all GERD patients. CONCLUSION: Partial responders to PPI treatment are more costly and score lower on physical and mental dimensions of HRQoL than patients responding well to PPI treatment and GERD patients in general.

A COMPARISON OF TEST-RETEST RELIABILITY OF SELF-REPORTED SF-36, WHOQOL, AND EQ-5D QUESTIONNAIRES BASED ON DIFFERENT ADMINISTRATION APPROACHES

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OBJECTIVES: This study aims to examine whether the test-retest reliability of SF-36, WHOQOL-BREF, and EQ-5D questionnaires will be changed by different administration approaches by which patients with chronic liver disease self-report their quality of life. METHODS: Patients with chronic liver disease were recruited from the outpatient department of a medical centre in Taiwan. Their self-reported questionnaires were collected by two approaches. The first approach patients received was an interview and questionnaire in hospital. They returned the retest questionnaire by mail two weeks later. In the second approach, patients were instructed to fill out both test and retest questionnaires at home and send back by two separate mails. The time gap was also two weeks. After scoring questionnaires, a paired-t test was conducted to compare test-retest reliability for three questionnaires. The mean score difference between two approaches was examined by independent t test. An analysis of mean score differences of different domains were performed by multiple linear regressions. RESULTS: Of 69 patients recruited for the first approach, 52 persons completed both questionnaires (75%), while the response rate of the second approach was 84% (127 of 151). The results indicate that there is no statistically significant difference in the test-retest reliability of SF-36, WHOQOL-BREF, and EQ-5D questionnaires. There was also no significant difference in the test-retest results between two approaches, except in the dimension ‘pain/discomfort’ mean difference (0.3 ± 1.2 and –0.1 ± 1.1, p = 0.03) by EQ-5D. Similar results (p = 0.04) were also found by multiple linear regression, after controlling age, sex, and education. This reflects that greater pain/discomfort was more likely to present in the first approach as compared to that in the second one. CONCLUSIONS: Alternative administration approaches did affect the results of test-retest questionnaires, which indicated that the Hawthorne Effect occurred in the interview in hospital.

VALIDATION OF A NOCTURNAL GASTROESOPHAGEAL REFLUX DISEASE (GERD) SYMPTOM SEVERITY AND IMPACT INSTRUMENT

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OBJECTIVE: Current GERD assessment questionnaires for adults are limited in their ability to capture nocturnal symptoms. The objective of this study was to develop and validate an instrument to assess severity and impact of nocturnal GERD symptoms. METHODS: Two focus groups and 16 cognitive debriefing interviews were conducted among patients with GERD to identify key issues and concerns related to nocturnal GERD symptoms. The resulting 29-item draft instrument was included in a study of 196 patients diagnosed with GERD at 12 clinics in the United States to evaluate the psychometric properties. Assessments were conducted at baseline and at 4 weeks. Construct validity was evaluated using the Patient Assessment of Upper Gastrointestinal Disorders Symptoms Questionnaire (PAGI-SYM), Patient Assessment of Upper Gastrointestinal Disorders-Quality of Life (PAGI-QOL), number of nights with symptoms, disability days, and clinician and patient assessment of GERD severity. Exploratory factor analyses and item response theory analyses were conducted to finalize items and subscales. RESULTS: Mean age of participants was 45 years; 76% were female and 68% were Caucasian. Patient-rated severity at baseline was mild or moderate for 69% of participants, with 48% reporting GERD-related symptoms 2–3 nights within the past week. The final questionnaire includes 20 items and consists of 3 subscales: nocturnal symptoms; morning impact; and concern regarding nocturnal GERD. The subscales demonstrated internal consistency reliability (Cronbach’s alpha 0.92–0.95). The subscale scores were statistically significantly correlated with subscales of the PAGI-SYM and PAGI-QOL (0.41–0.81; all p < 0.0001), number of nights with GERD symptoms (0.45–0.54; all p < 0.0001), disability days (0.19–0.43; all p < 0.05), and clinician and patient-reported disease severity (0.46–0.72; all p < 0.0001). CONCLUSION: Results support the reliability and validity of the newly developed questionnaire as a measure of severity of nocturnal GERD symptoms, morning impact, and concern related to nocturnal GERD.

PATIENT REPORTED PREVALENCE AND SEVERITY OF CONSTIPATION IN HOSPICE PATIENTS

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OBJECTIVE: To determine the prevalence and severity of constipation among persons receiving hospice care in the United States, using longitudinal patient-reported outcomes. METHODS: Data was obtained from excelleRx, Inc, a national hospice pharmacy. Patient-reported symptom outcome data were collected by telephone for each patient by trained research assistants within the first three days of hospice admission. Data collection continued every three to four days until patients were discharged, or unable or unwilling to report data or dead. Patients rated constipation on a four-point verbal rating scale of none, mild, moderate, and severe. The sample for our analysis came from five participating hospices and included all discharged or deceased patients receiving home hospice care with an admission assessment record and at least one subsequent telephone assessment for constipation between April 1, 2006 and October 20, 2007. The first patient reported constipation assessment score post hospice admission was used to estimate prevalence and severity of constipation. RESULTS: A total of 309 patients met the inclusion criteria, the majority of which were female (n = 167, 54%), Caucasian (n = 282, 91%), >65 years of age (n = 238, 77%) and had a primary diagnosis of cancer (n = 223, 72%). All patients were prescribed opioid therapy during their hospice experience. Constipation was reported at the first assessment post admission by 26% of the patients (n = 80), 28.7% of patients with cancer (n = 64) and 18.6% of patients without cancer (n = 16). Most patients who reported constipation were female (58.8%) and >65 years (78.8%). Constipation intensity was rated as mild (n = 32; 40%), moderate (n = 23; 28.8%).
and severe (n=25; 31%). CONCLUSION: Constipation was reported by approximately 25% of the hospice patients, a third of whom rated their constipation as severe. A substantial number of hospice patients may require aggressive management of constipation. This information may be useful as a process indicator of quality of care.

GASTROINTESTINAL DISORDERS—Health Care Use & Policy Studies

PGI24

RACIAL, SOCIAL, AND ECONOMIC DISPARITIES IN KNOWLEDGE AND CARE SEEKING BEHAVIORS FOR GASTRO-ESOPHAGEAL REFLUX DISEASE (GERD)

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OBJECTIVE: Assess knowledge and care seeking behaviors for gastro-esophageal reflux disease via a population-based approach. Identify variations in knowledge, attitude, and care seeking patterns between racial groups, while also investigating socio-economic disparities. METHODS: A questionnaire based upon previous work (Srinivansin, J Clin Gastro) was developed to assess knowledge, attitudes, and care seeking patterns for GERD and was translated into Chinese and Spanish. We worked with community and faith-based leaders to identify events for data collection. Four ethnic groups (White, Black, Asian, Hispanic) were compared. All descriptive and multivariate analyses were done using SAS 9.1. RESULTS: Although Hispanics had the highest prevalence rate for GERD, their familiarity with the condition was lower (61.2%), compared to Whites (68.9%) and Blacks (63.7%); Asians were the least familiar with GERD (44.6%) (P < 0.0001). There was a positive correlation between increased education level and awareness for GERD (P < 0.0001).

In general, Whites were the most likely to recognize GERD symptoms and behaviors to control GERD, while Asians were the least likely. Blacks and Hispanics were more likely to go to the Emergency Room for severe heartburn compared to Asians and Whites (P < 0.0001). Asians were least likely to go see a doctor when presented with a complication of heartburn (P < 0.0001). A total of 40.8% of Asians and 35.5% of Hispanics indicated that cost and the lack of health insurance would prevent them from seeing a doctor, higher rates than Whites and Blacks (P = 0.0073). CONCLUSION: Minorities lack an equal understanding of GERD, compared to Whites. Asians were particularly inaccurate in assessing symptoms for GERD and were least likely to see a doctor. Further research should focus on improving minority understanding of GERD symptoms and at what point to consult a physician. The impact of cost and lack of insurance on care seeking behaviors amongst Hispanics and Asians should also be examined.

PGI25

COSTS OF A PRIOR AUTHORIZATION ON LUBIPROSTONE FOR ELDERLY (AGE > 65) PATIENTS WITH CHRONIC CONSTIPATION IN A MEDICARE PART D POPULATION

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OBJECTIVE: To examine pharmacy costs of a Prior Authorization (PA) restriction on lubiprostone for chronic constipation (CC) patients in a Medicare Part-D plan. METHODS: Cost impact of PA was calculated by estimating annual pharmacy cost differences with PA (medication costs + co-payment and without PA (medication costs only). Model inputs included published estimates of CC prevalence; lubiprostone utilization from IMS Health, 2007; average PA approval rate, PA costs and co-payment from payer interviews; and lubiprostone wholesale acquisition costs. Annual medication costs in both scenarios included costs and utilization of lubiprostone less co-payment, assuming third-tier placement for lubiprostone. All previously rejected prescriptions were assumed to be approved after lifting PA, resulting in 21.24% increase in prescription volume. Sensitivity analyses were performed on PA cost, PA approval rate, and expected increase in prescription volume after lifting PA.

RESULTS: CC prevalence was 14.7%, of which 1.14% were lubiprostone users. For a 1-million member plan, this resulted in 1264 PA requests costing $27 each. Annual cost of PA administration was $34,130. PA approval rate for the elderly was 77.7% (or 982 approved users). Average number of fills per person per year was 3.8. A 30-day lubiprostone prescription cost $28.40 ($86.40 WAC-$56 co-payment + $2 dispensing fee). Drug costs were $105,997, resulting in total annual cost with PA of $140,127. Total annual costs without PA were $128,506, based on an additional 209 users, resulting in annual savings of $11,621. Sensitivity analyses indicated break even scenarios from removing PA on lubiprostone when cost per PA > $17.81 or PA approval rate > 69.18%, or expected increase in prescriptions from lifting PA < 32.20%. CONCLUSIONS: PA program for lubiprostone offers no financial savings to a Medicare plan based on current approval rates and annual utilization for elderly patients with CC in the base case as well as in sensitivity analyses.

PGI26

FINANCIAL IMPACT OF LIFTING A PRIOR AUTHORIZATION ON LUBIPROSTONE FOR CHRONIC CONSTIPATION PATIENTS IN A COMMERCIAL MANAGED CARE POPULATION (AGE < 65 YEARS)

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OBJECTIVE: To examine pharmacy costs of a Prior Authorization (PA) restriction on lubiprostone for chronic constipation (CC) patients in a commercial managed care plan. METHODS: Cost impact of PA was calculated by estimating annual pharmacy cost differences with PA (medication costs + PA administration) and without PA (medication costs only). Model inputs included CC prevalence estimates from the literature; lubiprostone utilization from IMS Health, 2007; average PA approval rate, PA costs and co-payment from managed care interviews; and lubiprostone wholesale acquisition costs. Annual medication costs in both scenarios included costs and utilization of lubiprostone less co-payment, assuming third-tier placement for lubiprostone. All previously rejected prescriptions were assumed to be accepted after lifting PA, resulting in 11.36% increase in prescription volume. Sensitivity analyses were performed on cost per PA, PA approval rate, and expected increase in prescription volume after lifting PA.

RESULTS: CC prevalence was 14.7%, of which 32.20%.

CONCLUSIONS: Minorities lack an equal understanding of GERD, compared to Whites. Asians were particularly inaccurate in assessing symptoms for GERD and were least likely to see a doctor. Further research should focus on improving minority understanding of GERD symptoms and at what point to consult a physician. The impact of cost and lack of insurance on care seeking behaviors amongst Hispanics and Asians should also be examined.