were discounted at 3.5%. The base case analysis used a conservative estimate of 80 kg for the patient. Uncertainty around the cost effectiveness estimates was explored using one-way and probabilistic sensitivity analysis. RESULTS: Infliximab versus celecoxib resulted in an ICER of £19,290 per QALY while infliximab therapy dominated standard care and surgery for ulcers. Changes in the utility estimates, medium term celecoxib co-lexicity, and long term effect on resource use in the ICER values being above the cost effectiveness threshold of £20,000 per QALY. CONCLUSIONS: Infliximab can be considered as a cost effective treatment compared to standard care in patients with severely active ulcerative colitis (UC) hospitalised with an acute exacerbation in Scotland.

RESOURCE UTILIZATION AND DIRECT MEDICAL COST OF CHRONIC HEPATITIS C (CHC) IN THAILAND: A HEAVY BUT MANAGEABLE ECONOMIC BURDEN

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OBJECTIVES: To estimate resource utilization and direct medical cost of chronic hepatitis C (CHC) from a Thai payer perspective. METHODS: Medical records of CHC patients hospitalised during 2003-2006 in 11 private and 7 major tertiary-care hospitals in Thailand were retrospectively reviewed. Data on CHC-related resource use were collected from diagnosis date to end of 2007 or the last follow-up date or death date, depending on which date came first. Using micro-costing method, resource utilization categorized as laboratory tests, outpatient visits (OPD), inpatient admissions (IPD), hospital procedures and medications were measured for 6 health states of CHC, i.e. CHC, compensated cirrhosis (CC), decompensated cirrhosis (DC), hepatocellular carcinoma (HCC), liver transplantation at year 1 (LT1), and subsequent years post-transplantation (LT2+). Costs were estimated using reference prices published by Ministry of Public Health and were valued in year 2008 Thai Baht (35 Baht = 1 USD). RESULTS: A total of 542 patients were identified with 1578 person-years of follow-up time. OPD rate was highest in HCC (7 visits/patient/year); IPD rates increased by 289% from CC to DC and 1177% from CC to HCC. Mean lengths of stay admission were 9 days in DC and 6 days in HCC. Usage rates of medications for liver complications were also increased in DC and HCC. Annual average treatment costs per patient were CHC: 243,292 Baht (US$6,951); CC: 251,148 Baht (US$7,176); DC: 154,68 Baht (US$4,162); HCC: 975 Baht (US$4,939); LT1: 608,771 Baht (US$17,253); and LT2+ 100,818 Baht (US$2,881). CONCLUSIONS: Resource utilization rates in CHC patients increase as the disease progresses. Although inpatient bed charges are relatively low and no doctor fee paid for outpatient visits in public hospitals, consumption of these health care resources could have been avoided. Interventions which prevent delay liver disease progressions will profoundly reduce economic burden of CHC.

TREATMENT OF MODERATE TO SEVERE PAIN WITH OXYCODONE/ NALOXONE TO REDUCE OPIOID-INDUCED CONSTIPATION: A COST-UTILITY ANALYSIS IN BELGIUM AND THE NETHERLANDS

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OBJECTIVES: Constipation is a frequent and possibly debilitating adverse event of analgesic treatment. In a 4-week analgesic episode. A new drug combining the opioid oxycodone with the opioid antagonist naloxone provides equivalent analgesia to oxycodone alone with significant improvement in bowel function, as demonstrated in a 12-week randomized controlled in moderate/severe non-cancer pain (OXN3001). This analysis assessed the cost-utility of oxycodone/naloxone vs. oxycodone in Belgium and The Netherlands. METHODS: A decision model was developed in MS Excel. In this model, costs (€, Societal perspective) and effects (QALYs) of both strategies were calculated over a 3 (base case) to 12-month horizon (no discounting). The proportion of patients experiencing opioid-induced constipation (OIC) was derived from the OXN3001 trial. Medical resource use for OIC prevention, treatment and complications was modeled using a Delphi panel including 24 Belgian and Dutch GPs. National tariffs were applied to obtain corresponding costs. Utility scores were derived from the SF-36 questionnaire collected during the OXN3001 trial. Deterministic and probabilistic sensitivity analyses were performed. RESULTS: At 3 months, oxycodone/naloxone was dominant over oxycodone in The Netherlands, while the incremental cost-effectiveness ratio (ICER) was €16,389/QALY in Belgium (incremental drug cost: The Netherlands €115, Belgium 153%; OIC-related savings The Netherlands 136%, Belgium €110; OICs gained: both countries 6.0%). At 12 months, the ICER was €12,786/QALY in The Netherlands and €25,421/QALY in Belgium. The proportion of patients experiencing at least 1 OIC episode during a 4-week analgesic treatment was the most sensitive parameter. A Monte Carlo analysis showed that, assuming a willingness to pay threshold of €20,000/QALY (The Netherlands) and €30,000/QALY (Belgium), oxycodone/naloxone was cost-effective in 58% (The Netherlands) and 63% (Belgium) of the 1000 simulations (3-month horizon). CONCLUSIONS: Analgesia with oxycodone/naloxone is cost-effective (Belgium) or even dominant (The Netherlands) at three months and remains cost-effective up to one year.

RESOURCE UTILIZATION AND COSTS ASSOCIATED WITH OPIOID-INDUCED CONSTIPATION (OIC) IN CANCER PATIENTS IN SWEDEN

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OBJECTIVES: To estimate the resource use and cost associated with treating opioid-induced constipation (OIC) episodes in cancer patients in Sweden where laxatives within current SPC-text have failed. METHODS: Nurses in 3 hospices and 10 home care centers across Sweden with experience in caring for cancer patients on opioid therapy were selected to participate in an interview series. An interview protocol was developed in consultation with an expert. The nurses reported on the frequency of OIC episodes, treatment practices and resources used to treat the episodes. Components included personnel costs (based on time spent on constipation-related tasks), transportation costs (for home care visits) and resource costs. The per hour rate for personnel costs was based on the average salary levels of applicable medical personnel in Sweden and overhead cost. The average cost per constipation episode was estimated and used to project direct health care cost of OIC in Sweden. RESULTS: The nurses reported that on average 24% of patients in home care and 45% of patients in hospitals had a constipation episode every second week or more often with laxatives in labeled doses. The nurses estimated the length of the constipation episode to be between 2-5 days. Three steps were identified in the treatment process—increase in dosage of laxatives (100%), provision of suppositories and enemas (40%) and manual dissection or bowel investigation/contrast X-ray (3% of cases). Nurses spent on average 3.5 hours ranging across 2 additional visits for treating each episode of OIC. The average cost per episode of OIC was estimated to £70,000. Direct health care costs of OIC in cancer patients who have failed laxatives within current SPC-text, were estimated to £40 million per year in Sweden. CONCLUSIONS: Opioid-induced constipation in cancer patients in Sweden is associated with significant resource use and costs.

CONSUMPTION OF HEALTH CARE RESOURCES ASSOCIATED WITH CURRENT MANAGEMENT STRATEGIES FOR NON-CIRCULATING UPPER GASTROINTESTINAL BLEEDING: AN OBSERVATIONAL EUROPEAN STUDY

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OBJECTIVES: To assess the extent and main drivers of health care resource consumption in patients admitted with non-variceal upper gastrointestinal bleeding (NVUGIB). METHODS: This observational, retrospective cohort study (NCT00797641; ENEHI1) was conducted in several European countries (Belgium, Greece, Italy, Norway, Portugal, Spain and Turkey). Eligible patients were those consecutively admitted to hospital (1 October–30 November 2008) who underwent endoscopy for overt NVUGIB (haematemesis, melena or haematochezia, with or without clini/aboratory evidence of acute upper gastrointestinal blood loss). Management of patients proceeded according to routine care at each centre. During a 30-day follow-up period, data on various clinical outcomes were collected from patient medical records. The present analysis reports differences between countries in consumption of health care resources. RESULTS: A total of 2464 patients (65% men; mean age 67.7 years) were enrolled. The mean number of days of hospitalisation (standard deviation (SD)) was 8.9 (5.9) days. A wide inter-country variation was observed, ranging from 7.4 (4.9) days in Turkey to 10.8 (7.5) days in Belgium. Empirical treatment for NVUGIB was administered pre-endoscopy in 65% of patients (range 53% [Turkey] to 77% [Turkey]). Most commonly performed related procedures were transfusions (any intravenous fluid, 84.6% of patients, range 74.0% [Belgium] to 92.3% [Portugal]) and additional endoscopies (28.7%, range 12.6% [Turkey] to 53.6% [Belgium]). Treatment for NVUGIB was administered post-endoscopy in 93.2% of patients, most commonly PPIs (92.6%); a narrow inter-country range was observed. CONCLUSIONS: Management of NVUGIB is associated with substantial consumption of health care resources in European countries. There is wide variation across Europe; generally, the highest rates of resource utilisation are observed in Belgium and the lowest in Turkey.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes Studies

EFFECT OF SUBCUTANEOUS (SC) METHYLNAALTREXONE ON GENERIC HEALTH RELATED QUALITY OF LIFE USING THE EQ-5D INDEX SCORES IN PATIENTS WITH CHRONIC NON-MALIGNANT PAIN AND OPIOID-INDUCED CONSTIPATION

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OBJECTIVES: To assess the effect of subcutaneous Methylnaltrexone on generic Health Related Quality of Life using the EQ-5D index scores in patients on opioid therapy for chronic non-malignant pain with opioid-induced constipation. METHODS: In this study, 469 subjects were randomized to either methylnaltrexone daily (QD), every other day (QOD) dosing or placebo for 4 weeks. Eligibility criteria included an

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opioid dose of ≥50 mg oral morphine equivalents/day for ≥2 weeks and <3 rescue-free bowel movements (FRBMs)/week. Rescue laxative use was standardized and allowed if needed. Patients completed EQ-5D questionnaire on day 1 and day 28. EQ-SD index scores were compared between treatment and placebo groups using analysis of covariance with group as factor and baseline scores as covariates. RESULTS: Majority of the patients in the study were female (60%), Caucasian (90%), average age of 49 years and back pain (60%) was the most frequently reported pain condition. The mean daily baseline morphine equivalent opioid dose was 222 mgs. The mean ± SD baseline EQ-SD index scores were 0.45 ± 0.33 in QD, 0.47 ± 0.33 in QOD and 0.44 ± 0.35 in placebo groups respectively. The adjusted mean (± SE) change from baseline in index score on day 14 in QD (0.04 ± 0.02) and QOD groups (0.06 ± 0.02) were not statistically significant compared to placebo (0.02 ± 0.02). At the end of the double blind period (day 28), a significantly greater change from baseline was detected in the index scores detected in the Methyltrexone QD dosing group (0.08 ± 0.01; p < 0.05) and QOD dosing group (0.08 Vs. ~0.01; p < 0.05) compared to placebo. CONCLUSIONS: Methyltrrexone QD and QOD groups showed a significantly greater improvement in health related quality of life as measured by the EQ-SD index scores at the end of four weeks of therapy compared to placebo.

PGI19

PATIENT RELEVANT ASPECTS OF DIAGNOSTIC QUESTIONNAIRES AND THEIR SUBSCALES IN GASTRO-OESOPHAGEAL REFLUX DISEASE (GERD)

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OBJECTIVES: Diagnostic self-administered questionnaires for GERD are widely used and provide brief and valid measure of gastrointestinal symptoms. Beyond end of treatment, quality of life (QoL) and other patient related outcome. Present study should examine relationship of symptoms and disease severity they are considered as proxy for Quality of Life (QoL) and other related outcome. METHODS: Randomly selected patients (n = 623) with chronic GERD symptoms treated by German office-based physicians in routine clinical care completed self-administered instruments for productivity (WPAL-GERD), and symptoms (RDQ, GES, GRSR) in assessing the response to treatment. WPAL-GERD includes a visual analogue scale (0–10) to rate the impairment of the ability to do regular daily activities in the preceding week. Reported reduction of daily activities was split between patients with and without, and compared using logistic regression, accounting for the potential confounders age and PPI medication. RESULTS: Only one subscale from each examined instrument—"dysphagia" (GSR), "impact" (GIS) and "dyspepsia" (RDQ)—were associated with reduced productivity in daily activities in the logistic model (OR: 1.29, 3.36 and 1.46). Mean scores were 1.58 ± 2.17 for subscale "dysphagia", 1.38 ± 1.91 for subscale "impact" and 0.61 ± 1.61 for subscale "dyspepsia". Prescribed PPI medication turned out to be independent, the odds of reduced productivity decreased with age slightly but significantly (OR 0.98). Both GRSR and RDQ have validated summary scores. "GSRS total" and "RDQ GERD" interacted strong with the dependent variable in the model (OR: 2.08 resp. 1.34). CONCLUSIONS: Validated diagnostic questionnaires for GERD are connected with patients' ability carrying out daily activities. However subjective measure of effect the perceived improvement in daily activities. Generic or disease specific Qol instruments should be used in addition for a comprehensive understanding of patient's burden in clinical practice.

PGI20

EFFECT OF SUBCUTANEOUS (SC) METHYLTREXONE ON PATIENT REPORTED CONSTIPATION SPECIFIC QUALITY OF LIFE IN A RANDOMIZED DOUBLE-BLIND CLINICAL TRIAL


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OBJECTIVES: To assess the effect of subcutaneous Methyltrexone on patient reported constipation specific quality of life. METHODS: In a double blind study 465 subjects on opioid therapy for chronic non-malignant pain and opioid induced constipation were randomized to either Methyltrexone QD or QOD dosing or placebo for 4 weeks and 460 received at least 1 dose. Subjects were eligible if they had an opioid dose of ≥50 mg oral morphine equivalents/day for ≥2 weeks and <3 rescue-free bowel movements (FRBMs)/week. Patients reported constipation specific quality of life using the Patient Assessment of Constipation—Quality of Life (PAC-QOL) questionnaire which is a validated 28-item questionnaire assessing physical discomfort (4 items), psychosocial discomfort (8 items), worries and concerns (11 items) and treatment satisfaction (5 items) on a 5-point Likert scale. Higher scores indicate poorer QOL. Change from baseline in mean domain and total scores were compared between methyltrexone and placebo arms on day 28 using analysis of covariance, with treatment group as factor and baseline score as covariate. RESULTS: Majority of the patients in the study were female (60%), Caucasian (90%), average age was 49 years and reported back pain (60%). At the end of the double blind period (day 28), a significantly greater improvement was detected in the Methyltrexone QD dosing group compared to placebo for: physical discomfort (~0.81 vs. ~0.39;p < 0.001), psychosocial discomfort (~0.51 vs. ~0.32; p < 0.05), worries and concerns (~0.49 vs. ~0.38; p < 0.001), satisfaction (~0.96 vs. ~0.48; p < 0.001) and overall PAC-QOL score (~0.74 vs. ~0.39; p < 0.001). Significantly greater improvement in physical discomfort (~0.60 vs. ~0.39; p < 0.05), satisfaction (~0.79 vs. ~0.48; p < 0.05) and the overall PAC-QOL scores (~0.59 vs. ~0.39; p < 0.05) were found in the methyltrexone QOD dosing group compared to placebo. CONCLUSIONS: Subcutaneous Methyltrexone showed a significantly greater improvement in patient reported constipation specific quality of life compared to placebo.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI21

TREATMENT OF CHRONIC HEPATITIS C WHICH DO NOT FOLLOW CLINICAL GUIDELINES IS INCREASING DIRECT MEDICAL COSTS

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OBJECTIVES: This analysis evaluates economic impact of compliance with guidelines for treatment of Chronic Hepatitis C (CHC), where treatment decision is based on results of quantitative HCV RNA test (qRNA). METHODS: Retrospective insurance claims analysis of 879 patients with CHC was performed. There were 334 patients tested for qRNA during the period from 1.1.2005 till 31.8.2008. Decision tree model was developed to evaluate treatment costs when qRNA test is used for treatment termination. RESULTS: In 2004 national guidelines for CHC were published, with recommended examination of qRNA before and 12 weeks after treatment initiation to detect early virological response (EVR) and treatment termination in case of negative results of EVR. In 334 patients there were 611 qRNA tests performed in total (150 patients had only 1 qRNA, 113 had 2 qRNA, in 35 there were 3 consecutive qRNA performed, 16 patients had consecutive qRNA 4 and 5 times). In our model, omission of EVR evaluation was defined as no or only one quantitative HCV RNA test or gap between two qRNA tests longer than 48 weeks. Omission of EVR evaluation was detected in 166 patients. In a decision tree model taking into account EVR results (followed by appropriate treatment termination) it was calculated that treatment cost in this group of 166 patients could be €4,013,880, while the treatment of the same group with omission of EVR evaluation would be €4,870,440. CONCLUSIONS: In analyzed group of 334 patients with HCV, there were almost 50% of cases were treatment termination could not be evaluated in accordance with guidelines, because of inappropriate performance of quantitative HCV RNA tests. Calculated savings are €856,560 in this group of patients. Preparation and implementation of clinical practice guidelines in national health and drug policy could have cost saving effect.

PGI22

CIRCULAR STAPLED HAEMORROIDOPEXY IN THE TREATMENT OF HAEMORRHOIDAL PROLAPSE: HTA REPORT—LOMBARDIA REGION, ITALY

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OBJECTIVES: Surgical management of Haemorrhoidal Disease includes Milligan-Morgan (MM) haemorrhoidectomy and stapled haemorrhoidopexy (PHH, Procedure for Prolapse and Haemorrhoids), which excises prolapsing tissues, whilst maintaining physiological functioning of haemorrhoidal plexus. Scope of work was to develop an HTA Report evaluating the impact of elective, non-emergency in terms of clinical, ethical, social, organizational and economic impact. METHODS: Literature search on Medline/PubMed, Embase databases; analysis of the clinical course for PHH vs. MM at 3 Hospitals in Lombardia Region: bottom-up costing of the surgical course (surgery, hospital admission) and of the clinical course (clinical evaluation, surgical course, follow-up); of Medical resources, collected by structured questionnaires, were valued (Euro 2008) on the basis of full hospital costs (personnel, operating theatre, hospital stay), regional outpatient tariffs (diagnostics), market prices (drugs, medical devices) and average per-capita Gross Domestic Product (working days). RESULTS: Cost analysis of the surgical course showed Hospital direct costs per patientcase of €2,306 and €1,558 respectively for PHH and MM (difference €748), and for the global course €235 for PHH and €1,781 for MM; these values exceed the fixed regional DRG 158 tariff (1209) for hospital reimbursement. Sensitivity analyses, based on published meta-analysis data, confirmed the robustness of basecase results. Average regained productivity was estimated to be 11.3 working days/year, with a potential social benefit of €752/patient. The impact benefit analysis, based on the difference of cost (€748) between the surgical courses to be applied as an extra-tariff for PHH, and on regional statistics for the intervention, estimated an extra-cost ranging from +1.7% to +16% over the current regional funding for the procedure of €9,24 mio/year. CONCLUSIONS: Analysis of hospital disease management courses for haemorrhoidal disease showed the inadequacy of current hospital surgical procedures, and provided an estimation of the effect of suggested tariff increase in order to adequately fund the local providers of Lombardia.