OBJECTIVES: The purpose of this project was to assess the prevalence and risk factors for diarrhea at a large tertiary care medical center. METHODS: Prospective cross-sectional study conducted on December 13, 2004 in a 600-bed tertiary care medical center. All patients hospitalized for greater than 24-hours on the study day were interviewed. Patients were asked if they were experiencing diarrhea (defined as passing of two or more unformed stools in the past 24-hours.) All patients reporting diarrhea were tested for Clostridium difficile. Patient demographics, and use of antibiotics, tube feeds, GI motility agents, steroids, chemotherapy proton pump inhibitors were collected for every patient. Chi-square analysis was used to determine risk factors for diarrhea. RESULTS: A total of 485 patients were interviewed for the study, of which 60 (12.3%) patients reported diarrhea. The risk factors for diarrhea include Clostridium difficile infection (OR 15.1, p < 0.0001), hospitalization duration (p < 0.0001), current use of antibiotics (OR 1.95, p < 0.0166), and tube feeds (OR 3.34, p < 0.0018). Prevalence of diarrhea increased with longer duration of hospitalization (p = 0.03). CONCLUSION: Twelve percent of hospitalized patients experienced diarrhea in our study. Common risk factors for diarrhea included C. difficile infection, current use of antibiotics, tube feeds, or longer hospitalizations.

THE BUDGET IMPACT OF TEGASEROD ON A MANAGED CARE ORGANIZATION FORMULARY

Bloom MA1, Barghout V2, Kahler KH2, Bentkover JD1, Kurth H1, Gralnek IM1, Spiegel B4

1Innovative Health Solutions, Brookline, MA, USA; 2Novartis Pharmaceuticals Corp, East Hanover, NJ, USA; 3David Geffen School of Medicine at UCLA, VA Greater Los Angeles Healthcare System, CURE Digestive Diseases Research Center, Los Angeles, CA, USA; 4Department of Gastroenterology and Hepatology, VA Greater Los Angeles Healthcare System, Los Angeles, CA, USA

OBJECTIVE: To develop a budget impact model that assesses the economic impact of adding tegaserod for the management of irritable bowel syndrome with constipation to a managed care organization’s (MCO) formulary. METHODS: The model estimates per patient and per-member per-month (PMPM) economic impact of two patient subgroups six-months prior to and six-months after the initiation of tegaserod. The incremental budget impact of tegaserod was then calculated by subtracting the prior period costs from the post period costs. The two patient subgroups were 1) females with an IBS diagnosis (FIBS); and 2) males and females with other GI diagnosis (GID). Resource utilization data were based on a retrospective, longitudinal study of 3365 tegaserod users from a large, geographically-diverse MCO utilizing medical and pharmacy administrative claims data. We used prevalence and tegaserod treatment rates observed from the aforementioned MCO. Sensitivity analyses were performed by varying several model inputs parameters. RESULTS: The base-case model resulted in an incremental PMPM budget impact associated with the use of tegaserod of $0.01. Total per-patient budget impact (for all resources, including tegaserod) for a six-month period was $274.34 for FIBS and $301.84 for GID. Overall, 25.9% (29.0% for FIBS and 21.9% for GID) of the cost of tegaserod was offset by decreases in resource utilization. Key drivers of post-tegaserod reductions in resource costs were hospital stays, abdominal and pelvic CAT scans, colonoscopies (for FIBS), and outpatient office consultations and emergency room visits (for GID). CONCLUSIONS: Tegaserod therapy can decrease GI-related resource use, resulting in a significant cost-offset percentage. When the associated budget impact of adding tegaserod to formulary is absorbed across an entire MCO population, the PMPM impact of tegaserod is small.
liver disease. Literature review was performed to obtain other probabilities for the model. The effectiveness measure was the number of patients immune to both HAV and HBV. RESULTS: The selective strategy was less costly but less effective with a cost-effectiveness ratio of $105 per patient immune to HAV & HBV. The universal strategy was more effective but more expensive with a cost-effectiveness ratio of $112 per patient immune to HAV & HBV. Compared with the selective strategy, universal strategy was associated with an incremental cost-effectiveness (ICE) ratio of $154 per additional patient immune to HAV and HBV. The universal strategy would become more cost-effective if the cost of combined vaccine reduces by >9.7% to <$0.75, if the cost of HBV vaccine increases by >25% to >$34.50, if the cost of blood tests for immunity increases by >23% to >$25.25, or if the prevalence of anti-HBs decreases to <24%. CONCLUSIONS: The selective vaccination strategy for HAV and HBV in our sample of patients with HCV is more cost-effective. However, the ICE for the universal strategy is minimal.

**PGIS**

COST-EFFECTIVENESS OF PEGINTERFERON ALFA-2A (40KD) COMPARED TO LAMIVUDINE FOR THE TREATMENT OF E ANTIGEN NEGATIVE CHRONIC HEPATITIS B IN THE UK

Veenstra DL1, Sullivan SD1, Lewis G2, Green J3

1University of Washington, Seattle, WA, USA; 2Roche Products Limited, Welwyn Garden City, Herts, UK; 3Hoffmann-La Roche, Nutley, NJ, USA

Peginterferon alfa-2a (40KD) (PEGASYS®), a new treatment option for patients infected with chronic hepatitis B (CHB), offers improved efficacy with a defined treatment duration compared with lamivudine (LAM), but at a higher cost. OBJECTIVE: To assess the clinical outcomes, costs and cost-effectiveness of PEGASYS for the treatment of patients with HBsAg-negative CHB, compared to LAM treatment for one-year and four-years. METHODS: A cost-effectiveness analysis from the UK National Health Service (NHS) perspective using a state-transition Markov model simulating the natural history of HBsAg-negative CHB. Efficacy data were obtained from a recent, randomized clinical trial comparing PEGASYS and LMV in patients with HBsAg-negative CHB. Patients: Hypothetical cohort of 40-year old patients with HBsAg-negative CHB. Interventions: PEGASYS and LAM monotherapy. Measurements: Life expectancy, quality-adjusted life expectancy, lifetime costs, and incremental cost-effectiveness ratios (ICERs). RESULTS: Forty-eight week treatment with PEGASYS compared to LAM resulted in higher total costs, but greater quality-adjusted life expectancy, yielding an ICER of £5047/quality-adjusted life year (QALY) gained. Although there is uncertainty associated with the prognosis of HBsAg-negative CHB, the ICER did not exceed £10,000/QALY gained despite variation in each parameter used in the analysis. In the analysis comparing 48-week treatment with PEGASYS to 208-week treatment with LAM, the ICER was £2767/QALY gained. CONCLUSIONS: Short-term treatment with PEGASYS compared to either short-term or long-term LAM treatment in CHB patients who are HBsAg-negative appears to offer life expectancy benefits at a cost-effectiveness ratio comparable to other currently reimbursed pharmaceutical interventions.

**PG16**

UTILIZATION, RE-TREATMENT, AND COST OF DIFFERING LENGTHS OF H. PYLORI TREATMENT REGIMENS FROM US HEALTH CARE CLAIMS DATABASES

Orsini LS1, Lenhart G1, Flanders S1, Huse D1, Dodd SL1, Lomax K1

1Thomson Medstat, Cambridge, MA, USA; 2Janssen Scientific Affairs, Grayslake, IL, USA; 3Janssen Medical Affairs, LLC, Silesia, MT, USA

OBJECTIVE: Evaluate utilization and expenditure for treatment of gastrointestinal infection with Helicobacter pylori (H. pylori) by different durations of treatment. METHODS: Retrospective analysis of pharmacy and outpatient procedure claims between January 1, 2000 and December 31, 2002 in the MarketScan® Commercial Claims and Encounters, Medicare Coordination of Benefits, and January 1, 1999 and December 31, 2001 in MultiState Medicaid databases. Patients were required to have one claim for any proton pump inhibitor (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole) and an antibiotic combination of amoxicillin/clarithromycin (AC) or metronidazole/tetracycline (MT). Treatment patterns were evaluated along with re-treatment rates (regimen effectiveness), testing rates, and pharmaceutical expenditures. RESULTS: In total, 10,203 patients were identified; the average patient age was 52.8 years, the majority of patients were female, 41.6% had privately funded insurance and 58.4% had publicly funded insurance. The majority of patients were naive to H. pylori eradication therapy over the 12 months prior to initial therapy and 92.6% of patients received AC as their antibiotic combination. Fourteen-day triple therapy (PPI + two antibiotics) was prescribed for majority (80%) of patients regardless of H. pylori eradication therapy treatment history. Re-treatment rates did not vary significantly among different triple therapy treatment regimen durations: 7.8% for seven day, 7.6% for ten day, and 7.9% for 14 day regimens. However, the cost of initial treatment for different treatment durations varied widely, $120.82 for seven day regimens, $178.79 for ten day regimens, and $294.49 for 14 day regimens. CONCLUSION: This study found significant differences in treatment costs by duration of therapy despite similar re-treatment rates among different lengths (seven day vs. 14 day) of H. pylori triple therapy regimens. There are potential economic benefits realized in shorter duration of treatment, as measured by the direct expenditures on the medications themselves, and associated re-treatment and testing expenditures.

**PG17**

MANAGING CROHN'S DISEASE: USE AND COST OF INPATIENT, EMERGENCY DEPARTMENT AND OBSERVATION UNIT SERVICES DURING ONE YEAR

O'Brien J, Pitioniak-Morse C

Caro Research Institute, Concord, MA, USA

OBJECTIVE: Crohn’s disease (aka: inflammatory bowel disease, regional enteritis) is a chronic autoimmune disorder that can occur at any age. This analysis examined use and cost of hospitalizations, observation unit (OU) stays and emergency department (ED) visits during a one-year period by patients with Crohn’s disease. METHODS: Using 2001–2002 Massachusetts ED, OU and inpatient data, a cohort was identified by personal identifiers and ICD-9 principal diagnosis codes (555.0–555.9). An encounter profile was established for each patient starting with the first stay or visit at any hospital, ED or OU in Massachusetts in 2001. From that index encounter, each contact for regional enteritis was tracked for 12 months for that patient. Cost estimates, reported in 2004 USD, include accommodations and ancillary services. Charges were adjusted using a 0.55 cost-to-charge ratio and appropriate inflation indices. RESULTS: A