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THE COST EFFECTIVENESS OF PEGINTERFERON ALFA AND RIBAVIRIN FOR THE TREATMENT OF HEPATITIS C IN CHILDREN AND YOUNG PEOPLE
Cooper K1, Baxter L2, Loveman E1, Hartwell D1, Brampton G1
1University of Southampton, Southampton, UK, 2London School of Hygiene, London, UK
OBJECTIVES: To assess the cost-effectiveness of peginterferon α-2a and peginterferon α-2b in combination with ribavirin compared to best supportive care (BSC), for the treatment of chronic hepatitis C virus (HCV) in children and young people aged 3 to 12 years with compensated fibrosis, with or without cirrhosis, in a Markov state-transition economic model of chronic HCV infection using decision analytic modeling. The model was developed using clinical data and treatment designated to previous treated patients. The annual costs of second line treatment were $2,114 [1,509,2.819] versus $2,920 [2,072,3.917] after second line failure. Hospitalizations accounted for about 75% of the costs. CONCLUSIONS: BSC with constipation leads to significant resource use and high costs certainly in case of second line treatment failure.

GASTROINTESTINAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

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AGREEMENT BETWEEN CHILD AND PARENT SYMPTOM DIARY RESPONSES IN CHILDREN WITH CHRONIC HEARTDISEASE: A MULTICENTER, PROSPECTIVE, RANDOMIZED STUDY IN ROMANIA
Kollánszky L1, Aschule 1, Carson RT1, Dzenne-Sommers B1, Abetz-Webb L1
1Adelphi Values, Rollington, UK, 2Forest Research Institute, Jersey City, NJ, USA, 3Endpoint Outcomes, Boston, MA, USA
OBJECTIVES: Using patient-reported and observed outcome measures to examine how well children are children is challenging. While the child is arguably the most ‘valid’ reporter, parents may provide more reliable responses. Our aim was to assess the agreement in child and parent ratings of IC/B/C-S symptoms collected through an electronic daily diary (eDiary). METHODS: Separate child and parent eDiaries were developed to assess IC/B/C-S symptoms based on concept elicitation interviews with 64 children and 75 parents. The eDiaries were completed by 36 children (aged 6-13) and 30 parents for 5-9 days prior to cognitive debriefing interviews. eDiary data were compared for five symptoms: abdominal pain, bowel movement (BM) frequency, stool form/consistency, straining and rectal pain during defection. RESULTS: There were moderate to high levels of agreement (child/parent) on the same level of response on a 0-11 point scale with a BM frequency of 56.9% agreement for BM frequency, 70.2% for stool form and 72.5% for rectal pain. Children’s reports of their ‘tummy hurting’ were consistent with parents seeing their children making a face (60.4% agreement) and parents being told by the child that his/her tummy hurt (74.6% agreement). Children’s reports of straining were consistent with parents observing their child making a face (60.4% agreement) and hearing their child grunt (52.3% agreement) during defection. Across all symptomatic agreement was 84.9% for 6-8 year old children, and their parents (mean 67.6% agreement) compared to 9-11 year old children and their parents (mean 58.4%). CONCLUSIONS: The results present evidence of moderate to strong agreement between children’s and parents’ reports of core IC/B/C-S symptoms, including levels of agreement in ratings amongst 9–11 year old children and their parents may be due to parents being less aware of their child’s symptoms.

PG140
VALIDATING THE UNIDIMENSIONAL FATIGUE IMPACT SCALE (U-FIS) FOR USE IN CROHN’S DISEASE
Wilburn J1, McKenna S2, Twiss J1, Kemp K1, Campbell S2
1Galen Research Ltd., Manchester, UK, 2Manchester Royal Infirmary, Manchester, UK
OBJECTIVES: Fatigue is usually defined as a feeling of exhaustion, lack of energy or tiredness and affects many aspects of daily living. Crohn’s Disease (CD) is often associated with fatigue, its a severe factor in CD patients who reported significantly to determine the mental and physical impacts of fatigue. It has been validated and shortened to 22 items and shown by Rasch analysis to be unidimensional. This study was designed to determine the validity of the U-FIS when used with CD patients. METHODS: CD patients were asked to complete the U-FIS and a subset of respondents completed it again two weeks later to assess test-retest reliability. Rasch analysis was applied to the full data set to determine unidimensionality. Construct validity was further supported by relating the U-FIS to the U-TOE on the UTOC on the Crohn’s Life Impact Scale (CLIQ) and the Nottingham Health Profile (NHP). RESULTS: A total of 158 CD patients (36.1% female; aged 16-79 years; mean 42.4; SD 15.0) completed the CLIQ and NHP questionnaires at baseline and 2 weeks later. Overall fit to the Rasch model was confirmed (p = 0.61) and no items misfit. Internal consistency (0.98) and reproducibility (test-retest reliability = 0.88) for the U-FIS were good. U-FIS scores correlated 0.79 with those on the CLIQ indicating the importance of fatigue to quality of life. U-FIS scores were also related as expected with NHP section scores. CONCLUSIONS: The U-FIS is a reliable and valid instrument for measuring fatigue in Crohn’s Disease. These findings replicate those found with the use of the measure with patients who have Multiple Sclerosis. The U-FIS is valuable as it provides a holistic index of the impact of fatigue from the patient’s perspective. The measure may prove valuable for use with patients who have a wide variety of chronic conditions.

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DEVELOPMENT OF THE CROHN’S DISEASE IMPACT QUESTIONNAIRE (CDIQ), THE FIRST PATIENT-REPORTED OUTCOME MEASURE SPECIFIC TO ADULTS WITH CROHN’S DISEASE
Wilburn J1, McKenna S2, Twiss J1, Kemp K1, Campbell S2
1Galen Research Ltd., Manchester, UK, 2Manchester Royal Infirmary, Manchester, UK
OBJECTIVES: The study was designed to identify the final CDIQ – the first patient-reported outcome measure specific to adults with Crohn’s Disease (CD) and determine its reliability and validity. METHODS: CD patients were sent a package consisting of the CLIQ, the Nottingham Health Profile (NHP), the Unidimensional Fatigue Impact Scale (U-FIS) and a demographic questionnaire. A subset of respondents completed a second package 2 weeks later. Rasch analysis was applied to responses for item reduction and assessment of unidimensionality. Assessments of internal consistency, test-retest reliability and construct validity were also undertaken. RESULTS: The CDIQ was completed by 273 CD patients (65.6% female; aged 16-79 years; mean 43.9; SD 15.1).