the lowest diagnostic detection accuracy (74%), followed by MRI (80%) and EUS (94%). With CT as the baseline comparator, the ICERs for MRI ($2,783) and EUS ($2,200) demonstrated that both were acceptable alternatives. **CONCLUSIONS:** Patients or physicians with low risk-tolerance are advised to avoid the watchful waiting approach. EUS, MRI and CT are all cost-effective diagnostic choices. Among the four choices, EUS is associated with the lowest risk and highest costs. EUS is the best monitoring choice when risk must be minimized irrespective of cost. Alternatively, annual MRI and CT scans may serve as a preferred option for patients and physicians aiming to balance risk-tolerance with procedure cost.

PGI19

COST-EFFECTIVENESS OF RADIOFREQUENCY ABLATION COMPARED TO ENDOSCOPIC SURVEILLANCE FOR PATIENTS WITH BARRETT'S ESOPHAGUS WITH LOW GRADE DYSPLASIA

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OBJECTIVES: Current guidelines for the management of patients with Barrett's esophagus (BE) with high grade dysplasia recommend radiofrequency ablation (RFA) as a treatment, based upon demonstrated clinical and cost-effectiveness. For patients with BE with low grade dysplasia (LGD), in contrast, the mainstay of management is surveillance endoscopy. The aims of this study were to estimate whether RFA is cost-effective for patients with Barrett's LGD compared to surveillance and to determine which factors influence the cost-effectiveness. **METHODS:** A cost-utility analysis was undertaken. A state transition Markov model was developed to estimate the costs and benefits of using RFA compared to surveillance in LGD. All direct medical costs were estimated from the perspective of the Australian health care system with adjustments for the US health care system. The model was run for the lifetime of the cohort of patients where quality of life differed by disease state. The incremental cost per quality adjusted life year (QALY) was estimated and uncertainty was explored using sensitivity analyses. **RESULTS:** Clinical evidence suggests that RFA is superior in treating LGD compared to surveillance. Replacing surveillance with RFA would yield an additional benefit of 0.129 QALYs. However the cost-effectiveness of RFA is highly uncertain. The main drivers of the cost-effectiveness results are the effectiveness of RFA, the probability of progression to cancer, and the cost of RFA. **CONCLUSIONS:** The available data suggest that active treatment with RFA provides significantly better clinical outcomes than surveillance, but the cost-effectiveness of RFA in this patient group remains highly uncertain. RFA is not cost-effective if the low estimates of cancer risk for LGD from recent population-based studies are used, but the accuracy of these estimates is unclear. Accurate estimates of the risk of developing cancer in patients with no dysplasia or LGD are needed to conduct valid and reliable cost-effectiveness analyses.

PGI20

ASSESSMENT OF PRACTICE PATTERNS AND TREATMENT-FAILURE MEDICAL COSTS AMONG PATIENTS WITH CHRONIC CONSTIPATION: FINDINGS FROM A PHYSICIAN SURVEY STUDY

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OBJECTIVES: Chronic constipation (CC) is a common chronic functional gastrointestinal disorder that may be associated with increased utilization of health care resources. The objective of this study was to understand resource utilization and associated costs for patients with CC based on treatment response. **METHODS:** A web-based survey was conducted with a sample of primary care physicians (PCPs) and gastroenterologists (GEs) across different US regions. The survey captured data on referral patterns (to/from GEs), test/procedure ordering, and follow-up physician visits for typical patients who did and did not achieve satisfactory relief of symptoms to a recent treatment for CC ("response"). Survey items included questions regarding the proportion of patients who would receive tests/procedures and follow-up physician visits. Health care costs were estimated by applying associated unit costs (derived from the 2012 Medicare physician payment schedule) to the corresponding utilization. All patients were assumed to begin treatment with PCPs. Median and mean costs of treatment failure were calculated as the corresponding cost differences between physician-deemed non-responders and responders, incorporating both PCP work-up costs and the costs of referrals to GEs. **RESULTS:** Twenty PCPs and 21 GEs completed the survey. These physicians treated a mean of 58 adults per month for CC. Most non-responders were referred to GEs by PCPs (median: 78%; mean: 68%). Non-responders were more likely to receive a test/procedure compared with responders (median: 90 vs. 0% for both PCPs and GEs; mean: 72 vs. 5% for PCPs; 72 vs. 24% for GEs). Thyroid function tests and colonoscopy were the most common tests/procedures that would be ordered. Median (mean) expected cost of follow-up due to non-response was estimated to be $1,132 ($865). **CONCLUSIONS:** Patients with CC who do not respond satisfactorily to treatments are likely to require additional follow-up testing and referrals to specialists, potentially leading to increased health care costs.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PGI21

IMPACT OF OPIOID-INDUCED CONSTIPATION: A MULTINATIONAL CROSS-SECTIONAL SURVEY OF PATIENTS AND HEALTH CARE PROVIDERS

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OBJECTIVES: Opioid-induced constipation (OIC) is a common gastrointestinal side effect of opioid treatment that can lead to alteration or discontinuation of opioid therapy. This multinational cross-sectional survey assessed OIC burden of illness. **METHODS:** Health care providers (HCPs) and a sample of their patients prescribed opioids for chronic noncancer pain were surveyed regarding patient laxative use, OIC symptoms, treatment patterns, and OIC impact on patient's pain management/daily life. **RESULTS:** HCPs (n=63) and patients from Canada (n=64), France (n=60), Germany (n=60), the UK (n=60), and the United States (n=60) participated. Sixty-nine percent of patients were characterized as inadequate responders to laxative treatment (used laxatives on ≥4 days in past two weeks and had continued constipation symptoms or symptom resolution with laxative side effects). Inadequate responders were more likely to have started an opioid regimen in the last six months and to have ≤1 bowel movement (BM)/wk versus ≥2 compared with responders. The proportion of patients self-reporting the following common gastrointestinal symptoms were higher than what physicians reported as the percent of their patients complaining of these symptoms: few normal or spontaneous BMs (88% vs 65%), hard lumpy stools (87% vs 71%), BMs different than normal (82% vs 59%), bloating (78% vs 71%), and abdominal discomfort/stomach cramps (75% vs 62%). Patients reported taking opioids less often (53%) or lowering the dose (57%) as a strategy to alleviate constipation, whereas HCPs reported recommending these strategies to approximately 10% of their patients with OIC. Approximately 40% of patients reported that constipation made it quite a bit harder or extremely harder to live with their chronic pain. **CONCLUSIONS:** Results indicate a disconnect in the frequency that OIC symptoms are experienced by patients versus perceived by their treating HCPs and also in the frequency of opioid dosing alteration to alleviate OIC by patients versus recommended by their HCPs.

PGI22

THE IMPACT OF OPIOID-INDUCED CONSTIPATION (OIC) ON QUALITY OF LIFE – A 10-YEAR LITERATURE REVIEW

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OBJECTIVES: Constipation is the most common and often most debilitating side effect of opioid therapy for chronic pain. It has been reported that some patients rank constipation as a more common source of distress than their pain. Opioid-induced constipation (OIC) compounds the burden in these patients and may lead to opioid alterations in dosing regimen, discontinuation, inadequate pain management, and increased cost of care. **METHODS:** Using standard methodology, a targeted literature review was undertaken of studies published in the last 10 years (2002–2012) reporting quality of life (QOL) in patients with OIC receiving opioid therapy for cancer or noncancer pain. The review focused on PubMed (MEDLINE) and Embase; abstracts from recent key conferences/meetings for gastroenterology and pain were also reviewed. **RESULTS:** A limited number of publications (one review, four surveys, two small qualitative studies) were identified. While only the PAC-QOL has been validated in this population, various additional instruments were used to describe OIC impact on QOL, such as EQ-5D, the SF-8 questionnaire, a 5-point scale, an 11-point scale, and qualitative descriptions. The burden of OIC on patient QOL was found to be considerable, with OIC patients experiencing worse QOL than patients without OIC in all four surveys. Of note, one survey showed that increasing severity of constipation correlated with decreasing QOL, while another indicated that patients with severe constipation were less satisfied with their pain treatment versus patients with mild, moderate, or no constipation. Mean satisfaction with pain treatment with no, mild, moderate and severe constipation was 6.6, 6.6, 6.2 and 5.2 (10-very satisfied). **CONCLUSIONS:** Current literature on the impact of OIC on QOL is very limited but consistently suggests that OIC adversely impacts QOL. More research is needed to fully quantify the impact on QOL and standardize research methodology. Alleviation of OIC may improve QOL and optimize pain management among these patients.

PGI23

FACTORS THAT INFLUENCE ULCERATIVE COLITIS PATIENTS' ANXIETY AND DEPRESSION FOLLOWING THE COLECTOMY SURGERY

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OBJECTIVES: To investigate the factors that potentially influence the UC patients' anxiety and depression after having a colectomy utilizing patient survey tools. **METHODS:** A cross-sectional survey was administered online or via paper to patients ≥18 years of age with UC who had a colectomy surgery within the last 10 years in Canada, Australia, and the UK. Anxiety and depression was measured using the Hospital Anxiety and Depression Scale (HADS); scores > 8 on the respective anxiety and depression scales indicate the presence of the condition. Other scales used included the Inflammatory Bowel Disease Questionnaire (IBDQ), 5-item EuroQol (EQ-5D) questionnaire, Body Image Questionnaire (BIQ), Medical Outcomes Study Sexual Functioning Scale (MOS-SFS), dietary restriction questions, and World Health Organization Health and Work Performance Questionnaire-Absenteeism and Presenteeism Questions (WHO-HPQ-AP). Logistic regression was used to investigate factors associated with anxiety. **RESULTS:** A total of 424 patients participated from Canada, UK, and Australia. Gender was equally distributed with a mean age of 42±13 years. Respondents were diagnosed with UC with a mean of 11.8±8.5 years ago and first

surgery occurred a mean of 4.2±2.5 years ago. Based on the HADS, 31% and 16% of patients had clinically meaningful anxiety and depression, respectively. Depression was significantly associated with poorer totaI IBDQ scores (p<0.0001) and higher BIQ scores (p<0.0001). Females are 2.15 times more likely to have anxiety than males (OR 2.15, 95% CI 1.19-3.88). Other factors associated with anxiety include loss of work productivity (OR 1.39, 95% CI 1.18-1.64) and poorer body image (OR 1.12, 95% CI 1.04-1.20). **CONCLUSIONS:** The findings from this multi-national study provide insight on important factors to inform patient-physician communications both prior to and post-colectomy.

PGI24

FATIGUE SEVERITY SCALE: RELIABILITY, VALIDITY AND INTERPRETATION OF CHANGE – EVIDENCE FROM TWO CLINICAL TRIALS IN PATIENTS WITH CHRONIC HCV INFECTION

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OBJECTIVES: Fatigue is the most common side-effect of treatment for chronic hepatitis C virus (CHC) infection with peginterferon-α and ribavirin (PR). Adequacy of the Fatigue Severity Scale (FSS) total scores for evaluating fatigue from the patients' perspective in CHC trials was assessed using blinded data from two CHC clinical trials. **METHODS:** 386 treatment-naïve patients (PILLAR) and 462 treatment-experienced patients (ASPIRE) were randomized to receive simeprevir (TMC435), a potent, oral, once-daily, investigational HCV NS3/4A protease inhibitor in Phase III clinical development and PR or placebo/PR. Patients completed the FSS and EQ5D in their native language throughout the 72 week trials. Reliability of the FSS was evaluated using Cronbach's co-efficient a at Week 24 (internal consistency reliability) and intraclass correlation (ICC) between FSS at Weeks 12 and 24 in stable patients (<0.5 g/dL change in hemoglobin between Weeks 12/24). Concurrent validity was assessed as correlation with the EQ5D visual analog scale (VAS). Known-groups validity of FSS scores was assessed using mean comparison by levels on the EQ5D daily activity item and by clinician-rated fatigue AEs at Week 24. Distribution- and anchor-based methods identified values representing a meaningful change in individual and mean FSS scores. **RESULTS:** FSS scores were highly reliable (Cronbach's α = 0.95, 0.96 and ICC: 0.74, 0.86 for PILLAR and ASPIRE, respectively). Concurrent validity (correlation of FSS and EQ5D VAS=-0.63, -0.66) and known groups validity (mean FSS scores by EQ5D daily activity levels or fatigue AEs severity ($p < 0.05$) were confirmed. Analyses suggest that a meaningful change in mean FSS scores ranges from 0.33-0.82, and that a 1 point change is a conservative indicator of an important within-subject change in FSS score. **CONCLUSIONS:** The Fatigue Severity Scale provides reliable and valid assessment and quantification of fatigue for clinical trials in patients with CHC infection.

PGI25

DEVELOPMENT OF PATIENT-REPORTED OUTCOMES (PRO) AND OBSERVER-REPORTED OUTCOMES (OBSRO) MEASURES FOR PEDIATRIC ULCERATIVE COLITIS: CONCEPT ELICITATION FINDINGS

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OBJECTIVES: The purpose of this research was to develop an electronic daily sign and symptom diary, the Daily Ulcerative Colitis Scale (DUCS), including a patient reported outcomes (PRO) version for children 8-17 years and an observer reported outcomes (ObsRO) version for caregivers of children aged 5-10 years. **METHODS:** Open-ended one-on-one concept elicitation interviews were conducted with children aged 8-17 years with a documented history of mild to moderate ulcerative colitis confirmed by endoscopy, recruited from three clinical centers. The interviews focused on signs or symptoms associated with UC. In addition, five pediatric gastroenterologists and three nurses were interviewed about the pediatric UC signs/symptoms, and parent blogs on an active UC website were reviewed; the blogs included discussions on 26 children with UC. Interview transcripts were developed, and a thematic analysis was conducted in which each new concept identified was coded using MaxQDA. **RESULTS:** The concept elicitation interviews included 22 children in remission (six aged 8-12; 16 aged 13-17) and 10 children with active disease (four aged 8-12; six aged 13-17). Information saturation (i.e., no new information reported in last patient interview) was achieved. A core set of seven signs/symptoms in pediatric UC emerged: abdominal pain, blood in stool, frequent stools, diarrhea, stool urgency, nocturnal stools, and tiredness. No substantial differences were observed across different ages, and descriptions were largely consistent across patients. Even when in remission, children reported occasional symptoms. The HCP interviews and blog data substantiated the interview findings; the HCPs confirmed that signs/symptoms of UC do not vary by age. **CONCLUSIONS:** Children with UC were able to report their signs/symptoms associated with UC, and these data informed the development of two measures with phrasing that should resonate with the pediatric and caregiver populations. These will be tested in cognitive debriefing interviews.

GASTROINTESTINAL DISORDERS – Health Care Use & Policy Studies

PGI26

THE COMPARISON OF THE USE OF H2-RECEPTOR ANTAGONISTS AND PROTON PUMP INHIBITORS BETWEEN SERBIA AND SCANDINAVIAN COUNTRIES

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OBJECTIVES: To analysis of the pattern of the consumption of histamine H2-receptor antagonists (H2RAs) and proton pump inhibitors (PPIs) (ATC subgroup A02B) in Serbia in correlation with Scandinavian countries (Denmark, Norway, Sweden and Finland). **METHODS:** The data on consumption of medicines during the four-year period (2007-2010) have been provided from the databases of the national regulatory agencies. The results were expressed as the number of defined daily doses per 1000 inhabitants per day (DID). A qualitative analysis was carried out according to the drug utilization 90% (DU90%) approach. **RESULTS:** During the period 2007-2010, the overall consumption of A02B subgroup medicines in Serbia decreased by 7.8%, opposite to Scandinavian countries where the consumption continuously increased in all countries, up to 56% in Denmark. In 2010, H2RAs accounted for 71.78% (16.46DID) of medicines used within A02B subgroup in Serbia, while in Scandinavian countries the share of H2RAs was in the range of 1.08 DID in Sweden up to 5.75 DID in Norway. Despite the increase by 34.3%, consumption of PPIs in 2010 in Serbia (6.45 DID) was up to 7.6 times lower than in the Scandinavian countries (49.1 DID in Denmark). The bulk of prescription (DU90%) in 2010 was made up of 3 (out of 7) medicines in Serbia, 2, 4 and 5 (out of 14) medicines in Sweden, Denmark and Finland respectively, and 5 (out of 10) medicines in Norway. Most frequently used medicine in Serbia was ranitidine (55.9%), in Sweden and Denmark omeprazole (80.3% and 30.3% respectively), in Norway esomeprazole (34.1%) and in Finland pantoprazole (28.5%). **CONCLUSIONS:** The overall utilization of medicines from A02B subgroup was notably lower in Serbia than in Scandinavian countries. Besides the quantity, the pattern of use showed significant differences suggesting that implementation of guidelines in Serbia is needed in order to achieve harmonization in prescribing practice.

PGI27

EVALUATION OF OUTPATIENT HEALTH CARE AND MEDICATION UTILIZATION IN PATIENTS WITH HUMAN IMMUNODEFICIENCY VIRUS/HEPATITIS C VIRUS (HIV/HCV), HIV, OR HCV INFECTION IN THE UNITED STATES

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OBJECTIVES: Few studies have explored how utilization of outpatient services differ for HIV/HCV coinfected patients compared to HIV or HCV monoinfected patients. The objectives of this study were to compare annual outpatient clinic visit rates between coinfected and monoinfected patients and to compare utilization of HIV and HCV therapies between coinfected and monoinfected patients. **METHODS:** Data were retrieved from the 2005-2010 National Hospital Ambulatory Medical Care Surveys. Clinic visits with a primary or secondary ICD-9-CM diagnosis code for HIV or HCV were included. Coinfection included visits with both HIV and HCV codes. Monoinfection included visits with only HIV or HCV codes. Patients <15 years of age at time of visit were excluded. Demographic characteristics and select comorbidities were compared by infection status using chi-square and ANOVA tests. Visit rates were computed using survey weights. **RESULTS:** Approximately 11,352,000 visits met study criteria for patients with HIV/HCV (8%), HIV (70%), or HCV (22%). The HCV cohort was older and had the highest proportion of females and whites as compared to HIV/HCV and HIV cohorts. The following comorbidities varied significantly across the three cohorts (HIV/HCV, HIV, HCV): current tobacco use (40%, 27%, 30%), depression (32%, 23%, 24%), diabetes (9%, 10%, 17%), and chronic renal failure (<1%, 3%, 5%), ($p<0.001$ for all variables). HIV/HCV visit rates were lower than both HIV and HCV visits rates and varied little across all study years. In contrast, there was a decrease in annual HIV visit rates and an increase in annual HCV visit rates. HIV therapy utilization increased for both HIV/HCV and HIV cohorts; the increase was more pronounced in the HIV/HCV cohort. HCV therapy utilization remained low for both HIV/HCV and HCV cohorts for all years. **CONCLUSIONS:** Low utilization of HCV therapy for HIV/HCV patients and HCV patients warrants further investigation.

PGI28

TREATMENT PATTERNS OF ADALIMUMAB AND INFLIXIMAB IN THE TREATMENT OF CROHN'S DISEASE OVER A THREE-YEAR PERIOD: A CANADIAN ASSESSMENT

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OBJECTIVES: A previous study indicated that after one year, the proportion of patients with a dose augmentation was higher with infliximab than with adalimumab. The objective of this study was to analyze, in a real world setting, trends in dose changes over a three-year period. **METHODS:** A retrospective cohort study was conducted using data from the Regie de l'assurance maladie du Quebec (RAMQ) for a randomly selected group of patients with a CD diagnosis, who had initiated (6month washout period) adalimumab or infliximab between February 2008 and March 2011. For adalimumab, dose increase was considered when the dose received exceeded 40mg every other week over at least an 8-week period. For infliximab, dose increase was considered either when the dose was increased or interval between doses was reduced for two periods of 8 weeks after the third injection. Statistical analyses were conducted using chi square test. **RESULTS:** The cohort included 1,517 patients (mean age: 33.9 years, 55.4% females). During the study period, 1,004 patients initiated infliximab (28 previously used adalimumab) and 513 patients initiated adalimumab (195 previously used infliximab). After 36 months, 28.2%(275/976) of patients with infliximab and 23.0%(73/318) of patients with adalimumab experienced a dose increase ($p<0.05$). For the non-naive patient subgroups, dose escalation occurred for 42.9%(12/28) with infliximab and for 27.2%(53/195) with adalimumab ($p<0.05$). Average annual cost of adalimumab was CDN$26,957 and CDN$18,577 for