Infections

Bacterial resistance in the multi-departmental hospital

OBJECTIVES: Curiosis and its complications, such as hepatic encephalopathy (HE) are the sixth cause of general mortality in Mexico. The objective of this study is to evaluate the cost-effectiveness relationship of medications used to treat hepatic encephalopathy from an institutional perspective in Mexico.

METHODS: A Markov model was constructed to simulate the progression of adult Crohn’s patients. Transitions were estimated from published clinical trials of certolizumab pegol and natalizumab. The costs were discounted at 3% over 5 years. The primary effectiveness measurement was quality-adjusted life years. Sensitivity and probabilistic sensitivity analyses were performed by varying the transition probabilities, costs and health state parameters.

RESULTS: The treatment with natalizumab yielded 39.295 more quality-adjusted life years compared with the treatment with certolizumab pegol. The incremental cost-effectiveness ratio was $164,431/quality-adjusted life year at 5 years. Sensitivity analysis demonstrated the robustness of the model findings. CER analysis showed that the strategy using ertapenem was dominating.

CONCLUSIONS: Ertapenem is an emerging alternative for treating acute hepatic encephalopathy from an institutional perspective in Mexico.

Pharmacoeconomic analysis of treatments used for acute hepatic encephalopathy

PQI23

COST EFFECTIVENESS ANALYSIS OF RIFAXIMIN FOR THE TREATMENT OF ACUTE HEPATIC ENCEPHALOPATHY

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OBJECTIVES: Curiosis and its complications, such as hepatic encephalopathy (HE) are the sixth cause of general mortality in Mexico. The objective of this study is to evaluate a cost-effectiveness relationship of medications used to treat hepatic encephalopathy from the perspective of the Mexican Institute of Social Security (IMSS).

METHODS: Cost-effectiveness analysis of treatments used for acute hepatic encephalopathy, based on a decision model, and considering a temporal horizon of 34 days, from the perspective of public health institutions. Existing relevant therapeutic options were available at the IMSS are: lactulose, L-ornithine L-aspartate (LOLA), neomycin and rifaximin (the new alternative). Proposed effectiveness measures were based on available published studies and based on evidence: Percentage of patients with improvement in signs and symptoms of hepatic encephalopathy. Only direct medical costs were considered from unitary medical attention costs reported by IMSS. A univariate sensitivity analysis, using relevant variables (price and effectiveness) and discount’s rates scenarios were performed.

RESULTS: Treatment costs for each alternative (1 USD = 13.3 MXN $) totaled: lactulose US$2394, LOLA US$3327, neomycin US$1301 and rifaximin US $3312. In relation to effectiveness, the percentage of patients who presented improved signs and symptoms for each alternative is as follows: lactulose and LOLA 55%, neomycin 64% and rifaximin 90%. Cost effectiveness ratios are: lactulose US$5991, LOLA US$5995, neomycin US$6880 and rifaximin US$6880. The incremental cost-effectiveness ratio analysis indicates that LOLA and neomycin are surpassed by lactulose and rifaximin, which are located on the efficiency line. Rifaximin can lessen hospital stay by at least one day and cut down at least one medical consultation. If these factors are taken into account for the sensitivity analysis, rifaximin takes the lead as dominating alternative.

CONCLUSIONS: Rifaximin is a highly cost-effective alternative for treating acute hepatic encephalopathy from the patient's perspective in Mexico.

Pharmacoeconomic analysis of treatments used for acute hepatic encephalopathy

PQI24

COST UTILITY ANALYSIS OF CERTOLIZUMAB PEGOL VERSUS NATALIZUMAB MAINTENANCE THERAPY FOR CROHN’S DISEASE

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OBJECTIVES: To determine whether certolizumab pegol was a cost-effective strategy compared with natalizumab for patients with moderate to severe Crohn’s disease.

METHODS: A Markov model was constructed to simulate the progression of adult Crohn’s patients. Transitions were estimated from published clinical trials of certolizumab pegol and natalizumab. The costs were discounted at 3% over 5 years. The primary effectiveness measurement was quality-adjusted life years. One-way and probabilistic sensitivity analyses were performed by varying the transition probabilities, costs and health state parameters.

RESULTS: The treatment with natalizumab yielded 39.295 more quality-adjusted life years compared with the treatment with certolizumab pegol. The incremental cost-effectiveness ratio was $164,431/quality-adjusted life year at 5 years. Sensitivity analysis demonstrated the robustness of the model findings. CER analysis showed that the strategy using ertapenem was dominating.

CONCLUSIONS: Ertapenem is an emerging alternative for treating acute hepatic encephalopathy from an institutional perspective in Mexico.

Pharmacoeconomic analysis of treatments used for acute hepatic encephalopathy

PQI25

PHARMACOECONOMIC ANALYSIS OF THE EFFECTS OF SECONDARY BACTERIAL RESISTANCE IN THE MULTI-DEPARTMENTAL HOSPITAL ON TREATMENT EFFICACY IN COMPLICATED ABDOMINAL INFECTIONS

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OBJECTIVES: To determine if adding aminoglycosides to standard antibiotic regimens was cost-effective in the treatment of complicated abdominal infections (C-HCV) in Europe.

METHODS: The pharmacoeconomic analysis utilized the cost-effectiveness analysis (CER). If the efficacy and the cost of any of the studied regimens exceeded those of the Russian recommendations, they were excluded. The C-HCV rate was calculated by multiplying the C-HCV rate observed in the Russian population by the number of patients in the C-HCV cohort treated in the Russian healthcare system. The incremental cost-effectiveness ratio was calculated by dividing the incremental costs by the incremental benefits. The incremental cost-effectiveness ratios were compared with the cost-effectiveness threshold of $50,000/QALY.

RESULTS: The incremental cost-effectiveness ratio was $164,431/quality-adjusted life year at 5 years. Sensitivity analysis demonstrated the robustness of the model findings. CER analysis showed that the strategy using ertapenem was dominating.

CONCLUSIONS: Ertapenem is an emerging alternative for treating acute hepatic encephalopathy from an institutional perspective in Mexico.
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 ≥ 21 years; no diagnoses of hepatitis B or HIV/AIDS; ≥ 21 year follow-up post-treatment initiation; no clinical trial participation. Treatment doses were based on standard, geographical, and costs (in 2009 USD). All patients were included in 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 834 patients (161 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 recruited. PEG2B±R treatment duration was ~3.5 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 $111,827 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

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 concepts were found to be convergent. 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 a variety of techniques may be necessary to demonstrate concept saturation and identify those symptoms which accurately represent a functional disorder such as CC.

CORRESPONDENCE OF MULTIPLE HEALTH OUTCOMES MEASURES IN RESPONSES 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 (Short-Form Inflammatory Bowel Disease [IBD] Questionnaire [SFIBD]), 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 using generic HRQoL, IBD-specific and comprehensive measures 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. Similar results obtained using different HO instruments confirm the treatment effect, and also indicate convergent validity among these instruments within this patient population.

PAIN AFTER LIVER TRANSPLANT: A CROSS SECTIONAL STUDY
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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

ENDPOINTS: INCORPORATING THE PATIENT’S VOICE
PGI29

RESPONSIVENESS TO MMXTM MESALAMINE TREATMENT FOR GASTROESOPHAGEAL REFUX DISEASE
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OBJECTIVES: The Treatment Satisfaction Questionnaire for Medication Version 1.4 (TSQM) is a widely used 14-item generic instrument measuring patient 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 treatment 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 therapies 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 TSQM completed 14-item version were analyzed for this study. Their mean age was 54.3 (12.4) years, 71.6% were females, 15.1% reported mild, 33.2% 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 (all p < 0.0001), while 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.

CORRESPONDENCE OF MULTIPLE HEALTH OUTCOMES MEASURES IN RESPONSES TO MMX™ MESALAMINE TREATMENT FOR PATIENTS WITH ULCERATIVE COLITIS
PGI32

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

EXPERIENCE
PGI33

ABSTRACTS