(NMA) has evaluated the relative efficacy of ciclosporin, prolonged-release (PR) and immediate-release (IR) tacrolimus in adult liver transplant recipients based on randomized controlled trials and large observational studies published since 2000. Based on the NMA findings, the present study evaluated the cost-utility of using PR tacrolimus relative to ciclosporin or IR tacrolimus in liver transplant recipients in the UK setting. **METHODS:** A Markov model was developed in Microsoft Excel to evaluate the cost-effectiveness of immunosuppressive regimens in liver transplant recipients. The model captured costs associated with immunosuppression, retransplantation and acute rejection (AR). Mortality, graft loss and AR odds ratios were derived from the NMA. Costs were taken from the British National Formulary and the NHS National Tariff and expressed in 2014 pounds sterling. Future costs and effects were discounted at 3.5% annually. **RESULTS:** Over a 25-year time horizon, PR tacrolimus resulted in increased life expectancy and quality-adjusted life expectancy (QALE) relative to IR tacrolimus and ciclosporin. Relative to ciclosporin, QALE increased by 1.17 quality-adjusted life years (QALYs) with PR tacrolimus while costs increased by GBP 18,107, yielding an incremental cost-effectiveness ratio (ICER) of GBP 15,443 per QALY gained. Relative to IR tacrolimus, QALE increased by 0.78 QALYs and costs by GBP 1,646, resulting in an ICER of GBP 1,646 per QALY gained. Sensitivity analysis showed the analysis to be most sensitive to the dosing assumptions. **CONCLUSIONS:** Based on a UK-specific analysis of the projected cost and effectiveness of PR tacrolimus relative to IR tacrolimus and ciclosporin, PR tacrolimus improved life expectancy and quality-adjusted life expectancy relative to both IR tacrolimus and ciclosporin. While costs of PR tacrolimus were higher, the incremental cost-effectiveness ratios fell below GBP 20,000.

PGI38

EVALUATION OF THE COST EFFECTIVENESS AND SOCIETAL IMPACT OF RIFAXIMIN-Á 550MG IN THE REDUCTION OF RECURRENCE OF OVERT HEPATIC ENCEPHALOPATHY IN THE NETHERLANDS

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OBJECTIVES: Hepatic encephalopathy (HE) is associated with high morbidity and mortality. Rifaximin-α 550mg is effective in reducing the recurrence of overt HE episodes, and hospital utilisation. We characterised the cost effectiveness including societal impact of rifaximin-α 550mg plus a standard of care (SOC) versus SOC alone (lactulose) in patients with liver cirrhosis in The Netherlands. **METHODS:** A Markov state transition model was used. Outcome metrics were incremental cost effectiveness ratios (ICERs), derived from cost/quality adjusted life years (QALYs) estimates and estimates of impact of work productivity loss upon patient/carer using a friction cost method reflecting patient and societal considerations in the model. Outcomes data were from two trials of rifaximin-α 550mg. Dutch costs data (2010) were derived from published sources and societal cost estimates were from the Dutch costing manual (2010) inflated to 2015 prices. Health-related utility was estimated indirectly from disease-specific quality of life RCT data. The time horizon was five years. Costs and benefits were discounted at 4% and 1.5%, respectively. Real world data were applied into the model for length of hospital stay and number of admissions. **RESULTS:** 5 year average costs of included care/societal elements was €88,386 in the rifaximin-α 550mg + SOC arm and €82,968 in the SOC arm, a €5,418 difference. Corresponding values for benefits were 2.45 and 1.89 QALYs/person, respectively, a difference of 0.56 QALYs over five years. This translated into a cost effective base-case ICER of €9,576 at a five year time horizon. **CONCLUSIONS:** Use of rifaximin-α 550 mg + SOC in patients with recurrent HE in the context of liver cirrhosis represented good value and was cost-effective compared with SOC alone, by reducing overt HE episodes, the likelihood of hospital admission and hospital length of stay.

PGI39

A COST-UTILITY ANALYSIS OF DIFFERENT ORAL ANTIVIRAL MEDICATIONS IN PATIENTS WITH CHRONIC HEPATITIS B IN IRAN: AN ECONOMIC MICRO-SIMULATION DECISION MODEL

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OBJECTIVES: Hepatitis B infection is the major cause of chronic liver disease in Iran.This study has been designed to evaluate the cost-effectiveness of different options of medication therapy for CHB in Iran. **METHODS:** An economic evaluation of cost-utility was conducted to assess five oral medication strategies including: Adefovir, Lamivudine, Adefovir + Lamivudine, Entecavir, and Tenofovir. A Markov micro-simulation model was used to estimate the clinical and economic outcomes in a life time horizon and based on a societal perspective. Medical and non-medical direct costs and indirect costs were included in the study and Life-Years Gained (LYG) and Quality-Adjusted Life-Years (QALY) were determined as the measures of effectiveness. The results were presented in terms of Incremental Cost Effectiveness Ratio (ICER) per QALY or LYG. The model was consisted of nine states of the disease; the transition probabilities for the movement between the states were obtained using clinical evidences and expert opinions collected from all over the world. Probabilistic sensitivity analyses (PSA) was used to measure the effects of uncertainty in model parameters. **RESULTS:** Results found that the Tenofovir treatment strategy was more effective and less costly than other options. In addition, Tenofovir had the highest QALY and LYG for the HBeAg -ve and HBeAg +ve with 13.52 and 15.21; 2133 and 21.53 (discounted) in all comparisons, respectively. Also, PSA proved the robustness of the model results. So that, The cost-effectiveness acceptability curves showed that TDF was the most cost-effective treatment in 86.1% and 87.7% of the simulations for the HBeAg -ve and HBeAg +ve with WTP thresholds less than PPP \$ 45270 (maximum WTP per QALY), respectively. **CONCLUSIONS:** The results showed that using Tenofovir in patients with CHB was a highly cost-effective strategy.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PGI40

PATIENTS' PERCEPTION OF ADHERENCE TO THERAPY IN ULCERATIVE COLITIS: RESULTS OF A SURVEY TO SPECIALIZED CENTERS

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OBJECTIVES: Patients with ulcerative colitis reported that the complexity of the treatment regimen, the amount and frequency of administration of the therapy are key elements in influencing non-adherence to therapy. **METHODS:** The objective of this work was to evaluate the perception of patients with ulcerative colitis compared to adherence to treatment, through a questionnaire distributed by clinicians of some Italian hospitals to patients with ulcerative colitis. **RESULTS:** The survey involved 1,064 patients with an average age of 48 years, with a range between 5 and 90 years; 46% of the sample is female, 54% are males. More than 50% of patients surveyed has a disease duration of less than 10 years and about 35% last less than 5 years (median 8 years). There is a prevalence of cases of ulcerative left (51%). About 34% reported pancolitis, 14% proctitis and 0.5% chron. The 73% denied having adherence issues; the perception of adequate intake of therapy is almost complete: only 19% admit to not be adherent. The main reason for non-adherence to treatment, regardless of the formulation prescribed, remains forgetfulness (48%), followed by the fact of feeling good (20%). In this respect there is a significant difference depending on whether the disease is in the active phase (47%) or in remission (67%). **CONCLUSIONS:** There is a strong adherence by patients, discordant from the literature. As regards the reasons for the non-adherence in the low percentage in our study, this result appears instead in line with what reported in literature. The direct consequence of a failure or suboptimal adherence to treatment involves more than the increase in the risk of recurrence of the disease, since patients often interrupt chronic medication because they feel good, even a simultaneous increase in costs borne by patients and health care system.

PGI41

HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE IN POLAND (APPLICATION OF THE EQ-5D AND SELF-ASSESSMENT OF HEALTH STATE)

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OBJECTIVES: The EQ-5D is a standardized, non-disease-specific instrument for describing and valuing patients' health-related quality of life (HRQoL). The aim of this study was to measure HRQoL with the use of the EQ-5D and to compare it with the self-evaluation of health state in patients with inflammatory bowel disease (IBD). **METHODS:** An online survey was performed. After having given informed consent and in order to gain experience with time trade-off (TTO) method, patients randomly chose two EQ-5D health states and assigned them appropriate utilities. Then, they were asked to assess their own health state by the means of EQ-5D, Visual analogue scale (VAS) and TTO. **RESULTS:** 169 patients (76M, 93F) completed EQ-5D, VAS and TTO. Mean age of respondents was 29.9±8.98 years (range: 18 to 61).73 patients suffered from ulcerative colitis (UC) and 84 from Cohn's disease (CD). In 40 patients the diagnosis was made within one year, 91 patients were 1-9 years and 38 at least 10 years since diagnosis. 43 patients had an operation because of IBD. Respectively, 30, 11, 67, 123 and 117 patients had at least moderate deterioration in domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Mean EQ-5D value (using Polish TTO norms) was 0.829±0.162 and mean VAS score was 64.23±21.17. There was a significant correlation between EQ-5D and self-evaluation of health state (mean value 0.83, r=0.279, p<0.001). There was no statistically significant difference in any of the subgroup analyses in any of the subgroup analyses (CD vs. UC: 0.821 vs. 0.839, ≤1 year vs. 1-9 years vs. ≥10 years from diagnosis: 0.827 vs. 0.815 vs. 0.866, operation vs. only conservative treatment: 0.823 vs. 0.831, p>0.05). **CONCLUSIONS:** EQ-5D appeared valid and informative in Polish IBD patients. However, it seems not to be sensitive enough to distinguish between different subgroups in this heterogeneous population.

PGI42

COMPOUND ATTRIBUTES FOR SIDE EFFECT IN DISCRETE CHOICE EXPERIMENTS: RISK OR SEVERITY - WHAT IS MORE IMPORTANT TO HEPATITIS C PATIENTS?

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OBJECTIVES: In order to make decisions experts and patients have to face trade-offs between benefit and harms. Harms can be expressed as the risk of occurrences and also the severity. Ideally a combination of both should be taken into account when making decisions. In the context of approval, allocation decisions and benefit assessment, the question arises as risk and severity of side-effects are included in the decision making process. **METHODS:** The discrete choice experiment used compound side-effect attributes of a hepatitis C treatment by combining severity and risk. Thus, patients' preferences regarding the probability of occurrence and severity of side-effects could be measured. The decision model included sustained-virological-response, duration of therapy and number of interferon injections and five compound side-effect attributes: rash, anemia, nausea/diarrhea, tiredness/fatigue and headache. The compound attribute were composed out of risk and severity, resulting in 6 levels per attribute. The experimental design (3*3+5*6) (Ngene) consisted of 72choices, which were divided into 6 blocks. **RESULTS:** N=561 hepatitis C-patients (58.1%male) participated in computer-assisted personal interviews. Within the random parameter logit model (95%CI) the preference analysis could show that participants valued severity and risk of side-effects differently. The analysis of the six levels e.g. for the side-effect "anemia" was weighted the following: coef."mild

severity*10%risk":0.355; coef."moderate severity *10% risk":0.112; coef."severe severity *10% risk":-0.246; coef."mild severity *40% risk": 0.165; coef."moderate severity *40% risk":-0.116; coef."severe severity *40% risk": -0.271. **CONCLUSIONS:** The DCE could prove that the included hepatitis C patients have different preferences with respect to the probability of risk relative to the severity of different side-effects. In all significant characteristics the dominance for less severity and less risk could be proven and both aspects were taken into account when making treatment decisions. For the first time compound side-effect attributes have been applied in a preference elicitation method and detected corresponding differences within patient preference measures.

PGI43
HEALTH RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS WHO HAVE UNDERGONE COLECTOMY FOR ULCERATIVE COLITIS: IMPACTS OF COMPLICATIONS POST-SURGERY

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OBJECTIVES: Ulcerative colitis (UC) management aims to reduce symptoms associated with the disorder as well as inducing and maintaining remission. Surgery is typically considered in severe or refractory UC patients who have not responded to maximal treatment. This study evaluated HRQL following surgery, along with experience and severity of complications, including those experienced in the longer-term. **METHODS:** UK adult UC patients (n=202) who had undergone bowel surgery completed an online survey including EQ-5D-5L utility assessment, Work Productivity and Activity Impairment (WPAI), Inflammatory Bowel Disease Questionnaire (IBDQ), post-surgical complications, and Female Sexual Function Index (FSFI) or International Index of Erectile Function (IIEF). **RESULTS:** Over 58% of participants were >1 year post-surgery. Mean EQ-5D utility for the overall sample was 0.74. Mean utility was significantly higher in those who reported no complications post-surgery than in those who did (0.90 vs 0.71; p<0.001). The most commonly reported symptoms since surgery were increased fatigue (56%), abdominal pain (42%), and increased stool frequency (31%). Participants with complications had reduced HRQL across bowel symptoms, systemic symptoms, emotional functioning and social functioning IBDQ domains. They also reported more work time missed, greater impairment while working and greater overall impairment of regular activities due to UC than those without complications. Of those responding about sexual function, FSFI scores for 68% of female participants indicated sexual dysfunction and IIEF scores for 52% of male participants indicated at least mild erectile dysfunction. A marked decrease in utility by IBDQ disease severity was observed: those classified as having severe disease had lower scores than those classified as being in remission (0.52 vs 0.88). **CONCLUSIONS:** Although surgery for UC is intended to be curative, IBDQ and EQ-5D data suggest that HRQL may not return to normal levels. These results may be related to severity of ongoing fatigue, bowel and sexual function problems.

PGI44
SYSTEMATIC LITERATURE REVIEW OF HEALTH-RELATED QUALITY OF LIFE IN PATIENTS RECEIVING PARENTERAL NUTRITION

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OBJECTIVES: Short bowel syndrome (SBS) is a rare, complex clinical condition that results from loss of intestinal absorptive capacity. Parenteral nutrition (PN) is often needed to maintain clinical status in patients with SBS. Teduglutide reduces, and in some cases eliminates, patients' dependency on PN. PN is not exclusively used in patients with SBS and, since robust utility data is often difficult to collect for rare conditions due to limited patient numbers, a wider body of published literature reporting a link between PN and health-related quality of life (HRQL) was considered. We assessed if an acceptable body of evidence was available to determine the HRQL impact associated with the use of PN that could support an assessment of the potential impact of reduced PN using teduglutide. **METHODS:** Searches were performed using MEDLINE, MEDLINE In-Process and Cochrane Library. Additionally, hand searches were performed at targeted conferences. Of 2,724 studies screened, 76 met the inclusion criteria: adults receiving PN for longer than 6 months and reported utilities or other HRQL data. **RESULTS:** Patients receiving PN were shown to have lower HRQL than the general population. HRQL was shown to increase at initiation of PN, compared to the pre-PN state. However, discontinuation of PN and intestinal transplantation (ITx) were associated with further improvements in HRQL. Trends associating increased number of PN complications, PN volume and PN frequency with lower HRQL were also identified. **CONCLUSIONS:** Improvements in HRQL achieved by discontinuing PN and ITx suggest that weaning patients with SBS off PN could increase HRQL. These, along with results of an ongoing vignette study in patients with SBS, may allow quantification of the HRQL associated with the use of teduglutide in SBS.

PGI45
TRANSLATABILITY ASSESSMENT AND LINGUISTIC VALIDATION OF THE PATIENT-REPORTED OUTCOME INSTRUMENT FOR IRRITABLE BOWEL SYNDROME WITH DIARRHEA (IBS-D PRO)

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OBJECTIVES: Following the 2009 FDA Guidance, a new PRO instrument was developed to support endpoints in multinational clinical trials assessing IBS with diarrhea (IBS-D) symptom severity. Our objective was to assess the translatability of the IBS-D PRO instrument into ten languages, and subsequently perform a cultural adaptation/linguistic validation of the questionnaire into US Spanish and Japanese.] **METHODS:** Translatability assessments of the US English version of the IBS-D PRO were performed by experienced PRO translators who were native speakers of each target language and currently residing in-country. Languages included: Chinese (China); Dutch (Netherlands); French (Belgium); German (Germany); Japanese (Japan); Polish (Poland); Portuguese (Brazil); Russian (Russia); Spanish (Mexico); and Spanish (US). The project team assessed the instrument to identify potential linguistic and/or cultural adaptation issues. After the identified issues were resolved, the instrument was translated into Spanish (US) and Japanese through a process of two forward translations, one reconciled translation, and one back translation. The project team reviewed the translated versions before the instruments were evaluated by cognitive debriefing interviews (CDIs) with samples of five Spanish (US) and five Japanese IBS-D patients. **RESULTS:** A few linguistic and cultural adaptation concerns were identified during the translatability assessment as requiring minor revisions: mainly the presentation of dates/times and word structure. During the CDIs, two out of five Spanish respondents misunderstood the term "bowel movement" to mean only diarrhea in the Spanish version. Consequently, the term was changed from "movimiento intestinal" to "evacuaciones." None of the Japanese respondents identified issues with the Japanese version. **CONCLUSIONS:** The translatability of the IBS-D PRO instrument into ten target languages was confirmed, with only minor changes made to the translations of the instrument. The translation and linguistic validation into Spanish (US) and Japanese provide evidence that this instrument can be used in multinational trials and clinical settings.

PGI46
DEVELOPMENT OF A VALIDATED QUESTIONNAIRE EVALUATING THE BURDEN OF THE HAEMORRHOIDAL DISEASE AND ANAL FISSURE (HEMO-FISS)

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OBJECTIVES: The haemorrhoidal disease is a frequent and chronic illness. The anal fissure is the second reason of proctologic medical visits. At the moment, there is only a clinical score measuring the grade of the haemorrhoids, but the impact of the disease on the patients' quality of life is not evaluated. The objective of this study is to validate a specific questionnaire to evaluate the burden of the haemorrhoidal disease and anal fissure (HEMO-FISS) on the patients' daily life. **METHODS:** The questionnaire HEMO-FISS, including 38 questions, has been submitted to patients suffering from a haemorrhoidal disease or an anal fissure and, consulting a participating proctologist in France during the study period (2012-2014). The psychometric properties were evaluated by testing the acceptability, construct validity and reliability. A principal component analysis (PCA) using Varimax rotation, a Spearman correlation coefficient with SF-12 and PGWBI and a multi-trait analysis (MTA) were conducted to assess the construct validity of the questionnaire. The reliability was evaluated using Cronbach's alpha coefficient (CAC). Backward Cronbach alpha curves (BCAC) were drawn. **RESULTS:** A total of 256 patients were included in the study. Following the factor analysis, four dimensions were defined: physical disorders, psychology, troubles defecating and sexuality. The number of questions was reduced from 38 to 28. Item reduction was based on MTA and BCAC. A strong correlation was observed between SF-12 and the dimensions regarding physical disorders (with PCS) and psychology (with MCS). The Cronbach's coefficient (all > 0.7) reflected a good internal consistency of the different dimensions of the questionnaire. **CONCLUSIONS:** The questionnaire HEMO-FISS displays good properties to evaluate the burden of haemorrhoids and anal fissures. Consecutive to this preliminary validation, a graded response model (GRM) will be developed to precise the unidimensionality of each dimensions.

PGI47
NUTRITIONAL ASPECTS AND DISINFORMATION IN LIVER DISEASE: A QUESTIONNAIRE-BASED SURVEY IN ITALIAN PATIENTS

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OBJECTIVES: The study focused on a secondary aspect of liver diseases, never investigated in Italy so far. The study purpose was in fact to obtain the patients' perception about the role of nutrition during the disease phases and in general for liver welfare, with the final aim of understanding the importance given to nutrition by patients and the current disinformation to be possibly tackled. **METHODS:** EpaC is the most important Italian NGO for hepatopathic patients. An anonymous web-based questionnaire was published on the association website www.epac.it. It was composed of multiple choice and open questions investigating the general info of the patient, health state, and opinions/perceptions about nutritional aspects. **RESULTS:** 483 patients participated the survey. The profile of participants was assessed concerning sex, age, health condition, presence of cirrhosis. Mean age was 52.9 (min 24 – max 80), 60% males, 76% HCV-positive, 15% cirrhotic. 99% know alcohol can damage the liver and 86% answered that any alcohol quantity is potentially harmful (79% do not assume alcohol and 62% go on after being cured). Besides alcohol, other foods believed to be harmful to liver are all fried foods, salami, sugar and sweets, meat (in particular red meat), cheeses (above all fat cheeses). Although in low percentages, 5% and 13% respectively consider vegetables and fruit as harmful. Moreover, 53% think a vegan/vegetarian diet is essential, but 81% would like to have a specialist nutritional advice. **CONCLUSIONS:** Considering that nutritional aspects are important in everybody's life, they are particularly relevant in case of liver disease. The results shown express patients' degree of knowledge about these aspects and highlights that a certain disinformation is widespread. The results also point out liver-suffering patients' need to receive clinicians' evidence-based advice/information on nutrition and lifestyle as part of the routine counselling and to develop an educational campaign on nutrition for hepatopathic patients.