country). Patient inclusion criteria were: C-HCV diagnosis within past 5 years; treated with peginterferon alfa-2a or alfa-2b plus ribavirin combination therapy (PEG2A+R or PEG2B+R, respectively); age ≥18 years; no diagnoses of hepatitis B or HIV/AIDS; ≥1 year follow-up post-treatment initiation; no clinical trial participation. Treatment dosing, duration, compliance, and costs (in 2009 €) were descriptively analyzed at the patient level. Published drug prices were used in all cost calculations. **RESULTS:** Hepatology, gastroenterology, and internal medicine were the predominant physician specialties observed, representing 22%, 30%, and 25%, respectively, of all physicians recruited. A total of 804 patients (~160 per country) were identified, of whom 65% were male with mean age of 46 years. More patients initiated PEG2A+R (69%) than PEG2B+R (31%). For both regimens, all major ribavirin doses (800, 1000, and 1200 mg) were seen, representing 36%, 35%, and 22%, respectively, of PEG2A+R patients and 39%, 47%, and 14%, respectively, of PEG2B+R patients. Mean treatment duration was ~35 weeks for both PEG2A+R and PEG2B+R, with distribution spikes at 24 and 48 weeks. Treatment compliance was relatively high, with ~75% of patients completing therapy as planned regardless of regimen. Mean weekly treatment costs ranged from €280 to €350 depending on the ribavirin dose. Mean total regimen costs were estimated at €11,827 and €11,109 per patient for PEG2A+R and PEG2B+R, respectively. **CONCLUSIONS:** Peginterferon-based regimens, although a mainstay of C-HCV management, are costly. Public health systems bearing the high economic burden of C-HCV treatment should be mindful of these costs when considering formulary access for alternative treatments.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes Studies

PGI29

SELECTING CHRONIC CONSTIPATION (CC) CLINICAL TRIAL ENDPOINTS: INCORPORATING THE PATIENT'S VOICE

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OBJECTIVES: 1. Identify a comprehensive set of symptoms for measurement in CC clinical trials. 2. Achieve saturation and provide support for the content validity of the corresponding set of endpoints in accordance with FDA's PRO guidance. **METHODS:** Twenty-eight in-depth interviews were conducted in two phases, in different geographic locations, with participants meeting modified Rome II criteria for CC. A semi-structured interview guide was used, beginning with a series of open-ended questions to elicit all relevant symptoms, followed by interviewer probes to fully understand the relationships among the concepts. Multiple rating and ranking methods were used to develop a subset of CC symptoms of greatest importance to patients. For example, participants were asked to identify their most bothersome CC symptoms, as well as those in which they would most like to see an improvement with treatment. **RESULTS:** When asked to describe their CC symptoms, the patients reported 62 potentially distinct concepts: 12 bowel symptoms, 21 abdominal symptoms, 25 additional physical symptoms, and 4 mental or emotional issues. Patient descriptions of symptoms revealed that symptom terms were highly related and/or could be considered secondary to CC. Results of the subsequent rating and ranking tasks suggest that the concepts of stool frequency, stool consistency, straining, incomplete evacuation, abdominal pain, abdominal discomfort, and bloating were distinct and comprise patients' most bothersome symptoms. Further, improvements in these symptoms would constitute an improvement in patients' CC overall, and PRO items addressing these symptoms were found to be clear and comprehensive. **CONCLUSIONS:** Patient input is vital to identify the full spectrum of symptoms, and to determine an optimal set of clinical trial endpoints. Interview results suggest that a variety of techniques may be necessary to demonstrate concept saturation and identify those symptoms which accurately represent a functional disorder such as CC.

PGI30

PSYCHOMETRIC PROPERTIES OF THE TREATMENT SATISFACTION QUESTIONNAIRE FOR MEDICATION IN PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE

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OBJECTIVES: The Treatment Satisfaction Questionnaire for Medication Version 1.4 (TSQM) is a widely used 14-item generic instrument to assess patients' satisfaction with medication, providing scores on four scales—Effectiveness, Side Effects, Convenience and Global Satisfaction. The objectives of this study were to assess the psychometric properties of the TSQM in a community-based population in the US receiving treatments for gastroesophageal reflux disease (GERD). **METHODS:** Patients were recruited for this study from multiple sources including physician, pharmacy and online referrals to a medication monitoring service (www.iGuard.org). A random sample of patients using GERD treatments were invited to complete the TSQM online. Internal consistency of the TSQM scales was evaluated using item-total correlations and Cronbach's alpha. Known-group validity was evaluated using analysis of covariance models based on the association of TSQM scale scores with a global item of patient rating the effectiveness of their medication. **RESULTS:** Data from a total of 1872 patients with at least one non-missing TSQM scale score were analyzed for this study. The mean (SD) age was 54.3 (12.4) years, 71.6% were females, 15.1% reported mild, 53.2% reported moderate and 31.7% reported severe disease severity. The TSQM scales had very good internal consistency, all item-total correlations were greater than 0.60. Cronbach's alpha for Effectiveness scale was 0.92, Side Effects scale was 0.89, Convenience scale was 0.83 and Global Satisfaction scale was 0.89. After adjusting for patient age, gender, self-reported severity, GERD therapeutic class and number of concomitant medications, as expected, all the TSQM scales scores were significantly associated with the global rating for medication effectiveness (all $p < 0.0001$), with higher TSQM scores among patients who believed that their medication completely cured their condition compared to those who rated medication effectiveness lower. **CONCLUSIONS:** The study provides evidence that the TSQM is a psychometrically sound and valid measure to assess patient satisfaction with GERD medication.

PGI31

PAIN AFTER LIVER TRANSPLANT: A CROSS SECTIONAL STUDY

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OBJECTIVES: There are multiple potential sources of pain in liver transplant (txp) pts with consequences of delayed healing, higher health care costs and decreased quality of life. The objective of this study was to assess the incidence, quality, management and treatment satisfaction of pain after liver txp. **METHODS:** This was a cross-sectional analysis of ambulatory liver txp pts. A questionnaire was developed using a modified Brief Pain Inventory. Pts described location, intensity, and pain quality. Pain symptoms were categorized as neuropathic, nociceptive and mixed pain. **RESULTS:** Sixty-eight pts were surveyed. Eleven pts were within 3 months of txp (Group 1) and 57 pts were > 3 mos post txp, mean of 60 ± 59 mos (Group 2). There were 38 males, 30 females; 10 AA, 58 Cauc; mean age 56 ± 9 yr. Forty-three pts (63%) reported having pain today: 90% of Group 1 and 58% of Group 2. Sixty-two percent of their pain was reported as new since txp. Forty-six percent of pain was nociceptive, 12% neuropathic and 42% mixed. Pain was most often in the lower extremities and lower back. Current pain was reported as being 4.5 (median) on a scale of 1–10. Pain interfered with sleep and normal work. Thirty-four pts were taking pain medications. Of these, more than 50% were taking 2 or more medication classes. Only 5 pts were being followed by a pain specialist, but 80% of these were completely satisfied with their pain management compared to 55% when followed by primary care and 40% when followed by the transplant team. **CONCLUSIONS:** Half of pts post liver txp have pain that impacts their lives and most often requires long term medication use for pain relief. Pts followed by pain specialists are more satisfied with their management than those followed by other health care providers.

PGI32

CORRESPONDENCE OF MULTIPLE HEALTH OUTCOMES MEASURES IN RESPONSIVENESS TO MMX™ MESALAMINE TREATMENT FOR PATIENTS WITH ULCERATIVE COLITIS

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OBJECTIVES: To understand how multiple health outcomes (HO) instruments could better measure health-related quality of life (HRQoL) and work productivity in ulcerative colitis (UC) patients, we examined interrelations among three HO instruments used in a clinical trial: a generic measure (SF-12v2), a disease specific measure (Shortened Inflammatory Bowel Disease [IBD] Questionnaire [SIBDQ]), and a work productivity measure (Work Productivity and Activity Impairment Questionnaire for UC [WPAI:UC]). **METHODS:** Mild-to-moderate UC patients received MMX mesalamine daily for 8 weeks in an open-label study. HO was measured at baseline and eight-weeks. SF-12v2 measures 8 domains of generic HRQoL. SIBDQ measures 4 domains of IBD-related QoL: bowel symptoms, systemic symptoms, emotional function, and social function. The WPAI:UC measures 4 dimensions of work-related productivity impacted by UC: absenteeism, presenteeism, work impairment, and activity impairment. Repeated-measures ANOVAs examined changes in HO scores. Associations among instruments in detecting HO change were assessed by intercorrelations among change scores, and correlations with patient-reported symptoms: bowel movement frequency (BMF) and rectal bleeding severity (RBS). **RESULTS:** 107 patients completed both assessments. Improvement occurred in 18 of 19 HO scale and summary scores ($p < 0.05$ for differences), indicating each instrument was responsive to treatment. Correlations indicated moderate associations in the predicted directions for change scores among all three instruments: the average correlation was 0.47 between SF-12v2 and SIBDQ scales, –0.39 between SF-12v2 and WPAI:UC scales, and –0.48 between SIBDQ and WPAI:UC scales. Improvement in scale scores for all measures was moderately correlated with improvement in both BMF and RBS (magnitude of average correlations ranged from 0.29 to 0.47). **CONCLUSIONS:** Instruments measuring different aspects of HO showed consistent responsiveness to eight weeks' treatment with MMX mesalamine in mild-to-moderate UC patients. Similar results obtained using different HO instruments confirm the treatment effect, and also indicate convergent validity among these instruments within this patient population.

PGI33

CURRENT EVIDENCE REGARDING THE HEPATITIS C PATIENT EXPERIENCE

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OBJECTIVES: To conduct a systematic review of studies reporting primary hrQoL data among patients with Hepatitis C and assess implications for adherence, work