2009. Subjects had to be continuously enrolled and be >= 18 years of age. Cases had to have at least one incident claim with a primary diagnosis of acute liver necrosis, hepatitis, hepatic coma, hepatorenal syndrome, or coagulopathy. 3:1 controls matched on age, gender, and geographic region were randomly chosen. Acetaminophen maximum and average daily doses were calculated in a range of acute periods (7, 20, and 30 days) and in the chronic one year prior period. Conditional logistic regression was used to estimate the risk of acetaminophen exposure adjusted for comorbidities, other hepatotoxic drugs, and health system factors. **RESULTS:** There were 1350 cases and 4050 controls with a mean age of 47.29 years and 53.85% were male. 116 (8.59%) cases and 144 (3.56%) controls were exposed to acetaminophen in the 30-day prior period with mean maximum daily doses of 3234.32 and 3021.40 mgs. Hepatotoxicity was associated with any acute acetaminophen exposure that decreased with longer look back periods; 7 days (OR=2.23, p<0.001), 30 days (OR=1.84, p<0.001). Cumulative dose in the year prior was not associated with hepatotoxicity (OR=1.05, p=0.889). Acute maximum daily doses >4gms/day were associated with greater risks of hepatotoxicity (OR=2.45, p<0.001). **CONCLUSIONS:** Acute exposure to prescription acquired acetaminophen is associated with increased risk of hepatotoxicity, however use over longer chronic periods was not. Further research is necessary before the safety of chronic acetaminophen can be established.

PGI3

CURRENT TREATMENTS FOR CHRONIC HEPATITIS B: A SYSTEMATIC REVIEW

Watt M[1], Mealing S[1], Huerta M[2], Eaton V[2], Lescrauwaet B[3], Mesa OA[4], Thursz M[5], Hawkins N[2]
[1]*Oxford Outcomes Ltd, Oxford, UK,* [2]*Oxford Outcomes Ltd., Oxford, UK,* [3]*Xintera Consulting BVBA, Leuven, Belgium,* [4]*Bristol-Myers Squibb Pharmaceuticals Ltd, Uxbridge, Middlesex, UK,* [5]*Imperial College, London, UK*

OBJECTIVES: The National Institute for Health and Clinical Excellence set the guidance review date for an updated health technology appraisal in the treatment of Chronic Hepatitis B (CHB), including the use of entecavir, as February 2012. The objective of this study was to summarize the published evidence on the clinical efficacy and safety of CHB treatments, through a systematic identification of relevant randomised controlled trials. **METHODS:** A systematic literature search of Embase, Medline, Medline in process and Cochrane CENTRAL databases was conducted based on a research protocol with pre-defined criteria. The search period covered from inception of databases until March 2011. All searches were limited to full publications in the English language pertaining to adults with CHB without HIV co-infection or liver cirrhosis at baseline. The search strategy contains a mixture of free text and index terms. Abstract review and data extraction were performed independently by two members of the project team. The comparators of interest were: Adefovir dipivoxil, Entecavir, Interferon alfa 2a, Interferon alfa 2b, Peginterferon alfa-2a, Peginterferon alfa-2b, Lamivudine, Tenofovir and Telbivudine. Any of the comparisons versus placebo or compared to another drug listed, were included. **RESULTS:** 2,994 articles were identified with 2,107 abstracts reviewed according to the predefined inclusion criteria. A total of 178 full papers were ordered and 27 papers (n=9,033) included in the final analysis. Extensive data was extracted related to key patient population details, interventions used, baseline characteristics, endpoint data at numerous time points (up to 24 months) and adverse events. The methodological quality of trials was assessed using the Cochrane Collaboration's tool for assessing risk of bias. **CONCLUSIONS:** Although the literature base is mature in terms of number of RCTs, due to the number of treatments available the evidence network is weak. From those results, further analysis through a network meta-analysis, adjusting for cross-trial differences between study populations, should be investigated.

PGI4

COST-EFFECTIVENESS OF ESOMEPRAZOLE VERSUS PANTOPRAZOLE IN ACUTE AND MAINTENANCE TREATMENTS OF REFLUX ESOPHAGITIS IN TURKEY

Ormeci N[1], Caglayan B[2]
[1]*Ankara Universitity, Faculty of Medicine,, Ankara, Turkey,* [2]*AstraZeneca Turkey, Istanbul, Turkey*

OBJECTIVES: To assess the cost effectiveness in Turkey of acute treatment of reflux esophagitis (RE) with esomeprazole (ESO) 40mg once daily (od) followed by maintenance treatment with 20mg od versus acute treatment with pantoprazole (PA) 40mg od followed by maintenance treatment with 20mg od. **METHODS:** In the present study, ESO and PA were compared in a decision analytic model in terms of costs and effectiveness. To assess the effectiveness, probabilities for treatment success, which was healing of RE during initial acute treatment or a relapse while on maintenance treatment, were obtained from the randomized, double-blind, multi-center EXPO study. Patients healed after initial four to eight weeks acute treatment received 6 months maintenance treatment. Therefore, all patients were followed for seven months in the model. Direct medical costs were assessed based on the perspective of the health care provider. Association between RE and lost work productivity was regarded as 5.3 hours per employed patient per week. Sensitivity analyses were performed by using upper and lower 95% confidence intervals of the clinical study effectiveness results, as well as by changing patient management assumptions. **RESULTS:** Probability of treatment success per patient in the ESO and PA strategy was 83.4 % and 69.6 %, respectively after 7 months. Mean direct medical costs per patient in the ESO and PA strategy were the same; 152 TL in both strategies. Total costs included direct medical costs and indirect costs, which consisted of work absence and reduced work productivity. Total costs for ESO and PA strategy were 247TL and 274TL, respectively implying a cost-saving of 27TL for ESO. Sensitivity analyses supported stability of main findings for a range of scenarios. **CONCLUSIONS:** When considering total costs from a societal perspective, results indicate that esomeprazole treatment is dominant; esomeprazole provided a better clinical effectiveness at lower costs.

PGI5

IRRITABLE BOWEL SYNDROME WITH CONSTIPATION (IBS-C): A EUROPEAN-FOCUSED SYSTEMATIC LITERATURE REVIEW OF DISEASE BURDEN

Wiklund I[1], Foster T[2], Travers K[2], Fortea J[3], Prior M[3]
[1]*United BioSource Corporation, London, UK,* [2]*United BioSource Corporation, Lexington, MA, USA,* [3]*Laboratorios Almirall S.A., Barcelona, Spain*

OBJECTIVES: To explore disease burden, economic impact, treatment landscape and unmet medical needs in patients with IBS-C. **METHODS:** We conducted a review of MEDLINE- and EMBASE-indexed and 'grey' literature (citeable material that is often not published in peer-reviewed, indexed medical journals, e.g.,web-based international treatment guidelines) published in the last decade (January 2000 to December 2010) pertaining to the epidemiological, clinical, economic, and humanistic impact of IBS-C with a European country focus (France, Germany, Italy, Spain, UK). **RESULTS:** Altogether 885 unique studies were identified; 106 were included in the analysis. Among patients with IBS, the prevalence estimates of IBS-C range from 24% to 44%. Comorbid conditions such as personality and psychological traits and stress, are common. Patients with IBS-C have lower health-related quality of life (HRQoL) compared with the general population (18 studies); treatment of IBS-C can improve HRQoL. The European societal cost of IBS-C is largely unknown; no European cost-of-illness (COI) studies were identified specifically on IBS-C. In the absence of European data, US data show IBS-C to be cost-intensive. Two cost analyses demonstrated the substantial societal impact of IBS-C, with adult patients experiencing reduced productivity at work or through work absenteeism (mean number of days off work annually: 8.5 to 21.6 days) due to severe, disruptive symptoms. European and local IBS treatment guidelines (where available) offer similar diagnostic/management recommendations; however, IBS-C treatment varies by country. Current monotherapy options for treating IBS-C are suboptimal. 5-HT4 agonists have been evaluated for IBS-C; however, they have been associated with ischaemic colitis or a lack of substantial benefit in IBS-C versus placebo. **CONCLUSIONS:** Our literature search indicates a lack of monotherapy treatment options to adequately manage IBS-C patients, and the need for European focussed burden of disease and COI studies, to address the evidence gaps identified in this systematic literature search.

PGI6

THE DEVELOPMENT AND EXTERNAL VALIDATION OF A MODEL TO PREDICT ONE YEAR ALL-CAUSE MORTALITY FOLLOWING LIVER FUNCTION TESTS IN PRIMARY CARE PATIENTS

Mclernon DJ[1], Dillon JF[2], Donnan PT[3]
[1]*University of Aberdeen, Aberdeen, Aberdeenshire, UK,* [2]*University of Dundee, Dundee, Tayside, UK,* [3]*University of Dundee, Dundee, Tayside, UK*

OBJECTIVES: In patients with raised liver function tests (LFTs) but without clinically apparent liver disease, the appropriate level of follow-up to take can be unclear. Our aim was to develop and validate a prediction model to estimate the risk of one year all-cause mortality in patients with LFTs taken in primary care. **METHODS:** A population-based retrospective cohort of patients, without clinically apparent liver disease, in Tayside Scotland was identified as having their first LFTs performed in primary care and followed for one year. Biochemistry data were record-linked to secondary care, prescriptions and mortality data to ascertain baseline characteristics including LFTs, age, gender, deprivation, comorbidities, alcohol and drug dependency, methadone use, and statin, NSAIDs or antibiotic use. Multiple imputation was used to impute missing values for LFTs. Parametric accelerated failure time survival models were fitted to predict all-cause mortality. The final model was assessed for discriminatory ability using the C-statistic. A separate validation cohort was obtained from 19 general practices across Scotland to externally validate the final model. **RESULTS:** Predictors of all-cause mortality model included male gender, age, social deprivation, history of cancer, renal disease, stroke, ischaemic heart disease and respiratory disease, statin use, and all LFTs. A model integrating these predictors had excellent discriminatory ability (C-statistic (95% CI) = 0.82 (0.80, 0.84)) and calibrated well internally. The external validation had a C-statistic of 0.86 (0.79, 0.90) with very good calibration. The model without LFTs had a C-statistic of 0.63 (95% CI 0.61, 0.66). **CONCLUSIONS:** This study has developed and externally validated a model that predicts risk of mortality in patients with no apparent liver disease but tested for LFTs in primary care. This model can be used in practice by general practitioners and others working in community settings to improve management of these patients with the potential to save costs to the health system.

Gastrointestinal Disorders – Cost Studies

PGI7

IMPACT OF COMPLICATIONS FROM DYSPHAGIA ON HOSPITAL CHARGES IN THE UNITED STATES

Jensen IS, Helm T, Cyr PL
Navigant, Inc., Boston, MA, USA

OBJECTIVES: Unmanaged dysphagia exposes patients to risk of malnutrition, dehydration, urinary tract infections (UTI) and aspiration pneumonia. It has been demonstrated that dysphagia screening and management may reduce the risk of developing complications and incurring increased hospital charges. The objective of this analysis is to quantify the additional charges associated with common complications of dysphagia. **METHODS:** Using 2008 Health Care Utilization Project (HCUP) data, individuals with a recorded diagnosis of dysphagia (ICD-9 CM: 438.82, 787.2-787.29) were identified. The mean (10% trimmed) hospital charges for indi-