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grouped by gender and age. The study was conducted from the societal perspective using Year 1996-1999 prices, adjusted to year 2000 by CPI. Life expectancies were adjusted for QOL using the Index of Well-Being. Probabilities and prices were collected from the literature, the SEER program, National Vital Statistics, and BLS. The model considered H. pylori reinfection and gastric carcinogenesis risk over time. One-way sensitivity analyses were conducted on critical or uncertain parameters and threshold analyses on pivotal parameters. RE-**SULTS:** The incremental cost-effectiveness ratio (ICE) for pooled patients (both genders) decreases with age from \$3,612 per quality adjusted life year (QALY) saved at age 40-44 to the minimum of -\$200 (dominant) per QALY saved at age 65-70. After age 70, the ICE increases with age. Females have higher ICEs than males in every age subgroup. The ICE was sensitive to discount rate, relative risk of gastric cancer (GC) in H. pylori infected patients, cost of treating GC, and cost of empiric antisecretory therapy, but not to the reinfection rate or infection rate of H. pylori, the change of the utility rate of GC and the one-year utility of dyspepsia patient under empiric antisecretory therapy. CONCLUSIONS: Taking \$50,000/ QALY as the societal ICE threshold, H. pylori screening and eradication is cost-effective for both genders at any age group, especially for male patients at older ages. Better estimates are needed for certain key parameters such as the relative risk reduction of GC with H. pylori eradication.

PGI3

#### A PROSPECTIVE, RANDOMIZED COST ANALYSIS OF MEPERIDINE AND MIDAZOLAM VERSUS PROPOFOL FOR COMPLEX UPPER ENDOSCOPY PROCEDURES

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OBJECTIVES: Meperidine/midazolam (M/M) and propofol (P) are clinically effective alternatives for sedation during endoscopic procedures. Propofol has a higher acquisition cost, but may be associated with cost savings due to shorter duration of post-procedure care. The objective of this project was to compare the costs associated with complex upper endoscopic procedures (ERCP/EUS) in subjects who received either M/M or propofol. METHODS: Subjects scheduled for ERCP/EUS were randomized to receive M/M or P during the procedure. A blinded observer assessed time to recovery using a standard 10-point postanesthesia recovery score (PARS) every 15 minutes. Once a PARS score of 10 was reached, the study terminated and the subject was discharged from the recovery ward. The cost of drug (source: Redbook), an anesthetist for the propofol group (source: Bureau of Labor Statistics), recovery room personnel costs (source: Bureau of Labor Statistics), and overhead costs were compared from the institutional perspective. A sensitivity analysis was performed by assuming generic drug, a nurse anesthetist, and licensed practical nurse (LPN) care in the recovery ward. RESULTS: 33 and 31 subjects were randomized to receive M/M and P, respectively. There were no significant differences detected between the groups in age, gender, case severity, or procedure duration. P group subjects had a significantly shorter postprocedure recovery time (19 minutes) compared with M/M group subjects (71 minutes, p < 0.001). Subjects in the M/M group cost an average of \$65 per case, while P group subjects cost an average of \$144 per case (p < 0.001). The sensitivity analysis resulted in an average cost of \$77 per case in the P group and \$34 in the M/M group (p < 0.001). CONCLUSIONS: Subjects in the P group had a significantly shorter post-procedure recovery time but this did not result in cost savings compared with subjects treated with M/M.

PGI4

# HEALTH-RELATED QUALITY OF LIFE (HRQOL) DATA REVEAL DIFFERENCES AMONG CLINICAL "RESPONDERS"

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OBJECTIVES: Treatment effects are often evaluated by comparing groups in terms of the proportion of "responders", i.e., patients who achieve some prospectively defined outcome. In the absence of additional data, it is assumed that responders in different treatment groups achieve comparable benefits and therefore that the treatment benefit is fully described by the responder rates. This study compared the HRQOL changes of responders in two treatment groups. METHODS: In two identical randomized, double-blind, placebo-controlled studies (S3BA3001; S3BA3002) in women evaluating 12 weeks of treatment with alosetron 1mg BID, patients completed the Irritable Bowel Syndrome Quality of Life Questionnaire (IBSQOL) at baseline and at the final treatment visit. A patient was classified as a responder if she achieved adequate relief of IBS pain and discomfort on at least 2 of 4 weeks for all 3 months. This post-hoc analysis compared responders from the two treatment groups in terms of IBSOOL change from baseline scores at the final visit using analysis of covariance. The analysis focused on patients with diarrhea-predominant IBS. RESULTS: Our analyses included 154 patients (96 alosetron and 58 placebo) in S3BA3001 and 172 (110 alosetron and 62 placebo) in S3BA3002. Compared with placebo responders, those in the alosetron group had significantly higher (p < .05) scores on 5 of 9 IBSQOL scales (sleep; energy; physical functioning, food and role-physical) in S3BA3001 and on 4 scales (sleep, energy, food and social functioning) in S3BA3002. CONCLUSIONS: Adequate relief responders in the alosetron group experienced significantly greater HRQOL improvements relative to placebo group responders. This suggests that treatment benefits may be underestimated when described only in terms of the additional proportion of responders. Reporting HRQOL difAbstracts 123

ferences between responders in the treatment groups provides a more comprehensive characterization of the treatment effect.

PGI5

### HEALTH CARE COST SAVINGS WITH BUDESONIDE CONTROLLED ILEAL RELEASE CAPSULES (CIR) IN CROHN'S DISEASE

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BACKGROUND: Economic aspects are important when assessing the overall benefit of a treatment strategy. The number of investigations of these aspects are few within the field of Crohn's disease (CD). OBJECTIVE: To assess the economic consequences, from a health care budget perspective, of treating CD patients with budesonide CIR (Entocort capsules) 6 mg per day as maintenance therapy compared to no maintenance treatment (NMT). METHOD: A validated decision-analytic model (Noble et al., 1998) on the treatment of CD in Sweden was used. The model used pooled patient data from randomised, double blind trials of budesonide CIR capsules (n = 90) versus placebo (n = 90) and covers a study period of one year. For events not investigated in the clinical trials, literature and panel data were used. Cost inputs for health care resources were based on costs observed for 11 regional hospitals in Sweden in year 1996. The analysis took into account costs for health care resources associated with managing inactive and active phases of CD, e.g., diagnostic and surgical procedures, physician visits, hospitalisations and drug consumption. Panel data and cost inputs were tested in a sensitivity analysis. RESULT: Average annual cost per patient was SEK 36,745 for budesonide CIR capsules patients compared to SEK 38,130 for NMT patients. With a Swedish prevalence between 13,000 to 18,000 patients this could mean annual savings of 18 to 25 million SEK (2-2.8 million USD). Stability of the results was confirmed when altering values on panel data and cost inputs. CONCLUSION: Budesonide CIR capsules, prolonging time in remission, is a cost-saving treatment strategy for the treatment of Crohn's disease in Sweden.

PGI6

### COST-EFFECTIVENESS ANALYSIS OF HELICOBACTER PYLORI ERADICATION TRIPLE THERAPY VERSUS CONVENTIONAL THERAPY FOR GASTRIC AND DUODENAL ULCERS IN JAPAN

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**OBJECTIVES:** Helicobacter pylori (H.pylori) eradication triple therapy with a combination of lansoprazole, amox-

icillin, and clarithromycin was approved in September 2000 in Japan. The objective of this analysis was to compare the cost-effectiveness of this eradication therapy with conventional H2RA therapy in Japan. METHODS: We used decision analysis software to establish two Markov models, one for gastric ulcers and the other for duodenal ulcers. The model design was based on the Japanese H. pylori eradication guideline and specialists opinions. The model input data were derived mainly from a literature review. The models predict the direct medical costs, number of disease free days (DFDs) and cost per DFD for five years. Sensitivity analyses were conducted by varying the success rate and the probability of endoscopic relapse in symptomatic patients. The payer's perspective was selected. RESULTS: According to the gastric ulcer model, the expected total costs of eradication and conventional therapies for an individual patient at the end of five years would be 169,719 Yen and 390,921 Yen, respectively; the expected DFDs 1,454 days and 1,313 days, respectively; and the expected cost per DFD 117 Yen and 298 Yen, respectively. According to the duodenal ulcer model, the expected total costs of the eradication and conventional therapies would be 134,786 Yen and 324,689 Yen, respectively; the expected DFDs 1,503 days and 1,387 days, respectively; and the expected cost per DFD 90 Yen and 234 Yen, respectively. The sensitivity analyses showed the results of baseline analysis to be robust. CONCLUSIONS: We found that this eradication therapy is less costly and more effective than conventional therapy for the treatment of gastric and duodenal ulcers in a Japanese medical setting. Thus, eradication therapy is recommended for gastric and duodenal ulcers from an economic as well as a clinical viewpoint, in Japan.

PGI7

# BUDESONIDE CIR IS COST-EFFECTIVE IN MAINTENANCE THERAPY OF CROHN'S DISEASE IN FINLAND

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**OBJECTIVE:** To assess the economic outcome, from a health care budget perspective, of treating Crohn's disease (CD) patients with budesonide controlled ileal release (CIR) 6 mg per day as maintenance therapy compared to no maintenance therapy (NMT). **METHODS:** A validated decision-analytic model (Noble et al., 1998) on the treatment of (CD) was used. The model was adjusted to specifically depict CD patient management in Finland. The analysis was based on pooled patient data from randomised, double blind clinical trials comparing budesonide CIR (n = 90) in maintenance therapy with placebo (n = 90). In accordance with the clinical trials the analysis covered a study period of up to one year. The analysis took into account clinical outcomes and consequences of