refractory GERD. **RESULTS:** A total of 135,139 GERD patients were analyzed (mean age= 52.9 (SD=14.5) years, 44% male). Approximately one-third (31%) of patients had refractory GERD. Versus patients with non-refractory GERD, refractory GERD patients were more likely to be female (59% vs. 55%, p<.0001) and had a higher Deyo Charlson Comorbidity score after GERD medication initiation (0.78 vs. 0.56, p<.0001); average age was similar in both groups. Compared to non-refractory GERD patients, refractory GERD patients had higher total all-cause costs (\$18,088 (SD=\$36,220) versus \$11,044 (\$22,985), p<.0001) and higher GERD-related costs (\$2,022 (SD=\$2,236) versus \$1,172 (SD=\$1,117), p<.0001). After controlling for demographic and clinical characteristics, refractory GERD was associated with an additional \$7,089 (SD=\$7,705) in total costs and \$845 (SD=\$111) in GERD-related costs. **CONCLUSIONS:** Refractory GERD is a common disease that may be associated with increased medical resource utilization and associated cost.

PGI8

COMPARING HEALTH-RISK BURDEN, LOST PRODUCTIVITY, AND TOTAL HEALTHCARE COSTS AMONG INDIVIDUALS WITH INFLAMMATORY BOWEL DISEASE AND FIVE MOST PREVALENT CHRONIC DISEASES

Naim A¹, Pitts J², Chen CY³, Wright D³, Chalk MB², Edington D³
¹Centocor Ortho Biotech Services, LLC, Horsham, PA, USA, ²Chalk & Associates, Austin, TX, USA, ³University of Michigan, Ann Arbor, MI, USA

OBJECTIVES: Inflammatory bowel disease (IBD) affects 1-1.4 million people in the United States. IBD affects people during their economically productive adult lives and can have potential economic impact of IBD on productivity loss in the workforce. We compared risk, absenteeism, and medical/pharmacy costs for employees with IBD and five most prevalent chronic conditions. **METHODS:** Health-risk information and self-reported illness days using health-risk assessment (HRA) data were examined and direct Healthcare costs (medical and pharmacy) using claims data for employees, retirees, and their adult dependents of a large self-insured employer were compared from 2002-2006 among individuals with IBD and five most prevalent chronic conditions; asthma, coronary artery disease/congestive heart failure (CAD/CHF), diabetes, hypertension, chronic obstructive pulmonary disease (COPD). **RESULTS:** 44 individuals with IBD were identified. The IBD cohort had moderate health-risk score (2.6/5) which was comparable to individuals with asthma (2.8/5), CHF (2.9), hypertension (2.6) and lower than diabetes (3.2/5) and COPD (3.4/5). Whereas, higher proportion (31.8%) of individuals with IBD had >5 illness days per year as compared with individuals with asthma (31.8%), CAD/CHF (25.9%), hypertension (20.4%), diabetes (28.4%), and COPD (33%). Annual direct healthcare costs were higher for individuals with IBD (\$24,911) as compared to individuals CAD/CHF (\$22,916), and hypertension (\$18,632), and lower as compared to individuals with asthma (\$25,814), diabetes (\$28,035), and COPD (\$38,839). **CONCLUSIONS:** Individuals with IBD have similar health-risks but higher illness days, and direct healthcare costs as compared to the individuals with five most prevalent chronic conditions. IBD is a high costs and lost productivity driver for employers. Population health based programs that engage employees in appropriately managing their chronic conditions can help employers reduce health-risks, improve productivity, and may help reduce healthcare costs as well.

PGI9

COMPARISON OF DIRECT MEDICAL COSTS AND SERVICES BY POINT OF SERVICE AND PRESCRIPTION COST FOR PERSONS WITH HEPATITIS-C WITH AND WITHOUT TREATMENT

Brook RA¹, Kleinman NL², Smeeding J³
¹The JeSTARx Group, Newfoundland, NJ, USA, ²HCMS Group, Paso Robles, CA, USA, ³JeSTARx Group, Dallas, TX, USA

OBJECTIVES: To compare the direct medical costs and services by point of service (PoS) and the prescription drug (Rx) costs and services for persons with Hepatitis-C (HCV) who are treated (HCV-Tx) and not-treated (HCV-noTx). **METHODS:** A retrospective analysis using the HCMS Research Reference database, which represents multiple US-based employers and contains employee data from 2001-2Q2007. This analysis compared the annual direct medical costs and services for healthcare by PoS, and Rx costs and services for HCV employees with and without Tx. ICD-9 Codes were used to identify employees with HCV. All subjects were required to have ≥ 1 month of eligibility. The first ribavirin, interferon or peginterferon Rx was the HCV-Tx cohort's index date. The HCV-noTx cohort was assigned the average index date (by company) of the HCV-Tx cohort. Two-part regression models were used to compare the cohorts adjusting for demographics, job-related variables, eligibility months, and Charlson Comorbidity Index. PoS Locations include: doctors office (MD), inpatient hospital (IN), outpatient hospital or clinic (OUT), emergency department (ED), laboratory (LAB), and other. Annual Rx costs and services were

also calculated. All costs were inflated to 2010 US\$. **RESULTS:** Data were available for 900 employees (HCV-Tx=216;HCV-noTx=684). The cohorts differed in salaries, the %married, %white, and %exempt. Mean HCV-noTx cohort IN (\$836, P=0.0001) and OUT (\$488, P=0.0018) costs were higher, and HCV-Tx MD (\$564, P<0.0001), LAB (\$42, P<0.0001) and Rx (\$21,420, P<0.0001) costs were higher. The HCV-noTx cohort had more IN services (1.83, P=0.0021), while the HCV-Tx cohort had more MD (15.48, P<0.0001), LAB (3.31, P<0.0001) and Rx (12.0, P<0.0001) services. Overall, HCV-Tx direct medical costs were \$3556 (services=54.40) which were lower than the HCV-noTx (\$4234; services=35.39). The HCV-Tx cohort had 27.84 Rxs (\$22,726) vs the HCV-noTx cohort's 15.84 Rxs (\$1408). **CONCLUSIONS:** Higher costs associated with HCV Treatment in the MD office offset IN and OUT costs.

PGI10

EXAMINATION OF RESOURCE UTILIZATION PATTERNS ACROSS SUBGROUPS OF GASTROESOPHAGEAL REFLUX DISEASE PATIENTS

Gerson LB¹, Balu S², McLaughlin T³, Lunacek O³, Jackson J³

¹Stanford University, Palo Alto, CA, USA, ²Eisai, Inc., Woodcliff Lake, NJ, USA, ³Xcenda, LLC., Palm Harbor, FL, USA

OBJECTIVES: To determine if subsets of gastroesophageal reflux disease (GERD) patients vary with respect to healthcare utilization. **METHODS:** This retrospective analysis identified commercial enrollees 18-75 years old with claims for GERD (ICD-9-CM: 530.81 or 530.11) and proton pump inhibitors (PPI) during 01/01/05 - 06/30/09. Patients were further required to have no claims for HIV, pregnancy, inflammatory bowel disease or cancer at any time, or GERD prescription or gastric/duodenal ulcer prior to initial GERD diagnosis. Eligible patients were then stratified based on medical claims for other symptoms during a 12 month period centered on their first GERD diagnosis: Stage A (GERD diagnosis, no other symptoms); Stage B (GERD + respiratory symptoms); Stage C (GERD + Barrett's esophagus); Stage D (GERD + esophageal stricture); Stage E (GERD + iron deficiency anemia or acute hemorrhage). The stages were compared with respect to GERD treatment, other gastrointestinal symptoms and GERD-related or all-cause costs for outpatient, inpatient, and pharmacy care during the first six months after initial diagnosis using univariate statistics. **RESULTS:** 174,597 patients were analyzed: Stage A: 74%, Stage B: 20%, Stage C: 1%, Stage D: 2%, Stage E: 3%. Versus stages A and B, patients in Stages C-E were more likely to visit a gastroenterologist (53.9% vs. 12.9%), receive multiple PPI (11.5% vs. 7.4%) and had higher rates of gastritis/duodenitis (17.0% vs. 5.9%), esophageal ulcers (4.4% vs. 0.3%), and esophageal surgery (7.6% vs. 0.3%). Six month GERD-related costs ranged from \$615/patient (Stage A) to \$1,714/patient (Stage D); all-cause costs ranged from \$4,195/patient (Stage A) to \$11,340/patient (Stage E) (p<0.0001 for all contrasts). **CONCLUSIONS:** While GERD patients with additional complications represented a relatively small portion of the total sample, their significantly higher costs and events suggest an opportunity for improving patient care.

PGI11

THE ECONOMIC AND QUALITY OF LIFE BURDEN OF ILLNESS IN CHRONIC CONSTIPATION (CC) AND IRRITABLE BOWEL SYNDROME (IBS): A SYSTEMATIC REVIEW

Yee K¹, Nellesen D¹, Chawla A¹, Carson R², Lewis B³

¹Analysis Group, Inc., Menlo Park, CA, USA, ²Forest Research Institute, Jersey City, NJ, USA, ³Ironwood Pharmaceuticals, Cambridge, MA, USA

OBJECTIVES: To systematically review literature on the burden of illness in patients with CC and IBS subtypes. **METHODS:** Medline, Medline In-process, EconLit, CINAHL, Cochrane Library, and AGA abstracts were searched. Studies reporting economic and quality of life (QOL) outcomes in IBS or CC patients were included. Study designs included case control, observational studies, surveys, and retrospective analyses. RCT and studies reporting outcomes attributable to a specific therapy were excluded. **RESULTS:** 882 unique studies were identified and 35 selected: 16 evaluated economic measures only, 16 humanistic measures only, and 3 economic and humanistic measures. Studies were excluded if patient populations or outcomes were not relevant. Selected studies included a total of 63,816 patients: 1,706 IBS-C, 2,264 IBS-D, 2,892 IBS-A, 15,830 IBS sub-type unspecified, and 1,278 CC patients. Nineteen studies assessed economic measures: 11 evaluated direct costs, 1 indirect costs, and 7 direct and indirect costs. Indirect costs generally reflected estimated work productivity loss due to IBS symptoms or healthcare-seeking behavior. US-based estimates of direct costs per IBS patient were \$1,562/year (2002 USD) to \$7,547/year (year NR, published in 2000); direct costs per CC patient were \$1,912/year (2002 USD) to \$7,522/year (2002-2003 USD). Indirect per IBS patient costs ranged from \$791/year (1998 USD) to \$7,737/year (year NR, published 2005). No study assessed costs associated with IBS-C/D/A subtypes. In studies comparing IBS patients to non-IBS controls, IBS patients had significantly lower SF-36 domain scores, notably in vitality, general health, and physical functioning. **CONCLUSIONS:** Our research identified a range of methods and estimates of the burden of IBS and CC. No economic study reported recent cost estimates by IBS subtypes; only two estimated direct costs of CC. No studies presented QOL information in CC patients; however, patients suffering from IBS had measurable burden of disease based on QOL scores.

PGI12

DOSE VARIATIONS WITH ADALIMUMAB AND INFlixIMAB IN THE TREATMENT OF CROHN'S DISEASE: A CANADIAN ASSESSMENT

Lachaine J¹, Beauchemin C¹, Goyette A², Martel M²

¹University of Montreal, Montreal, QC, Canada, ²Abbott Laboratories, St-Laurent, QC, Canada

OBJECTIVES: In Canada, adalimumab and infliximab are approved for the treatment of moderate to severe active Crohn's disease (CD). Product monographs suggest that the dose may be increased in case of incomplete response. The objective of this study was to analyze, in a real world setting, dose variations in CD patients

who initiated adalimumab or infliximab treatment. **METHODS:** A retrospective cohort study was conducted using data from the Regie de l'assurance maladie du Quebec (RAMQ) for a random sample of patients with a CD diagnosis, who had initiated adalimumab or infliximab between February 2008 and December 2008. For adalimumab, dose increase was considered when the dose received exceeded 40mg every other week over at least an 8-week period. For infliximab, dose increase was considered either when the dose was increased or interval between doses was reduced for two periods of 8 weeks after the third injection. **RESULTS:** The cohort included a total of 290 patients of which 135 patients were initiated with infliximab and 155 with adalimumab. The mean age was 42.2 years (SD=16.9). After 12 months, 14.2% (22/155) of patients with adalimumab and 22.2% (30/135) of patients with infliximab had experienced a dose increase (p<0.05). Average medication costs in the year following initiation of adalimumab or infliximab, for patients who did not adjust doses were CAD\$10,250 and CAD\$14,957, respectively (p<0.01). For patients who experienced a dose increase or reduced interval between doses, average medication costs were CAD\$19,789 with adalimumab and CAD\$25,550 with infliximab (p=0.013). **CONCLUSIONS:** CD patients treated with infliximab had a significantly higher rate of dose increases compared with patients treated with adalimumab. Results of this RAMQ database analysis illustrate that, in a real-world setting, dose increase or reduction of interval between doses are associated with increased treatment costs. In both recommended and adjusted dosing, adalimumab demonstrated significant cost savings over infliximab.

PGI13

PERCEIVED VALUE ASSESSMENT OF ENTECAVIR VERSUS NO TREATMENT IN CHRONIC HEPATITIS B

Vorobyev P¹, Telegina I², Borisenko O¹, Jakouloff D³

¹Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia, ²Stavropol State Medical Academy, Stavropol, Russia, ³BMS, Moscow, Russia

OBJECTIVES: To assess the economic value of treating CHB patients with Entecavir relative to the current situation in Russia with no treatment. **METHODS:** We carried out the Perceived Value Assessment (PVA) of Entecavir (937 patients) vs. no treatment (971 patients) using a multilayered Markovian model (disease state transition model: F0/F1 - F2/F3/F4 (Fibrosis) - >F4 (Advanced Fibrosis/Cirrhosis) - Decompensated Cirrhosis - Hepatocellular Carcinoma - Liver Transplant - Post Liver Transplant), developed by J. Wells from Monitor Group. It is consistent with a cost-benefit analysis, where the clinical benefits of treatment with ETV (occurrence of histological improvement and CHB disease regression, avoidance of renal adverse events, avoidance of additional monitoring requirements) are expressed in monetary terms (Rubles). Costs of treating a chronic Hepatitis B patient per day avoided by 5 years of Entecavir treatment and 25 years of follow up (total 30 years) can be considered as benefits of treating. **RESULTS:** As patients progress into more advanced disease states their treatment becomes disproportionately more expensive: 420.7 USD for F0/F1, 1 935.2 USD for F2/F3/F4, 2 515.6 USD for >F4, 10 947.1 USD for Decompensated Cirrhosis, 4 549.9 USD for Hepatocellular Carcinoma, 10 092 USD for Liver Transplant, 49 613.6 USD for Post Liver Transplant. Costs of treating a CHB patient avoided by 5 years of Entecavir treatment and 25 years of follow up - 30.3 USD per day: 4.8 USD per day for F0/F1, F2/F3/F4 and >F4; 3.2 USD per day for Decompensated Cirrhosis; 0.6 USD per day for Hepatocellular Carcinoma; 0.45 USD per day for Liver Transplant; 21.25 USD per day for Post Liver Transplant. Cost of Entecavir treatment is 8.8 USD per day (29.1% of total costs avoided per patient per day of Entecavir treatment). **CONCLUSIONS:** Entecavir represents a true "spend to save" strategy: cost of therapy is fully outweighed by the economic benefits of treatment.

PGI14

PERCEIVED VALUE ASSESSMENT OF ENTECAVIR VERSUS TENOFOVIR IN CHRONIC HEPATITIS B

Vorobyev P¹, Telegina I², Borisenko O¹, Jakouloff D³

¹Russian Society for Pharmacoeconomics and Outcomes Research, Moscow, Russia, ²Stavropol State Medical Academy, Stavropol, Russia, ³BMS, Moscow, Russia

OBJECTIVES: Chronic hepatitis B (CHB) can lead to progressive liver disease, including cirrhosis, hepatocellular carcinoma and death. New options for long-term antiviral treatment decrease financial burden of CHB to the healthcare system and require physicians, payers and healthcare decision-makers to evaluate its economic value. To assess the economic value of treatment with Entecavir relative to treatment with Tenofovir in the Russian healthcare system. **METHODS:** We carried out the Perceived Value Assessment (PVA) of Entecavir (ETV) vs. Tenofovir (TFV) using multilayered Markovian model (disease state transition model: F0/F1 - F2/F3/F4 (Fibrosis) - >F4 (Advanced Fibrosis/Cirrhosis) - Decompensated Cirrhosis - Hepatocellular Carcinoma - Liver Transplant - Post Liver Transplant), developed by J. Wells from Monitor Group. In terms of PVA model we evaluated the comparative value provided to the health care system by Entecavir versus Tenofovir treatment (total of 30 years modeled) depending on duration of treatment and the follow-up period. The primary outcome measure of the model is the "Per pill Cost". **RESULTS:** As patients progress into more advanced disease states their treatment becomes disproportionately more expensive: 420.7 USD for F0/F1, 1 935.2 USD for F2/F3/F4, 2 515.6 USD for >F4, 10 947.1 USD for Decompensated Cirrhosis, 4 549.9 USD for Hepatocellular Carcinoma, 10 092 USD for Liver Transplant, 49 613.6 USD for Post Liver Transplant. ETV's price is only 0.11 greater than TFV's price. Value gap between ETV and TFV for 5 years of therapy with 25 years of follow-up period was 4.8 USD per pill. It was determined by the long-term efficacy of ETV. **CONCLUSIONS:** PVA Cost benefit simulation with 30 year time horizon and maximum treatment duration of 5 years demonstrated ETV's economic value was 4.8 USD greater than that of TFV.