OBJECTIVES: To conduct a cost-utility analysis of sofosbuvir for genotype 2 chronic hepatitis C virus (HCV) infection in Japan. METHODS: The Markov model, “Sofosbuvir cost-effectiveness model”, which was constructed originally for a similar study in UK, was modified and used for this analysis, where imputed data were replaced with Japanese data, as far as possible. Various health states, such as non-cirrhotic hepatitis, sustained virological response (SVR), compensated cirrhosis, decompensated cirrhosis and hepatocellular carcinomas were incorporated to the model. Analyses were conducted for 4 scenarios, classified by treatment history (naive/experienced) and eligibility for interferon. Peg-interferon alpha with ribavirin was assumed for the first 12 weeks of treatment for those who were interferon eligible in the model. SVR was derived from clinical trials conducted in Japan. Other transition probabilities and utility scores of each health state were obtained from published data in Japan. Cost data for interferon-alpha and ribavirin were derived from national drug tariff. (2014). For sofosbuvir, average European price was adopted since it was not yet approved in Japan. Other cost data, such as costs related to health states, were mainly obtained from claim data, provided by JMDC (Japan Medical Data Center). Time-horizon was set to lifetime. Costs and outcomes were discounted with 2% per annum, according to Japanese guideline. RESULTS: For interferon-unsuitable patients, sofosbuvir was dominant to no-treatment. Sofosbuvir would save overall costs for JPY1,470,000 and prolonged 2.36QALY for treatment-experienced. ICER was JPY1,551,000 and prolonged 2.23QALY for treatment-naives. It would increase JPY1,551,000 and prolonged 2.36QALY for treatment-experienced. ICERs were JPY1,470,000 and JPY657,000 per QALY gained, respectively. CONCLUSIONS: Sofosbuvir was considered to be cost-effective for treatment of genotype-2 HCV patients in Japan.

PG131
COST-UTILITY ANALYSIS OF FIDAXOMICIN COMPARED TO VANCOMYCIN IN THE MANAGEMENT OF SEVERE CLOSTRIDIUM DIFFICILE INFECTION IN POLAND
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OBJECTIVES: In recent years a number of infections caused by Clostridium difficile has been significantly increasing. In Poland oral metronidazole constitutes the therapy of choice of non-severe infection and first-recurrence, while oral vancomycin is recommended in case of severe complications and second/subsequent recurrences. Fidaxomicin is a novel treatment for Clostridium difficile infections (CDI). The aim of this study was to perform a cost-utility analysis of fidaxomicin for the treatment of severe CDI compared to vancomycin. METHODS: A meta-analysis of two randomized clinical trials phase III comparing oral fidaxomicin and oral vancomycin in CDI was conducted. A Markov model was used to determine the cost-utility of fidaxomicin in patients with severe CDI. The cycle length was 10 days and the time horizon was 90 days. One patient entered the model in the severe CDI health state and was given either fidaxomicin or vancomycin for 10 days. The analysis was performed from the third-party payer perspective – the Polish National Health Fund. Only direct medical costs (drugs cost, hospitalizations) were included. Given the lack of formal utility measures for CDI, the utilities for the alternative health states described in the literature were adapted. RESULTS: In the base case, fidaxomicin was associated with higher costs, resulting in cost-utility ratio 805 and an incremental QALY gain of 0.015. Fidaxomicin was associated with higher cost savings (PLN 30,883) assuming that patients with severe CDI would be hospitalised at intensive care unit. One-way sensitivity analyses revealed that fidaxomicin remained dominant even if considering marginal values of both antibiotics’ acquisition cost. CONCLUSION: Fidaxomicin was dominant compared to vancomycin, generating additional QALY’s with cost savings in severe CDI patients in Poland.

PG132
ECONOMIC EVALUATION STUDIES IN GASTROENTEROLOGY IN BRAZIL: A SYSTEMATIC REVIEW
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OBJECTIVES: The aim of this study was to systematically review the economic assessment studies carried out in Brazil, published between January 1990 and December 2013, assessing the technologies studied, study types, the and temporal evolution and quality. METHODS: We systematically searched in MEDLINE (PubMed), EMBASE, LILACS, SciELO, WHO TED, HTA Database (CDB), BVS ECOS, SCOPUS, Web of Science, and SISREBRATS. We selected partial and full economic evaluation studies in gastroenterology, where at least one of the authors was affiliated to a Brazilian institution. Two authors performed study selection and data extraction independently. Disagreements were resolved through consultation with a third reviewer. The study characteristics were summarized in figures and summary tables. RESULTS: Forty studies were included. The first study was published in the 80s, 12 studies (30.0%) were published in the 90s and 22 studies (55.0%) were published in the last 4 years. Seventeen economic evaluations were incomplete (42.5%) and 23 complete (57.5%). In the 23 complete reviews, 11 (47.8%) studies were cost-utility analyses, 7 (30.4%) were cost-effectiveness analyses, 4 (17.4%) cost-consequences analyses. In 14 (63.0%) cost-minimizations were performed. The cost-effectiveness analysis was the most common tool for economic evaluations. Conclusions of economic evaluations were mainly medications in 25 studies (62.5%), 7 (17.5%) medical and surgical procedures, 3 (7.5%) medical and hospital equipment, 1 (2.5%) vaccines and 4 (10.0%) evaluated more than one type of technology. When classified by disease, 22 (55%) were studies on viral hepatitis, and in its most published after the year 2010 (63.4%). Five studies were related to digestive cancers and other included peptic disease, infectious diseases and other. CONCLUSIONS: There was a considerable increase in publications of economic evaluations in Gastroenterology in Brazil, being mostly studies of drugs for treatment of viral hepatitis. The high cost of these treatments and increased of lawsuits seem to account for this increase.

PG133
ESTIMATING THE COST OF LIVER TRANSPLANTATION IN PATIENTS DIAGNOSED WITH CHRONIC HEPATITIS C AND B IN THE UK
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OBJECTIVES: Liver transplantation is an effective treatment option for end-stage liver disease and acute liver failure, including patients with hepatitis C (HCV) and hepatitis B (HBV). Recent health technology assessments of treatments for HCV and HBV have relied on data from a large cohort study of transplanted patients to inform cost-effectiveness. However, this was conducted in the 1990s. The overall aim of this study was to estimate the current cost of liver transplant for patients with HCV and HBV in the UK. METHODS: Historical summary data from the original cohort study were updated to reflect current unit costs and current practice in clinical practice. Semi-structured interviews were conducted with experts and a computer-based user-interface was developed to elicit estimates of key resource use weights. Uncertainty in the experts’ estimates was captured by eliciting probability distributions for each item from each expert. Updated unit costs were obtained from national sources. Data were analysed by phase of the transplant procedure. RESULTS: The expert elicitation exercise included two hepatologists, three transplant surgeons and one liver transplant coordinator. Few patients with HBV are now being transplanted due to improvements in anti-viral treatments. Mean total costs for patients with HCV were £18,055 pre-transplantation, £64,452 during the transplant phase and £36,009 in two years post-transplant. The average cost per liver transplant patient with HCV from assessment to two-year post-transplant is £111,810. CONCLUSIONS: There have been some significant changes in clinical practice since the original study such as change in standard immunosuppression therapy, more patients with co-morbidities being placed on the transplant waiting list, increased use of sub-optimal organs and reluctance to re-transplant patients with graft failure and recurrence of HCV.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies
PG134
ADHERENCE RATES FOR PegINTERFERON + ribAVIRIN COMPARED TO TELAPREVIR + PegINTERFERON + ribAVIRIN IN MEDICAl AND COMMERCIAL PATIENTS TREATED FOR CHRONIC HEPATitis C
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OBJECTIVES: Prior to approval of telaprevir (TPV), the treatment for chronic hepatitis C virus (HCV) included peginterferon (P) weekly injections and ribavirin (R) orally twice daily in 2011. TPV was approved for coadministration with P+R during the first 12 weeks. Though TPV improved viral clearance, it also increased the treatment duration to a 28-day period. The clinical complexity of care also increased. This study compared adherence rates over 24 weeks during TPV+P+R compared to those in P+R. METHODS: Large US commercial and Medicaid health insurance claims data were used to identify HCV patients initiating treatment with PR (2007 to 2009) or TPV+PR (post-TPV [2011 to 2013]). The index date was the date of 1st HCV drug prescription. Adherence was measured by medication possession ratio (MPR) for all patients at 4 weeks intervals thru 24 weeks. Regression analyses adjusted for age, sex, comorbidities, liver disease severity, and pill count prior to HCV treatment. RESULTS: The study included 7,601 and 1,487 treated HCV patients in the commercial and Medicaid databases. Unadjusted and adjusted adherence was high for both cohorts throughout the study period (>88% for Medicaid and >82% for the commercial at 24 weeks). Adherence was not significantly different between the FR and TPV+P+R cohorts at any time point in the Medicaid patients (98.9% [TPV+PR] and 90.5% [PR] at 24 weeks). Adherence was also similar between the cohorts in the commercial patients (82.7% [TPV+PR] and 83.2% [PR] at 24 weeks) but was statistically different at weeks 8 and 12, though not clinically meaningful. Age was the only factor consistently associated with adherence. CONCLUSIONS: Among HCV patients, adherence rates were high and were similar between the cohorts, despite the higher daily pill count for patients on TPV+PR.

PG135
QUALITY OF LIFE OF DIARRHEAL CHILDREN AND CAREGIVERS IN THAILAND
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OBJECTIVES: To estimate the utility scores for diarrheal children aged under 5 years and their caregivers and to identify the influencing factors which affected on their preferences. METHODS: Hospitalized diarrheal children aged between 3 months and 5 years and their caregivers at were recruited in this cross-sectional study at three hospitals in Phetchabun province. The EQ-5D instrument was used to collect the quality of life (QoL) data at the first day of admission. Quality of life of diarrheal children and caregivers were measured through EQ-5D visual analog scale (VAS) and measured as self-report. The raw data was converted to utility values using the Thai algorithm. The clinical severity of diarrheal children was rated using the Venkani clinical severity scoring system. Spearman correlation and linear regression was applied to explore the impact of the various factors on the utility value of children and adults.
carrergers. RESULTS: 468 children and caregivers were included in this study. Mean child age was 7.17 years. The caregivers’ utility and themselves as 0.604 (95% CI: 0.597, 0.613) and 0.618 (95% CI: 0.606, 0.629), respectively. Mainly domains of diarrhea children were affected as pain/discomfort and anxiety/depression similarly to their caregivers. On multivariate regression analysis, factors which affected the child’s utility (OIC) were body mass index (BMI) over 18 kg/m², greater number of stools per day, and OIC status (OIC vs. non-OIC). In children, OIC status impacted worse in girls, those with higher severity score and was associated with age. In addition, the diarrheal severity and female gender reduced the impact of diarrhea on Qol of caregivers. These results can be useful to evaluate the cost-effectiveness of vaccines against diarrhea such as rotavirus vaccines.

PG134

HOW DOES NON-MALIGNANT APOID INDUCED CONSTIPATION (OIC) IMPACT HEALTH STATE UTILITY? Lawson R1, Marsh K1, Atincalal A1, King F1

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OBJECTIVES: Little is known about the impact of OIC and treatments for OIC on health state utility. Studies often focus on collecting data on changes in OIC status. The objective of this paper is to examine if the utility impact of treatment is driven by change in OIC status, and what the magnitude of the change in utility associated with changes in OIC status is. METHODS: 1352 patients without malignant OIC were allocated to one of two, phase III, 12 week randomised controlled trials to study OIC. These trials were pooled and prospective analyses on these data were undertaken. Both trials included the relevant EQ-5D-3L (EQ-5D) at baseline, week 4 and week 12. EQ-5D scores were converted into estimates of utility using a tariff approach for the UK general population. A repeated measures mixed model (RMMm) regression analysis was conducted to identify the impact of the following factors on utility: age, gender, race, BMI, duration of opioid use, treatment (naloxegol 12.5mg, 25mg or placebo), baseline utility and OIC status (OIC vs. non-OIC). RESULTS: Baseline utility across all patients was 0.559. The regression demonstrated that baseline utility score (β = 0.535, SE = 0.023) and OIC status (β = 0.032, SE = 0.012) were the only significant predictors of change in utility score (p < 0.05 and p < 0.001 respectively). Further univariate analyses examined the effect of OIC status in patient subgroups that had different experiences of laxative treatment. OIC status had an increased and meaningful impact on patients who had previously responded inadequately to laxatives. CONCLUSIONS: OIC status is a significant factor on the impact of treatment on patient’s utility. Furthermore the impact of OIC status is increased in patients who had previously responded inadequately to laxatives.

PG137

MAPPING MAY CAUSE STRAINING: THE INCONSISTENCY RELATIONSHIP BETWEEN A DISEASE-SPECIFIC QUESTIONNAIRE (PAC-QOL) AND EQ-5D MAPPING IN CONSTITUTION Vegers S1, Hatwell AJ2

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OBJECTIVES: Patients with constipation often use the term ‘hard’ to describe their stool and prefer a double-blind, placebo-controlled clinical study with liquid/semi-liquid opioid-induced constipation (OIC), OB3-1033, included the EQ-5D generic quality-of-life instrument, and the PAC-QOL, a constellation-specific measure. This study calculated utility values for patients using the PAC-QOL and compared the resulting utilities to those calculated from a published mapping formula between the PAC-QOL and EQ-5D that was derived in chronic idiopathic opioid-induced constipation (OIC). METHODS: EQ-5D responses from OB3-1033 were converted to utilities using the EQ-5D UK value set. These were compared with utilities generated with the published mapping algorithm. Following this step, an attempt was made to map the PAC-QOL to the EQ-5D in OIC. The root mean squared error (RMSE), adjusted R2, and predicted/observed plots were used to assess the quality of mappings. RESULTS: Patients in OB3-1033 had low utility values at baseline: mean ± SD of 0.45 (Standard Deviation 0.33, n = 439). Using the published algorithm, the predicted mean utility was much higher: 0.74. This led to a high RMSE (0.43), indicating a poor fit to the data. Replicating the mapping using OB3-1033 PAC-QOL and EQ-5D data showed the PAC-QOL, although correlated with the EQ-5D, had a poor predictive value (RMSE = 0.31, R² = 0.59). High utilities were underestimated and low utilities overestimated. CONCLUSIONS: Mapping algorithms are a vital tool for generating utility values when none are available. However, the relationship derived between instruments should be assessed cautiously. Mappings with the same instruments may not be reliable if cross-cultural disease areas – even if the symptoms experienced by patients appear similar. Data show patients in OB3-1033 entered the study with poorer health status than those in the chronic constipation mapping (utility of 0.45 vs 0.81), likely due to comorbid conditions (the reason for opioid prescribing). This led to a different relationship between the PAC-QOL and EQ-5D, compared to the previous estimate.

PG138

A COMPARISON BETWEEN THE HEALTH-RELATED QUALITY OF LIFE REPORTED BY THE GENERAL POPULATION AND BY PATIENTS WITH MAJOR LIVER DISEASES Contesi PA1, Rota M1, Scalzone L1, Cazzolinno F1, Cesana G2, Mantovan I1, Okoliscanyi S1, Ciaccio A1, Gemma M1, Fagiolini S1, Valsecchi MG1, Belli LS1, Zrazhazovska M1 1University of Milan - Bicocca, Monza, Italy, 2CHAARTKA Foundation, Milan, Italy, 3University of Naples, Naples, Italy, 4Vapa Gianni XXIII Hospital, Bergamo, Italy, 5Niguarda Hospital, Milan, Italy

OBJECTIVES: The impact of liver diseases (LDs) on health-related quality of life (HRQoL) is an important aspect to understand the burden of these conditions and improve their management. A well characterized impact of the major LDs on HRQol of the general population is still lacking. The aim of our study was to fill this gap (A369). METHODS: A dataset from a multicenter liver disease study (A369) of the general population of most populated Italian region was matched with the dataset from a multicenter study conducted in the same region and time period to generate and validate a set of health care outcomes indicators for the major LDs (chronic hepatitis B (HVB), hepatitis C (HVC), compensated cirrhosis (CC), decompensated cirrhosis (DC), hepatocellular carcinoma (HCC), autoimmune hepatitis (AIH), primary biliary cirrhosis (PBC), primary sclerosing cholangitis (PSC), NAFLD/ NASH). This dataset was obtained through a cross-sectional study of 875 patients with major LDs (43% CC, 28% DC, 21% HVC, 5% AIH, 1% HCC). Data were collected using the EQ-5D-3L. Multivariable logistic and Tobit regressions were then performed adjusting for possible confounders (age, sex, education and working status). RESULTS: A total of 6,800 “healthy subjects” and 3,105 subjects with LDs were included in the analyses. Multivariable analyses showed that DC, HCC, and NAFLD/NASH-in Anxiety/depression. Similar results were obtained with the Tobit model performed using FAS and Utility-index. DC, HCC, AIH and NLH reported the highest decrease in VAS and Utility score. CONCLUSIONS: HRQoL decreased due to the impact of major LDs on the patients’ HRQoL compare to the general population, and therefore is a key tool for decision-making in care delivery for liver diseases.

PG139

TRANSLATION AND CULTURAL ADAPTATION DIFFICULTIES ENCOUNTERED DURING LINGUISTIC VALIDATION OF THE BRISTOL STOOL SCALE Edwards A, Williams H, Anderson H

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OBJECTIVES: The aim of this study was: (1) to investigate translation difficulties encountered during linguistic validation of the Bristol Stool Scale; (2) to discover whether certain items consistently posed problems across different languages; and (3) to identify any plausible solutions. METHODS: This study was conducted from October 2012 to January 2013 as part of the Adelphi patient QoL mapping project. The Bristol Stool Scale was translated into 24 languages across the following four areas: (1) continents (Europe, Asia, Oceania, Africa); (2) countries with similar income level; (3) countries with higher literacy; and (4) countries with a lower literacy. RESULTS: For more than a third of the languages reviewed (European and 9 Asian Pacific, including Indian), difficulties were experienced when attempting to translate certain items word-for-word. The majority of these difficulties centred on the food-related similes used in the scale to describe the different stool types. In all of the Indian languages in this study, attempts to translate such related similes were deemed necessary (e.g. ‘banana’ replacing ‘sausage’) in order to ensure that the wording was culturally relevant. Of the other languages, Thai and Romanian preferred similes that did not relate to food (‘bolus’ and ‘beads/little round bits’ respectively) instead of appropriate. METHODS: The investigation was made up of the following stages: (1) collection of back translation reviews of the Bristol Stool Scale for 30 European and Asian-Pacific languages; (2) identification of problematic words and phrases, based on discussion with lead translators; (3) investigation of patterns that became apparent across different languages; and (4) review of methods used to overcome the translation difficulties. RESULTS: For more than a third of the languages reviewed (European and 9 Asian Pacific, including 7 Indian), difficulties were experienced when attempting to translate certain items word-for-word. The majority of these difficulties centred on the food-related similes used in the scale to describe the different stool types. In all of the Indian languages in this study, attempts to translate such related similes were deemed necessary (e.g. ‘banana’ replacing ‘sausage’) in order to ensure that the wording was culturally relevant. Of the other languages, Thai and Romanian preferred similes that did not relate to food (‘bolus’ and ‘beads/little round bits’ respectively). Alternative solutions were then performed adjusting for possible confounders (age, sex, education and working status).