

study of 100 adult asthmatics. **RESULTS:** The table reports outcomes over a 10-year period. Results were driven by the impact of ICS on quality of life, rather than on mortality. Findings were stable over most input data ranges. However, at efficacy levels below 3% and toxicity rates greater than 2.9%, the cost-effectiveness estimate exceeded \$100,000/QALY. **CONCLUSION:** Results suggest that inhaled steroids deliver good comparative value in mild-to-moderate adult asthma. More research is needed, however, on the impact of ICS toxicity on patient preferences.

Strategy	Cost	QALY	\$QALY
Quick Relievers alone	\$5,185	6.77	—
+ICS in moderate disease	\$5,961	6.84	\$10,300
+ICS in mild disease	\$7,616	6.93	dominated
+ICS in mild/mod. disease	\$8,392	7.00	\$15,000

## CONTRIBUTED POSTER PRESENTATIONS

### ARTHRITIS, OSTEOPOROSIS & MUSCULOSKELETAL DISORDERS

PAM I

#### JOINT COUNTS IN PATIENTS WITH NEW ONSET RHEUMATOID ARTHRITIS: PATIENT VS. PHYSICIAN ASSESSMENT

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**BACKGROUND:** Both physician-assessed and patient self-reported joint counts have been used in the assessment of disease activity in rheumatoid arthritis. The objective of this study was to compare patient vs. physician reported joint counts in patients with new onset RA. **METHODS:** Baseline data was analyzed from the Study of New Onset Rheumatoid Arthritis (S.O.N.O.R.A.SM), a five-year prospective, longitudinal, inception cohort study to document long-term functional, clinical, and humanistic outcomes and patterns of treatment in patients with new onset RA. Baseline data collection consisted of physician and patient surveys. Physicians assessed swollen (SJ) and tender/painful joints (TJ) while patients reported painful joint (PJ). Physician's SJ and TJ consisted of examination in 64 and 66 joints, respectively. Patient's PJ was assessed in 16 joint areas with use of a mannequin. The Pearson product moment correlation coefficient was calculated for SJ, TJ, and PJ counts. **RESULTS:** One hundred and seven patients completed the baseline survey. Mean age of the sample was  $55 \pm 15$  years; 79% were female; 80% were Caucasian. Mean joint counts were 12.6 (SE = 0.9) SJ, 14.0 (SE = 1.3) TJ, and 6.6 (SE = 0.4) PJ. Patient-reported PJ correlated with physician-

reported SJ ( $r = 0.22$ ,  $p = 0.023$ ) and TJ ( $r = 0.55$ ,  $p < 0.001$ ). **CONCLUSION:** Higher correlation was observed between PJ and TJ compared to SJ. Patient, self-reported joint counts may be a useful surrogate of joint activity in the absence of physician assessment. However, caution should be taken given that the accuracy of patient, self-reported joint counts still needs further evaluation. Five-year follow-up of this population will provide further insight on the sensitivity to change for both patient and physician reported joint counts as it relates to disease activity.

PAM2

#### AN ECONOMIC EVALUATION OF OSTEOPOROSIS MEDICATION USE PATTERNS IN A MANAGED CARE ORGANIZATION: A TIME TO FRACTURE ANALYSIS

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Osteoporosis affects approximately 24 million Americans and accounts for an estimated annual direct medical costs of over \$13.8 billion. An economic analysis that evaluates the effectiveness of osteoporosis medications for prevention of bone fractures in a naturalistic setting has not been formally conducted. **OBJECTIVES:** To compare differences among four therapeutic alternatives [estrogen replacement therapy (ERT), raloxifene, nasal calcitonin, and alendronate] with respect to health care costs (pharmacy, medical, and total), and time to fracture. **METHODS:** Retrospective pharmacy and medical claims data from a large managed care organization were analyzed. Patients were included if they were diagnosed with osteoporosis and newly initiated on medication between 1/1/98–12/31/98. All patients were followed for exactly 1 year. Cost data was log-transformed to correct for skewness. ANCOVA was conducted to compare total health care costs; Cox Proportional Hazard Model was performed to compare the risk of fracture. Total health care costs was defined as all osteoporosis-related services covered. **RESULTS:** There were 12,757 female patients identified for the analysis and the average age was 70 (S.D. = 10). A total of 1,721 (13.5%) patients had a fracture after initiation of drug therapy. After adjusting for age, prior medication costs, prior fracture event, and comorbidities, adjusted means (95%CI) of log-transformed total health care costs was lowest for ERT 5.87(5.84–5.90), compared to raloxifene 6.32(6.19–6.46), alendronate 6.55(6.51–6.59) and calcitonin 7.20(6.61–7.80). Compared to calcitonin, the adjusted hazard ratios (95%CI) for a fracture were 0.174(0.078–0.39) for ERT, 0.175(0.078–0.39) for alendronate, and 0.160(0.068–0.377) for raloxifene. **CONCLUSIONS:** In this population, ERT was associated with statistically significant lower total health care costs compared to raloxifene, alendronate, and calcitonin. Raloxifene was associated with statistically significant lower total health care costs

compared to calcitonin and alendronate. Furthermore, hazard ratios showed that patients taking ERT, raloxifene, or alendronate were approximately 83% less likely to experience fracture at any point in time compared to calcitonin.

**PAM3****THE COST OF OSTEOPOROTIC FRACTURES IN THE UNITED KINGDOM**

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**BACKGROUND:** The UK has more than 19 million people aged over 50, including about 9.4 million aged over 65. Demographic changes will lead to increases in the over-50 population of 10% and 25% by 2010 and 2020, respectively. There are already 3 million UK residents with osteoporosis, but the prevalence of osteoporosis increases with age, and the public health impact of osteoporosis will increase substantially over the next 20 years. **OBJECTIVE:** To predict fracture numbers and corresponding costs for men and women aged 50–99 years in the UK for the years 2000 to 2020. **METHODS:** A Markov model was designed to simulate the natural history of osteoporosis within the UK population. Inputs to the model included age/sex specific fracture incidence rates, published unit costs for different fracture types (hip, vertebral, forearm/wrist, other), age/sex specific mortality rates, and age/sex specific population totals. Total fracture numbers were adjusted using published site-specific attribution figures to identify the number that were a consequence of osteoporosis. Iteration techniques were employed across ages 50–99 in men and women, to generate the distribution of prevalence-based estimates of fractures and costs for the base year 2000. Osteoporosis costs and fracture numbers were then projected into future years by applying growth rates in age/sex specific population totals to these year 2000 estimates. **RESULTS:** In 2000 there were 190,000 osteoporosis-related fractures at a cost of £1.8 billion. Men accounted for 32,000 fractures and £330 million. By 2020, annual osteoporotic fracture numbers increased by over 21% to 230,000, with costs growing by 20% to over £2.1 billion. Cumulative totals for 2000–2010 were 2.2 million fractures and £20.3 billion. **CONCLUSIONS:** Osteoporotic fractures will have substantial and increasing impacts on UK health services unless highly effective preventative interventions achieve widespread use.

**PAM4****USE OF COX 2 NSAIDS IN SUBJECTS WITHOUT RISK OF GASTROINTESTINAL SIDE EFFECTS**

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**OBJECTIVE:** While Cox 2 inhibitors have a theoretical advantage over other nonsteroidal anti-inflammatory drugs (NSAIDs) by reducing gastrointestinal (GI) side effects, not all individuals are at increased risk of GI complications and therefore may benefit equally from non-Cox 2 specific NSAIDs. This study determined the use of Cox 2 inhibitors by subjects with no identifiable GI risk. The cost of this “inappropriate use” was estimated. **METHODS:** This was a longitudinal claims data analysis using 1999 medical, pharmacy and enrollment data from a large national health plan. Subjects were identified as either Cox 2 users (n = 23,190) or other NSAID users (n = 192,079) from pharmacy claims, and total NSAID costs were calculated for a six-month period. **RESULTS:** Cox 2 users were more likely to have a GI risk factor, (prior GI events, age over 60 years, chronic NSAID use of two or more prescriptions in the six months prior to the first Cox 2 claim, and prior corticosteroid use) compared to other NSAID users. Because individuals with arthritis may require on-going NSAID use, a diagnosis of arthritis (OA or RA) was also considered a risk factor for GI complications. Having an arthritis diagnosis was more likely among Cox 2 users compared to other NSAID users (44.1% and 13.0% respectively). Twenty-six percent of Cox 2 users had neither a discernable GI risk nor an arthritis diagnosis. An unadjusted cost comparison between Cox 2 subjects with no GI risk and no arthritis and similar other NSAID subjects found a significant mean difference of \$131 per person in NSAID costs for six months. **CONCLUSIONS:** Despite health plan policies to manage the use of Cox 2 inhibitors, a quarter of Cox 2 users appeared to be inappropriate. The total health system cost of this potentially inappropriate use was \$775,000 for six months.

**PAM5****INVESTIGATING THE CONSTRUCT VALIDITY OF A DISEASE SPECIFIC AND A GENERAL QUALITY OF LIFE INSTRUMENTS OF PATIENTS WITH RHEUMATOID ARTHRITIS**

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**OBJECTIVES:** Quality of life is a key parameter in describing the health status patients of rheumatoid arthritis. Construct validity of a generic (EQ-5D) and a disease specific (RAQoL) quality of life instrument was tested with the intention of further use in clinical and health economic trials and burden of disease studies in Hungary. **METHODS:** RAQoL and EQ-5D have been recently adapted into Hungarian. Authors analysed the demographic and QoL data from a cross-sectional postal survey of patient with rheumatoid arthritis. The convergent validity of EQ-5D, RAQoL scores has been compared to functional measurement scores from the Health Assessment Questioner (HAQ). Pearson correlation coef-

ficients were used to assess the level of association. **RESULTS:** 81 patients participated in the study. Mean age of the sample was 57.3 (SD = 10.1) years, 89% (n = 72) were female. The average disease duration among patients was 14.5 (SD = 10.6) years. RAQoL scores were relatively strongly correlated (Pearson coefficient = 0.662) with HAQ scores. The EQ-5D index scores showed higher correlation (0.627) with HAQ than the Visual Analogue Scale of EQ-5D (0.463). The Pearson Correlation Coefficient between RAQoL and EQ-5D index scores was 0.515, and between RAQoL and EQ-5D VAS scores was 0.396. **CONCLUSIONS:** Results suggest that the Hungarian RAQoL is a valid instrument of measuring QoL of rheumatoid arthritis patients. The EQ-5D index provides also appropriate results, and can be proposed for cost-utility analyses. However EQ-5D VAS scores are not recommended to describe the QoL of patients with rheumatoid arthritis.

**PAM6**

### **COST-EFFECTIVENESS OF ROFECOXIB VERSUS NSAIDS IN THE TREATMENT OF OSTEOARTHRITIS**

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**OBJECTIVES:** The purpose of this study is to examine the cost-effectiveness (CE) of rofecoxib versus NSAIDs in the treatment of osteoarthritis. **METHODS:** The authors used decision-analysis from a societal perspective to model a hypothetical cohort of osteoarthritis patients on long-term NSAID therapy. Incremental cost per QALY (C/QALY) estimates were calculated for a hypothetical trial population and for patients at high risk of G.I. adverse events. High-risk patients were defined in the literature as having four risk factors combined: history of G.I. bleeds, history of peptic ulcer, cardiovascular disease and age 75 years or greater. All costs were expressed in 1997 prices. Utility estimates were obtained from a separate analysis of pharmacy claims data including the Health Utilities Index Mark 2 from a large HMO. Confidence intervals were assessed using the maximum and minimum values from the literature. Univariate sensitivity and threshold analysis were conducted. **RESULTS:** The C/QALY range is \$5,658 to \$108,831 for osteoarthritis patients; base case C/QALY is \$103,597 for all osteoarthritis patients, -\$9,374 for high-risk patients. Rofecoxib is cost-effective (C/QALY ≤ \$50,000) if the incidence of perforations, ulcers and bleeds (PUB) is 0.098 per year or greater. Sensitivity: the most sensitive parameters were: symptomatic dyspepsia utility; rofecoxib price; symptomatic peptic ulcer utility; incidence of G.I. symptoms; NSAID price and incidence of PUBs. However, the parameters with greatest uncertainty and variability in the literature are incidence of PUBs and G.I. symptoms. **CONCLUSION:** The point estimate C/QALY of rofecoxib for all osteoarthritis patients varies from very cost-effective to not cost-effective depending on assumptions

for the probability of PUBs and G.I. symptoms. Rofecoxib is cost saving for patients at high risk of developing G.I. complications.

**PAM7**

### **THE CORRELATION BETWEEN ARTHRITIS SPECIFIC MEASURES AND SF-36 SCALES IN RHEUMATOID ARTHRITIS PATIENTS**

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**OBJECTIVE:** To evaluate the correlation between general measures of function and well-being, as measured by the 8 domains of the SF-36, with arthritis specific measures of function and symptom frequency. **METHODS:** We identified 606 patients from a longitudinal, observational study of RA (RAPOLO). Patients completed telephone interviews about arthritis specific function (HAQ, RA Status and Symptoms), the SF-36 domains, Physical and Mental Summary Scores (PCS, MCS) and the Arthritis Specific Health Index (ASHI). We present correlations between the SF-36 domains, PCS, MCS and ASHI with selected arthritis measures. All correlations are presented as absolute values. **RESULTS:** All correlations were in the anticipated direction. A correlation >0.6 = good-excellent, and <0.4 = below average. The HAQ was highly correlated with the SF-36 physical scales, and had weak correlations with the emotional function scales and the ASHI. Other arthritis specific scales (joint swelling, joint pain, morning stiffness, RA fatigue and RA pain) were strongly correlated with the ASHI, the SF-36 pain, physical function, role function-physical and energy/fatigue scales; and had weak correlations with the emotional functioning and general health scales. **CONCLUSIONS:** In RA patients, the SF-36 measures aspects of functioning and well-being not covered by the arthritis specific measures, especially in the areas of emotional functioning. This is indicated by the moderate to weak correlations between the arthritis specific measures and the domains of emotional function, role emotional function, and mental health and the MCS.

**PAM8**

### **COST COMPARISON OF TREATING OSTEOPOROSIS PATIENTS WITH ESTROGENS OR SELECTIVE ESTROGEN RECEPTOR MODULATOR IN A MANAGED CARE POPULATION**

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**OBJECTIVE:** To compare osteoporosis treatment charges among patients treated with an estrogen versus a selective estrogen receptor modulator (SERM) in a managed care population. **METHODS:** Patients 40 years of age with a

diagnosis of osteoporosis between January 1 and June 30, 1999 and 2 pharmacy claims for an estrogen or SERM were selected from the PharMetrics Integrated Outcomes Database. Patients were excluded if they had less than 6 months of continuous enrollment following the first (index) prescription claim for an estrogen or SERM or received other drugs for osteoporosis, such as bisphosphonates or calcitonin-salmon. The frequency of hip, vertebral, forearm/wrist or other fracture and/or related surgical procedures and osteoporosis-specific charges were assessed over the 6-month period following the index prescription. **RESULTS:** 252,892 patients met the selection criteria, including 245,650 treated with estrogen and 7,242 with SERMs. The estrogen cohort was significantly younger than the SERM cohort (mean age: 54.3 vs. 59.0 years,  $p < 0.001$ ) and had less frequent fractures/surgical procedures (1.0% vs. 1.6%,  $p < 0.001$ ). The SERM group had higher mean osteoporosis-related pharmacy (\$309 vs. \$106) and medical charges (\$73 vs. \$29) resulting in a total charge difference of \$247 ( $p < 0.001$ ). Stratified analyses indicated that the SERM cohort had consistently higher mean charges across all age ranges compared to the estrogen cohort. **CONCLUSION:** In this initial cost comparison between SERM and estrogen therapy for osteoporosis, short-term (6-month) osteoporosis-related charges were significantly higher in the SERM group primarily due to the difference in drug costs. Longer-term studies are required to examine all of the costs associated with these therapies.

**PAM9**

### **COST COMPARISON OF TREATING RHEUMATOID ARTHRITIS PATIENTS WITH COX-2 INHIBITORS OR NSAIDS IN A MANAGED CARE POPULATION**

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**OBJECTIVE:** To compare rheumatoid arthritis (RA) treatment charges with a cyclooxygenase-2 specific inhibitor (COX-2) versus a non-steroidal anti-inflammatory drug (NSAID) therapies in a managed care population. **METHODS:** Patients with a diagnosis of RA between January 1 and June 30, 1999 who had prescriptions for COX-2s or NSAIDs were selected from the PharMetrics Integrated Outcomes Database. Patients were excluded if they had osteoarthritis or did not have 6 months of continuous enrollment following the first (index) COX-2 or NSAID pharmacy claim. COX-2 and NSAID-treated groups were compared on their demographics, comorbidities, and total RA-specific charges during the 6 month follow-up period. **RESULTS:** A total of 5,261 patients met the patient selection criteria, including 668 who received COX-2 and 4,593 who received NSAID. The COX-2 group was older (53.7 versus 49.6 years,  $p < 0.0001$ ) on average and more likely to have at least one comorbidity (46.0% vs. 31.9%,  $p < 0.001$ ) compared to

the NSAID group. They also had higher RA-related pharmacy (\$914 versus \$636) and medical charges (\$611 versus \$566). Total mean charges for the COX-2 cohort were \$323 higher ( $p = 0.019$ ) than the NSAID cohort. **CONCLUSION:** In this initial cost comparison between COX-2s and NSAIDs, the mean charge for a 6-month period with COX-2s was 27% higher than with NSAIDs, mainly due to higher pharmacy charges. Longer-term studies are required to examine whether the higher acquisition costs of COX-2 are offset by savings in the costs of treating gastrotoxicity.

**PAM10**

### **THE IMPACT OF EARLY RHEUMATOID ARTHRITIS ON PRODUCTIVITY**

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**BACKGROUND:** Rheumatoid arthritis (RA) leads to physical and psychosocial functional disabilities affecting productivity of patients in their daily activities. **OBJECTIVE:** to evaluate the impact of early RA on productivity. **METHODS:** Baseline data was analyzed from the Study of New Onset Rheumatoid Arthritis (S.O.N.O.R.A.S.M), a five-year prospective, longitudinal, inception-cohort study to document long-term functional, clinical, and humanistic outcomes and patterns of treatment in patients with new onset RA. Telephone interviews were performed by trained interviewers to collect data on employment status, annual household income (AHI) and productivity at work and normal activities, outside of paid job (NAOPJ), including absenteeism over the past 4 months, reason for absenteeism, and effectiveness at work and NAOPJ when working with arthritis symptoms (AS). **RESULTS:** One hundred thirty one patients completed the baseline survey. Mean age was  $56 \pm 15$  years; 78% were female; 82% were Caucasian. Employment status reported was full-time (52%), part-time (2%), retired (26%), and other (20%). AHI were  $< \$50,000$  (63%),  $\$50,000-74,999$  (17%),  $> \$75,000$  (18%), and 2% refused to provide AHI. Ninety-one percent of patients were employed at a paid job. The mean absenteeism at work and NAOPJ were 4.3 days (SE = 1.1) and 25.9 days (SE = 3.3), respectively. Of the participants reporting absenteeism, 40% and 69% reported that the majority of absenteeism was due to AS for work and NAOPJ, respectively. Compared to their normal performance, patients were 78% and 64% as effective when working with AS at work and NAOPJ, respectively. **CONCLUSION:** Despite new onset of RA in this population, negative impact on productivity was observed. A greater decline in productivity was reported for NAOPJ. This may imply that NAOPJ is compromised before work activities in early RA patients. Five-year follow-up of this population will provide further insight on productivity changes and the economic burden associated with progressive disease.

**PAM11****APPLYING BACKGROUND RISK DISTRIBUTION TO EVALUATE THE COST-EFFECTIVENESS OF THREE PREVENTIVE DRUG THERAPIES FOR OSTEOPOROTIC FRACTURES**

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**OBJECTIVE:** To evaluate cost-effectiveness (CE) of three drug therapies for preventing osteoporotic fractures in postmenopausal women from a state Medicaid Program perspective using the estimated risk distribution in the study population. The three therapies are: hormone replacement therapy (HRT), alendronate, and raloxifene. **METHODS:** A hypothetical cohort of white women aged 45–85 years, postmenopausal, and without past incidence of osteoporotic fractures was treated with one of the three alternatives, and tracked over 3 years in a decision model. The CE ratio was defined as the treatment costs [e.g., medications, monitoring, adverse events (AE)] divided by the number of fractures averted. Treatment Willingness-To-Continue (WTC) rate was also considered. Data were collected from literature, expert panel survey, Medicaid claims data, and a risk survey in the study population. Monte Carlo simulations were conducted (distributions used: background risk, cost, and risk reduction rate). Risk or probability of osteoporotic fracture was also divided into three strata: low (risk <0.1), medium (0.10.3). **RESULTS:** Compared to no therapy, the expected CE of HRT was \$29,119 per fracture averted, alendronate: \$35,101, and raloxifene: \$39,760. The incremental CE was \$42,181 for alendronate (relative to HRT) and \$85,509 for raloxifene (relative to alendronate). The incremental CE of alendronate and raloxifene were \$151,981 and \$697,270 among women with low risk (43% of the sample), compared to \$11,099 and \$34,017 respectively among high-risk women (26% of the sample). CE was not sensitive to discount rate and AE probabilities. **CONCLUSIONS:** HRT is the most cost-effective strategy even though it may have relatively high monitoring and AE costs, and low WTC rate. The significant decrease in marginal costs of Alendronate and Raloxifene in high-risk women indicates an economic condition to use these two drugs. The study provides a framework to make risk-appropriate coverage decisions for chemo-preventive agents.

**PAM12****COST-MINIMIZATION ANALYSIS OF THE TREATMENT OF RHEUMATOID ARTHRITIS WITH LEFLUNOMIDE IN COMPARISON WITH THE COMBINATION OF INFlixIMAB AND METHOTREXATE**

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**OBJECTIVES:** To carry out a pharmacoeconomic analysis to compare the efficiency of two rheumatoid arthritis treatments in Spain. **METHODS:** The study consisted of a systematic review of efficacy and toxicity as well as a cost-minimization analysis, carried out using a pharmacoeconomic model, comparing the treatment with leflunomide and the combination of infliximab and methotrexate during one year. **RESULTS:** Clinical trials directly comparing both treatments are not available. The response rate ACR20 combined, after one year, was 53.0% (CI95%: 49.2%–56.4%) with Leflunomide and 42.0% (CI95%: 31.2%–52.5%) with the combination of Infliximab and Methotrexate (P = 0.051). There were no statistically significant differences in the ACR50 response (27.0 vs 21.0, respectively; P = 0.19). There were fewer infections with Leflunomide than with the combination, both respiratory (15.0% and 34.0%, respectively; P = 0.0003) as well as urinary (0.0% and 3.0%, respectively; P = 0.10). In the basic case, the cost per patient of a yearly treatment with Leflunomide or with Infliximab and Methotrexate is estimated to be 315,023 Ptas (Spanish pesetas) (1,893 euros, €) and 2,596,286 Ptas (15,604 €), respectively. Therefore, the incremental cost of the combined treatment would be 2,281,263 Ptas (13,711 €). The sensitivity analysis was carried out using the minimum and maximum costs given by the standard deviations of the unit costs and by modifying other variables, as no significant differences compared to the basic case were found. **CONCLUSIONS:** The cost per patient after one year of treatment is higher with the combination of Infliximab and Methotrexate compared to Leflunomide, this is basically due to the higher acquisition cost of Infliximab.

**PAM13****A COST-EFFECTIVENESS MODEL COMPARING CELECOXIB AND ROFECOXIB TO TRADITIONAL NSAIDS FOR OSTEOARTHRITIS TREATMENT**

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**OBJECTIVES:** Recent studies have demonstrated slightly improved gastrointestinal (GI) complication rates with cyclooxygenase-2 (COX-2) inhibitors versus non-steroidal anti-inflammatory (NSAID) medications in patients not taking aspirin, however the cost avoidance from such events alone does not justify the high costs of these agents. Evidence that other non-GI adverse events may be lower with COX-2 inhibitors is emerging. Since efficacy of these agents appears to be similar, analysis of value can be compared by evaluating adverse event profiles. The purpose of this pharmacoeconomic model is to characterize the relative cost-effectiveness of celecoxib and rofecoxib compared to traditional NSAIDs in osteoarthritic patients not taking aspirin from the perspective of the Veterans Affairs (VA) Health care System. **METH-**

ODS: Data from recently published outcome studies was incorporated into TreeAge software to construct the one-year decision analysis model. The primary cost drivers thought to influence cost-effectiveness were complicated GI bleeds, hospitalizations, and symptomatic ulcers, as well as differences in renal toxicity, dyspepsia, anemia, hypertension and edema. Sensitivity analysis was performed on all major indices based on variations in results found in reviewed studies. **RESULTS:** Overall rates of adverse events were similar for all agents (75% NSAIDs, 72% celecoxib, 78% rofecoxib), however celecoxib was associated with less events relating to primary cost drivers. These differences are attributed mainly to variances among adverse event probabilities for hypertension and edema (NSAIDs 4.7%, 4.4%, celecoxib 1.6%, 2.9%, rofecoxib 6.4%, 6.3%, respectively). Cost of drug treatment per year for NSAIDs, celecoxib, and rofecoxib are \$36.00, \$466.00, and \$482.00, respectively, based on Federal Supply Schedule (FSS) pricing. **CONCLUSIONS:** Based on preliminary data, therapy with COX-2 inhibitors does not appear to be cost-effective to prescribe for all osteoarthritic patients within the VA Health care System. Results may be extrapolated to other health care settings assuming medical costs are similar.

**PAM14**

#### **TREATMENT WITH LEFLUNOMIDE IMPROVES THE UTILITY OF PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS: AN APPLICATION OF THE SF-6D**

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**OBJECTIVES:** To evaluate the changes in patient utility with treatment of active rheumatoid arthritis (RA) with leflunomide (LEF), placebo (PBO) or methotrexate (MTX). **METHODS:** A 52 week multicenter double-blind controlled trial comparing treatment with leflunomide, methotrexate or placebo in patients with active rheumatoid arthritis was used to derive patient utilities. Short Form 36 (SF-36) data were used to generate utility scores using the algorithm developed by Brazier et al (1999). These utilities would reflect general population values and would not be specific to an RA population. Inclusion in the utility analysis required consistent SF-36 responses, a baseline and at least one other completed assessment, and valid responses to derive the SF-6D utilities. The area under the curve was calculated for completers and the intent-to-treat population in order to estimate incremental quality adjusted life years (QALYs) for the treatments. **RESULTS:** The clinical study population consisted of 182 LEF, 180 MTX and 118 PBO patients. The population used for the utility analysis consisted of 165 LEF, 164 MTX and 114 (PBO). Baseline utility values were comparable between groups, ranging from 0.622 to 0.637. Incremental QALYs gained for

completers was statistically significantly superior for LEF over PBO ( $p = 0.0317$ ) and MTX ( $p = 0.0130$ ). Treatment with LEF resulted in an incremental gain of 0.084 QALYs, starting from a baseline of 0.622. Similar results were seen with the intent-to-treat population. **CONCLUSIONS:** Treatment of RA with LEF statistically improves patient health state utility values and QALY gain over MTX and PBO.

**PAM15**

#### **EVALUATING DIRECT AND INDIRECT MEASURES OF UTILITY: STABILITY OF THE SF-6D IN A RHEUMATOID ARTHRITIS POPULATION**

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**OBJECTIVES:** To evaluate the stability and discriminative ability of direct and indirect measures of utility in a population of rheumatoid arthritis patients. **METHODS:** Clinical trial data was used to compare the stability of direct measures of utility (SG and VAS) to that from an indirect approach to utility development (SF-6D). SF-36 data were transformed to the SF-6D utility using the algorithm developed by Brazier et al.(1999) based on values of the general UK population. These data were compared to SG and VAS data collected in the same trial. Ability to discriminate across functional classes and variance around point estimates was examined. **RESULTS:** The SF-6D generated utilities that were consistently lower than the directly elicited SG and were closer to the VAS valuations. The standard deviations, however, were consistently smaller.

	Baseline	Week 24	Week 52
SG	0.7759 (0.2399)	0.8684 (0.1850)	0.8794 (0.1858)
VAS	0.5902 (0.1942)	0.7425 (0.1623)	0.7701 (0.1629)
SF-6D	0.6287 (0.1290)	0.7323 (0.1109)	0.7443 (0.1089)

**CONCLUSIONS:** The indirect measure of utility (SF-6D) was more stable in terms of variance of parameter estimates and was able to discriminate across functional classes. The reduced variance around these estimates enhances statistical testing and accurately reflects changes experienced by the patient.

**PAM16**

#### **COST IMPACT OF COX-2 INHIBITORS IN A MANAGED CARE PLAN: IMPLICATIONS FOR FORMULARY DECISION-MAKING**

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**BACKGROUND:** Regence BlueShield, a 1.2 million-member Washington health plan currently requires prior

authorization for coverage of COX-2 inhibitors. Evidence-based coverage criteria limit these drugs to members who are at moderate to high-risk of NSAID-induced GI events. Regence was interested in the economic impact of the COX-2s. However, cost-effectiveness data were not available from the manufacturers. **OBJECTIVES:** 1) To evaluate the cost impact of COX-2 inhibitors on a managed care population. 2) To determine the appropriateness (in economic terms) of the prior authorization criteria. **METHODS:** The VIGOR trial assessed the development of clinically important ulcer events and complicated upper GI events, including perforation, obstruction, and bleeding (POBs), in patients using either rofecoxib or naproxen. Using the same DRGs and ICD9 codes in the VIGOR study, Regence obtained their own patient data for these events in the year 2000. The number needed to treat (NNT), cost to prevent one clinically significant upper GI event, and the cost to prevent one complicated upper GI event (needing hospitalization) were calculated from the data presented in the VIGOR trial. **RESULTS:** The average COX-2 drug cost per patient per year is \$1,100. The cost to prevent one clinically significant NSAID-induced upper GI event is \$46,000, and the cost to prevent one NSAID-induced complicated upper GI event requiring hospitalization, is \$137,500. In the year 2000, 443 Regence members were hospitalized for an upper GI POB with a total cost of nearly \$4 million (average \$9030 per hospitalization). **CONCLUSIONS:** In the absence of complete cost-effectiveness data, a large health plan conducted a simple, yet very useful cost impact analysis to support and inform drug policy for COX-2 inhibitors. The cost per hospitalization avoided is much higher than the actual hospitalization costs. This supported the Regence decision to limit coverage of COX-2 inhibitors to a moderate to high-risk population.

#### PAM17

### IMPORTANT ISSUES IN NUMBER NEEDED TO TREAT ANALYSIS IN OSTEOPOROSIS TREATMENT

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Number Needed to Treat (NNT) is calculated in clinical trials by taking the inverse of the difference in absolute risk in the placebo group from the treatment group. It captures how many people would need to receive a treatment to prevent a disease or event. **OBJECTIVES:** To determine the roles of treatment efficacy and population characteristics in Number Needed to Treat (NNT) calculations within randomized clinical trials of osteoporosis pharmacological agents. **METHODS:** Data were collected from publications of three major clinical trials of pharmacological osteoporosis agents. Trials evaluated were the Multiple Outcomes of Raloxifene Evaluation (MORE), Fracture Intervention Trial 1&2 (FIT) which evaluated Alendronate, and Vertebral Efficacy with

Risedronate Therapy (VERT). NNT, mean age, baseline Bone Mineral Density (BMD) at spine, baseline vertebral fracture rate, vertebral fracture rates in the placebo and treatment groups, and relative risk reductions were abstracted. **RESULTS:** The Number Needed to Treat not only varied among different agents but also in different populations where the same treatment was used. The MORE trial reported two NNTs. The "MORE 1" trial, where few participants had a prevalent vertebral fracture (11%), found an NNT of 46 while "MORE 2", where most participants had a prevalent vertebral fracture (88%), found an NNT of 16. FIT1, where all participants had prevalent vertebral fractures, reported an NNT of 15 while FIT2, no participants had a prevalent fracture, reported an NNT of 60. The VERT trial's NNT was calculated to be 20 using the above method. VERT had an 80% prevalent vertebral fracture rate. **CONCLUSION:** Variation in NNT is due to the different characteristics like placebo fracture rates as well as treatment efficacy. If one compares the trials with the most similar placebo group fracture rates, "MORE2", FIT1, and VERT, the Number Needed to Treat is quite similar. Dissimilar population characteristics as opposed to differences in treatment efficacy can be responsible for differences in NNT.

#### PAM18

### PERFORMANCE ASSESSMENT OF TWO FATIGUE INSTRUMENTS IN AN EARLY RHEUMATOID ARTHRITIS COHORT

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**OBJECTIVE:** The importance of assessing fatigue in rheumatoid arthritis (RA) has been confirmed in numerous studies. Several instruments are available to assess fatigue, however, the psychometric properties of most have been determined in various populations other than RA and the instruments tend to measure different aspects of fatigue. The objective of this study was to assess the performance of two fatigue instruments, one was developed in the RA population and the other in a nondisease-specific population. **METHODS:** This study is an ongoing prospective, multi-center, observational study conducted to document long-term functional, clinical, humanistic and economic outcomes, and treatment patterns in patients with new onset rheumatoid arthritis. Two fatigue instruments were used to assess RA patients: The Functional Assessment of Chronic Illness Therapy-Fatigue Subscale (FACIT-F), an instrument used primarily in oncology populations, and the Multidimensional Assessment of Fatigue (MAF), developed in an RA population. MAF measures four dimensions of fatigue (severity, distress, degree of interference in daily activities, and timing). At baseline, patients were requested to complete both the 16-item, MAF and the 13-item, FACT-F via telephone interview. Using baseline data only, the correlation between the MAF and the FACIT-F was tested in 133 patients with early RA (signs and symptoms >3 months and

<12 months). **RESULTS:** Patients mean + SD age was 55 + 15 years and 77% were female. Mean + SD MAF score was 23.3 + 12.3 with a normal range of 1(no fatigue)–50(fatigue). Mean FACIT-F score was 33.2 + 9.3 with a normal range of 52 (no fatigue)–0 (fatigue). The aggregate scores for each instrument were highly correlated with a Pearson's coefficient of  $-0.81$  ( $p < 0.001$ ). **CONCLUSION:** Based on this analysis, it appears that the FACIT-F has validity for use in the early RA population. However, as follow-up assessments are completed, a more detailed analysis may reveal additional psychometric properties of the instrument in the early RA population and with disease progression.

#### PAM19

### A REVIEW OF FUNCTIONAL STATUS MEASURES FOR WORKERS WITH UPPER EXTREMITY DISORDERS

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**OBJECTIVES:** This review identifies instruments for measuring functional status among workers with mild-to-moderate disorders of the upper extremity. Functional status measures correlate pain and discomfort to performance, with direct, practical relevance to employers and workers. While many functional status measures exist for patients with severe or degenerative illness, few measures were designed for relatively healthy active workers. In fact, the impact of mild-to-moderate disorders on the workforce is largely unknown. The recently released OSHA Ergonomics Program Standard has given this issue a new sense of urgency. The intent is to give investigators a tool for choosing appropriate functional status measures in a specific research or clinical context. **METHODS:** To identify self-reported functional status instruments for upper extremity disorders among workers, a Medline literature search was conducted for English-language publications between the years 1966 and 2000. Keywords included: carpal tunnel syndrome, functional status, health surveys, musculoskeletal, occupational health, outcome measures, questionnaire, neck, upper extremity, and worker. In selecting functional status instruments for review, three criteria were used: 1) Relevance to neck and upper extremity conditions (indicated by question content); 2) Assessment among workers; and 3) Relevance to mild-to-moderate disorders (indicated by level of severity). Parameters of interest were validity, reliability, and responsiveness to change. **RESULTS:** Among 13 functional status instruments reviewed, six measures were tested among workers, including three measures relevant for mild-to-moderate disorders: the Nordic Musculoskeletal Questionnaire, Upper Extremity Questionnaire, and Neck and Upper Limb Instrument. **CONCLUSIONS:** The identification of three functional status measures should encourage their use in studies, to

improve communication among investigators. Further research is needed to address neglected aspects of measurement—specifically, for mild-to-moderate upper extremity disorders among workers—and to standardize valid and reliable instruments.

#### PAM20

### COST-EFFECTIVENESS OF ACETYLICISTEINE AND DIMETHYLSULPHOXIDE (DMSO) 50% FOR THE TREATMENT OF PATIENTS WITH REFLEX SYMPATHIC DYSTROPHY

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**OBJECTIVE:** The aim of this study was to determine the cost-effectiveness of Acetylcysteine and DMSO in the treatment of patients with reflex sympathetic dystrophy (RSD). **METHODS:** The study was a prospective, double-dummy, double blind, controlled trial. Patients were followed for one year. The primary outcome measure was the Impairment-level Sum Score (ISS). Cost data were prospectively collected using cost-diaries. Utilities were determined using the EuroQol. Both cost-effectiveness and cost-utility analyses were performed. Differences in mean direct, indirect and total costs between groups were estimated with corresponding 95% Confidence Intervals (CI). Also cost-effectiveness and cost-utility ratios with corresponding 95% CI were calculated using bootstrapping techniques. **RESULTS:** There was a statistically significant difference in effect (ISS). DMSO generated more reduction than Acetylcysteine (diff: 1.82 CI:  $-4.90$ ;  $-1.27$ ). This significant difference appeared also in the subgroup of patients with warm RSD. The total costs were statistically significant lower in the DMSO compared to the Acetylcysteine group (diff: 2866 CI: 666;5179). This significant difference was also found in the subgroup of patients with warm RSD. The cost-effectiveness and cost-utility ratios showed that DMSO is dominant over Acetylcysteine. **CONCLUSION:** In general, DMSO is the preferred method of treatment for patients with RSD. There are some indications that Acetylcysteine may be more cost-effective for cold RSD, but this was found in a small subgroup only and should be confirmed in a larger trial.

#### PAM21

### MANUAL THERAPY IS MORE COST-EFFECTIVE THAN PHYSICAL THERAPY AND GP CARE FOR PATIENTS WITH NECK PAIN

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**OBJECTIVES:** This paper presents the results of an economic evaluation in conjunction with a randomized controlled trial to evaluate the cost-effectiveness of manual therapy, physical therapy and GP care for patients with



neck pain. **METHODS:** Patients were recruited by 42 general practitioners if they had been suffering from neck pain for at least two weeks. The 183 patients were randomly allocated to manual therapy (spinal mobilization,  $n = 60$ ), physical therapy (exercise therapy and massage, 59), or GP care (counseling, education and medication,  $n = 64$ ). Clinical outcomes included perceived recovery, pain intensity, functional disability and quality of life (EuroQol). Direct and indirect costs were measured by means of cost diaries completed by patients during the intervention period and the 52-week follow up. Differences in mean costs between groups were evaluated by applying non-parametric bootstrapping techniques. **RESULTS:** The total costs of the manual therapy (Euro 447) were approximately one-third of the costs of the physical therapy (Euro 1,297) and GP care (Euro 1,379). These differences were found to be statistically significant when bootstrapping was applied. The cost-effectiveness ratios and the cost-utility ratios showed that manual therapy was dominant (less costly and more effective), compared to physical therapy and GP care. The recovery rates based on perceived recovery after 12 months were 72% for manual therapy, 63% for physical therapy and 56% for GP care. With regard to pain intensity and functional disability, manual therapy was also found to be dominant over time, compared to physical therapy and GP care, for these clinical outcomes, although the differences were small. **CONCLUSIONS:** This study showed that manual therapy (spinal mobilization) is more effective and less costly than physical therapy and GP care.

**PAM22**

### STUDYING PREDICTORS OF FRACTURES AMONG OMNICARE NURSING HOME RESIDENTS

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Upon admission to a skilled nursing home facility, information is recorded on a Minimum Data Set (MDS), a 400 item instrument used as the basis of 1) reimbursement for Medicare eligible nursing home stays and 2) care planning, survey and certification for all nursing home stays. **OBJECTIVE:** To predict and evaluate variables related to hip fractures in the nursing home setting. **METHODS:** Electronic MDS data was available from 200 homes for variable evaluation times. The first available Assessment Reference Date (A3A), was the baseline for a regression of time to first fracture. Excluded were 1) patients with a fracture having an A3A date within the first 10 days of baseline visit, and 2) patients with <60 days of follow-up, from first to last A3A visit. Analysis included a Kaplan-Meier curve summarizing time to fracture, and a Cox Proportional Hazards regression model.

**RESULTS:** The initial data set included 23,045 patients. 11,465 met the inclusion criteria, and 336 of these had fractures. Most important variables, based on the coefficient size, associated with increasing risk, were unsteady gait, deterioration in ADL function, a hospital stay in the last 90 days, use of full bed rails, and Alzheimer's disease. The risk was also higher among females and whites. The need for full physical help while standing had a lower risk when compared to need for less support, but this is likely due to a lowered potential for falling, and increased vigilance on the part of staff. "Deteriorated" ADL function had almost twice the risk when compared to "improved" ADL. **CONCLUSION:** Unsteady gait, deterioration in ADL, use of bed rails, presence of Alzheimer's disease, and hospital admissions were associated with an increased risk of hip fracture. A larger sample of fractures would be more likely to be successful in studying additional relationships.

**PAM23**

### VERTEBRAL FRACTURES AMONG GLUCOCORTICOID PATIENTS SIGNIFICANTLY INCREASE MEDICAL CARE COSTS

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**BACKGROUND:** Previous studies have demonstrated that high levels of glucocorticoid (GC) exposure are associated with increased fracture risk. However, none has reported potential cost impacts. **OBJECTIVE:** To estimate the marginal costs from vertebral fractures among GC patients. **METHODS:** Subjects 18–64 years old with different GC exposure levels, with and without fractures, were selected ( $n = 50,191$ ). GC exposure was categorized into three levels: high (3+ claims of continuous use or >9.5 prednisone-equivalent mg/day), low (other GC use), and no GC use. Fractures, comorbid conditions, and costs were determined 15 months before and up to 3.5 years after index date. Regression models were used to estimate the marginal effects of vertebral fractures on pharmacy costs, medical costs and total costs. The models controlled for age, gender, pre-index date costs, GC exposure/fracture combinations, and pre-index and new post-index date comorbid conditions. **RESULTS:** Vertebral fractures led to significant per-member per-month (PMPM) cost increases in each GC exposure group. Furthermore, the additional increase in marginal cost from vertebral fracture on total PMPM costs among high GC patients versus low GC patients was 83% (\$170;  $p < 0.001$ ). Differential increases in pharmacy and medical PMPM costs between high and low GC patients were 151% (\$56;  $p < 0.01$ ) and 68% (\$115;  $p = 0.014$ ), respectively. **CONCLUSIONS:** Vertebral fractures were associated with increased PMPM costs, holding constant patients' underlying conditions. High GC patients had greater PMPM increases from vertebral fractures com-

pared to those with low or no GC exposure. These findings provide new evidence that vertebral fractures have substantial increases on treatment costs among GC patients. Also, greater PMPM increases from vertebral fractures among high GC patients versus low GC patients suggest vertebral fractures increase in severity with GC exposure. These results also support the need for adjuvant therapy to reduce fracture risk and associated morbidities.

## ASTHMA & RESPIRATORY DISORDERS

### PAR I

#### COST OF ASTHMA IN CHILDREN IN VLADIVOSTOK

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**OBJECTIVES:** Estimation the cost of asthma in children in Vladivostok. **METHODS:** In cost of disease we determined direct expenses: pharmacotherapy, hospital, outpatient and emergency expenditures; indirect expenses: disability pension, temporary invalidity of parents and quality of child's life with asthma in Vladivostok during 1995–1998. 645 families with asthmatic children filled in a questionnaire. **RESULTS:** Family expenses on pharmacotherapy of asthmatic child during the 1996 year averaged 1520,81 roubles (rb) (\$303), in 1998—increased to 2149,45 rb at the expense of basic therapy. In 1996 direct family expenses on asthmatic child was  $10,98 \pm 1,33\%$  of annual income, in 1998— $13,70 \pm 1,46\%$  and bulk of the expenditures was pharmacotherapy. 1159 children with asthma in 1995 had 618 cases of hospitalization, total duration was 16 058 days. One child with asthma in 1995 year had  $13,64 \pm 1,0$  days of hospitalization, in 1998— $8,81 \pm 0,92$ . Volume of hospitalization depended on heaviness of disease. In 1996 among 22 651 emergency cases in city 230 (1,02%) was to asthmatic children. In 1998 this index was decreased to 109. In 1996 out-patient expenses one asthmatic child was  $223,05 \pm 32,50$  rb, in 1998— $272,46 \pm 36,96$  rb. In 1997–1998 expenses for allergologist and pulmonologist are increased. In 1996 among 1028 asthmatic children 37 got disability pension (270 rb in month). Total family expenses on asthmatic child in Vladivostok in 1996 was  $4070,84 \pm 86,70$  rb ( $\$810,83 \pm 10,63$ ), in 1997— $4767,58 \pm 69,94$  rb ( $\$821,99 \pm 8,46$ ), in 1998— $4203,58 \pm 46,24$  rb. In 1996 on asthmatic child in Vladivostok bulk of the expenditures was hospitalization, in 1998—pharmacotherapy. **CONCLUSION:** Introduction in Vladivostok in 1997–1998 the National program of treatment asthma in children resulted in wide use of basic therapy, increasing family expenses asthmatic child on pharmacotherapy and decreasing municipal expenses on hospitalization, emergency care and indirect losses of family.

### PAR 2

#### USE OF RESPIRATORY ASSIST DEVICES BY MEDICARE BENEFICIARIES

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**OBJECTIVES:** To identify factors associated with the increase in the use of bilevel positive pressure ventilators with timed backup in the Medicare population from 1996 through 1999. **METHODS:** We extracted durable medical equipment claims for bilevel positive pressure ventilators with and without timed backup (RAD and RAD-timed, respectively), continuous positive airway pressure devices (CPAP) and oxygen supplies (gas, liquid, concentrator) from the 1994–1999 claims files for 5% of Medicare beneficiaries, and compared disease prevalence, oxygen use, and other factors in the different user groups. **RESULTS:** Between 1994 and 1998, new use increased for both RAD and RAD-timed devices, but was significantly greater for the latter. Oxygen use remained relatively stable among CPAP and RAD users, but increased in RAD-timed users. RAD-timed users were more likely than RAD users to have claims for oxygen (80% vs. 44%), or diagnoses suggesting chronic lung disease (86% vs. 35%) in the first year of device use; RAD users were more likely to have a diagnosis of sleep apnea/other sleep disorder in the first year of use (73% vs. 14%). **CONCLUSIONS:** Debate continues over appropriate indications, servicing and reimbursement for respiratory assist devices, particularly those with timed backup. RAD and RAD-timed device users differ significantly. The high prevalence of COPD diagnoses reflects current interest in the use of these devices in the long-term treatment of this disorder; other indications suggested in the literature, such as respiratory support in neuromuscular disorders or congestive heart failure, appeared rarely. Growth in the use of the more costly RAD-timed devices among oxygen users varied by region as well as by year, possibly reflecting regional differences in coverage, medical practice or marketing. Person-level, longitudinal analysis of claims data supports the development and implementation of coverage and payment policies, by helping to delineate the demographic and clinical characteristics of user groups.

### PAR 3

#### THE STANDARDIZED ASTHMA-RELATED QUALITY OF LIFE QUESTIONNAIRE (AQLQ-S): DOES SOCIOECONOMIC STATUS EFFECT MEASUREMENTS?

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**OBJECTIVE:** The objective of this analysis was to evaluate the impact of social class on correlation between the standardized AQLQ, self-rated asthma severity and con-

rol, and patient utility. **METHODS:** 84 asthmatic subjects completed the AQLQ. Self-rated asthma severity and control was measured on a 5-point Likert scale and utilities were measured using a rating scale. SES was defined based on receipt of social assistance. Correlations between AQLQ scores and each other variable were measured using Spearman's Rank correlation coefficient ( $r_s$ ). Differences in  $r_s$  between social classes ( $r_{s,diff}$ ) were analyzed using Fisher's  $r$  to  $z$  transformation (2-tailed). **RESULTS:** 38 (45%) patients were receiving social assistance. In the entire sample, there was significant correlation ( $p < 0.05$ ) between all AQLQ scores (symptoms, activity, emotion, environment, and global), self-rated asthma severity ( $r_s = 0.21-0.38$ ), control ( $r_s = 0.21-0.38$ ), and utilities. Symptom, activity, and global AQLQ scores were correlated strongly with utility ( $r_s = 0.53-0.54$ ;  $p < 0.0001$ ) and moderately with environment and emotion scores ( $r_s = 0.38$ ;  $p = 0.002$ ). However, AQLQ scores were consistently more strongly correlated with self-assessed severity and control in lower SES patients. Although  $r_s$  diff ranged from 0.07 to 0.55 (mean = 0.27), only the most extreme difference was significant (activity score and control -  $r_s$  diff = 0.55;  $p = 0.01$ ). Conversely,  $r_s$  between all AQLQ scores and utility were consistently lower (mean  $r_s$  diff = 0.18; range 0.9-0.23) in patients on social assistance, although not significantly. **CONCLUSIONS:** Correlations between AQLQ scores and utility were consistently lower in lower SES subjects, suggesting that AQLQ may be a better measure of overall health in higher SES patients. Conversely, AQLQ scores correlated more strongly with self-rated asthma severity and control in lower SES subjects. Although most differences were not significant despite their magnitude, this is likely due to a recognized lack of power of the Fisher's  $r$  to  $z$  transformation test.

#### PAR4

### COMPARISON OF TWO QUALITY OF LIFE INSTRUMENTS IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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**OBJECTIVE:** The St. George's Respiratory Questionnaire (SGRQ) has been validated and widely used in assessing health-related quality (HRQL) of life among Chronic Obstructive Pulmonary Disease (COPD) patients but it is complicated to score and can be a burden on respondents when there is limited time. A shorter and more concise instrument, Airways Questionnaire (AQ30), was developed to measure Quality of Life (QoL) of patients with obstructive airways. The AQ20 contains 20 items on the AQ30. The purpose of this study was to evaluate and compare the responsiveness of the AQ20 and the SGRQ questionnaires to measure health-related quality of life of patients with COPD. **STUDY DESIGN:** Responses from a survey of 1,000 COPD patients participating in a pilot health management program were included in the analysis. A total of 181 COPD patients

completed the AQ20 and the SGRQ. Spearman's Rank correlation was used to determine if the AQ20 and the SGRQ scores for symptoms, activity and impact and the overall score were correlated. A high correlation suggests that both surveys are capturing the same information. **RESULTS:** Scores for both AQ20 and the SGRQ were available for 181 cases. The correlation between the AQ20 and the symptoms component scores was 0.67 ( $p < 0.05$ ). Correlation between the AQ20 and the activity component was 0.69 ( $p < 0.05$ ) and the AQ20 and the impact component was 0.79 ( $p < 0.05$ ). The correlation between the AQ20 and the total SGRQ was 0.82 ( $p < 0.05$ ). **CONCLUSION:** The AQ20 appears to have similar properties and responsiveness that are similar to complex questionnaires such as the SGRQ. Because it is short and easy to administer the AQ20 may be useful in settings with limited time for HRQL assessments.

#### PAR5

### DIRECT AND INDIRECT COSTS OF RESPIRATORY INFECTIONS

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**OBJECTIVES:** Morbidity due to respiratory infections leads to significant adverse societal and economic consequences. This study investigates the extent to which treatment for respiratory infections imposes a financial burden on an employer, and documents variations in employer payments between specific respiratory infections. **METHODS:** The data source is a rich administrative claims database for a national, Fortune 100 manufacturer. It includes 1997 medical, pharmaceutical, and disability claims for employees, spouses, dependents, and retirees ( $n > 100,000$ ) under age 65. The research sample consists of individual patients with one or more medical or disability claims for at least one of eleven respiratory infection condition. Resource utilization is contrasted with a 10 percent random sample of the employer's overall beneficiary population. **RESULTS:** Direct (medical and pharmaceutical) and indirect (disability and sporadic absenteeism) costs are analyzed. The average per capita annual costs are: for the entire employer population, \$2,368; for all respiratory infections patients, \$4,397; and for respiratory infections employees eligible for disability, \$6,838. Total costs for respiratory infections patients are 1.8 times those for the typical beneficiary. Total costs are highest for patients with pneumonia (\$11,544) and lowest for patients with acute tonsillitis and acute pharyngitis (\$2,180). Medical and pharmaceutical treatment account for 65% of total costs for all respiratory infections employees, while the remaining 35% of costs are attributable to disability and sporadic absenteeism. **CONCLUSIONS:** Respiratory infections impose a significant financial burden on the employer. Resource utilization by respiratory infections patients is substantial, not only for

the direct treatment of respiratory infections, but also for the treatment of co-morbid medical conditions of respiratory infections patients. These costs also vary considerably by type of respiratory infection. The study also shows that respiratory infections impose substantial indirect costs on employers from work loss associated with these infections.

**PAR6**

### PROPHYLACTIC MEDICATION UTILIZATION AND HEALTH CARE COSTS IN OLDER ADULTS WITH CHRONIC PULMONARY AILMENTS

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**OBJECTIVES:** To examine the relationship between self-reported health status, prophylactic medication utilization, and health care service utilization in older adults with asthma. **METHODS:** *Design:* A prospective longitudinal cohort study was conducted over a 2-year post-enrollment period in a population of managed care enrolled asthmatic older adults. Patients completed a comprehensive health risk screen at time of enrollment in the plan. *Setting:* A Medicare HMO in the Southeastern United States with prescription benefit. *Participants:* A total of 129 Medicare-HMO enrolled older adults with asthma using inhaled corticosteroid therapy as prophylaxis were available for complete follow up. *Measurements:* We measured self-reported health perception, falls, lifestyle, depressive symptomatology, and pre-enrollment health care service use using a comprehensive risk screen. We used the medication possession ratio and total annual health care charges as measures of post-enrollment inhaled corticosteroid and health care service use. **RESULTS:** After adjusting for the effects of other variables we found that depressive symptomatology (DS) at baseline and increased comorbidity severity (using the Charlson comorbidity index) were associated with significant reductions in prophylactic medication possession (27% with DS, and 6% with unit increase in Charlson's index,  $p < 0.05$ ). Additionally we found, after adjusting for the effects of baseline health status, a 10% increase in prophylactic medication possession was associated with a 5% decrease in total annual health care charges in this population ( $p < 0.05$ ). **CONCLUSIONS:** There seem to be strong associations between poor health status at time of enrollment, decreased post-enrollment prophylactic medication use and increased post-enrollment health care service utilization in older adults with asthma.

**PAR7**

### VALIDATION OF A MODEL OF SEVERITY OF ILLNESS IN CHRONIC RESPIRATORY DISEASE

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**OBJECTIVES:** The purpose of this study is to adapt a previously validated questionnaire to a pharmacy claims database and examine its construct validity in measuring severity of illness in chronic respiratory disease (CRD). **METHODS:** The authors modified an asthma severity of illness questionnaire (13 items, total score range 0–28) based upon symptoms, medication use, hospitalization information and intubation history to a scale that is more conducive to retrospective data analysis. The adapted CRD scale (CRDS) was based on pharmacy claims data and hospitalization history (11 items, total score range 0–18). The CRDS was compared to utility as measured by a general health visual analogue scale and quality of life (QoL) as measured by the Physical Component Scale (PCS), Physical Function (PF) and General Health (GH) domains of the SF-36. Panel data analysis was performed on pharmacy claims and survey data from the Kaiser Permanente/USC Consultation Study. QoL and utility were regressed on the CRDS, along with covariates. A non-respiratory chronic disease score was used to control for chronic disease while avoiding significant multicollinearity. The analysis was limited to 126 patients with CRD followed over 3 years. The Hausman specification test was used to determine the appropriateness of the random-effects model formulation. **RESULTS:** The Hausman specification test suggested the use of the fixed-effects formulation for utility ( $m = 8.2, p > m = 0.0420$ ). The CRDS was negative and significant ( $-1.79, p < 0.0286$ ). The Hausman test suggested a fixed-effects formulation for PCS ( $p > m = 0.0333$ ) and random-effects for GH ( $p > m = 0.0628$ ) and PF ( $p > m = 0.1495$ ). The CRDS was significant and negative for all three QoL domains: (PCS:  $-0.68, p < 0.0085$ ; PF:  $-0.97, p < 0.0130$ ; GH:  $-0.065, p < 0.0077$ ). **CONCLUSION:** The adaptation of the asthma severity of illness questionnaire appears to be a valid measure of chronic respiratory disease in a pharmacy claims database.

**PAR8**

### A COST-EFFECTIVENESS ANALYSIS COMPARING LEVALBUTEROL AND ALBUTEROL IN THE TREATMENT OF MODERATE TO SEVERE ASTHMA

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**OBJECTIVES:** Adult patients with moderate to severe asthma could potentially avoid utilizing excessive health care resources by reducing the need for management of severe adverse effects associated with albuterol. This modeled analysis was performed from a managed care payer perspective to determine if nebulized levalbuterol is associated with a lower cost per decreased use of rescue inhaler, as compared with nebulized racemic albuterol over a four week period. **METHODS:** Cost data was obtained from a public hospital, an HMO, and the Red Book. Costs were measured in 2000 US dollars. Probabilities were derived from a clinical controlled trial and the National Center for Health Statistics. The primary out-

come of interest was cost per decreased puff of rescue medication per twenty eight days. **RESULTS:** Levalbuterol (1.25 mg) decreased puffs by 7.5 over twenty eight days. However, the average expected costs for treatment with racemic albuterol (2.5 mg) is \$116.94/month, \$171.46/month for levalbuterol (0.63 mg) and \$182.33/month for levalbuterol (1.25 mg). Cost-effectiveness ratios were \$8.35, \$24.50, and \$8.80 for albuterol (2.5 mg), levalbuterol (0.63 mg) and levalbuterol (1.25 mg), respectively. Results were unchanged after sensitivity analyses. **CONCLUSIONS:** Levalbuterol (1.25 mg) was beneficial over racemic albuterol (2.5 mg) in decreasing puffs of rescue medication over twenty eight days, but at an additional cost. An incremental cost-effectiveness analysis demonstrated it costs \$9.73 for each additional decreased puff per day. The decision-maker needs to evaluate whether the additional effect is worth the added cost.

**PAR9**

### **VALIDATION OF A RATING INSTRUMENT ASSESSING THE INHALATION SKILLS OF CHILDREN WITH ASTHMA**

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**OBJECTIVES:** Despite their complexity appropriate use of asthma inhaled medicines is crucial to ensure optimal drug delivery to the airways. We describe the validation of an instrument to assess inhalation skills in children. **METHODS:** The instrument includes a breakdown of the steps necessary for appropriate inhalation. We videotaped 25 children taking a placebo inhaler (metered dose inhaler (MDI), MDI with AeroChamber® (MDI-AE®), and Diskus®). A gold standard (GS) was developed by agreement of two asthma experts watching the videotaped demonstrations. Twenty-one raters scored the randomly ordered demonstrations twice within a 2-week interval (sessions 1 and 2). Intra-class correlation coefficients (ICCs) were calculated to assess validity (comparing GS to raters' scores), interrater reliability, and test-retest reliability for each step of the inhalation. **RESULTS:** ICCs varied considerably by both, the device and the step. In session 1, a small proportion of raters agreed with the GS on whether patients actuated the MDI and inhaled simultaneously (9.5%, ICCs 0.62 to 0.74) and whether patients hold their breath (19%, ICCs 0.62 to 1.00). A better agreement was observed for the MDI-AE® where actuation (43%, ICCs 0.43 to 0.56) and inhalation (57%, ICCs 0.43) are two separate steps. The best interrater agreement was on the shaking of the MDI (ICC = 0.83) and the MDI-AE® (ICC = 0.74). Agreement for the Diskus® was poor for all steps. Results for session 2 were similar. The best intra-rater agreement was for the Diskus® (ICCs = 1 for 5 steps), though only a small proportion of raters agreed on these steps (5% to 21%). **CONCLUSIONS:** There was large variability within and between raters' scores. Some steps were better assessed than others. These results suggest that in addition to a detailed instrument, training of

raters is crucial to obtain a valid assessment of the children's inhalation technique.

**PAR10**

### **IMPLEMENTING RASCH ANALYSIS IN PSYCHOMETRIC EVALUATION OF PATIENT-PHYSICIAN INTERACTION SCALE**

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**OBJECTIVES:** The study involved validating the scaling properties of patient-physician interaction scale in a pulmonary specialty clinic using a clinic-specific scale through the implementation of Rasch analysis. **DATA:** Cross-sectional data from 65 adult asthma patients at the University of Illinois Asthma clinic was used. Physician interaction was measured using eight Likert-type items. Patients responded from "strongly disagree" (1) to "strongly agree" (4). **METHODS:** Scaling properties were assessed by investigating its fit to a Partial Credit Rasch Rating scale model that enabled item-by-item analysis. Winsteps® was used for analysis. Model determined scale robustness in terms of unidimensionality, additivity and functioning of the rating scale. **RESULTS:** Analyses found person separation index of 1.86 with reliability of 0.77. The mean patient measure (0.69 logit) was greater than mean difficulty of items (0.00 logit) implying patient ability was greater than item difficulty. On average, ordering of items found item 'physician instructed patients on home steroid treatment' (STETX) had the highest logit measure of 0.69, however it misfitted the model. Item 'physician asked about smoking habits' (ASKSMOK) had lowest measure of -0.70 logits. Fit statistics revealed high infit and outfit mean square (MNSQ) values (>1.4) for 16 patients. Seven items had MNSQ values within desired range of 0.6-1.4. **CONCLUSIONS:** Items exhibited adequate reliability in separating persons, but they displayed ceiling and floor effects in measurement. Some evidence of construct validity was established since only one item misfitted the model. Item STETX was the most difficult to endorse (higher on construct), since it might not be applicable to all, but severe asthmatics. Item 'ASKSMOK' was easiest to endorse, probably because it is a standard asthma care question. Nevertheless, misfitting persons implied inappropriate measurement of some patient attitudes. Thus, some plausibility in the unidimensionality and validity of the scale existed, and it exhibited moderate scaling properties.

**PAR11**

### **THE LONG-TERM SOCIETAL ECONOMIC AND HUMANISTIC BENEFITS OF TREATING ACUTE EXACERBATIONS OF CHRONIC BRONCHITIS (AECB) WITH GEMIFLOXACIN VERSUS CLARITHROMYCIN**

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**OBJECTIVES:** To prospectively evaluate the long-term societal economic and humanistic benefits of acute treatment of AECB with gemifloxacin compared with clarithromycin. **METHODS:** Patients with AECB were randomized to receive acute, double-blind, double-dummy treatment with either gemifloxacin 320 mg o.d. for 5 days or clarithromycin 500 mg b.d. for 7 days. Patients in US (n = 386) and Canadian centers (n = 52) were followed for 26 weeks from treatment initiation and the following assessments were made: AECB recurrence requiring antibiotic treatment; respiratory tract infection-related: health care resource utilization, time off and performance at work and usual activities; and health-related quality of life using the St George's Respiratory Questionnaire (SGRQ). **RESULTS:** In full sample analysis, significantly more patients who received gemifloxacin remained recurrence free after 26 weeks (73.8% [158/214] vs. 63.8% [143/224]; p = 0.024) and were hospitalized less (2.34% [5/214] vs. 6.25% [14/224]; p = 0.059). Cost-effectiveness analysis indicated average direct and indirect cost savings of \$329 per patient for gemifloxacin vs. clarithromycin. Ninety-five percent confidence intervals for bootstrapped incremental cost-effectiveness ratios ranged from a cost saving of \$14,175 to a cost of \$8,888 per recurrence-free patient considering all costs. There was an 82.5% probability of gemifloxacin being both cost saving and more effective than clarithromycin from the societal perspective. A greater improvement in total weighted SGRQ score (lower scores being better), adjusted for baseline, was observed for gemifloxacin vs. clarithromycin at 4, 12 and 26 weeks after initiation of acute treatment (43.3 vs. 44.6 [p = 0.38], 39.4 vs. 41.8 [p = 0.20] and 37.7 vs. 41.0 [p = 0.09], respectively). There was significantly less impact on performance at work (p = 0.01) and usual activities (p = 0.03) at 26 weeks, due to bronchitis, among patients who received gemifloxacin. **CONCLUSIONS:** Gemifloxacin was very cost-effective from the societal perspective and improved long-term patient outcomes compared with clarithromycin for the treatment of AECB.

#### PAR 12

### PROSPECTIVE USE OF WEB BASED TECHNOLOGY TO EVALUATE HEALTH OUTCOMES IN A LARGE COHORT OF SEVERE OR DIFFICULT TO TREAT ASTHMATICS

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Severe and difficult to treat asthma patients represent a small percentage of all asthmatics, yet they account for much of the morbidity, mortality, and cost of the disease. The factors that make this group of asthmatics difficult to manage are poorly understood. **OBJECTIVE:** To es-

tablish a cohort of severe or difficult to treat asthmatics to examine the relationships between features of asthma, treatments and health outcomes using the Internet. **METHODS:** This study, "An Observational Study of The Epidemiology and Natural History of Asthma: Outcomes and Treatment Regimens (TENOR)," is designed to follow at least 5000 subjects for 3 years. Subjects 6 years or older with a diagnosis of asthma and considered by their physician to have severe or difficult to treat asthma are eligible for enrollment. Physicians and coordinators will conduct biannual visits to collect data including: health care utilization, days of work or school missed, the asthma therapy assessment questionnaire (ATAQ), asthma-related quality of life (AQLQ), medications, IgE level, and lung function. Data will be entered onto a secure website. **RESULTS:** Subjects are being enrolled into the cohort from over 300 US pulmonologists and allergists in managed care organizations, community practices, and academic centers. All study sites have Internet access. The TENOR website was built using WebCollectSM services and PhaseForward's InFormTM application. Built-in edit checks and an automatic electronic audit trail ensure data accuracy and completeness. This technology eliminates the need for paper case report forms and improves data cleaning efficiency. **CONCLUSIONS:** TENOR provides a unique opportunity to examine factors related to poor health outcomes in this understudied patient population. The Internet allows real time access to data and facilitates dissemination of data to investigators and the asthma community. TENOR may serve as a model for future large epidemiologic or clinical studies using web-based technology.

#### PAR 13

### HYPOTHETICAL VERSUS REAL WILLINGNESS TO PAY IN THE HEALTH CARE SECTOR: RESULTS FROM A FIELD EXPERIMENT

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**OBJECTIVE:** Despite increased use in the health care sector (HCS), the contingent valuation (CV) method remains controversial. The nucleus of the controversy is the extent to which hypothetical choices in the CV method mimic real economic choices. Correspondence between hypothetical and real willingness to pay (WTP) has been studied for private and environmental goods. These experiments demonstrate that dichotomous choice (DC) CV questions lead to hypothetical bias (overestimation of real WTP). Hypothetical bias has not been assessed in the HCS. We conducted an experiment directly comparing responses to a DC CV question with real purchase decisions using a pharmacist provided asthma management

service as the item being valued. We examined whether DC CV questions lead to hypothetical bias for this good, and we tested whether “definitely sure” hypothetical yes responses, as identified in a follow-up question, correspond to real yes responses. **METHODS:** 172 subjects with asthma were recruited from 10 Kentucky community pharmacies. Subjects received either a DC CV question or were given the opportunity to actually purchase the service. Three different prices were used: \$15, \$40, and \$80. **RESULTS:** In the hypothetical group 38% of subjects stated they would purchase the good at the given price, but only 12% of subjects in the real group purchased the good ( $p = 0.000$ ). We cannot, however, reject the null hypothesis that “definitely sure” hypothetical yes responses correspond to real yes responses. **CONCLUSIONS:** The DC CV method overestimates WTP in the HCS, but it may be possible to correct for this by sorting out “definitely sure” yes responses.

#### PAR14

##### ASSESSMENT OF THE RELATIONSHIP BETWEEN DISEASE SEVERITY, QUALITY OF LIFE AND WILLINGNESS TO PAY IN ASTHMA

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**OBJECTIVE:** The primary objective was to evaluate the relationship between willingness to pay (WTP), quality of life (QOL), and disease severity measures in asthma patients. The hypothesis studied was that asthma patients with more severe disease, as measured objectively via forced expiratory volume percent predicted (FEV1%), are willing to pay more for a hypothetical cure from asthma than those with less severe disease. **METHODS:** One-hundred asthmatic patients were recruited from community pharmacies in Kentucky for 30 minute face-to-face interviews. Spirometry was used to assess objective disease severity while a multiple choice question assessed subjective disease severity. The Short Form 36 (SF-36) and Asthma Technology of Patient Experience (Asthma TyPE) measured QOL. WTP was obtained via a dichotomous choice contingent valuation question. **RESULTS:** WTP was significantly related to both objective disease severity ( $p = 0.02$ ) and subjectively assessed disease severity ( $p = 0.01$ ). For objective disease severity the mean monthly WTP was \$90 for mild asthma, \$131 for moderate asthma and \$331 for severe asthma; and for subjective disease severity the mean monthly WTP was \$48 for mild asthma, \$166 for moderate asthma and \$241 for severe asthma. A majority of the QOL measures were correlated with WTP. **CONCLUSIONS:** The results suggest that the WTP for a cure from asthma is related to both objective and subjective disease severity.

#### PAR15

##### COMPARISON OF HEALTH CARE RESOURCE UTILIZATION OF COPD PATIENTS ON CILOMILAST, 15 MG BID VERSUS PLACEBO

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**OBJECTIVES:** Cilomilast is a potent and selective phosphodiesterase type 4 (PDE4) inhibitor currently under development for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. **METHODS:** COPD-related health care resource utilization including physician visits, emergency room visits, hospitalizations and medication use were prospectively collected in a 6 month randomized, double-blind, placebo controlled, parallel group study of patients on cilomilast, 15 mg bid ( $n = 431$ ) versus patients on placebo ( $n = 216$ ). Methods of analysis included descriptive statistics, Kaplan-Meier estimates and Poisson regression. **RESULTS:** In the year prior to the study, COPD-related health care resource utilization was comparable between patients eventually randomized to cilomilast and those randomized to placebo; the majority of all patients had no or one emergency room visit or hospitalization. During the entire 24-week study period, the cumulative incidence of health care utilization was significantly lower in the cilomilast group than the placebo group in terms of all utilization (11.0% vs. 21.1%,  $p = 0.004$ ); including physician visits (11.9% vs. 23.1%,  $p = 0.002$ ), emergency room visits (0.6% vs. 4.5%,  $p = 0.004$ ) and hospitalization (0.5% vs. 3.4%,  $p = 0.021$ ). The relative utilization rates per patient-month of follow-up for each of the utilization types were lower in the cilomilast group than in the placebo group. Treatment with cilomilast resulted in reduction of all utilization by 51% (C.I.: 31%, 65%), physician visits by 41% (C.I.: 15%, 59%). ER visits and hospitalizations were also significantly reduced. **CONCLUSIONS:** In this study, cilomilast was associated with significantly less COPD-related health care resource utilization, including hospitalizations, emergency room visits and physician visits than placebo.

#### PAR16

##### COST OF TREATING ASTHMA IN A MANAGED CARE POPULATION

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**OBJECTIVES:** Asthma is a common medical condition that is increasing in prevalence. The purpose of this study was to examine costs associated with treating asthma patients within a managed care organization (MCO). **METHODS:** Data for this study were obtained from a managed care organization located in the Western region of the US. Patients were eligible for inclusion if they met one of the following criteria: a diagnosis of asthma (ICD-9 code of 493.xx); two or more prescriptions used to control asthma (e.g., inhaled corticosteroid, leukotriene

modifier, mast cell stabilizer, xanthine derivative, or a long acting beta agonist); or one prescription for an asthma controller and one or more prescriptions for a short acting beta-agonist. Patients also had to be full year members of the MCO. Patients with a diagnosis of chronic obstructive lung disease were excluded. **RESULTS:** A total of 351,140 persons were continuously enrolled in the MCO during 1999. A total of 8,051 persons were identified as having asthma (2.3% of the MCO enrollees), with 43% being male. Persons under 18 years of age comprised 28.8% of persons with asthma. Median pharmacy costs were \$472, median medical costs were \$483, and median total health care costs were \$1199 for this population. **CONCLUSIONS:** Asthma appears to affect a significant number of enrollees within this MCO, with persons less than 18 years of age representing almost 29% of the treated patients. Health care costs in persons with asthma appears to be substantial.

**PAR 17****PATIENT SATISFACTION WITH NON-SEDATING ANTIHISTAMINES**

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**OBJECTIVES:** The objective of this study is to determine the factors that influence satisfaction with non-sedating antihistamines (NSA) among people who suffer from allergies/hay fever. **METHODS:** An online survey was conducted in September, 2000 on respondents who had been told by a health care professional that they suffer from allergies/hay fever and were recently (within 12 months) prescribed one of three NSAs to relieve their symptoms. The sample was weighted to ensure the generalizability of the results. Satisfaction was measured according to the medication's ability to relieve side effects and control symptoms from allergies/hay fever. A total of 4,081 respondents were included in the analysis. **RESULTS:** (1) The mean satisfaction score for the first time users (defined as never having taken any medication for allergies/hay fever) was higher than those who had used some medication in the past ( $p < .01$ ) (2) Of the respondents who had a specific choice of medication in mind, those who received their first choice medication had a higher satisfaction score than those who did not ( $p < .01$ ). (3) The respondents who discussed their medication jointly with their physician had a higher satisfaction score than those whose doctor chose their medication for them ( $p < .01$ ). (4) Respondents who were not taking any over-the-counter (OTC) medications reported higher satisfaction scores than those who supplemented their NSA with over-the-counter medications ( $p < .01$ ). (5) Finally, respondents who had never requested a prescription after seeing an advertisement for any medication had a higher satisfaction score than those who did. ( $p < .01$ ) **CONCLUSIONS:** The data provides evidence to suggest that past knowledge or experience with NSAs, patient preference, and patient involvement in the treatment decision-

making process all play a role in determining satisfaction with NSAs. Furthermore, both over-the-counter medication usage and direct-to-consumer advertising are likely to influence how satisfied people are with their NSA.

**PAR 18****COSTS OF TREATING COPD IN ITALY: A BURDEN OF ILLNESS STUDY**

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**INTRODUCTION:** Despite the high prevalence, morbidity and mortality of COPD, remarkably little is known about its impact on health care costs and utilization of services. Information about health care utilization and costs among patients with Chronic Obstructive Pulmonary Disease (COPD) is needed to improve care and for appropriate allocation of resources. **OBJECTIVE:** The purpose of this study was to quantify the burden of illness in Italy, in terms of both medical consumption and lost productivity associated with COPD. **METHODS:** *Design:* In 1998 an epidemiological study was conducted in Italy. Retrospectively, from a community perspective, we quantified COPD's costs related both with health care consumption and lost of productivity and/or school days. *Main Outcomes Measures:* The main goal of the present study was to evaluate economic outcomes in a cohort of 355,000 patients with current diagnosis of COPD. **RESULTS:** As reported in previous studies, prevalence rate for COPD in Italy is about 4,6% (2,637,000 subjects). Among all COPD patients, 42,5% suffers from mild disease while 56,7% is affected by moderate-severe COPD, on the basis of Flow Expiratory Value (FEV1) % of predicted criteria. The total cost of COPD we have quoted is the sum of direct and indirect costs: it is worth US\$18 billion, equal to US\$6,843 average/patient/year. We have not included intangible costs because they cannot be quantified correctly as yet. **CONCLUSIONS:** COPD is associated with significant both direct and indirect costs. Previous studies reported that prevalence figures for COPD based on recorded diagnoses are underestimated. Notwithstanding, data from our study suggest that when patients seek medical advice they were correctly diagnosed and treated. Education of patients will allow them to take control of their disease and of costs related to COPD.

**PAR 19****IMPACT OF THE ADDITION OF SALMETEROL TO THE TREATMENT OF ASTHMA PATIENTS IN A MEDICAID FEE-FOR-SERVICE POPULATION**

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**OBJECTIVE:** Salmeterol, a long acting beta-2 agonist, improves lung function and symptom control with twice daily dosing in moderate-to-severe asthmatics. This in-



investigation was performed to determine whether the introduction of salmeterol to moderate-to-severe asthmatics in a Medicaid fee-for-service population reduces the overall asthma related health care expenditures. **METHODS:** The New Mexico Medicaid fee-for-service claims database was searched between 1/1/94 and 12/31/98 to identify both a salmeterol and control group. The inclusion criteria for the salmeterol group were: patients receiving salmeterol, who were 66% compliant with salmeterol therapy, had a diagnosis of asthma (ICD-9: 493.0, 493.1, 493.9), were 13 years of age or older, did not have a diagnosis of COPD (ICD-9: 496.x) and must have been Medicaid eligible for 2 consecutive years. In addition to the above criteria for the salmeterol group, to be included in the control group, patients must not have received salmeterol between 4/12/95 and 4/12/97 (around the median start date of salmeterol, 4/12/96), and in order to match for severity must have received other asthma maintenance medications. Patients meeting these criteria for the salmeterol and control groups were 57 and 58, respectively. ANCOVA were performed to compare costs between the two groups controlling for baseline costs. Average per patient benefit-cost ratios were calculated by dividing total cost savings by increase in medication costs for both groups. **RESULTS:** No significant difference existed among average per patient total health care expenditures between the salmeterol and control groups (\$2266 and \$1955, respectively). Interestingly, in the salmeterol group, total medication costs increased significantly ( $t = -7.895$ ,  $p = 0.000$ ) while total health care costs decreased, although not significantly. The average per patient benefit-cost ratio for the salmeterol group was 0.061 (\$41/\$668). **CONCLUSION:** Introduction of salmeterol in the New Mexico Medicaid fee-for-service population did not significantly reduce total asthma related health care costs.

#### PAR20

### EFFECTIVENESS OF COMPLIANCE ON HEALTH CARE RESOURCE USE IN ASTHMA PATIENTS TREATED WITH MONTELUKAST VS. INHALED CORTICOSTEROIDS

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**OBJECTIVES:** To compare effectiveness of compliance on health care utilization between montelukast and standard therapy (inhaled corticosteroid—ICS) patients. Indicators for health care resource use include drug use, ER visits, and total charges. **METHODS:** Retrospective cohort analysis using LifeLink employer claims database of 1.6 million Americans. ANOVA models examined health care resource use of montelukast and ICS patients in six months prior (pre-period) and six month following (post-period) new treatment of interest adjusting for age, gender, region, plan type, and prescriber specialty. **RE-**

**SULTS:** The study cohort consisted of 3,775 montelukast patients and 7,331 ICS patients. Average compliance, defined as medication possession ratio, of montelukast patients (63%) was significantly greater ( $p = 0.001$ ) than that of ICS patients (31%). Montelukast patients were more likely to receive short-acting beta-agonist therapy in pre-period than ICS patients ( $p = 0.001$ ), which suggests more severe patients in montelukast group, but there was no significant difference between two groups in post-period ( $p = 0.854$ ). Among patients with concomitant methylxanthine therapy, montelukast patients had more days of methylxanthine therapy than ICS in pre-period ( $p < 0.001$ ), but there was no significant difference in post-period ( $p = 0.130$ ). For patients with at least one asthma-related ER visit, montelukast patients had more ER visits per patient than ICS patients in pre-period ( $p = 0.010$ ), but no significant difference was noted in post-period ( $p = 0.325$ ). Average total charges for montelukast were higher than for ICS patients in both pre-period ( $p < 0.001$ ) and post-period ( $p < 0.001$ ). **CONCLUSIONS:** Compliance with montelukast treatment was markedly better than with ICS therapy. Initially, montelukast patients were higher resource users than ICS patients. During six months treatment with montelukast, some health care resources used decreased to the level of ICS patients. Results suggest that markedly improved compliance of montelukast decreased asthma-related health care utilization, however total charges for montelukast patients remained higher than for ICS patients.

#### PAR21

### LEVALBUTEROL USE IS ASSOCIATED WITH DECREASED HEALTH CARE COSTS IN PATIENTS WITH MORE SEVERE ASTHMA

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Preliminary pharmacoeconomic analyses suggest that levalbuterol (LEV) therapy is associated with decreased outpatient asthma health care costs. **OBJECTIVE:** Examine treatment costs in asthma patients stratified by the number of prescribed controller medications (CM), an index of asthma severity. **METHODS:** Claims data on patients prescribed LEV and RAC were obtained from the PharMetrics Integrated Outcomes Database. Age- and sex-matched samples of patients initiating therapy with LEV or RAC (no prescriptions for either agent in prior 6 months) were selected and their asthma-related charges were assessed over 6 months following the initial prescription. **RESULTS:** 544 LEV-treated patients were identified and matched to 544 RAC-treated patients. 62% of RAC patients previously received no CM, 20% had 1 CM, and 18% had >1 CM. Following RAC treatment 30% had 1 CM and 29% had >1 CM. Use of leukotriene modifiers increased from 8% to 14% and corticosteroid use increased from 33% to 46%. Although

LEV patients previously received more CM (41% no CM; 24% 1 CM; 34% >1 CM), after treatment the percent with >1 CM declined to 28%. Their leukotriene modifier use increased from 22% to 25% while long-acting bronchodilator use decreased from 13% to 10%. In patients without prior CM, mean charges declined by similar amounts in both groups (LEV: \$360, RAC: \$306) following treatment. In patients with 1 CM, LEV was associated with a \$116 reduction despite a \$121 increase in pharmacy charges while RAC was associated with a \$22 decrease. In patients with >1 CM, LEV was associated with a \$435 reduction in mean charges while RAC was associated with a \$311 increase. **CONCLUSIONS:** Asthmatic patients treated with LEV required no additional CM and some patients reduced the number of CM. Cost reductions associated with LEV increased with severity.

#### PAR22

### IMPACT OF LEVALBUTEROL VERSUS RACEMIC ALBUTEROL ON OUTPATIENT ASTHMA CARE CHARGES

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Preliminary evidence suggests that levalbuterol (LEV), the therapeutically active isomer of albuterol, can improve clinical outcomes while reducing health care costs compared to racemic albuterol (RAC). **OBJECTIVE:** Explore the impact of LEV versus RAC on resource utilization, co-medication use, and cost of therapy in asthmatics. **METHODS:** Claims data on patients prescribed LEV and RAC were obtained from the PharMetrics Integrated Outcomes Database. Age- and sex-matched samples of patients initiating therapy with LEV or RAC (no prescriptions for either agent in prior 6 months) were selected and their asthma-related charges were assessed over 6 months following the initial prescription. **RESULTS:** 544 LEV-treated patients were identified and matched to 544 RAC-treated patients. 70% of all patients were <12 years of age. 32% of RAC patients and 59% of LEV patients received asthma controller medication during the prior 6 months. Mean asthma-related (pharmacy and medical) charges during the prior 6 months were \$872 versus \$587 in the LEV and RAC groups respectively. During the 6 months follow-up period, controller medication use increased among RAC patients to 59%, while use among LEV patients remained unchanged. Overall mean charges decreased by \$298 for LEV and \$61 for RAC. In patients receiving concomitant controller medications, LEV was associated with a \$247 decline in charges versus a \$116 increase for RAC. Among patients treated in primary care (pediatricians, family practitioners, and internists), the reduction in mean charges was \$262 for LEV, while RAC was associated with a \$180 increase. **CONCLUSIONS:** 1) LEV was prescribed to patients who were “sicker” than those pre-

scribed RAC; 2) Patients treated with RAC, but not LEV, tended to require additional controller medications; 3) LEV was associated with greater reduction in total cost compared to RAC, which in “sicker” and primary care patients was associated with increased cost.

#### PAR23

### DETERMINANTS OF INAPPROPRIATE ANTIBIOTIC PRESCRIBING

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**BACKGROUND:** Previous studies have shown that antibiotics are prescribed for nasopharyngitis, upper respiratory infection, and acute bronchitis approximately 40–80% of the time. Because these conditions tend to be viral in nature, the efficacy of treating with antibiotics is questionable at best and potentially dangerous at worst. **OBJECTIVE:** The purpose of this study is to determine those physician characteristics that are associated with inappropriate antibiotic prescribing. **METHOD:** This study reviewed the antibiotic prescribing patterns of 138 physicians treating members of the NJ Carpenters Funds from 1997–1998 for upper respiratory infection and acute bronchitis. Using logistic regression analysis, the rate of antibiotic prescribing was used to evaluate the potential relationship with the following physician characteristics: specialty, year of graduation from medical school, gender, ABMS (American Board of Medical Specialties Status), type of practice (group versus solo), and foreign versus domestic medical graduate status. **RESULTS:** The results indicate that there were significantly disparate rates of prescribing by physician specialty, as compared to pediatricians: family practitioners (OR 3.296 95% CI 2.459–4.419), internal medicine (OR 1.67 95% CI 1.145–2.436) and other (primarily general practice) (OR 1.421 95% CI 1.008–2.003). In the pediatric subgroup, there was a definite trend in inappropriate antibiotic prescribing according to the year of graduation from medical school (1950s: OR 3.779 95% CI 1.774–8.051; 1960s: OR 3.088 95% CI 1.994–4.783, and 1970s: OR 1.713 95% CI 1.123–2.614). **CONCLUSION:** Although some of these findings are significant, the majority of physician characteristics reviewed were not significantly related to inappropriate antibiotic prescribing. The findings may be indicative of the fact that this problem is widespread and multi-faceted. This study suggests that there is a definite need for education of both patients and physicians to change long held beliefs that antibiotics are a cure-all for all types of infections, and that there are no negative consequences to inappropriate antibiotic use.

**CANCER****PCN1****CATEGORIZATION OF RISK OF PROSTATE CANCER: PILOT TEST OF CLINICAL OUTCOMES AND RISK PERCEPTIONS**

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**OBJECTIVES:** To define clinically useful categories for prostate cancer (PC) risk and associated outcomes. Translating relative risk (RR) and cumulative risk (CR) into risk categories is important if studies of PC epidemiology and genetic predisposition are to have clinical utility for education, counseling and decision-making. Individual risk perceptions compared to clinical risk are important for the study of behavioral outcomes. **METHODS:** Risk categories were determined by an extensive review of the literature. Using RR and CR for specific risk factors, 4 categories were defined from low to very high. The categories were then used to assess PC outcomes in men at increased risk for PC (defined by race and family history). Risk perceptions were assessed by asking men to rate their chance of getting PC on a scale from 0 to 100%. **RESULTS:** 264 men participated in this study. Mean age was 47.7 years, and 52% were African American, 48% were Caucasian. By nature of study eligibility, only 3(1%) men were in the low risk category. According to study criteria, 54(20%) were in the moderate risk, 129(49%) in the high risk, and 62(24%) in the very high risk categories, 16(6%) were unknown. PC was diagnosed in 0 of the low and unknown, 7% of the moderate, 5% of the high and 10% of the very high-risk groups. Of the 62 men who answered the risk perception item, there was no correlation between risk category and risk perceptions. **CONCLUSIONS:** Lacking a Gail-like model for PC risk, the search continues for quantifiable risk categories with clinical utility. The extreme categories proposed in this pilot study show a trend toward clinically meaningful categorization of PC risk. A meta-analysis of RR and CR is underway to refine the categories. Risk categories and risk perceptions were not associated, as has been shown in breast cancer.

**PCN2****WHICH VARIABLES DO METASTATIC BREAST CANCER PATIENTS AND ONCOLOGY NURSES ANCHOR ON WHEN USING THE EUROQOL DESCRIPTIVE SYSTEM IN MEASURING UTILITIES WITH THE STANDARD GAMBLE TECHNIQUE?**

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**OBJECTIVE:** To determine which of seven EuroQoL descriptives used in collecting utility scores were the an-

chors for metastatic breast cancer patients (pts) and oncology nurses (nur). **METHODS:** Eight states of health describing metastatic breast cancer were presented to 45 pts and 56 nur. Each health state had seven bullet points describing varying degrees of severity in the following categories: Mobility, Activities of Daily Living (ADL), Hand/finger use (NOT EuroQoL), Usual Activity, Anxiety/Depression, Ability to think (NOT EuroQoL), and Pain/Discomfort. After the utility scores were obtained, subjects were asked which of the seven variables were most important and second most important to them. **RESULTS:**

	Most Important Variable, N (%)	Next Most Important Variable, N (%)	Row Total, N (%)
<b>PATIENTS, N=45</b>			
Mobility	11 (24.4)	3 (6.7)	14 (31.1)
ADL or Self Care	14 (31.1)	10 (22.2)	24 (53.3)
Hand or finger use	0 (0)	0 (0)	0 (0)
Usual Activity	3 (6.7)	7 (15.6)	10 (22.2)
Anxiety/Depression	9 (20.0)	11 (24.4)	20 (44.4)
Ability to Think	5 (11.1)	10 (22.2)	15 (33.3)
Pain/Discomfort	3 (6.7)	4 (8.9)	7 (15.6)
Column Total	45 (100%)	45 (100%)	
<b>NURSES, N=56</b>			
Mobility	9 (16.1)	7 (12.5)	16 (28.6)
ADL or Self Care	18 (32.1)	14 (25.0)	32 (57.1)
Hand or finger use	0 (0)	0 (0)	0 (0)
Usual Activity	1 (1.8)	3 (5.4)	4 (7.2)
Anxiety/Depression	14 (25.0)	15 (26.8)	29 (51.8)
Ability to Think	4 (7.1)	9 (16.1)	13 (23.2)
Pain/Discomfort	10 (17.9)	8 (14.3)	18 (32.2)
Column Total	56 (100%)	56 (100.1% rounded)	

**CONCLUSIONS:** It appears that both pts and nur anchored mainly on the Self-Care variable. Combining the most important with the next most important variable demonstrates that the Anxiety/Depression variable was also an important anchoring variable for both groups. Pts appear to anchor more on Usual Activity than nur. Nur appear to anchor more on Pain/Discomfort than pts. The results also suggest that the Hand and Finger use variable (NOT a EuroQoL variable) may not be necessary and may actually overburden subjects. Overall, these findings may help explain why metastatic breast cancer patients differ from oncology nurses on utility scores.

**PCN3****PREDICTORS OF CHEMOTHERAPY-RELATED NEUTROPENIA: A REVIEW OF THE CLINICAL LITERATURE**

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**OBJECTIVES:** A literature review was conducted to identify risk factors and predictors of chemotherapy-related grade 3-4 and/or febrile neutropenia to assist

with assessing who might benefit from treatments such as prophylactic G-CSF. **METHODS:** The literature review included publications from 1990–2000 of adults with any tumor type; 121 articles were identified that referenced risk factors or predictors for severe/febrile neutropenia. Study design, patient characteristics, chemotherapy treatment, and incidences of neutropenia were recorded. **RESULTS:** Twenty-one relevant publications, including prospective, retrospective, and modeling studies, were further analyzed. These articles yielded 27 potential risk factors/predictors in 3 categories: patient ( $n = 14$ ), treatment-related ( $n = 8$ ), and disease-related ( $n = 5$ ) characteristics. Although most of the 27 potential risk factors/predictors were not validated to identify patients at higher risk for severe/febrile neutropenia, the review suggests that several simple-to-use and commonly available risk factors may be reliable predictors of neutropenia. These included low hemoglobin and neutrophil counts in cycle one; depth of the neutrophil nadir; low lymphocyte, monocyte and platelet levels; and a precipitous, early drop in blood cell counts. Several other risk factors, such as serum albumin  $\leq 3.5$ g/dL on day 1, serum LDH  $>1\times$  normal alone or combined with bone marrow involvement, and high dose chemotherapy, also warrant further investigation. **CONCLUSIONS:** Few studies have explicitly explored risk factors associated with the occurrence of Grade 3–4 neutropenia. However, this literature review identified several common characteristics that may be measured with early and frequent CBC monitoring and may reasonably predict predisposition of patients to severe/febrile neutropenia.

**PCN4**

#### **COMPARING MEAN VERSUS MEDIAN SURVIVAL AS A PRELUDE TO COST-EFFECTIVENESS (C/E) ANALYSES**

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**BACKGROUND:** In a multinational trial designed to determine the efficacy of epoetin alfa in chemotherapy-induced anemia, patients receiving non-platinum chemotherapy having a hemoglobin 10.5 g/dL or less, or a decline in hemoglobin of 1.5 g/dL or greater were randomized (2:1) to epoetin alfa or placebo. A total of 375 patients (251 epoetin alfa, 124 placebo) were assessed for survival status twelve months after completing the protocol, but prior to unblinding. A log-rank test showed a trend in survival favoring epoetin alfa (median of 17 vs. 11 months,  $p = 0.128$ ). **OBJECTIVES:** The primary efficacy endpoint for many cancer clinical trials is median survival. In preparing for an economic analysis, however, we analyzed mean survival, the appropriate survival endpoint for a C/E analysis. **METHODS:** Sampling with replacement, we conducted a post hoc analysis that examined the difference in mean survival by drawing 10,000 samples in a bootstrapping simulation. Within each sam-

ple the survival curves were truncated to maintain identical follow-up periods between treatment groups. The difference in mean survival was computed for each sample. The probability of superior efficacy was obtained by sorting the results from the samples. **RESULTS:** The average mean survival difference, across the 10,000 samples, showed a 0.212-year survival benefit for epoetin alfa. The probability that the difference in mean survival favors epoetin alfa was 0.965. **CONCLUSIONS:** Comparing differences in median and mean survival may lead to different conclusions about the value of a therapy. Given that mean survival is the appropriate effectiveness endpoint for survival-based C/E analyses, a non-significant difference in median survival does not preclude full C/E analyses. Specifically, the mean survival results from this trial warrant a full C/E analysis of epoetin alfa in treating anemia for patients receiving non-platinum chemotherapy.

**PCN5**

#### **DOCETAXEL/DOXORRUBICIN (DD) AS FIRST LINE CHEMOTHERAPY: QUALITY OF LIFE (QOL) IN PATIENTS (PTS) WITH METASTATIC BREAST CANCER (MBC)**

Bonicatto SC

FUNDONAR Foundation, La Plata, Argentina

**OBJECTIVE:** In spite of initial treatment of MBC with DD showed high level of efficacy expressed as improved disease-free interval, time to relapse and overall response, it remains as a palliative one. Because of there is some evidence that QOL is improved with this treatment, we designed the study to investigate the impact and changes on QOL in patients (pts) with MBC treated with DD, and its relationship with clinical parameter of response. **MATERIAL AND METHODS:** Between July 1999 and July 2000, we treated 42 MBC pts with doxorubicin 50mg/m<sup>2</sup> and docetaxel 75 mg/m<sup>2</sup>, i.v., day 1. Inclusion criteria: female between 18–75 years old, ECOG PS 0-2, and stage IV of MBC histologically confirmed. QOL was assessed at baseline and prior to the first, third and fifth cycle of chemotherapy with the EORTC QLQ-C30 version 2.0, an integrated measurement system to evaluate QOL of cancer pts. **RESULTS:** To date, 33 pts (median age = 51.7; range 40–67) with available data, have completed 5 cycles of chemotherapy. Repeated measures analysis of variance (MANOVA) showed time effects statistically significant ( $p < 0.5$ ) for Emotional Functioning (EF;  $p = .001$ ), and Cognitive Functioning (EF;  $p = .001$ ) scales, and pain ( $p = .000$ ), insomnia ( $p = .05$ ) and constipation ( $p = .02$ ) symptom scales. When baseline QOL was compared with that after 5 cycles (paired t-test), it was observed significant improved in EF ( $p = .003$ ), pain ( $p = .005$ ) and Insomnia ( $p = .04$ ). We grouped pts with CR and PR ( $n = 14$ ) for comparing with SD pts ( $n = 19$ ) and we observed significantly improve in the first group after the fifth cycle, in physical functioning ( $p = .05$ ) and social functioning ( $p = .005$ ). **CONCLUSION:** These preliminary data suggest that pts with MBC undergoing DD chemotherapy experience improvement in several QOL pa-

rameters, showing correlation with the clinical response achieved. There were significant changes in major components of QLQ-C30 in pts who achieved clinical response.

#### PCN6

### CAN ICD-9 CODES BE USED AS A PROXY FOR DISEASE STAGING IN ECONOMIC EVALUATIONS?

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Administrative health care databases are increasingly used as a source of data for economic studies in cancer. In order to adjust for disease severity, several investigators have utilized ICD-9 codes indicating metastases as a proxy for cancer staging. **OBJECTIVE:** To determine the validity of using ICD-9-CM codes indicating metastases as a proxy to classify lung cancer patients by stage of disease. **METHODS:** This retrospective database analysis used diagnosis codes to classify subjects to either localized or advanced stage disease and then compared this classification to the tumor registry staging, which was considered as the “gold standard”. Study subjects included all lung cancer patients treated at an academic institution during 1996–97 who were also members of a large insurance company. Data was derived from inpatient cancer-related claims linked with the institution’s tumor registry data. Advanced stage disease (stages II to IV) was defined by claims indicating lymph node involvement or metastases (ICD-9 codes 196-199.1). The tumor registry staging of the disease for these patients were clustered into two groupings, stages 0–I (localized) and stages II–IV (advanced). **RESULTS:** Tumor registry entries were identified for 85.7% of patients. The crude concordance between the claims and tumor registry classifications was 74.2% (Kappa coefficient = 0.4848). The positive predictive value of identifying localized disease utilizing ICD-9 coding was 57.6%, while the predictive value of a negative test was 91%. The sensitivity and specificity for dichotomized disease stage was 86.4% and 68.2% respectively. **CONCLUSIONS:** For a population of lung cancer patients in an academic institution, the use of ICD-9 coding was associated with modest predictability for disease staging. The use of ICD-9 coding as a proxy for disease staging in economic evaluations should be executed with caution.

#### PCN7

### ECONOMIC EVALUATION OF GEMZAR AND BEST SUPPORTIVE CARE (BSC) RELATIVE TO BEST SUPPORTIVE CARE ALONE IN THE TREATMENT OF NON SMALL CELL LUNG (NSCLC) CANCER IN THE UK

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**OBJECTIVES:** Lung cancer is a leading cause of morbidity and mortality. Chemotherapy is one of the main treatment options but its availability in the UK is limited in comparison to other countries, is inconsistent across geographical regions, with many patients receiving only palliative care. The present study reports results of an economic evaluation of Gemzar (one of the newer agents available) and best supportive care (BSC) relative to BSC in the treatment of advanced NSCLC. BSC relates to all forms of care which are non-curative in intent excluding chemotherapy. **METHODS:** The study is undertaken from the perspective of the UK NHS. Data were extracted from a comparative trial undertaken in the UK (Anderson et al in 1997). Cost estimates are based on: chemotherapy and associated infusion, hospitalisations, health care professional visits, concomitant medications, radiotherapy and terminal palliative care. Resource utilisation data from the clinical trial were combined with unit-cost data from various UK sources. Costs are presented in 2000 price levels and the time horizon for their estimation is one year; hence discounting was unnecessary. Treatment effectiveness is measured by progression-free survival and tumour response. Extensive sensitivity analysis was also performed. **RESULTS:** Total treatment cost per patient in the Gemzar/BSC arm was estimated at £5,502 and at £3,861 for the BSC arm, the difference attributed mainly to the drug (Gemzar) and its administration costs. The intervention arm had lower radiotherapy/concomitant medication costs, but this did not offset the drug acquisition cost. Progression free life years and overall tumour response rates were 0.789 and 18.5% in the Gemzar/BSC arm and 0.474 and 0% in the BSC arm. The incremental cost-per-progression-free-life-year gained in Gemzar/BSC relative to BSC is £5,228 and the incremental cost-per-tumour-response £8,873. Changes in the key variables varied the above ratios between £3,000 and £23,000. **CONCLUSIONS:** The economic evaluation presented above shows that Gemzar/BSC is a cost-effective therapy for advanced NSCLC relative to BSC alone.

#### PCN8

### ECONOMIC EVALUATION OF GEMZAR IN THE TREATMENT OF PANCREATIC CANCER IN THE UK

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**OBJECTIVES:** Pancreatic cancer is a significant and increasing cause of morbidity and mortality in the UK. Treatment with chemotherapy has shown to improve symptoms and survival of patients. Gemzar is licenced for treatment of pancreatic cancer in the UK. This study reports on an economic evaluation of Gemzar relative to 5-FU, a commonly used regimen for advanced pancreatic cancer patients in the UK. **METHODS:** The perspective is that of the UK-NHS. Data were derived from a clinical

trial (Burriss et al in 1998). Total treatment costs estimates are based on chemotherapy, infusions, hospitalisations, visits to health care professionals and concomitant medications. Resource utilisation data, derived from the trial, were combined with unit cost data from various UK sources. The time horizon is 18 months and costs relate to 2000. A 6% discounting rate was applied. Effectiveness was measured by: survival, progression-free survival, and % of clinical benefit responders. Extensive sensitivity analysis was performed to test the robustness of the results. **RESULTS:** Total treatment cost per patient on Gemzar was estimated at £3,569 and on 5-FU at £1,262—the difference attributed mainly to higher drug acquisition costs. Gemzar was associated with an incremental gain of 0.188 life years, 0.116 progression-free-life-years and 19% of patients could be classified as clinical benefit responders. As such, relative to 5-FU, the incremental cost-per-clinical-benefit-responder with Gemzar is £12,172, the incremental cost-per-life-year-gained is £12,206 and the incremental cost-per-progression-free-life-year gained is £19,888. Sensitivity analyses showed that the results did not vary significantly with changes of the parameters. When 5-FU is administered by continuous infusion, the cost per patient increases to £1,900 and the incremental cost-effectiveness of Gemzar is improved. **CONCLUSIONS:** This economic evaluation demonstrates that Gemzar consists a cost-effective alternative to an existing therapy that is commonly used in the UK for treatment of pancreatic cancer. The incremental cost-effectiveness of Gemzar compares favourably with that of other treatments funded by the NHS.

**PCN9**

### **ECONOMIC EVALUATION OF GEMZAR/ CISPLATIN RELATIVE TO OTHER NEW AGENTS FOR NON SMALL CELL LUNG CANCER (NSCLC) IN THE UK**

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**OBJECTIVES:** Lung cancer is a leading cause of morbidity and mortality. Chemotherapy is a main treatment option but its availability in the UK is limited in comparison to other countries and is not consistent across geographical regions. The present study reports on two economic evaluations of Gemzar/cisplatin relative to: paclitaxel/cisplatin, paclitaxel/carboplatin, docetaxel/cisplatin (evaluation 1); and vinorelbine/cisplatin (evaluation 2). **METHODS:** The perspective is that of the UK-NHS. Information was derived from randomised clinical trials (Schiller et al 2000 (evaluation 1), Comella et al 2000 (evaluation 2)). Total treatment costs include: chemotherapy and infusion, hospitalisations, visits to health care professionals, and concomitant medications. Resource utilisation information was combined with unit cost data from various UK sources. Costs relate to 2000 and were adjusted

with the NHS inflation index if necessary. The time horizon for the estimation of costs is one year; hence discounting was unnecessary. Treatment effectiveness is mainly measured by time to disease progression and overall survival. **RESULTS:** In the first evaluation the cost per patient in the Gemzar/cisplatin, paclitaxel/cisplatin, paclitaxel/carboplatin, docetaxel/cisplatin arms was £5,537, £9,043, £8,444, and £5,779 respectively. Thus, the Gemzar/cisplatin achieves cost savings up to -£3506, which is driven by lower chemotherapy costs. Progression-free-life-years for each treatment arm, in the order presented above, were 0.375, 0.292, 0.300 and 0.275 respectively. Thus, the Gemzar/cisplatin combination dominates the other three combinations. In evaluation 2, a conservative approach was used whereby the survival outcome was assumed to be equivalent between Gemzar/cisplatin and vinorelbine/cisplatin arms. However, the cost in the Gemzar/cisplatin arm was £4,476 and in the vinorelbine/cisplatin arm £5,047. Despite significant changes to important parameters Gemzar with cisplatin maintains dominance or achieves very low positive incremental cost-effectiveness ratios, the maximum of which is £1,200. **CONCLUSIONS:** Gemzar/cisplatin is less expensive and equally or more effective than the other alternative regimens. Thus, on cost-effectiveness grounds, it should be encouraged in the treatment of NSCLC patients in the UK.

**PCN10**

### **COST-EFFECTIVENESS MODEL OF PROSTATE-SPECIFIC ANTIGEN (PSA) SCREENING FOR PROSTATE CANCER**

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**BACKGROUND:** Prostate cancer is the most common type of malignancy found in US male population and the second leading cause of cancer fatality in men. PSA screening is a common test in prostate cancer diagnosis. This research investigates its cost-effectiveness. **METHODS:** A cost-effectiveness model is constructed following a cohort of patients aged 60 to 75 taken from a general US population. Clinical outcomes, costs, and transition state probabilities were derived from medical literature and used to construct a Markov state probability model. The analysis takes a societal perspective and all costs were converted to 2000 dollars. Discount rate in base case was 3%. The parameters in the base-case were assessed for robustness using one-way sensitivity analysis. **RESULTS:** We found that a screening program with annual PSA testing starting at age 60 would result in cost-effectiveness ratios of \$8000 per QALY. One-way sensitivity testing found the results to be very stable. Threshold analysis revealed that screening ceased to be cost-effective (CE ratio >\$50,000/QALY) only when costs for procedures such as prostate surgery approached \$500,000 or prostate cancer was detected at high levels (80% true positives in first year of testing, up from cur-

rent 20%) in the population. **CONCLUSIONS:** The model suggests that annual PSA screening of male population for prostate cancer is extremely cost-effective, given current data. Further research into outcomes of prostate cancer is needed to estimate cost-effectiveness of screening in various subpopulations. In particular, given the long clinical progression of prostate cancer, more research is required into outcomes and cost-effectiveness in relatively healthy patients versus those burdened by serious co-morbidities.

**PCN11**

**ECONOMIC EVALUATION OF LIPOSOMAL DOXORUBICIN VS TOPOTECAN FOR RECURRENT OVARIAN CANCER IN THE UK**

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**OBJECTIVES:** To conduct an economic evaluation of an open label, phase III randomized trial involving centers in North America and Europe. **METHODS:** There were 239 and 235 patients in the liposomal doxorubicin (50mg/m<sup>2</sup> every 4 weeks) and topotecan (1.5mg/m<sup>2</sup> for 5 days every 3 weeks) arms, respectively. Overall median survival was 420 days and 397 days for liposomal doxorubicin and topotecan, respectively (hazard ratio = 1.12 (90% CI 0.92,1.37; p = .34)). Because the outcomes were not clinically different for the 2 groups, a cost minimization analysis was performed. Costs included were: study drug; drug administration; and management of adverse events. Actual mg of drug administered and frequency and severity of adverse events were obtained from the clinical trial. Expert opinion was used to estimate the resources used in the treating adverse events, and unit costs were based on UK practice data. Further validation of the expert opinion is currently underway. **RESULTS:** Severe (Grade III/IV) toxicities were more frequent for liposomal doxorubicin versus topotecan in terms of palmar-plantar erythrodysesthesia (PPE) (n = 64 vs. 0), and stomatitis/pharyngitis (n = 32 vs. 2) but less frequent for thrombocytopenia (n = 3 vs. 238), anemia (n = 19 vs. 146), neutropenia (n = 55 vs. 764) and fever (n = 2 vs. 13). The average cost per patient was estimated to be EUR16,230 (95% CI 14,780 to 17,680) and EUR20,554 (95% CI 18,764 to 22,344) for liposomal doxorubicin and topotecan, respectively. Per patient cost for drug + administration were similar between the two groups, (EUR14,974 and EUR15,073); the main differential in cost was management of anemia (EUR407 and EUR2,219) and neutropenia (EUR57 and EUR1,454) for the liposomal doxorubicin and topotecan groups, respectively. **CONCLUSIONS:** In settings where the current standard of care for platinum refractory or resistant ovarian cancer is topotecan, liposomal doxorubicin offers the potential for savings through reduction in cost of adverse event management.

**PCN12**

**COST-UTILITY ANALYSIS COMPARING PACLITAXEL TO DOCETAXEL IN THE TREATMENT OF METASTATIC BREAST CANCER**

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Cost-utility analysis is rapidly becoming the standard pharmacoeconomic measure in oncology. **OBJECTIVE:** To compare paclitaxel (pac) and docetaxel (doc) in the treatment of second line or greater metastatic breast cancer using a cost-utility analysis. **METHODS:** Utilities were collected from 45 patients using eight modified Markov modeled health states (Pharmacoeconomics, 1996; 60:504) describing metastatic breast cancer; the standard gamble procedure was utilized to obtain utility. Costs were collected prospectively from 31 patients in a single outpatient center. Direct medical costs were collected (e.g., all medications, physician/clinic/laboratory visits, ER, hospitalizations, home health care, consultations, special procedures, transfusions, phone calls, and miscellaneous) and costs were defined using Medicare reimbursement rates and AWP for drugs. Sensitivity analyses are currently underway. **RESULTS:** The average cost per cycle of chemotherapy was \$4,298 and \$2,869 for doc and pac respectively. The mean utility score obtained from patients was .78 and .76 for doc and pac respectively. The utility scores suggest that doc offers 7.3 days of perfect health when compared to pac. However, the incremental cost-utility analysis (cost of doc – cost of pac/QALY of doc – QALY of pac) indicates that the use of doc costs \$71,450 per Quality Adjusted Life Year (QALY) when compared to pac. Another way to view these results is that it costs \$195.75 more per Quality Adjusted Day (QAD) to treat a patient with docetaxel. **CONCLUSIONS:** Our results indicate that docetaxel is more expensive (\$4,298/cycle vs. \$2,869/cycle) than paclitaxel, and that metastatic breast cancer patients do not perceive the drugs as being different (utility scores .76 for pac and .78 for doc). This cost-utility analysis suggests that the use of docetaxel over paclitaxel may not be justified in the treatment of metastatic breast cancer.

**PCN13**

**COST OF THROMBOCYTOPENIA-RELATED BLEEDING AMONG PATIENTS WITH CANCER**

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**OBJECTIVE:** Chemotherapy-induced bone marrow toxicity is expensive because of the cost of managing complications of pancytopenia. Growth factors minimize these complications. Economic analyses of growth factors typically focus on common, less serious outcomes, rather

than on rare, serious outcomes. As a result, the samples are too small to estimate the financial burden of less common outcomes; underestimation of the economic value of these agents may occur. To illustrate, we examined the cost of a less common, but serious outcome of chemotherapy, thrombocytopenia-related bleeding, in large and small samples of cancer patients. **METHOD:** The cost of 1562 chemotherapy cycles in 612, randomly-chosen cancer patients was estimated from retrospective review of medical and administrative databases. Cost was estimated using a resource-based strategy (pharmaceuticals, hospital and clinic costs, transfusions) from the provider's perspective, in 1999 dollars. Twelve random, 10% samples of the cycles were selected, approximating the size of most growth factor trials. Mean costs were compared with two-tailed t-tests. **RESULTS:** Using the entire sample, cycles with thrombocytopenia were more expensive than those without (\$7933 vs 4875,  $p < 0.0001$ ). Cycles with bleeding were more expensive than those without (\$13,728 vs \$7374,  $p < 0.0001$ ). They were comparable in the costs of all inpatient and outpatient services except monitoring (\$538 vs \$472,  $p = 0.01$ ), transfusions to prevent bleeding (\$1367 vs \$758,  $p = 0.007$ ), and bleeding treatment (\$4702 vs \$0,  $p < 0.0001$ ). However, the cost of cycles with bleeding (range: \$8289–\$16,277) was significantly higher than cycles without bleeding (range: \$5796–\$8872) in only 5 of the 12 small samples. **CONCLUSIONS:** The economic impact of uncommon, but expensive outcomes should be examined in samples large enough to permit calculation of stable estimates of cost. The high cost of rare outcomes such as bleeding will be better appreciated, as will the importance of avoiding such episodes by preventing thrombocytopenia.

**PCN14**

**CHOICE OF LOCALIZED BREAST CANCER TREATMENTS IN A MEDICARE POPULATION: A COMPARISON OF OUTCOMES AND COSTS**

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**OBJECTIVES:** In this study we compared outcomes and costs between three treatment options (mastectomy (MRM), breast conservation surgery with radiation (BCSRT), and breast conservation surgery only (BCSO)) for elderly women with localized breast cancer. **METHODS:** The sample was a national random sample from Medicare claims of 2,821 elderly women treated between 1992 to 1994 for localized breast cancer. Data on patient preferences were collected in patient interviews conducted in 1997. The outcomes studied were 5-year survival, Quality Adjusted Life Years (QALY), total costs

and cost/QALY. For each outcome we used univariate, multivariate and instrumental variable analysis to compare the differences between treatments. The instrumental variables used were geographic region, and distance to nearest radiation facility. **RESULTS:** There were 1813 patients who received MRM, 704 who received BCSRT, and 304 who received BCSO. The multivariate analysis showed significantly higher survival for BCSRT relative to MRM (4.21 vs. 4.13) and significantly higher QALYs (3.50 vs. 3.45), but the IV analysis found an insignificant difference opposite in sign. Costs were significantly higher for BCSRT relative to MRM (\$54,073 vs. \$37,327 in multivariate analysis). The cost-effectiveness ratio of BCSRT relative to MRM is \$334,920/QALY (CI:\$80,000 to NW) per QALY using multivariate estimates and dominated using IV estimates. **CONCLUSION:** Survival and QALYs are statistically higher in traditional analyses of the BCSRT group relative to MRM, but the IV analysis suggests an upward bias due to the selection of healthier patients into BCSRT. This finding is consistent with previous studies. Costs are unequivocally higher in the BCSRT group suggesting BCSRT is not a cost-effective option relative to MRM. Supplemental analyses suggests that the presence of choice between MRM and BCSRT raises the quality of life for all elderly women independent of the choice that is made. Thus, choice is costly but valuable.

**PCN15**

**DIFFERENCES BETWEEN PREFERENCES FOR HEALTH STATES: THE CHEMOTHERAPY ADVERSE EVENT SELF-ASSESSED RESPONSE (CAESAR) QUESTIONNAIRE**

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**OBJECTIVE:** This study assesses the health state preferences for adverse effects of chemotherapy on healthy individuals. Time trade off (TTO), Standard Gamble (SG), and Visual Analogue Scale (VAS) scores were compared between side-effects and across two time points. **METHOD:** A convenience sample of healthy pharmacy students self-administered a questionnaire of TTO, SG and VAS preferences for 12 different chemotherapy-related side-effects ranging from anorexia to severe nausea. Respondents completed the questionnaire on two separate occasions separated by 2 weeks. **RESULTS:** Ninety-three students completed at least one survey; 53 subjects completed both surveys (57%). The mean age of the sample was 25 years; 21% were male. While no missing values were seen in VAS questions, 23 missing responses were noted in the TTO and 72 in the SG. TTO had the highest test-retest correlation (ranging from 0.35 to 0.75) and VAS had the lowest correlation (ranging from 0.29 to 0.65). The order of the preference measures was consistent across nine of the twelve side-effects. The widest



range of preferences occurred in the VAS, with the mean score for severe nausea rated at 0.27, and anorexia at 0.82. The TTO and SG ranges were narrower than the VAS (0.55 to 0.90, and 0.80 to 0.95, respectively). Consistent with other studies, the lowest median score for all three preference measures was severe nausea. **CONCLUSION:** Similar scores were obtained from the three methods to estimate preferences for cancer related health states, although the narrowness of the TTO/SG distributions may limit the ability to distinguish between the 12 side-effects. The methods were not equivalent in ease of administration as shown by the number of missing items in the TTO/SG. Additional comparisons across these three methods and different populations would assist in determining the association between side effects and preferences.

**PCN16**

### CHEMOTHERAPY TREATMENT IN NEWLY DIAGNOSED BREAST CANCER PATIENTS IN A MANAGED CARE POPULATION

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**OBJECTIVE:** To characterize the antineoplastic treatment of newly diagnosed breast cancer patients in a managed care population. **METHODS:** Adult subjects contained within PharMetric's Integrated Outcomes database possessing a diagnosis of breast cancer (ICD-9-CM = 174) followed by a procedure code for chemotherapy during 1997–1999 were eligible for study inclusion. Patients with diagnoses for other neoplasms and pre-diagnosis treatment were excluded. Utilization of antineoplastic agents, radiation therapy (RT) and mastectomy during the 6-month post-diagnosis period was measured. **RESULTS:** 6,652 patients met the inclusion criteria. The mean age was 53.7 years. 3,396 (51.1%) patients received RT, while 3,469 (52.2%) patients underwent mastectomy. Patients 61 year of age and older were significantly less likely to undergo RT or mastectomy as compared to younger patients ( $p < 0.0001$ ). Doxorubicin and cyclophosphamide were extensively used in younger patients (ADR: 32.7% in 71+ vs. 64.4% in <40; cyclophosphamide: 53.3% in 71+ vs. 73.2% in <41). In contrast, fluorouracil and methotrexate appeared to be the drug of choice in elderly (5-FU: 49.1% in 71+ vs. 33.3% in <41; MTX: 30.9% in 71+ vs. 19.8% in <41). Use of paclitaxol was consistent across all age categories (24.4%). Elderly were less likely to undergo partial mastectomy (8.7% in 71+ vs. 23.1% in <41). The difference in the rate of modified radical mastectomy between age groups was less pronounced (22.3% in 71+ vs. 29.5% in <41). After adjusting for age, RT and health plan identifier, the administration of cyclophosphamide or doxorubicin was more likely to follow any mastectomy, while the association between mastectomy and fluorouracil use was limited to modified radical. RT was likely to be used

as adjunct therapy to all antineoplastics, with the exception of cyclophosphamide. **CONCLUSIONS:** The elderly appeared to be treated less aggressively with anti-neoplastic agents. The choice of agent is governed by age and the mode of other treatments.

**PCN17**

### AN ANALYSIS OF RESOURCE USE IN THE TREATMENT OF ADVANCED COLORECTAL CANCER IN THE UK

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**OBJECTIVE:** This study aims to estimate the non chemotherapy costs of treatment of advanced metastatic colorectal cancer from the perspective of the UK National Health Service. **METHODS:** Resource use collected during comparative clinical trials often is insufficient in determining the actual costs of patient management. Large data bases can be used to estimate patient health care resource consumption, but these are not always available. Soliciting expert opinion from clinicians may provide the only reasonable data source. A questionnaire was developed to obtain resource utilization for routine treatment and monitoring, adverse event management and other clinical parameters in the first line setting. Responses were obtained from five oncologists from various centres in the UK with experience of treating advanced metastatic colorectal cancer with chemotherapy. Data on second line treatment came from resource use collected during a trial. **RESULTS:** The clinicians estimated that 40% of first line patients would receive only palliative care at disease progression and 60% would receive second line therapy. Resources included physicians, acute care admissions, labs, hospice, palliative drugs, community nurses and radiology.

Non-Chemotherapy Costs	Average cost/ patient/week £
One time cost for insertion of tunneled catheter at start of chemotherapy	250
Non chemotherapy costs during 1st line chemotherapy	485
Non chemotherapy costs during disease remission (1st time)	116
Non chemotherapy costs during 2nd line chemotherapy (derived from trial)	108
During Terminal Palliative Care	256

**CONCLUSIONS:** Chemotherapy drug costs are only a part of the costs incurred in treating advanced colorectal cancer. These results clearly show the substantial non-chemotherapy costs throughout the remaining life of patients that also need to be considered when treating these patients.

**PCN18****COLORECTAL CANCER SCREENING: AWARENESS, UTILIZATION, AND BARRIERS**Straus W<sup>1</sup>, Schaffner P<sup>1</sup>, Gold K<sup>2</sup>, Pashos C<sup>3</sup>, Mansley E<sup>1</sup><sup>1</sup>Merck & Co., Inc, West Point, PA, USA; <sup>2</sup>Abt Associates Inc, Cambridge, MA, USA; <sup>3</sup>Abt Associates Clinical Trials, Cambridge, MA, USA

**BACKGROUND:** Screening can reduce colorectal cancer mortality, yet screening rates remain low. Data from the Centers for Disease Control and Prevention (CDC) for 1999 suggest that only 33.7% of US adults over 40 have ever received a sigmoidoscopy (SIG) or colonoscopy (COL), and 31.1% have ever received a fecal occult blood test (FOBT). **OBJECTIVE:** To inform policy that may improve screening rates, we sought to characterize the barriers associated with low screening compliance. **METHODS:** A national random sample of US adults 50 years and older was conducted via random digit dial methods. A computer assisted telephone survey was administered to 502 subjects. Data including utilization of FOBT, SIG, COL and x-ray with barium enema (XBE), as well as demographics, awareness, concerns, attitudes and beliefs about those tests were collected. **RESULTS:** Screening rates were low, with awareness and screening rates lower for Blacks/Hispanics than for Whites. For example, Blacks and Hispanics were less aware of screening tests (aware of FOBT = 73.3%; SIG = 51.7%; COL = 70%; XBE = 68.3%) than Whites (88.1%, 81.8%, 87.6% and 80.1%, respectively) ( $p < .05$ ). Significantly lower screening compliance is apparent with FOBT screening rates of 21.7% (Blacks/Hispanics) compared with 34.8% (Whites). Other significant barriers to screening found were: discomfort with exam; low health care seeking behavior; low belief in value of prevention; and low perceived personal health threat (all  $p < .05$ ).

	Knowledge of Test	Ever Had Test	Compliant with Standards
FOBT	86.7%	70.3%	33.5%
SIG	78.1%	52.0%	29.7%
COL	85.1%	40.7%	31.1%
XBE	78.1%	38.5%	17.5%

**CONCLUSIONS:** Lack of awareness about screening still exists, especially among Blacks and Hispanics. Barriers to screening have been observed and can potentially be addressed by outreach and education programs.

**PCN19****COLORECTAL CANCER SCREENING TESTS: VARIATION IN PREFERENCES BASED ON GENDER AND RACE**Straus W<sup>1</sup>, Schaffner P<sup>1</sup>, Gold K<sup>2</sup>, Pashos C<sup>3</sup>, Mansley E<sup>1</sup><sup>1</sup>Merck & Co., Inc, West Point, PA, USA; <sup>2</sup>Abt Associates Inc, Cambridge, MA, USA; <sup>3</sup>Abt Associates Clinical Trials, Cambridge, MA, USA

**BACKGROUND:** There exists a larger number of screening procedures for colorectal cancer than for any other type of cancer. Unfortunately, screening rates remain low. Data from the Centers for Disease Control and Prevention (CDC) for 1999 suggest that only 33.7% of US adults over 40 have ever received a sigmoidoscopy (SIG) or colonoscopy (COL), and only 31.1% have ever received a fecal occult blood test (FOBT). **OBJECTIVE:** To better understand the types of barriers associated with each screening method (stool-based, scope-based, x-ray/enema-based) in order to develop patient-based preference profiles that could be used to increase compliance with one of the recommended screening regimens. **METHODS:** A national random sample of US adults 50 years and older was conducted via random digit dial methods. A computer assisted telephone survey was administered to 502 subjects. Data including utilization of FOBT, SIG, COL and x-ray with barium enema (XBE), demographics, concerns, attitudes and beliefs were collected. **RESULTS:** There were significant gender differences in screening rates based on procedure. Overall, 26.2% of women were in compliance with SIG recommendations compared to 38.6% of men ( $p < .01$ ). White respondents appeared to be the source of this difference. Black/Hispanic men and women had similar SIG screening rates. Conversely, there was a significant difference in stool-based screening compliance between Black/Hispanic men (40.0%) and women (15.6%) with no gender difference among Whites. The importance of some potential barriers differed significantly with exam type ( $p < .05$ ), with respondents being less bothered by, and associating less discomfort with, the FOBT. **CONCLUSIONS:** Preferences and perceptions with respect to screening procedures varied by patient characteristics. The impact of screening barriers varied by procedure. Understanding these variations may help in education and information dissemination and may also assist in directing patients to more compatible screening regimens. This might increase screening rates for this largely preventable disease.

**PCN20****COST MINIMIZATION ANALYSIS OF CEFEPIME VERSUS IMIPENEM-CILASTATINE IN CANCER PATIENTS WITH SHORT-DURATION FEBRILE NEUTROPENIA**

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**OBJECTIVE:** To perform pharmacoeconomical comparison of cefepime versus imipenem-cilastatine used for empiric therapy in cancer patients with short-duration febrile neutropenia in Russia. **METHODS:** The decision tree was designed to analyse the costs and outcomes of studied treatment. Probabilities of clinical success, adverse events, switching to a new drug and adding extra antibiotics were extracted from a published multicenter randomised clinical trial. Firstly the study was planned to be a cost-effectiveness analysis, but data obtained from the trial, demonstrated equal efficacy of both drugs. So fi-

nally the study was performed as cost-minimization analysis. The following costs were taken into account: the drug acquisition price, drug preparation and administration, medications to treat failures and adverse events, including antibiotics added to main medication. Schemes of treatment for adverse events and choice of antibiotics for treating clinical failures typical for clinical practice in this country were obtained from expert panel. Costs of drugs were derived from official price-lists of pharmacies. Hospital costs were excluded, as there was no difference in the length of treatment between the groups according to the results of the trial. **RESULTS:** According to clinical trial the probability of clinical success for short-duration febrile neutropenia treatment in cancer patients is equal in both drugs (79 % for cefepime and 72% for imipenem, equivalence,  $p < 0.0001$ ). Cost of treatment of 1 patient with imipenem-cilastatine including added antibiotics, drugs for treating failures and adverse events was 21 207,2 roubles (757,4 USD), for cefepime—10 512, 32 roubles (375,44 USD). **CONCLUSION:** Cefepime monotherapy being clinically as effective as imipenem-cilastatine is twice less costly for the empirical treatment of fever in short-duration neutropenia. Changing of widely recommended for empiric therapy of febrile neutropenia imipenem-cilastatine for cefepime will save 10 694,88 roubles (382 USD) in each treated patient.

**PCN21**

### HEALTH-RELATED QUALITY OF LIFE AFTER ANDROGEN DEPRIVATION THERAPY IN MEN WITH PROSTATE CANCER

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**INTRODUCTION and OBJECTIVES:** Treatment for prostate cancer has significant impact on health-related quality of life (HRQOL). We examine HRQOL in a cohort of men who opted for surveillance as initial treatment followed by androgen deprivation therapy (ADT) and compare them with other treatments. **METHODS:** CaPSURE (Cancer of the Prostate Strategic Urologic Research Endeavor) is a national observational database of men with prostate cancer. We identified a cohort of newly diagnosed men with prostate cancer who completed two or more instruments that measure generic and disease-specific HRQOL. Individuals were grouped by initial treatment: ADT, surveillance, radical prostatectomy, and radiation therapy. **RESULTS:** Initial treatment was as follows: ADT ( $n = 167$ ), surveillance ( $n = 106$ ), radical prostatectomy ( $n = 351$ ), radiation therapy ( $n = 75$ ). Sixty-seven men selected surveillance followed by ADT. Mean age at diagnosis was 73 years with surveillance patients being older. Men had significantly poorer urinary (decline of 7 points on a 100 point scale) and sexual function (decrease of 10 points) compared with surveillance. HRQOL for ADT, surveillance and radiation therapy patients changed little over the year following

treatment, while men undergoing radical prostatectomy showed improvement in all aspects of HRQOL. Scales are scored from 0–100 with 100 = better function and a difference of 7–10 points is considered clinically significant. **CONCLUSIONS:** Patients receiving ADT had reduced energy, poorer sexual and urinary function and were more bothered by their urine function than patients undergoing other treatments. Longer follow-up after start of ADT and surveillance is needed to discern the impact of other factors, including comorbidities.

**PCN22**

### COST-EFFECTIVENESS ANALYSIS COMPARING PACLITAXEL TO DOCETAXEL IN THE TREATMENT OF METASTATIC BREAST CANCER

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**OBJECTIVE:** To compare paclitaxel (pac) and docetaxel (doc) in the treatment of second line or greater metastatic breast cancer using a cost-effectiveness analysis. **METHODS:** Costs were collected prospectively from 31 patients in a single outpatient center. Direct medical costs were collected (e.g., all medications, physician/clinic/laboratory visits, ER, hospitalizations, home health care, consultations, special procedures, transfusions, phone calls, and miscellaneous) and costs were defined using Medicare reimbursement rates and AWP for drugs. Effectiveness measures were obtained from two phase III trials conducted by Nabholz. Sensitivity analyses are currently underway. **RESULTS:** The average cost per cycle of chemotherapy was \$4,298 and \$2,869 for doc and pac respectively. The objective response rates (OR) obtained for doc and pac in the phase III trials were 30% and 26% respectively. The cost-effectiveness (CE) ratio for doc is \$14,327 per one-percent increase in OR. The CE ratio for pac is \$11,035 per one-percent increase in OR. An incremental CE analysis suggests that using doc costs \$35,725 per one-percent increase in OR compared to pac. **CONCLUSIONS:** The cost-effectiveness ratios suggest that pac is the more cost-effective choice. The incremental cost-effectiveness analysis still supports the use of pac; however, doc is not out of the standard range of payment for gains in effectiveness. Physicians and third party payers should use this information along with cost-utility studies to help guide decisions on treatment for metastatic breast cancer patients.

**PCN23****DISEASE MODELING: DEVELOPING THE INFRASTRUCTURE FOR A COMPREHENSIVE, MULTI-NATIONAL, CLINICAL AND ECONOMIC BREAST CANCER TREATMENT MODEL**

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**OBJECTIVES:** To develop the cost data infrastructure to support a comprehensive, multi-national breast cancer treatment decision-analysis model. The specifications required a user-friendly interactive interface for over 70 comparators composed of nearly 350 cost components used in 24 unique decision trees. The model required an ability to vary components readily and add new treatments and cost components to multiple trees. **METHODS:** Since standard decision-analysis software doesn't permit categorization of variables or application of the same variable to multiple decision trees: (1) trees were programmed in Visual Basic for the interactive interface, and (2) cost data were loaded into a Microsoft ACCESS database linked to the trees. Because of this structure, it was possible to categorize cost data as: 1) Drug Acquisition and Administration, 2) Adverse Events/Complications, 3) Concomitant Medications, 4) Hospitalizations, and 5) Monitoring Costs. For each country in the model, a separate database was developed with country-specific costs obtained from standardized databases, government sources, published literature, and a provider survey. **RESULTS:** This model was developed for six countries—US, U.K., Germany, Japan, France, and Italy—and included clinical and economic variables related to the diagnosis, treatment, and outcomes of breast cancer. The structure permits dynamic analyses via varying cost and probability scenarios that reflect country-specific treatment practices and international variations. Each country's cost database applies to four distinct decision trees representing different stages of breast cancer. The costs can be easily summarized by category and modified so that multiple cost components in multiple trees can be varied with one edit. New cost components can be added to each country's database and linked to the trees. **CONCLUSION:** When constructing large models (such as disease models) with several treatments having common cost components in multiple decision trees, using a categorized cost database linked to the treatment pathways will generate a user-friendly model with easily-varied cost inputs.

**PCN24****INCIDENCE AND COST OF HOSPITALIZATION FOR 5-FU TOXICITY AMONG MEDICARE BENEFICIARIES WITH METASTATIC COLORECTAL CANCER**

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**BACKGROUND:** While treatment with 5-fluorouracil (5-FU) plus leucovorin has been shown to prolong survival in patients with metastatic colorectal cancer, it also can cause significant toxicity, sometimes necessitating hospitalization. The incidence and costs of these admissions have not been fully documented. **OBJECTIVE:** To estimate the incidence and cost of hospitalizations for toxicities associated with 5-FU therapy in patients with metastatic colorectal cancer. **METHODS:** Using the 1994 Medicare 5% sample, we identified all patients with metastatic colorectal cancer who underwent colorectal surgery. We stratified these selected subjects into those who received 5-FU therapy within 90 days of their surgery ("5-FU group") and those who did not receive any chemotherapy ("no-chemotherapy group"); patients receiving chemotherapeutic agents other than 5-FU were dropped from the sample. Using techniques of survival analysis, we then compared the incidence and cost of all hospital admissions with listed ICD-9-CM diagnosis codes (principal or secondary) for conditions that may be related to 5-FU toxicity (e.g., volume depletion, stomatitis, nausea and vomiting). **RESULTS:** A total of 441 patients met all study entry criteria, including 192 who received 5-FU and 249 who did not receive chemotherapy following surgery. 5-FU patients were significantly younger than those in the no-chemotherapy group ( $p < .001$ ). Mean ( $\pm$ SD) follow-up time was slightly longer in the 5-FU group ( $137 \pm 96$  days vs  $117 \pm 88$  days for no chemotherapy). The incidence at 10.5 months of toxicity-related hospitalizations (principally volume depletion, agranulocytosis, gastroenteritis, and nausea and vomiting) was 31% among patients who received 5-FU and 8% among those who did not receive chemotherapy. The cost of inpatient care was \$2,716 higher among 5-FU patients. **CONCLUSIONS:** Hospitalization for 5-FU toxicity is frequent and costly among Medicare patients with metastatic colorectal cancer.

**PCN25****A QUALITY OF LIFE AUDIT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER HAVING CHEMOTHERAPY AT ONE INSTITUTION**

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**OBJECTIVES:** Establish the impact that present chemotherapy management is having on the quality of life (qol) of patients being treated at the Prince Charles Hospital; Allow comparison of the effect on the patients qol between established treatment modalities; Allow comparison of the effects on patients qol between established and future trial treatment protocols. We report the interim findings of this ongoing quality of life study. **METHODS:** All patients referred for chemotherapy management of their non-small cell lung cancer (NSCLC) were asked to participate. The EORTC QLQ 30 and LC 13 were used to assess patients qol when disease restaging tests were conducted. Data was entered into an access database that allowed comparison. Protocols used were CIV, CV- adjuvant-neoadjuvant setting, CG and single agent Gemcitabine 1000mg/m<sup>2</sup> on days 1, 8, 15, in the palliative setting. **RESULTS:** Patients ages ranged 39 to 73 yrs, average age 53 yr, median, 51, mode 47years. The sample consisted of 3 females & 12 males, 6 patients are not reported, 3 neoadjuvant had progressive disease after two cycles and were not followed, 3 palliative patients died after one cycle of treatment. Of the 21 patients treated 15 (71%) had improved Quality of Life scores paralleled other measures of assessment. Scans show response to single agent Gemzar in the palliative setting and response to CIV in the neoadjuvant setting. **CONCLUSION:** we demonstrated 71% of our patients had qol improvements. Management of patients with NSCLC should consider chemotherapy. **FUTURE DIRECTION:** An outcomes study is being conducted at two campuses in Brisbane. This study seeks to include all newly diagnosed lung cancer patients and follow their progress through their disease using clinical Quality of Life and economic criteria to determine outcome. Comparison between treatment and within treatment arms will be compared.

**PCN26**

**SYSTEMATIC ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS FOR USE IN CLINICAL TRIALS OF NON-SMALL CELL LUNG CANCER**

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**OBJECTIVE:** To critically evaluate the quality of health-related quality of life (HRQoL) instruments for use in clinical trials of non-small cell lung cancer (NSCLC). **METHODS:** A structured review of literature was conducted by searching MEDLINE (1975–2000) and PsycINFO (1977–2000) using the keywords “lung cancer”, “quality of life” and “questionnaire”, and manually. HRQoL instruments that had been used in or designed for lung cancer were selected for review. Each instrument was assessed for its general features, feasibility, scoring and interpretation, and psychometric properties. **RESULTS:** Ten instruments were selected for review: EORTC-QLQ30, EORTC-LC13, FACT-L, LCSS, FLIC,

CARES, CARES-SF, RSCL, FLIC and MQOL. Most questionnaire items were appropriately generated through multiple cycles of input from patients and clinicians. The most studied psychometric properties were internal consistency and convergent/divergent validity, with most instruments having Cronbach's  $\alpha > 0.7$  and acceptable correlation coefficients for convergent/divergent validity. Responsiveness, interpretability of the scale score, and validity testing in cross-cultural settings were either inadequately evaluated or missing. All instruments have a good readability level, an administration time less than 20 minutes, a time horizon of one week or less, and are multilingual. All questionnaires have been used in clinical trials for non-small cell lung cancer except CARES, CARES-SF and MQOL. **CONCLUSIONS:** There are several reliable and validated HRQoL instruments that are appropriate for use in clinical trials of NSCLC. In particular, the EORTC-QLQ30 and its lung cancer supplement, the LC13, LCSS, RSCL, FACT-L, and CARES have greater evidence of good psychometric properties. Further research is required to evaluate the cross-cultural performance, score interpretability and correlation with clinical outcomes of these instruments.

**PCN27**

**COST OF TREATMENT FOR SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK IN THE UNITED STATES**

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**BACKGROUND:** Cancer of the head and neck is the 11th most common cancer in the US, however, there are no published, comprehensive studies examining the costs associated with the treatment of head and neck cancer in the United States. The objective of this research was to design a model to estimate the cost of treatment for squamous cell carcinoma of the head and neck (SCCHN). **METHODS:** A decision analytic model was designed to project the outcomes and costs associated with SCCHN. The model was stratified by site of disease, stage of presentation, treatment, and outcome. The most common therapeutic options for SCCHN were modeled: 1) surgery, 2) radiation therapy, 3) surgery and radiation therapy, 4) radiation therapy and chemotherapy, and 5) palliation. Base case data were obtained from the National Cancer Data Base, the published literature, a modified Delphi survey of experts, and an analysis of the Medicare Standard Analytic Files. **RESULTS:** Average per patient cost of care for SCCHN in the US was estimated to be \$20,876. Higher costs resulted for patients that present with advanced cancers. The estimated cost of treating a patient with Stage IV lip SCC (\$19,274) was four times that of Stage 0 lip SCC (\$5,062). The site with the lowest cost of treatment was lip (\$7,261) while the highest cost was associated with hypopharyngeal SCC (\$28,584). The cost per patient for palliative care ranged from \$2,052 for lip SCC (28% of total cost of care) to \$7,172 for si-

nonasal SCC (30% of total cost of care). The lifetime cost of managing annual incident SCCHN cases was estimated to approximate \$976 million. **CONCLUSION:** This study found that tumor stage and location are useful predictors of increased treatment costs. The results suggest that prevention and early detection are critical in reducing the treatment costs of SCCHN.

**PCN28**

**DETECTING RECURRENT PAPILLARY OR FOLLICULAR THYROID CANCER IN CLINICAL PRACTICE: NEED FOR A CHANGE?**

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**OBJECTIVES:** Patients with thyroid carcinoma (TC) can present a diagnostic dilemma when elevated tumormarkers (thyroglobulin, Tg) suggest relapse but whole body 131-iodine scanning (131I WBS) is negative. Then, battery of imaging modalities is available. In recent years, positron emission tomography has been proposed as an effective and comprehensive staging procedure. To estimate the effort and yield of present clinical practice, we performed a retrospective study. **METHODS:** From our Tg database we identified all TC patients, and included those with elevated Tg levels (>1.5 pmol/l on thyroid hormone medication) after ablation with 131I, between 1-5-96 and 1-1-98, and recorded the applied diagnostic work-up. **RESULTS:** Tg data were identified from 116 patients with TC. Twenty met the inclusion criteria, 18 of which (90%) had a complicated work-up. Recurrent disease was confirmed in 16. The mean number of imaging tests required to arrive at a clinical conclusion was 5 (range 3–9), within a mean period of 18 months. Since 1997, PET has been performed in 15 patients with negative or equivocal high dose 131I WBS (8 positive and 7 negative scans). Tumor sites first disclosed by PET were found in 5 patients. **CONCLUSIONS:** The current diagnostic trajectory in the majority of the patients with elevated Tg and negative 131I WBS proved to be protracted and complicated. Even though prognosis may not necessarily be adversely affected by this delay, patient anxiety is a considerable problem. FDG-PET may solve clinical problems in some of these patients, but the currently available evidence does not allow for implementation of a routine diagnostic algorithm.

**CARDIOVASCULAR DISEASE****PCV1**

**A COST-EFFECTIVENESS ANALYSIS OF CLOPIDOGREL VERSUS ASPIRIN AS PREVENTION OF ISCHEMIC EVENTS IN PATIENTS WITH ESTABLISHED PERIPHERAL ARTERY DISEASE**

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**OBJECTIVES:** Since becoming widely recognized for its antithrombotic effects in the 1970s, aspirin has become first-line antiplatelet therapy across most patient populations. However, newer data suggests that clopidogrel is more effective than aspirin for prevention of ischemic events in peripheral artery disease (PAD) patients. In this analysis, a decision analytic model was constructed in order to evaluate the cost-effectiveness of clopidogrel versus aspirin as prevention of ischemic events in patients with established PAD. **METHODS:** Data on the probability of ischemic events was extracted from the PAD subgroup of the CAPRIE trial, in which event rates for clopidogrel and aspirin were 3.71% and 4.86%, respectively. Costs included in this analysis were obtained from the medical literature. **RESULTS:** In the base case analysis, the expected cost of treatment over a one-year time frame with clopidogrel and aspirin was \$2075 and \$1088, respectively. Furthermore, to effectively treat one patient, it would cost \$2155 with clopidogrel and \$1144 with aspirin. An incremental cost-effectiveness analysis concluded that one additional event of vascular death, MI, or ischemic stroke will be prevented with clopidogrel at an additional one-year cost of \$85,826. A univariate sensitivity analysis demonstrated that aspirin must have ischemic event rates greater than 13% for clopidogrel to be the preferred option based solely on cost. Furthermore, in order for clopidogrel to be considered cost-effective with an event rate of 3.71%, aspirin must have an event rate of 11.48%, a rate 2.4 times greater than was observed in the CAPRIE trial. **CONCLUSIONS:** The result of this analysis concluded that it would cost a third-party payer an extra \$85,826 to effectively treat one additional patient over a one-year period when using clopidogrel instead of aspirin. This cost can play a major role in the decision of appropriate antiplatelet therapy used to treat PAD patients in the prevention of ischemic events.

**PCV2**

**VENOUS THROMBOEMBOLIC (VTE) COMPLICATIONS FOLLOWING MAJOR ORTHOPEDIC SURGERY: FREQUENCY AND ECONOMIC CONSEQUENCES IN HOSPITAL**

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**OBJECTIVES:** The risk of VTE disease in patients undergoing major orthopedic surgery (MOS) has extensively been studied in randomised clinical trials and more recently in cohort studies. Our objective was to estimate the risk of VTE disease in a much larger population and to calculate its economic consequences in hospital. **METHODS:** We conducted a retrospective study of the risk of occurrence and associated costs of VTE complications (including deep vein thrombosis (DVT) and pulmonary embolism (PE)) in patients undergoing MOS (including hip replacement, hip fracture and knee replacement). Data were obtained from the National Inpatient Diagnosis Related Group (DRG) data base with ex-

haustive information concerning all the patients having undergone MOS in the year 1998 in France. These patients were stratified based on the presence or absence of a listed secondary diagnosis of DVT or PE. Length of stay in hospital and cost of inpatient care were then compared between patients with and without secondary diagnosis of VTE. **RESULTS:** 105,952 hospital stays, 37,034 and 58,135 were respectively recorded for hip replacement, knee replacement and hip fracture. Rates of VTE were recorded to be 1.4% and 2.6% for hip replacement and knee replacement respectively. For each primary Diagnosis Related Group, the length of stay was shown to be significantly higher in case of occurrence of VTE complications (19.1 days versus 15.1 for hip replacement, 18 days versus 15.2 for knee replacement, 21.4 days versus 13.8 for hip fracture). Consequently, total costs of inpatient care were substantially higher for patients with VTE complications. **CONCLUSION:** The rates of VTE observed from the National inpatient database provide information on the frequency of VTE complications after MOS in real setting. In patients undergoing major orthopedic surgery, the occurrence of VTE is associated with a longer hospital stay and higher cost of inpatient care.

**PCV3**

#### **AN ANALYSIS OF THE COST OF ADVERSE EVENTS ASSOCIATED WITH THE USE OF HMG-COA REDUCTASE INHIBITORS**

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**OBJECTIVE:** To perform an analysis of the cost of adverse events (AEs) associated with treatment by atorvastatin, fluvastatin, lovastatin, pravastatin, and simvastatin following NCEP low density lipoprotein-cholesterol (LDL-C) guidelines. **METHODS:** Data come from a 54-week randomized, open-label, double-blind controlled trial conducted in 158 US centers between May 1997 and January 1999. Patients (n = 3916) with or without coronary heart disease and/or peripheral vascular disease were randomized to receive atorvastatin (n = 1958), fluvastatin (n = 497), lovastatin (n = 498), pravastatin (n = 481), and simvastatin (n = 482). Inclusion criteria included elevated LDL-C for patients 18–80 years of age. Exclusion criteria included known hypersensitivity to HMG-CoA reductase inhibitors, use of selected medications, and other patient characteristics. Data were collected on AEs. **RESULTS:** A total of 9707 AEs were reported during the trial. Of these AEs, 1327 (14%) were related to the use of study medications. Related AEs involved the digestive system (387, 29%), musculoskeletal system (356, 27%), central nervous system (269, 20%), skin (124, 9%), abnormal laboratory values (68, 5%), respiratory system (40, 3%), urogenital system (25, 2%), cardiovascular system (24, 2%), and miscellaneous (35, 3%). The 1327 medication related AEs were associated with the use of 1384 medical services. Many AEs were

treated at scheduled study visits (239, 18%) and did not involve additional costs. Additional medical services typically consisted of physician office visits. There was one hospitalization (gastroenteritis). Costs of AEs were measured at Medicare payment rates—a third party perspective. The average cost of treating AEs were similar among study arms: atorvastatin \$27.78, fluvastatin \$31.78, lovastatin \$26.58, pravastatin \$25.17, and simvastatin \$32.58 (no differences were significant at  $p < 0.1$ ). **CONCLUSIONS:** Results suggest that the cost associated with adverse events related to study medications did not vary significantly among HMG-CoA reductase inhibitors used to treat patients with elevated cholesterol levels.

**PCV4**

#### **ASSESSING QUALITY OF LIFE IN PATIENTS SIX MONTHS AFTER A MYOCARDIAL INFARCTION USING THE SF-12**

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**OBJECTIVES:** To assess patients' quality of life (HQL) post-myocardial infarction and to identify related variables. **METHODS:** Patients admitted to the University of Michigan Medical Center with diagnosis of MI were identified consecutively and prospectively from October 1999 to May 2000. Clinical data were obtained retrospectively from medical records. Six months after discharge, patients were administered the Short Form-12 (SF-12), via telephone, to determine physical (PCS-12) and mental (MCS-12) functional status. **RESULTS:** Complete information was obtained from 148 patients. The mean age of patients was 64.7 years ( $\pm 13.2$ ) and 79.1% were male. The mean PCS-12 scores were 35.4 ( $\pm 9.12$ ), and the mean MCS-12 scores were 51.6 ( $\pm 10.01$ ). The median PCS-12 scores were significantly lower in patients with an ejection fraction (EF)  $< 40\%$  (31.9 versus 38.4 for EF $\geq 40\%$ ,  $p = 0.02$ ), and prior MI (31.2 versus 38.5 without a history of MI,  $p = 0.01$ ), congestive heart failure (CHF) (32.6 versus 37.4 without a history of CHF,  $p = 0.03$ ), renal insufficiency (27.9 versus 37.7,  $p = 0.003$ ), or peripheral vascular disease (29.4 versus 38.2 without a history of PVD,  $p = 0.004$ ). The median MCS-12 scores were significantly lower for patients under 65 years of age (49.6 versus 57.4 for patients  $\geq 65$  years of age,  $p = 0.001$ ) and with a history of coronary artery bypass graft (CABG) (60.1 versus 54.7 without history of CABG,  $p = 0.01$ ). There were no differences detected between gender, type of MI, diabetes, hypertension, angina, or smoking. **CONCLUSIONS:** HQL scores were lower for patients post-MI with various comorbidities. Physical scores were significantly lower for patients with low EFs, prior MI, or CHF. Mental scores were significantly lower for patients  $< 65$  and those not having already undergone CABG surgery. Post-MI, particular attention should be paid to these patients. Further

work is needed to determine whether interventions aimed at these patients will result in improved quality of life.

#### PCV5

### **COST OF TREATMENT AND PREVALENCE OF CARDIOVASCULAR DISEASE COMORBIDITIES AND RISK FACTORS IN THE SEVERE AND PERSISTENTLY MENTALLY ILL**

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**OBJECTIVE:** It has been estimated that 92% of geriatric psychiatric patients have at least 1 comorbid physical disorder. The baby boomers will be turning 65 by 2011 and over 130 million people will be over 45 by 2050. The severe and persistently mentally ill population have not been extensively studied concerning comorbidities and physical and behavioral risk factors of cardiovascular disease. We propose to determine the cost of treatment and prevalence of these comorbidities and risk factors in this population. **METHODS:** We conducted a chart review of all adult inpatients (N = 179) of a state psychiatric hospital during July and August 2000. All subjects had a medical history, physical exam, screening blood tests, ECG and medical service utilization data collected. The cost of treatment and prevalence of cardiovascular disease in our population was compared to a control group of Medicaid recipients matched for age and sex. **RESULTS:** Subject Characteristics: 47 + 16 years; 113 male; 29% African American, 10% Hispanic. Cardiovascular Disease Comorbidities: 40% ECG abnormalities, 15% Hypertension, 10% Diabetes, 7% Thyroid Dysfunction, 6% CAD. Physical and Behavioral Risk Factors: 69% overweight (BMI > 25), 38% obese (BMI > 30); 18% hyperlipidemia, 67% nicotine & 49% alcohol abuse, 35% chemically addicted. Cost of Treatment: Total cost: \$2539 (\$2257–\$2821), Cost of cardiovascular disease comorbidities: \$3889 (\$2105–\$5673). **CONCLUSION:** 49% had cardiovascular disease comorbidities. 62% had multiple behavioral and physical risk factors for developing cardiovascular disease in their life time. The sample size limits our ability to make population inferences yet an association between severe and persistently mentally ill patients and a increased risk for cardiovascular disease exists in our group (T = -8.101, df = 356, P < .00001). This association is also evident in the greater cost of treatment \$1985 (\$1518–\$2452) of the severe and persistently mentally ill compared to the control group (T = 4.78, df = 108, P < .00001).

#### PCV6

### **ESTIMATING INCREMENTAL COSTS FOR ADDITIONAL HOSPITAL DAYS**

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**OBJECTIVE:** Methods to develop resource costs from administrative data remain underdeveloped. Our objective was to improve current methods of estimating daily hospitalization cost by determining the pattern of resource utilization for patients hospitalized with cardiovascular-related diagnoses. **METHODS:** Using a proprietary cost-accounting system, we assessed the proportion of total hospital costs for each hospital day for patients within 10 DRGs. From these proportions, a series of equations were developed to calculate cost for each day of hospitalization. The dataset for this analysis included records for 2,698 patients for FY 2000. **RESULTS:** 27.39% of costs occurred on Day 1 for medical DRG 127 (Heart Failure, ALOS = 5). For each of the remaining four days the proportion of cost was 18.15%. For surgical DRG 112 (PTCA, ALOS = 3), 65.56% of costs occurred on Day 1 and 17% occurred on each of the remaining two days. The average proportion of costs for the first day of hospitalization and for each day thereafter for the remaining medical and surgical DRGs were 30% and 17%, and 62% and 19%, respectively. To illustrate, the average cost per day of a DRG 112 hospitalization was \$4,333, totaling \$13,000. By using the developed equations, the cost for the first day of hospitalization was calculated to be \$8,500. The cost for each remaining day was \$2,238.60. In this example, use of an average cost per day overestimates the marginal cost of the last day by approximately \$2,000. **CONCLUSION:** Average cost per day grossly overestimates the cost savings of reduced length of stay, especially for surgical diagnoses. The developed methodology will more accurately reflect any cost savings from a reduced length of stay by accounting for the greater intensity of care during the first day of a hospital admission.

#### PCV7

### **COST-UTILITY ANALYSIS OF DRUG THERAPY OPTIONS FOR INTERMITTENT CLAUDICATION**

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Peripheral artery disease manifests as intermittent claudication in over 4 million people in the US. In people older than 60 years, intermittent claudication occurs in 5% of men and 3% of women. **OBJECTIVES:** The purpose of this study was to develop a cost-utility model to compare cilostazol, pentoxifylline, and placebo based on published randomized control trial data. **METHODS:** In the trial, 698 patients received either cilostazol 100 mg twice a day, pentoxifylline 400 mg 3 times a day, or placebo. Quality of life was measured with the SF-36. Survival was projected to be similar between the three groups from this study of 24 weeks duration and SF-36 was converted to a single utility score using the regression formula published by Bosch. **RESULTS:** On SF-36, cilostazol was significantly better on the physical components over baseline. Pentoxifylline and placebo were not significantly different on either the physical or mental compo-



nents over baseline. On the Bosch calculated single index, cilostazol was better than pentoxifylline and placebo. Pentoxifylline had a lower calculated QALY score than cilostazol or placebo. Based on this model, cilostazol had an incremental cost per QALY of \$72,153 over placebo and \$21,294 over pentoxifylline. As expected the model is sensitive to changes in price and utilities, and patients who have substantial improvements in QOL scores over baseline have better cost per QALY results. From a managed care perspective with a patient co-pay of 20%, the patient's incremental cost of cilostazol over placebo was \$14,431 per QALY and the managed care plan cost is \$57,722 per QALY. **CONCLUSION:** Based on this analysis of treatments for intermittent claudication, cilostazol had a reasonable incremental cost per QALY over pentoxifylline or placebo. Lower cost per QALY results can be obtained by continuing on therapy patients who attain higher than average gains in quality of life scores from baseline.

**PCV8**

**PATIENT COMPLIANCE WITH DIFFERENT PRESCRIBED REGIMENS OF DILTIAZEM IN ANGINA PECTORIS: DATABASE ANALYSIS IN FRANCE**

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**OBJECTIVE:** Patient compliance is an important component in the successful management of any disease. In general, it is assumed that in disease states involving periodic, intense pain, such as angina pectoris (AP), compliance rates would be high, and unaffected by dosing regimen. We verified this hypothesis by examining the compliance rates of patients taking different formulations (o.d. (200–300mg), b.d. (90–120mg) and t.d.s. (60mg)) of diltiazem (princeps) for AP. **METHOD:** We performed a retrospective analysis of 3455 electronic patient records with a diagnosis of AP and a prescription of diltiazem (princeps) from June 1st 1997 to June 1st 1998 (Mediplus-IMS Health) with a one-year follow-up. The above patient cohort was then divided into 3 subgroups according to the different formulation taken. The two subgroups b.d. and t.d.s. were paired to the third one, according to 4 criteria: age, sex, disease history and comorbidities. Compliance was assessed using initial prescription and refill rates ((pills dispensed/daily dose)/duration of therapy). **RESULTS:** The proportion of patients showing “good compliance” (> 0.8) was significantly higher for the o.d. versus b.d. (36.1% versus 25.9%,  $p = 0.001$ ) and for the o.d. versus t.d.s. (36.1% versus 27.1%,  $p = 0.008$ ). We observed the same trend when we compared the mean rate of compliance for the o.d. versus b.d. (0.62 versus 0.55,  $p = 0.0027$ ) and for the o.d. versus t.d.s. (0.62 versus 0.60,  $p = 0.0121$ ). **CONCLUSION:** Even for life threatening cardiac disease like AP, dosing regimens have a significant effect on compli-

ance. Giving diltiazem as an o.d. formulation could significantly improve compliance and potentially decrease health care resources used.

**PCV9**

**AN ECONOMIC ANALYSIS OF CONGESTIVE HEART FAILURE (CHF) IN THE LOUISIANA MEDICAID PROGRAM**

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**OBJECTIVE:** To examine the cost of illness of Congestive Heart Failure (CHF) in the Louisiana Medicaid program. **METHODS:** Study design: A retrospective review of the medical and pharmacy claims data (1999–2000) in the Louisiana Medicaid program. We reviewed pharmacy and medical claims data for the years 1999–2000 from the Louisiana Medicaid program. The data were obtained from Unisys, the fiscal intermediary for the Louisiana Medicaid program, in a PC compatible format. We extracted the claims for CHF patients on the basis of the ICD-9-CM codes. A total of 13,947 patients met the study criteria, which included at least one primary or secondary diagnosis of CHF and availability of claims data for at least one year after the first CHF diagnosis related claim. We reviewed all the charges incurred for a one-year period after the initial CHF claim. **RESULTS:** The total cost for CHF patients for one year was over \$182 million. The majority of the patients (73.63%) were female and accounted for 70% of the total cost. The mean age was 70 years and the largest portion of the total cost (55%) came from those 65 years and older. Of the 13,947 patients 11,065 (79%) were hospitalized at an average cost of \$4,679 per hospitalized patient. Approximately 87% of the study population received prescription drugs at an average cost of \$2,897 per prescription drug user. Hospitalizations and prescription drugs contributed 28% and 19.38% respectively to the total cost. Almost one third of the total cost was due to long-term care at \$13,817 per utilizer. Costs for CHF diagnosis related claims were 14% of all costs. **CONCLUSION:** CHF represents a significant financial burden from the perspective of the Louisiana Medicaid program. Improved management of the condition is needed to reduce the cost of treatment associated with CHF.

**PCV10**

**INCIDENCE OF RHABDOMYOLYSIS IN PATIENTS INITIATED ON HMG CO-A REDUCTASE INHIBITOR THERAPY IN A MANAGED CARE ORGANIZATION**

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Recent evidence suggests there is an increased risk of rhabdomyolysis in patients initiated on cerivastatin compared to patients initiated on other HMG CoA reductase

inhibitors (HMGs). **OBJECTIVE:** The primary objective is to determine if there are differences among specific HMGs regarding the incidence of rhabdomyolysis. The secondary objective is to identify significant risk factors associated with rhabdomyolysis such as age, gender, and concurrent gemfibrozil use. **METHODS:** Retrospective pharmacy and medical claims from a large managed care organization were analyzed. Patients were included if they received any HMG (cerivastatin, fluvastatin, atorvastatin, lovastatin, pravastatin, or simvastatin) during the period between 7/1/99 to 12/31/99. All patients were followed for 6 months. ICD-9 diagnosis codes for rhabdomyolysis (idiopathic), myalgia and myositis not otherwise specified, or adverse effect to antilipemics were used to define rhabdomyolysis events. **RESULTS:** There were 133,454 patients identified who received an HMG during the identification period. The average age was 67.8 years (S.D. = 11.1) and 51.5% were female. The rates of rhabdomyolysis with and without concurrent gemfibrozil use were 0.861% and 0.632%, respectively ( $P = 0.13$ ). Overall, the incidence across individual drugs was similar for cerivastatin [0.486% (95% CI = 0.363%–0.609%)], fluvastatin [0.679% (95% CI = 0.589%–0.769%)], atorvastatin [0.889% (95% CI = 0.783%–0.995%)], lovastatin [0.741% (95% CI = 0.158%–1.332%)], pravastatin [0.530% (95% CI = 0.468%–0.592%)], and simvastatin [0.378% (95% CI = 0.212%–0.544%)]. With concurrent gemfibrozil use, the incidence was significantly higher for cerivastatin [6.341% (95% CI = 3.005%–9.677%)] compared to fluvastatin [0.713% (95% CI = 0.000%–1.439%)], atorvastatin [0.494% (95% CI = 0.062%–0.926%)], lovastatin (0.0%), pravastatin [0.452% (95% CI = 0.091%–0.813%)], and simvastatin (0.0%). In a logistic regression model, there was no significant relationship between the incidence of rhabdomyolysis and age or gender. **CONCLUSION:** In this population, it appears that the risk of rhabdomyolysis is substantially higher when cerivastatin is used concurrently with gemfibrozil. The findings of this analysis indicate there is a substantial need for managed care organizations and pharmacy benefits management companies to proactively prevent the concurrent use of cerivastatin and gemfibrozil.

#### PCV11

### COST OF WARFARIN TREATMENT OF ATRIAL FIBRILLATION IN CLINICAL PRACTICE

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**OBJECTIVES:** Trials of anticoagulation in non-rheumatic atrial fibrillation have demonstrated a reduction in the risk of stroke by two-thirds. In these trials, the safety of anticoagulation appeared good, but this may be related to highly selected patient groups. Exclusion rates of 93% were reported. Participants may have had fewer complications than might be expected among less selected patients in clinical practice. No trials had actually looked at the costs of anticoagulation in a real day-to-day

clinical practice. The aim of this study is to investigate the actual cost of warfarin treatment of atrial fibrillation in a real clinical practice. **METHODS:** A one-year retrospective study involving patients of all ages admitted to hospital with non-rheumatic atrial fibrillation on long-term oral anticoagulation. Patients were interviewed and their medical records reviewed. The costs of anticoagulation were viewed as follows: 1. The cost of the active drug. 2. The cost of monitoring the patient's INR i.e. traveling costs, staffing cost, and analysis costs. 3. The costs associated with bleeding complications. **RESULTS:** We studied 139 patients. The mean (SD) age was 73.6 (8.9) years, ranging from 41 to 93 years. The mean duration of oral anticoagulant therapy was 36 months (range 2 to 105 months), forming a total of 417 patient-years of treatment. Mean (SD) INR was 2.5 (0.36). The target range of 2.0–3.0 was achieved 54% of the time. Bleeding occurred in 21 patients, with incidence of 7.2% per patient-year for minor bleeding, 2.4% per patient-year for major bleeding and 0.2% for fatal bleeding. The cost of warfarin tablets was £14.6 (\$23.36), per patient-year, but was £262.6 (\$420.16), per patient-year after considering monitoring and bleeding complication costs. The cost per stroke prevented was estimated at £8,141 (\$13,026). **CONCLUSION:** Anticoagulation appeared safe and cost-effective in clinical practice but control was not as good as in clinical trials.

#### PCV12

### QUALITY OF CARE IN OLDER PATIENTS ADMITTED TO HOSPITAL WITH HEART FAILURE

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**OBJECTIVES:** To evaluate the quality of care given to older patients hospitalised with heart failure and to identify areas in which treatment could be improved. **METHODS:** A two-year retrospective study involving the analysis of the case notes of a random sample of 145 elderly patients (aged  $\geq 75$  yrs) admitted to hospital with heart failure. From The International Classification of Diseases, we identified patients with a principle discharge diagnosis of heart failure (ICD codes 428.0–428.1–428.9). Cases were excluded if the diagnosis could not be validated by medical record review. A total of one hundred and forty five patients formed all the admissions with heart failure during the study period. The standard of care received was evaluated using the relevant quality of care indicators derived from the Agency for Health Care Policy and Research (AHCPR) Clinical Practice Guidelines. **RESULTS:** The study sample included 145 patients. The mean age (SD) was 82 (5) years. Symptoms and signs of heart failure were documented in 145 (100%) patients. All patients with symptoms and signs of hypervolaemia received diuretic therapy. Only fifty-five patients (38%) had an objective assessment of left ventricular

function by echocardiography. After exclusion of patients in whom Angiotensin Converting Enzyme (ACE) inhibitors were contraindicated, only seventy-five (58%) patients received ACE inhibitors of whom, only 7 (9%) patients received the target dose recommended by the clinical practice guidelines. There was no documentation in the records regarding patient counselling about medication, diet, weight, exercise or smoking. **CONCLUSION:** ACE inhibitors were underused in elderly patients with heart failure; also achieving the target dose was poor. This data demonstrated a very low rate of use of echocardiography in elderly patients with heart failure. Counseling appeared to be a neglected aspect of patient care.

**PCV13**

**IMPACT ON QUALITY ADJUSTED LIFE YEARS OF ENOXAPARIN FOR PREVENTING THROMBOSIS AMONG HOSPITALIZED MEDICAL PATIENTS**

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**OBJECTIVES:** Prophylactic anticoagulants, such as low molecular weight heparin, to prevent thrombosis in hospitalized medical patients has been recommended in clinical guidelines, however the impact on quality adjusted life years (QALYs) is unclear. This pilot study evaluated enoxaparin for this indication among elderly (>age 59) hospitalized medical patients. **METHODS:** Patients were randomized to receive subcutaneous injections of enoxaparin 30 mg or placebo daily. Patients who had medical indications for anticoagulation (e.g., myocardial infarction, history of thrombosis) were excluded. QALYs were measured for the period of 30 to 90 days post randomization, using the Health Utilities Index (HUI). At 30 and 90 days, 51 and 40 patients in the active group completed the HUI versus 49 and 36 patients in the placebo group, respectively. Surveys were received at both time points among 40 enoxaparin and 21 placebo patients. QALYs and changes in domain scores were analyzed over the time between the two surveys. Data were analyzed using t-tests. **RESULTS:** Significantly more QALYs were gained ( $p = .007$ ) among enoxaparin treated patients. The mean QALY values were  $0.005 \pm 0.015$  vs  $-0.008 \pm 0.015$ . The change in the HUI, Mark III domain score for ambulation approached significance ( $p = 0.053$ ). The mean values were  $0.012 \pm 0.098$  for enoxaparin versus  $-0.027 \pm 0.056$  for placebo. A significant change in the HUI, Mark II domain score for mobility was found ( $p = 0.017$ , mean values  $0.015 \pm 0.064$  versus  $-0.022 \pm 0.050$ ). **CONCLUSION:** Among medical patients prophylactic treatment with enoxaparin was associated with increased QALYs.

**PCV14**

**IMPACT OF OBESITY ON HEALTH-RELATED QUALITY OF LIFE (HRQOL): AN ANALYSIS OF BEHAVIORAL RISK FACTOR SURVEILLANCE SYSTEM (BRFSS) DATA**

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**OBJECTIVES:** With over one-third of the population considered to be obese, obesity has reached epidemic proportions in the US. The direct costs associated with obesity are currently estimated at about \$238 billion. As the underlying cause of various chronic diseases, obesity negatively impacts quality of life due to impaired physical and mental well being and reduced daily functions. The objective of this study is to evaluate the relationship between obesity and health-related quality of life using the Centers for Disease Control and Prevention's (CDC) Behavioral Risk Factor Surveillance System (BRFSS) data. **METHODS:** The BRFSS is an ongoing, state-based, random digit dialed telephone survey of the civilian, non-institutionalized population aged  $\geq 18$  years conducted by CDC. Data from sixteen states that collected information on health status (4 items), HRQoL (10 items), and demographic characteristics including weight and height from 50,454 participants in 1998 were utilized for the analysis. Participants who had a Body Mass Index (BMI)  $\geq 30$  were defined as obese. Prevalence of obesity by demographics and disease presence was determined, as were corresponding HRQoL scores. **RESULTS:** On the basis of BMI, 31.9% of the respondents were identified as obese. Obesity was higher in males as compared to females and higher among African-Americans and Hispanics as compared to whites. Obesity increased with age but decreased as income and education increased. Obese respondents reported poorer health status. Impact of obesity on HRQoL due to reduced physical and mental functioning in the presence of no health problems, as well as in presence of self-reported major health problems such as arthritis, cardiovascular disease, diabetes, cancer, depression, and pulmonary disease is discussed. **CONCLUSIONS:** Health related quality of life is significantly affected due to obesity and should be an important consideration in the treatment of obesity. It also has important implications in case of illnesses that have obesity as an underlying cause.

**PCV15**

**ECONOMIC EVALUATION OF OUTPATIENT ANTICOAGULANT/ANTIPLATELET THERAPY FOLLOWING CORONARY STENTING IN A MANAGED CARE POPULATION**

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**OBJECTIVE:** To determine the impact of outpatient anticoagulant/antiplatelet therapy on treatment charges in

patients receiving coronary artery stents in a managed care population. **METHODS:** Patients were selected from the PharMetrics Integrated Outcomes Database who underwent coronary angioplasty and stent insertion between January 1 and June 30, 1999 and who had at least 6 months of continuous enrollment in their health plan following the beginning of the treatment episode. Patients were grouped according to whether they received outpatient anticoagulant/antiplatelet prescription drug therapy following their stent procedure. Patients were also stratified by history of acute myocardial infarction (AMI) and presence of comorbid conditions (diabetes and hypertension). Total charges associated with the stenting treatment episode (up to 6 months following the procedure) were assessed. **RESULTS:** 2,713 patients receiving anticoagulant/antiplatelet therapy and 438 untreated patients met all selection criteria. The two treatment groups were similar in age (58.6 vs. 58.0 years respectively,  $p = 0.322$ ) and in the frequency of AMI (37.7% vs. 37.9% respectively,  $p = 0.939$ ) and of one or more comorbidities (73.3% vs. 71.5% respectively,  $p = 0.427$ ). Mean charges over the study period for the anticoagulant/antiplatelet cohort exceeded those in the untreated cohort by \$4,748 ( $p = 0.014$ ). Pharmacy charges accounted for only \$297 of this excess (\$660 vs. \$363, respectively). Most of the difference between treatment groups was in the medical costs of interventional cardiology. **CONCLUSION:** Among coronary stent recipients, the mean charge for a 6-month period in patients who also received anticoagulant/antiplatelet prescription drug therapy was 14% higher than in the untreated cohort, due mainly to higher medical charges. It is possible that untreated patients were less severely ill or had a favorable risk profile. Further investigation of these data will examine this issue.

**PCV16**

**COST-EFFECTIVENESS ANALYSIS OF ENOXAPARIN VERSUS UNFRACTIONATED HEPARIN IN ACUTE CORONARY SYNDROME PATIENTS IN POLAND**

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**OBJECTIVE:** To estimate the cost-effectiveness of enoxaparin (1 mg/kg s.c. bid) vs unfractionated heparin (UFH) (i.v. bolus and constant infusion adjusted to maintain a therapeutic APTT) in acute coronary syndrome (ACS) patients from a Polish hospital perspective. The intention was to facilitate the decision-making process in selecting the most cost-effective treatment for ACS. **METHODS:** Decision model was used to quantify costs and effectiveness of alternative treatments. Published results from ESSENCE study were used to estimate the probability for clinical end-points (death, MI, recurrent

angina) at 30 days. Probabilities of patients receiving revascularisation procedures were obtained from the GRACE registry (961 patients at 6 centres in Poland). The analysis assessed only direct medical costs resulting from the treatment of events comprising the composite end-point, revascularisation procedures, enoxaparin and UFH therapy, related medications. The costs were determined from actual resource consumption on a patient-specific basis (6 months observational study) and estimated using Polish data on unit costs. One- and two-way sensitivity analysis and threshold analysis were performed. **RESULTS:** At 30 days 19,8% of patients receiving enoxaparin compared with 23,3% of patients receiving UFH reached one event of the composite end-point ( $p = 0,02$ ). The average costs (in PLN, 1 USD = 4 PLN) were 1085 per patient receiving enoxaparin compared with 1097 per patient receiving UFH. Therefore for every 29 patients treated, enoxaparin therapy would not only avoid one event of the composite end-point, it would also save 348 PLN. The threshold analysis revealed, that enoxaparin would lose the dominance, when cost of enoxaparin therapy would increase by 30%, cost of UFH—decrease by 47%, probability end-point in enoxaparin arm increase to 0.22 or in UFH arm decrease to 0.2. **CONCLUSION:** Since enoxaparin resulted in a better effect at a lower cost, this antithrombotic strategy was considered to be dominant for Polish patients with ACS.

**PCV17**

**QUALITY OF LIFE AND PATIENT PREFERENCE AS PREDICTORS FOR RESOURCE UTILIZATION AMONG PATIENTS WITH HEART FAILURE; INTERIM ANALYSIS**

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**OBJECTIVE:** The objective of this study was to examine the role of quality of life (QOL) and patient preference as predictors for resource utilization among patients with heart failure (HF). **METHODS:** QOL, patient preference, resource utilization, and survival are being assessed in 94 patients with HF managed in an urban HF specialty clinic. QOL is measured using a disease-specific questionnaire, the Kansas City Cardiomyopathy Questionnaire (KCCQ) and a generic questionnaire, the Short Form 12 (SF-12), at baseline, 3 months, and 6 months. Patient preference is measured using standard gamble technique at baseline. Resource use including hospitalization, ER visits, procedures, and outpatient visits are captured by patient interview and verified by clinic and hospital records. Health care costs are derived from clinic cost data, University Health System Consortium database, and literature. **RESULTS:** To date, 81 patients have completed 3 months follow-up (mean age  $49.9 \pm 14.0$  years; 69% African American; 53% male; NYHA class I = 15,

II = 24, III = 38; mean left ventricular ejection fraction = 34.3%  $\pm$  15.5). Mean disease-specific QOL (KCCQ Overall Summary Score = 66.9) and generic QOL (Physical Component Summary = 38.7; Mental Component Summary = 48.2) were similar to literature values for HF patients. Mean utility was 0.832. Using linear regression, lower KCCQ scores, SF-12 scores, and utility at baseline were all significantly associated with higher resource utilization at 3 months. When patients were grouped into three categories based on their baseline KCCQ Overall Summary Score (I = 0–50, II = >50 to £75, III = >75), resource utilization over 3 months was significantly different across the groups (I = \$4033; II = \$2500; III = \$2010;  $p = 0.0003$ ). **CONCLUSION:** Among patients with HF, QOL and patient preference appear to predict future resource utilization.

**PCV18****FRAMINGHAM RISK EQUATIONS PREDICT HOSPITAL USAGE AND MORTALITY**

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Risk equations based on the Framingham Heart Study (FHS) are used in NZ to predict the 5y risk of incident cardiovascular (CV) events. **OBJECTIVE:** To establish how well the FHS equations predict first hospitalisation or mortality from CV events in a New Zealand (NZ) population without overt CV disease. **METHODS:** Observations were taken from a cohort study with 6354 (4638 M +1716 F) participants age 32–74 without known CV disease, taken from the workforce of a nation-wide multi-industry corporation plus a random sample of the Auckland electoral rolls. Prognostic factors were assessed in 1992/93 by a questionnaire plus physiological measurements (BP, cholesterol etc.). Age-specific risk predictions from the FHS were compared with age-specific mortality plus relevant hospital discharges from January 1988 to December 1998 (NZ Health Information Service). **RESULTS:** The 5y incidence of first hospitalisation for any CV event was 6.4% (male) and 4.4% (female). Table 1 compares observed hospitalised events or mortality with predicted incident events, averaged across 5y age bands.

Ratio of observed to predicted events, averaged across 8  $\times$  5y age bands

Mean ratio ( $\pm$ SD)	Male	Female	Both
CHD	1.03 $\pm$ 0.15	0.92 $\pm$ 0.35	1.03 $\pm$ 0.06
MI	1.24 $\pm$ 0.19	1.49 $\pm$ 1.19	1.26 $\pm$ 0.15
STROKE	0.98 $\pm$ 0.40	0.74 $\pm$ 0.57	0.94 $\pm$ 0.42

**CONCLUSIONS:** FHS risk equations accurately predict age-specific incident hospitalized CHD or stroke events or mortality for NZ males age 30–74 but under-estimate MI events. Prediction is less accurate and precise for females.

**PCV19****DISCRIMINABILITY FOR RISK OF CARDIOVASCULAR EVENTS**

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Risk equations based on the Framingham Heart Study (FHS) are used in NZ to predict the 5y risk of an incident CV event for individuals without cardiovascular (CV) disease. **OBJECTIVES:** To establish in a NZ population without overt CV disease: (i) the discriminability of the relevant FHS risk equation for prediction of first hospitalisation or mortality for any cardiovascular event; (ii) whether FHS risk equations have better discriminability than single risk factors. **METHODS:** Observations were taken from a cohort study with 6354 (4638 M + 1716 F) participants age 32–74 without known CV disease, taken from the workforce of a nation-wide multi-industry corporation plus a random sample of the Auckland electoral rolls. Prognostic factors were assessed in 1992–93 by a questionnaire plus physiological measurements (BP, cholesterol etc.). Outcomes data were CV mortality and hospital discharges from Jan. 1988 to Dec. 1998 (NZ Health Information Service). Risk predictions were compared with outcomes, and receiver-operator characteristics (ROC) curves were constructed. The area under the ROC curve was obtained by fitting a dual-Gaussian unequal variance model. **RESULTS:** Table 1 shows the area under the ROC curves.

Area under ROC curves ( $\pm$ 95% CI).

	Male	Female	Total
FHS	.72 $\pm$ .030	.78 $\pm$ .055	.74 $\pm$ .025
Age	.70 $\pm$ .029	.77 $\pm$ .058	.71 $\pm$ .026
SBP	.62 $\pm$ .034	.69 $\pm$ .062	.64 $\pm$ .030
Chol/HDLc	.61 $\pm$ .034	.64 $\pm$ .066	.63 $\pm$ .030
BMI	.56 $\pm$ .034	.61 $\pm$ .063	.58 $\pm$ .029

**CONCLUSIONS:** FHS risk equations or age alone provide moderate discriminability for individuals with 5y risk of a CV event that requires hospitalisation. SBP and serum lipids have weaker discriminability.

**PCV20****ASSESSING THE TOTAL COST OF MANAGEMENT OF A PATIENT WITH DEEP VEIN THROMBOSIS (DVT) IN FRANCE AND IN ITALY**

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**OBJECTIVES:** Economic studies on the cost of DVT usually take into account the acute care costs only although the patients are treated and followed-up after hospital discharge for at least six months. We calculated the true economic burden of the disease. **METHODS:** We assessed from the Health Care System perspective the total cost of managing a patient with DVT over a one-year

period in France and in Italy. For assessing the inpatients costs, we used the National inpatient Diagnosis Group data base in France and in Italy. We studied the patient profile, the mean length of stay and the subsequent complications. Data on outpatient care for DVT were based on literature, questionnaire filled in by practitioners, ambulatory care data base (in France) and compared to practice guidelines. Inpatient and outpatient costs were combined to provide total costs of care for DVT over an one-year period. In addition, we modelled, from published data, the risk of pulmonary embolism (PE) and DVT recurrences, and we costed these complications. **RESULTS:** The average French inpatient cost for DVT is 3,220 Euros (average length of hospital stay: 9.6 days) while this cost is 2,865 Euros in Italy (average length of hospital stay: 7 days). In both countries, the total cost of management of a DVT patient over an one-year period was calculated to be at least 30% higher than the only costs of acute care. **CONCLUSION:** The assessment of the global economic burden of DVT has to take into account the costs occurring after hospital discharge. Our approach was conservative as we did not take into account the risk of occurrence of Post Phlebotic Syndrome and its economic consequences.

**PCV21**

**COST-EFFECTIVENESS ANALYSIS OF ABCIXIMAB, EPTIFIBATIDE, AND TIROFIBAN IN PATIENTS WITH CORONARY SYNDROMES**

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**BACKGROUND:** In recent years, significant advances have been made in the pharmaceutical treatment of coronary syndromes. The GPIIb/IIIa receptor antagonists have been shown to increase the success rate of invasive procedures, such as PTCA. However, acquisition costs for these agents are high when compared with traditional therapy (i.e., heparin). Three GPIIb/IIIa receptor antagonists have been approved for use by the US Food and Drug Administration. **OBJECTIVE:** To assess the relative cost-effectiveness of abciximab, eptifibatide, and tirofiban when treating US patients with coronary syndromes. **METHODS:** A decision analytic model compared the three drugs on the basis of major bleeding events and myocardial infarction. Costs included those for medications and adverse events. Transition probabilities were based on published trials and clinical judgement. The time horizon for the model was 30 days. Cost-effectiveness ratios were computed for the three agents and rank order stability analysis used to test the robustness of results. A hospital perspective was adopted for the analysis. **RESULTS:** Average per-patient treatment cost was \$1,393, \$2,480, and \$2,409 for eptifibatide, abciximab, and tirofiban, respectively. The probability of successful treatment (i.e., no bleeding or myocardial infarction) was 0.86, 0.89, and 0.78 for eptifibatide, abciximab, and tirofiban, re-

spectively. The cost per successfully treated patient was \$1,616, \$2,799, and \$3,080 for eptifibatide, abciximab, and tirofiban, respectively. The incremental cost of eptifibatide was \$45,292 less than abciximab and \$12,700 less than tirofiban per successfully treated patient. Estimates of cost-effectiveness were robust to alterations in model parameters. In order for eptifibatide and abciximab to be equally cost-effective, the bleeding rate for eptifibatide would have to increase by 26.9% or the probability of myocardial infarction for eptifibatide would have to increase by 12.8%. **CONCLUSIONS:** Results indicate that the higher costs of abciximab and tirofiban may not be justified when treating US patients with coronary syndromes. Our model was limited by the availability of event probability estimates for eptifibatide and tirofiban.

**PCV22**

**IN-PATIENT AND OUT-PATIENT RESOURCE UTILIZATION AMONG PATIENTS WITH ACUTE ISCHEMIC STROKE—THE VA EXPERIENCE**

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**OBJECTIVE:** To study patterns of medical resource utilization among VA patients following admission to VA hospitals for acute ischemic stroke. **METHODS:** All VA patients were identified with a first-listed live discharge diagnosis of acute ischemic stroke between 1991 and 1997. The frequency and type of re-admissions, total bed section days, and of outpatient clinic visits was measured. **RESULTS:** A total of 49,101 patients were identified. Mean age of the predominantly male (98.2%) cohort was 67.8 years and 72.5% were Caucasian. Over 48% of patients were re-hospitalized, and 13% of these re-admissions were for recurrent stroke. There were an average of 3.3 re-admissions and the mean time to readmission was 0.9 years. Readmitted patients spent most days in rehabilitation wards (26.8 days), followed by general/acute medicine wards (22.5 days), surgery (15.1 days), neurology (14.9 days), and cardiology (8.5 days). Thirty-five percent of outpatient medical clinic visits were to specialty clinics and 41% of these visits were to neurology followed by cardiology (22%) and Coumadin clinics (21%). **CONCLUSIONS:** Hospitalization for recurrent stroke is high among VA stroke patients and much of the inpatient and outpatient resource utilization is associated with stroke rehabilitation and neurologic care. Efforts should focus on innovations in acute stroke treatment to improve the functional status of these patients at the time of the index admission and reduce the incidence of subsequent adverse events.

**PCV23****PHARMACOECONOMIC EVALUATION OF USAGE OF UNFRACTIONATED HEPARIN AND LOW MOLECULAR WEIGHT HEPARIN IN THE TREATMENT OF DEEP VEIN THROMBOSIS IN LONG-TERM CARE RESIDENTS**Karki SD<sup>1</sup>, Bellnier TJ<sup>1</sup>, Karki J<sup>1</sup>, Patterson W<sup>2</sup>, Masood R<sup>2</sup><sup>1</sup>SUNY University at Buffalo School of Pharmacy, Buffalo, NY, USA; <sup>2</sup>Clifton Springs Hospital & Clinics, Clifton Springs, NY, USA

**OBJECTIVE:** Nursing home residents with acute proximal deep-vein thrombosis (DVT) are usually transferred to the hospital and treated initially with unfractionated heparin administered by continuous infusion for five to seven days. The anticoagulant response to this treatment varies markedly among patients and therefore the dosage must be adjusted by measuring the activated partial-thromboplastin time closely. With the availability of low molecular weight heparins and their proven efficacy and safety in treatment and prophylaxis of deep vein thrombosis and no need to closely monitor any parameter and adjust the dosage, it has become possible to treat DVT in nursing home setting. We describe our findings of the economic implications of two different therapies. **METHOD:** All residents treated for DVT in the last 2 years were identified and their charts reviewed as to the use of heparin or enoxapirin (formulary LMWH in our institution). Charts of 25 residents from each group matched for sex and age were randomly reviewed as to efficacy, transfer to hospital, days of hospitalization and costs of treatment. **RESULTS:** The residents, in the heparin arm, were transferred to the hospital, treated with continuous heparin infusion, initiated on warfarin therapy and then transferred back to the nursing home. The hospitalization ranged from 5–15 days and the mean hospitalization cost was \$4196 + 225. Of the residents on enoxapirin arm, only 9 residents were transferred to the hospital and the hospitalization ranged from 3–5 days. The mean hospitalization and nursing home costs were \$2258 + 150. There was additional drug cost \$490 in the heparin arm and \$800 in the of enoxapirin arm resulting in cost saving of \$1628 per resident in the enoxapirin arm **CONCLUSION:** Our results indicate that enoxapirin is cost-effective in the treatment of DVT in the nursing home residents.

**PCV24****BEYOND THE FIRST YEAR: PATTERNS AND PREDICTORS OF LONG-TERM STATIN UTILIZATION**Benner JS<sup>1</sup>, Federman AD<sup>1</sup>, Smitten AL<sup>2</sup>, Duty S<sup>2</sup>, Glynn RJ<sup>1</sup>, Avorn J<sup>1</sup><sup>1</sup>Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA; <sup>2</sup>Harvard School of Public Health, Boston, MA, USA

**INTRODUCTION:** Noncompliance with lipid-lowering medications has important implications for clinical and

economic outcomes of therapy. Little is known about long-term utilization of HMG Co-A reductase inhibitors (statins) because previous data have been based on closely monitored trials or have observed patients for short periods of time. **OBJECTIVE:** To describe patterns and predictors of long-term compliance with statin therapy in a US elderly population. **METHODS:** Cohort study (n = 607) of enrollees in the New Jersey Medicaid and Pharmacy Assistance for the Aged and Disabled (PAAD) programs aged 65 and older who began statin therapy in the first half of 1990. Filled prescription data were used to assess the proportion of days with any statin available in each of 12 consecutive 6-month intervals after initiation of therapy. Demographic and clinical predictors of noncompliance, measured at baseline, were identified using linear models for repeated measures. **RESULTS:** Mean days with statin available was 64% in the first 6 months of therapy and 45% in the next 6 months; it then decreased linearly to 32% at the end of year 6. The proportion of patients with 80% of days covered was 41% in the first 6 months, 30% in the next 6 months, and 25% at the end of year 6. After controlling for baseline demographic and clinical variables, lower compliance in years 2 through 6 was significantly associated with duration of treatment, black race, lower income, older age, and taking fewer other medications. By contrast, first-year compliance was significantly better among blacks than other races and age was not associated with utilization. **CONCLUSIONS:** Compliance with statin therapy declines over time, with the greatest reductions occurring in the first year of treatment. Predictors of short- and long-term compliance differ, with long-term noncompliance most strongly predicted by age, race, and socioeconomic status.

**PCV25****CHD RISK FACTORS AND THERAPY DURATION OF HMG-COA REDUCTASE INHIBITORS (STATINS) IN A MEDICAID POPULATION**Nichol MB<sup>1</sup>, Bron MS<sup>1</sup>, Yu W<sup>2</sup><sup>1</sup>University of Southern California, Los Angeles, CA, USA;<sup>2</sup>Wellpoint Pharmacy Management, Thousand Oaks, CA, USA

**INTRODUCTION:** The purpose of this research is to explore the relationship between the number of CHD risk factors (RF) and duration of therapy of statins. CHD risk factors play an important role in choice and goals of lipid-lowering therapy. **OBJECTIVE:** To determine if the median duration of therapy differs among Medicaid hypercholesteremic patients with 0,1,2 and 3 or greater CHD risk factors who were treated with statins currently on formulary. **METHODS:** Retrospective database analysis of pharmacy claims data for an intent-to-treat analysis of Medicaid monotherapy statin patients. Patients were required to be eligible 35 days before and 365 days after the first statin prescription. New patients (n = 767) must have a 90 day washout period. Continuing patients (n = 1191) do not. The Medians test was used for non-

parametric data. OLS regression tested the relationship between duration of therapy and presence of CHD risk factors. **RESULTS:** For each statin, days on therapy differed significantly ( $p < 0.001$ ) by the number of risk factors. The number of CHD risk factors was positively significant in predicting duration of therapy ( $p < 0.0001$ ) in both new and continuing therapy. Duration of therapy was associated with an increase of 48 days for each risk factor for new patients and 58 days for continuing patients. **CONCLUSIONS:** Number of CHD risk factors is positively correlated with length of therapy when using statins as lipid lowering therapy for new and continuing patients.

Statin	Risk Factors (RF): 0	RF: 1	RF: 2	RF: 3 OR 4
Overall Median	305	431	481	550
atorvastatin	345	419	424	562
fluvastatin	289	428	505	568
pravastatin	303	444	469	533

**PCV26**

**CARING FOR HYPERTENSION ON INITIATION: COSTS AND EFFECTIVENESS (CHOICE). DESIGN AND RATIONALE OF A NATURALISTIC STUDY**

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**INTRODUCTION:** Naturalistic studies are essential to prospectively study real-world antihypertensive treatment **OBJECTIVE:** to evaluate the feasibility of performing a naturalistic study in newly diagnosed hypertensives in terms of enrollment, adequacy, timeliness of data collection, and study procedures. **METHODS:** CHOICE prospectively collected actual practice data on the treatment of newly-diagnosed hypertensive patients. Initial therapy was randomly assigned to either Group 1 (beta blockers or diuretics) or Group 2 (ACE inhibitors or calcium channel blockers). The protocol made no demands in scheduling visits or changing treatment during follow-up. Physicians were blind to study purpose and hypotheses. Only a final visit at  $5 \pm 1$  months, if none occurred naturally, was mandated. Direct involvement of the CHOICE study team was minimized using a Remote Study Monitoring System to collect data and communicate with study sites. **RESULTS:** Within 30 weeks, a total of 55 physicians enrolled 512 patients with a mean age of 51 years and blood pressure of 158/99 mmHG. In all, 46 different antihypertensive medications were prescribed and 2,554 office visits (range = 1–16 visits per patient) were attended. Other medical resource use was low during the study period. A final, clean database was ready for analysis 30 days after last patient last visit. **CONCLUSIONS:** It has been demonstrated that CHOICE is a

feasible framework to study the real-world effectiveness of initial therapy for newly diagnosed hypertension. Protocol flexibility and a novel electronic data entry system are core elements of this naturalistic design.

**PCV27**

**A PHARMACOECONOMIC MODEL TO EVALUATE TREATMENT OPTIONS FOR DVT PHARMACOPROPHYLAXIS**

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Economic analysis of various treatment modalities used to prevent deep vein thrombosis (DVT) in various medical and surgical at-risk patients has been limited by lack of consistent and representative methods to evaluate various resource costs attributed to both the prevention of DVT and the diagnosis and treatment of prophylaxis failures. **OBJECTIVE:** To develop a systematic and comprehensive method to identify and prioritize all direct costs associated with DVT prophylaxis. **METHODS:** A decision tree was developed to identify and prioritize all medical, surgical and diagnostic procedures that contribute to overall direct cost. Included were costs of prophylaxis, cost of diagnosing a prophylaxis failure (a DVT) and costs of major complications of this therapy (pulmonary embolism, major bleeding and thrombocytopenia.) Diagnostic procedures were also prioritized clinically as either a “standard”, “alternative or confirmatory”, or “supplemental” procedure. This prioritization allows for probability multipliers to be assigned to each category of diagnostic procedures in order to get a weighted average of the cost of this procedure. Likewise, the various costs associated with prophylaxis failure were prioritized. Next a spreadsheet was developed to match this decision tree. This spreadsheet contained all identified resource costs shown on the decision tree and indicated the quantity or units of each resource that are typically used. Lastly, the corresponding CPT and ICD9 codes for all resources were identified. **RESULTS:** Major categories of resources identified include diagnostic, treatment, and monitoring. These 3 areas are divided into 13 sub-categories which in turn include over 60 specifically identified cost related resources. **CONCLUSION:** This model allows any institution to accurately identify, prioritize and analyze institution specific resource costs instead of using literature values to determine the cost-benefit of various pharmacoprophylactic regimens including unfractionated heparin and various low molecular weight heparins used at their site.

**PCV28**

**CHOLESTEROL REDUCTION SUCCESS RATES AND RESOURCE UTILIZATION BY GENDER**

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**OBJECTIVE:** To assess relative success rates and resource utilization differences between males and females treated to NCEP and EAS cholesterol goals with HMG-CoA reductase inhibitors. **METHODS:** In three open-label clinical trials in the US and Europe, 998 patients (375 females and 623 males) with a CHD risk factor, documented CHD and/or PVD, were randomized to receive one of five HMG-CoA reductase inhibitors (atorvastatin, fluvastatin, lovastatin, pravastatin, or simvastatin). Physician visits occurred every 6 weeks and dose titrations (either increased statin dose, or the addition of colestipol or cholestyramine) were made every 12 weeks if target LDL-C concentration levels were not achieved. The analysis takes a third party perspective by using insurance payment rates for study medications, physician visits, add-on therapies and treatments for adverse events, all denominated in 1997 US dollars. **RESULTS:** NCEP or EAS LDL-C targets were achieved with similar frequency by males (75.7%) and females (74.7%). Accordingly, resource utilization was similar for males and females. Mean total costs were similar for all males (\$1529.94) and females (\$1470.99,  $p = 0.776$ ); males (\$1280.62) and females (\$1252.95,  $p = 0.665$ ) reaching goal and males (\$2306.32) and females (\$2115.59,  $p = 0.103$ ) not reaching goal. Finally, mean total costs for males and females (and respective percentages achieving LDL-C targets) were similar among study medications: atorvastatin \$1044.49 (88.2%) and \$1020.29 (90.7%); fluvastatin \$1815.03 (58.4%) and \$1709.72 (55.5%); lovastatin \$2031.78 (77.9%) and \$2045.43 (80.3%); pravastatin \$1878.90 (53.6%) and \$1776.19 (35.7%) and simvastatin \$1475.48 (80.3%) and \$1293.43 (77.0%). **CONCLUSIONS:** Successes in achieving LDL-C targets and resource utilization were independent of gender. However the ability to reach target LDL-C, by use of specific study medications, significantly impacts the total cost of cholesterol reduction.

**PCV29**

**ECONOMIC OUTCOMES OF PATIENTS RECEIVING CARVEDILOL COMPARED TO THOSE RECEIVING NO BETA-BLOCKER THERAPY FOR THE TREATMENT OF CONGESTIVE HEART FAILURE IN A MANAGED CARE ORGANIZATION**

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Considerable clinical trial data is available to support the use of beta-blockers for the treatment of congestive heart failure (CHF). **OBJECTIVES:** The primary objective is to compare differences in health care costs (pharmacy, medical, and total) between patients receiving carvedilol and those not receiving a beta-blocker for the treatment of CHF. The secondary objective is to determine differences among cohorts with respect to CHF-related costs and total health care costs (CHF and non-CHF related).

**METHODS:** Retrospective claims data from a large managed care organization were analyzed. Patients were included if they had an ICD-9 diagnosis code for CHF between 1/1/97 and 12/31/99, received an ACE inhibitor and a diuretic, were continuously eligible, and at least 18 years old. The carvedilol group was newly started on carvedilol and did not receive another beta-blocker. The non beta-blocker group did not receive any beta-blockers and had no contraindications to beta-blocker therapy. All patients were followed for 1 year. Total health care costs include costs for all services covered. CHF-related costs include those directly related to the treatment of CHF. **RESULTS:** There were a total of 9,439 patients, 52.3% were female, and the average age was 77 (S.D. = 9.5) years. Total cost (CHF and non-CHF related) were measured after adjusting for age, gender, pre-total cost, and Charlson Comorbidity Index. Patients in the carvedilol group had higher pharmacy cost (\$2,586 versus \$1,343,  $P < .0001$ ), lower medical cost (\$18,196 versus \$22,168,  $P = 0.362$ ), and lower total cost (\$20,782 versus \$23,511,  $P = 0.619$ ). When measuring only CHF-related costs, patients in the carvedilol group had higher pharmacy cost (\$1,489 versus \$416,  $P < .0001$ ), lower medical cost (\$2,232 versus \$3,105,  $P = 0.450$ ), and slightly higher total cost (\$3,721 versus \$3,521,  $P = 0.959$ ). **CONCLUSION:** The higher pharmacy cost of carvedilol use appears to be offset by a reduction in total (CHF and non-CHF related) medical cost.

**PCV30**

**COST-EFFECTIVENESS MODEL OF THROMBOLYTIC THERAPY FOR ACUTE MYOCARDIAL INFARCTION**

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**OBJECTIVE:** To conduct a cost-effectiveness analysis of tissue-Plasminogen Activator (t-PA) versus Streptokinase (SK) for treating acute myocardial infarction (AMI). **PER-SPECTIVE:** Societal. **DATA SOURCES:** The cost, clinical outcomes and utilities were obtained from literature. **METHODS:** Decision analytical model was used to evaluate the short and long-term outcomes and costs associated with the use of SK or t-PA for AMI. Clinical benefit is expressed as Quality Adjusted Life Years (QALY) resulting from the treatment. Patients presenting within six hours after onset of symptoms, with a certain probability of death may be treated with SK or t-PA. Survivors may either get a disabling stroke or no stroke, patients with no disabling stroke may or may not have a reinfarction. Inpatient and long-term costs of coronary disease and disabling stroke were included. Costs and QALYs were discounted at 3%. Expected costs and QALYs yielded the Incremental Cost-effectiveness Ratio (ICER). Sensitivity analyses were performed on important factors. **OUT-COMES:** QALY which incorporated 30 days mortality, impacts of disabling stroke, reinfarction. Short-term and

long-term medical costs. **RESULTS:** Using 30-day mortality data from the Global Utilization of Streptokinase and Tissue Plasminogen Activator for Occluded Coronary Arteries (GUSTO) trial, the baseline analysis yielded an ICER for t-PA of \$24,882/QALY compared to SK. The ICER was sensitive to the difference in reinfarction rate (baseline 3.83%: 3% ICER \$19,326: 6% ICER \$120,767) and mortality rate (baseline 6.3%: 6.7% ICER \$46,688: 7.2% ICER \$197,850) of t-PA. **CONCLUSION:** t-PA is a cost-effective therapy for MI compared to SK. In addition, despite using costs and utilities from varied sources, and employing a simpler model the findings support previously published results.

**PCV31**

**CLOSURE OF ATRIAL SEPTAL DEFECT: MEDICO-ECONOMIC ARGUMENTS TO CHOOSE BETWEEN INVASIVE SURGERY AND PERCUTANEOUS TECHNIQUE USING SEPTAL OCCLUDER**

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**OBJECTIVES:** The medical device implantation techniques via percutaneous aboard tend to substitute to surgical techniques, in various cardio-vascular therapeutics. However, prosthesis implantation is often accompanied high implementation costs (linked to the device acquisition) which are difficult to justify to the decision-maker, in a context of high financial constraint. **METHOD:** Available clinical data show similarity of effectiveness and complication rates between these two techniques. Therefore, the economic appraisal consists in a cost minimization approach. First, we modeled the two technique protocols before costing each action (personnel, facilities, . . . ) according to the internal costs of Grenoble hospital. Moreover, we estimated the budgetary productivity of these two strategies using the French DRG classification system used to adjust the annual financial allocation of French public hospitals. **RESULTS:** Results show the percutaneous technique (septal occluder Amplatzer®) is dominant (1.5 times less expensive than surgery), mainly by decreasing the hospital stay (two hospitalization days instead of 12 days in the surgery strategy). DRG system classification generates 1473 ISA (hospital productivity index) for the percutaneous technique and 7556 ISA for invasive surgery. **CONCLUSIONS:** Comparing between cost-minimization technic using internal costs and incremental budgetary impact using French DRG classification, we conclude that the prosthesis implantation via percutaneous aboard is economically dominant (cheaper than invasive surgery) but 5 times less contributive to annual budget allocation. Therefore incitation for the hospital decision-maker to use septal occluders must come with the adaptation to new technologies of financial public allocation using the DRG classification.

**PCV32**

**STRATEGIES FOR IMPROVING COMPLIANCE WITH HMG-COA REDUCTASE INHIBITORS**

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**OBJECTIVE:** To assess medication compliance and predictors of compliance with HMG-CoA reductase inhibitors for patients following a myocardial infarction (MI) or other atherosclerotic event. **METHODS:** Patients were identified from a managed care organization (MCO) database who had an MI or other atherosclerotic event in 1997 or 1998 and were continuously enrolled in the MCO for the year following the event. All patient records were collected following guidelines for HEDIS reporting. Pharmacy claims data review identified 216 patients who had at least one prescription filled for a statin. A number of compliance measures were calculated, including the CMA, a continuous multiple-interval measure of medication availability. A multivariate linear regression of CMA included the following independent variables: age, sex, ICD-9 of admission, DRG of admission, statin prescribed, medication days supply dispensed, number of unique medications prescribed, number of unique chronic medications prescribed, and prescription drug copay amount. **RESULTS:** The mean CMA was 0.820. Regression results (adjusted r-square 0.11) indicate that several factors had potentially large impacts on CMA, but the estimates were associated with large standard errors (age, gender, ICD-9 of admission, DRG of admission, statin prescribed). Four factors with estimates statistically significantly different from zero are as follows (t-statistics in parentheses): days supply (each 30-day increment) 0.116 (3.61), number of concomitant unique medications -0.009 (2.29), number of concomitant unique chronic medications 0.012 (1.83), copay (each \$1) -0.007 (2.84). **CONCLUSIONS:** Compliance with statins was high in this sample, but not ideal (1.0). Strategies for improving compliance that may have merit include: providing patients with 60 or 90-day supplies (rather than 30-day supplies), controlling the number of other medications prescribed and having lower patient copayments for these important medications.

**PCV33**

**COST-ANALYSIS OF CABG SURGERY IN PATIENTS WITH AND WITHOUT RETHORACOTOMY FROM THE HOSPITAL PERSPECTIVE IN GERMANY**

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**OBJECTIVES:** German hospitals receive the same reimbursement by the statutory health insurance for CABG

surgery irrespective of whether or not a rethoracotomy, which involves higher in-hospital costs, has to be performed following hemorrhage. In order to evaluate the in-hospital costs for CABG with and without rethoracotomy from the hospital perspective, a cost-analysis of CABG surgery was performed. Furthermore, the cost-effectiveness of prophylactic administration of the antihemorrhagic agent aprotinin was investigated. **METHODS:** The detailed resource utilization of 138 CABG patients, 68 with rethoracotomy and 70 without, was analysed based on sample of patient medical records from 7 German hospitals. Resource costs were provided by hospital administrations and supplemented by literature. The overall costs for both groups were then combined with rethoracotomy rates in patients with and without prophylactic administration of aprotinin derived from a published meta-analysis of all relevant clinical trials in open heart surgery. **RESULTS:** The total in-hospital costs per patient with CABG were on average DM 21,241 and increased to DM 31,326 for a CABG patient requiring rethoracotomy. Besides the costs of the rethoracotomy, the costs of intensive care were the main cost driver in patients with rethoracotomy. The meta-analysis showed with statistical significance that aprotinin can reduce the rethoracotomy rate from 5.0% to 1.8% in patients undergoing heart surgery. When combining the cost data with the results of the meta-analysis, the expected average costs per patient treated with aprotinin (including drug costs) were DM 21,432 compared to DM 21,655 per patient without aprotinin treatment. A cost-effectiveness analysis (costs per patient without rethoracotomy) resulted in a difference of DM 970 in favour of the prophylactic antihemorrhagic treatment. **CONCLUSION:** The analysis showed that CABG patients requiring an additional rethoracotomy generated about 47% higher costs than patients with CABG surgery only. The administration of the antihemorrhagic agent aprotinin can be recommended in the light of the reduced complication rate and improved cost-effectiveness of CABG-surgery.

**PCV34**

**DECISION ANALYSIS MODEL OF ABCIXIMAB, EPTIFIBATIDE OR STANDARD THERAPY IN ELECTIVE STENT PLACEMENT: A CANADIAN PERSPECTIVE**

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The use of glycoprotein 2b/3a receptor antagonists has been shown to be beneficial in elective coronary stent implantation. In Canada, the cost of abciximab has limited widespread use in this population. Recently presented data comparing eptifibatide with heparin alone in a similar population has suggested a significant improvement in clinical outcomes with this less expensive agent. There are no trials directly comparing these two agents in the elective stent patient population. **OBJECTIVE:** the pur-

pose of this study was to assess the cost-effectiveness of abciximab or eptifibatide compared to standard therapy in patients undergoing elective stent placement in a Canadian setting using a decision analysis model. **METHODS:** Clinical outcome data was abstracted from the Epistent and Esprit trials. Economic data assessing direct costs for coronary intervention procedures and complications was acquired from the London Health Sciences Centre hospital cost database for the period 1998–99. The composite clinical endpoint was freedom from death, myocardial infarction and urgent revascularization at 30 days. The primary study outcome was the incremental cost per event prevented. **RESULTS:** In the baseline analysis, both agents compared favorably with standard therapy. Abciximab had an incremental cost-effectiveness of \$US 10,320 per event prevented. Eptifibatide was less costly and more effective, hence dominant over standard therapy. The baseline analysis yielded a benefit of 6 events per 1,000 patients treated in favour of abciximab over eptifibatide. However the incremental cost per event prevented was \$US 125,218, a less favorable value. **CONCLUSION:** The incremental cost-effectiveness of abciximab compared to eptifibatide was sensitive to the cost of abciximab and to the incidence of myocardial infarctions. A randomized trial comparing abciximab and eptifibatide in elective coronary stent placement is necessary to better assess this issue.

**PCV35**

**COMPARABILITY OF PUBLISHED STUDIES ON COST-EFFECTIVENESS OF ANTIHYPERTENSIVE THERAPY: DO THE RESULTS HELP THE DECISION-MAKING PROCESS?**

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**OBJECTIVES:** Cost-effectiveness studies can provide valuable information for decision-making processes, where limited resources need to be allocated across a variety of different treatments. However, it is argued that the current methods for conducting and reporting cost-effectiveness results for this purpose are sub-optimal. This literature review and analysis compares the most recent hypertension cost-effectiveness studies. The goal is to contribute information so that future cost-effectiveness studies of hypertension treatments will provide more optimal information for clinicians and other decision-makers for the choice of antihypertensive treatment. **METHOD:** A literature search of several databases for the years 1995–2000 was conducted using the following keywords: hypertension and cost-effectiveness and/or economics. **RESULTS:** The search resulted in 89 articles, of which only 11% (10 studies) were true pharmacoeconomic studies that contained actual data analysis. Of the 10 studies, the majority reported outcome measures in terms of cost per life year gained, but usually considered more than one outcome measure. Coronary heart dis-

eases and stroke were the most consistent endpoints across the studies but the number and types of endpoints that were included differed significantly among the studies. Only two studies included within-clinical trial treatment effectiveness data, whereas the remaining studies modeled treatment effects from previously published trials. The projected cardiac event rates and life expectancy were most often derived and estimated from the Framingham study. Treatment costs were obtained from several different sources outside clinical trials, and only one study considered costs solely from the trial. **CONCLUSION:** Despite the increasing emphasis on hypertension as one of the most costly long-term diseases, and the need to reduce costs associated with it, there are relatively few recently published studies on the cost-effectiveness of antihypertensive therapies. Methodologically, these published studies are very different and they do not seem to agree on a common way to provide a cost-effectiveness measure for hypertension treatment, making interpretations and comparability of results across different studies more difficult.

**PCV36**

**EVALUATION OF COMPLIANCE AND PERSISTENCE WITH HMG-COA REDUCTASE INHIBITORS AFTER A MYOCARDIAL INFARCTION USING PHARMACY CLAIMS DATA**

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**OBJECTIVE:** To determine compliance and persistence with cholesterol-lowering therapy with HMG-CoA reductase inhibitors (statins) in patients following a myocardial infarction (MI) or other atherosclerotic event. **METHODS:** Patients were identified from a Midwestern managed care organization (MCO) database who had an MI or other atherosclerotic event in 1997 or 1998 and were continuously enrolled in the MCO for the year following the event. Patient records were collected following HEDIS reporting guidelines. Pharmacy claims data review identified 216 patients who had at least one prescription filled for a statin. Compliance and persistence were assessed using length of therapy, single-interval medication availability, multiple-refill-interval medication availability, single-interval medication gaps, and multiple-refill-interval medication gaps. **RESULTS:** The population was predominantly male (76%) and the mean age was 61 years (SD 10.2 years, range 34 to 77). The cardiovascular events were as follows: 52% MI, 45% coronary atherosclerosis, and 4% other atherosclerotic event. The proportion of patients persistent with statin therapy at 3, 6, 9, and 12 months were 88, 86, 80, and 69 percent respectively. Patients achieved 90% compliance with each refill (SD 25%, median 94) and cumulative compliance for all refills was 83% (SD 24%, median 92). The average single-interval treatment gap was 11 days (SD 28.5 days, median 2 days) while the average cu-

mulative total treatment gap over the study period was 44 days (SD 70 days, median 13 days). **CONCLUSIONS:** Compliance with HMG-CoA reductase inhibitors as measured by single-interval and multiple-refill-interval was generally high, but not ideal (100%) following an MI or other atherosclerotic event. These pharmacy claims data may be further analyzed using multivariate regression to determine the impacts of age, sex, diagnosis, number of concomitant medications, medication days supply, type of statin prescribed, and patient copay on compliance and persistence with therapy.

**PCV37**

**THE COST-EFFECTIVENESS OF STATINS: EVIDENCE FROM THE ACCESS TRIAL**

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**OBJECTIVE:** There are now a host of HMG-CoA reductase inhibitors (statins) for treating persons with elevated cholesterol levels. The objective of this is to determine the relative cost of treatment among statins. **METHODS:** The ACCESS study was a 54-week open label trial of atorvastatin as compared to fluvastatin, lovastatin, simvastatin and pravastatin. After a screening phase and a lead-in phase, patients were treated to NCEP target LDL-C levels with statins, starting at the lowest dose level. At six-week intervals (weeks 6, 12, 18) patients who had not yet reached their LDL-C target were titrated up to the next dose level, to a maximum of 40–80 mg, depending on the statin. Costs of services used were recorded, including: study medications, physician visits, laboratory and diagnostic tests associated with cholesterol treatment and other medical services associated with adverse events. **RESULTS:** A total of 3916 patients were enrolled in ACCESS, with 3262 patients completing the study. Patients treated with atorvastatin had the highest rate of NCEP goal achievement (76.3% v. 34.2%–57.9%;  $P < 0.01$  for each comparison). As a result of NCEP goal achievement, atorvastatin-treated patients required the fewest physician visits through weeks 6–18 (2.81 v. 2.95–3.45;  $p < 0.01$  for each comparison) and the lowest direct study cost per patient achieving NCEP goal (\$915 v. \$1393–\$2421;  $p < 0.01$  for each comparison)—the ultimate measure of cost-effectiveness. **CONCLUSIONS:** The ACCESS trial demonstrates that treatment with atorvastatin yielded the highest proportion of patients reaching NCEP LDL-C goals at the lowest cost per patient.

WITHDRAWN

**PCV38**

and drug costs. **RESULTS:** Of the 691 patients in the atorvastatin arm, 682 used health care resources. Of the 337 patients in the simvastatin arm, 332 used health care resources. The monthly drug costs with atorvastatin was \$48.30 for 10mg, \$66.93 for 20mg, with simvastatin at \$42.06 for 10 mg, \$58.12 for 20mg. The average cost of health care for atorvastatin and simvastatin was \$460.48 and \$490.11 respectively ( $p = 0.47$ ). Adverse events accounted for 60% of all health care costs in the atorvastatin group, 77% in the simvastatin group. The weighted average monthly drug costs (WAMDC) after 6 weeks of treatment were \$48.30 for atorvastatin and \$42.06 for simvastatin. 38% of patients reached NHF target cholesterol levels on atorvastatin, 25.5% on simvastatin. The cost per responder was \$1.27 with atorvastatin, \$1.63 with simvastatin. After 12 weeks of treatment the WAMDC was \$59.53 for atorvastatin, \$53.77 for simvastatin with 47.5% and 33.8% response rates, respectively. The incremental cost-effectiveness of an extra patient achieving target on atorvastatin was \$0.50 at 6 weeks, \$0.42 at 12 weeks, \$0.26 at 18 weeks and \$0.51 at 24 weeks. **CONCLUSION:** Atorvastatin achieved a greater percentage reduction in total cholesterol per mg than simvastatin, and was equally well tolerated. While drug costs for atorvastatin were slightly higher, overall health care costs were lower than for simvastatin. Atorvastatin was more cost-effective than simvastatin in achieving NHF targets. The incremental cost-effectiveness of atorvastatin suggests additional patients can achieve NHF targets relatively inexpensively.

**COST OF TREATMENT OF  
HYPERCHOLESTEROLAEMIA TO NHF GOALS  
IN AUSTRALIA**

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**OBJECTIVE:** To estimate the comparative cost-effectiveness of atorvastatin and simvastatin. **METHODS:** A randomized clinical trial set in general practice. Effectiveness was measured by percentage reduction in total cholesterol and percentage of patients achieving NHF targets. The costs calculated in the study were hospital admissions, emergency room/clinic visits, visits to GPs and specialists, tests/investigations, treatment of adverse events

**PCV39**

**PCV40**  
**COST-EFFECTIVENESS OF LIPID LOWERING  
INTERVENTIONS IN A NATIVE AMERICAN  
CARDIOVASCULAR RISK  
REDUCTION PROGRAM**

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**OBJECTIVES:** To determine the cost-effectiveness (CE) of managing patient low density lipoprotein-cholesterol (LDL-C) levels with exercise plus nutritional therapy and exercise plus nutritional plus pharmacotherapy from the Indian Health Service perspective. **METHODS:** A retrospective database analysis was performed on data collected from a pharmacist managed Cardiovascular Risk Reduction Program (CVCRRP) from March 1997 through October 1999. Patients received exercise plus nutritional therapy (Group 1) or exercise plus nutritional plus pharmacotherapy (Group 2). Effectiveness measures included unit and percent LDL-C reduction from initial to last recorded visit. Costs (fixed plus variable) and reimbursements were determined in terms of 1999 dollar values through clinic staff interviews and billing records

analysis. Average and incremental cost-effectiveness ratios (ICE) were calculated. One-way sensitivity analyses were performed varying pharmacist salary, medication costs, and levels of reimbursement. **RESULTS:** Net cost-per-patient in Group 1 (n = 40) was \$1,204; in Group 2 (n = 32) was \$1,432. Mean LDL-C reduction was 12.67mg/dl (Group 1) and 42.03mg/dl (Group 2). Mean percent LDL-C reduction was 8.95% (Group 1) and 50.70% (Group 2). Average CE ratios were \$95.01 (unit LDL-C reduction) and \$134.50 (percent LDL-C reduction) for Group 1; \$34.07 (unit LDL-C reduction) and \$50.70 (percent LDL-C reduction) for Group 2. ICE ratios for Group 2 versus Group 1 was \$7.77 (unit LDL-C reduction) and \$11.82 (percent LDL-C reduction). The obtained CE ratios were robust to sensitivity analysis parameters. **CONCLUSIONS:** The CVCRRP showed positive lipid management results for enrolled patients. Group 2 (those including pharmacotherapy) interventions were associated with higher costs and better LDL-C outcomes. Group 2 interventions also resulted in more favorable average CE ratios compared to Group 1. Study results could be used to develop similar cardiovascular risk reduction programs, expanding the clinical role of the pharmacist and improving patient outcomes.

**PCV41**

**SOCIOECONOMIC RELEVANCE OF TREATMENT OF CHRONIC HEART FAILURE STAGE NYHA II WITH CRATAEGUS EXTRACT WS 1442—ONE-YEAR-RESULTS OF A PROSPECTIVE PHARMACOECONOMIC STUDY**

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**OBJECTIVES:** To evaluate the pharmacoeconomic properties of crataegus treatment compared to any other treatment option of CHF at stage NYHA II, a prospective 3-year observational study has been conducted since summer 1999. A cost-utility-analysis will be performed to investigate, if crataegus treatment avoids rapid deterioration with higher costs and lower HRQL. The results of the first year are presented. **METHODS:** Open, non-randomized observational cohort study. The first cohort (Crataegus-Cohort, CC) comprises patients receiving crataegus extract therapy of CHF. In the second cohort (Standard-Cohort, SC) patients without crataegus but any other treatment were observed. In 217 study centres 952 patients were included (CC: 588; SC: 364). For measuring HRQL the EuroQoL-5D was used. The perspective of the German statutory health insurance funds and the matched-pairs technique were applied. **RESULTS:** No significant differences in physical condition and demographic variables were detected between the matched groups. HRQL (143 pairs) shows significant improvement in both cohorts. The mean EuroQoL-VAS value for the CC is 55.50 before and 67.13 after half-a-year (SC:

58.06 before and 66.78 after). Improvement of HRQL in the CC is significantly higher (p = 0.023). After one year, an improvement of clinical symptoms were diagnosed in both cohorts (79 pairs) but slightly higher in the CC with no significance. Mean direct costs for CC patients amounted to DM 1,373 in the first year whereas SC patients amounted to DM 1,551 with no significant difference (p = 0.998, 98 pairs). Cost driving factors were drug acquisition and physicians fees. **CONCLUSIONS:** Even if the first analysis of the three-year-study indicates comparable direct costs in both cohorts and suggests improved HRQL in the CC further investigation in the second and third period is mandatory.

**PCV42**

**PATIENTS' WILLINGNESS TO PAY FOR PHARMACIST MANAGED WARFARIN THERAPY AT COMMUNITY PHARMACIES**

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**OBJECTIVES:** This study determined the benefits of pharmacist managed warfarin therapy (PMWT) at community pharmacies by the contingent valuation (CV) method. Benefits of PMWT in clinic have been documented. These are reduction in hospitalizations, emergency room visits and thromboembolic events due to side effects of inappropriate dosing and monitoring. However, these benefits were never measured from patient's perspective using CV method. This study elicited willingness-to-pay (WTP) values for PMWT from community pharmacy patients. **METHOD:** A self-administered 24 question CV survey was mailed to 2800 patients' homes. These patients were selected from files in community pharmacies or a rural health plan. They were divided into warfarin clinic (ex post) and non-warfarin clinic (ex ante) groups. A payment card method with visual aid charts elicited WTP values in form of out-of-pocket (OOP) expense and additional insurance premium (INS) for PMWT with six probabilities for success (3 probabilities for reduction in hospitalizations & 3 probabilities for reduction in blood clot events). **RESULTS:** Five hundred and thirty patients (393 usable) responded. Overall mean WTP values for PMWT in the form of OOP or INS were significantly greater than zero. The monthly mean OOP WTP amounts for 28% blood clot event reduction and 26% hospitalization reduction were \$17.19 ± 15.57 and \$19.26 ± 17.56 respectively. The monthly mean INS WTP for the same probabilities were \$11.97 ± 13.66 and \$12.66 ± 14.63 respectively. Regression analysis identified that annual household income, selection of health plan with PMWT and attitude towards the health plan's inclusion of PMWT were significant predictors for OOP scheme and only annual household income and selection of health plan with PMWT for INS scheme. **CONCLUSION:** Patients were able to assign WTP values to different sizes of health gains. Range bias and inconsistency of choice were detected from this sampled population.

**PCV43**

from a national managed care database representing 6 million lives in 23 US health plans and 8 geographic regions over a 4 year period. Cohorts by agents were created based on diabetes type and initial treatment agent. Cost and utilization analysis included evaluation of patients by age, gender, geographic region, type of medical service and provider speciality. Diagnosis codes were used to differentiate between all health care services and disease related services. Treatment analysis evaluated treatment progression, compliance with therapy and dose progression. Treatment efficacy and practice patterns in five possible outcomes were defined for each cohort. **RESULTS:** The highest proportion of patients in each cohort remained on the initial therapy. Combination therapy was the most frequent therapeutic choice for patients failing monotherapy. Evaluation of the maximum daily dose (MDD) showed patients who were switched to an alternate agent of the same class reached 41–48% of MDD, a different class 49–57% MDD and combination therapy 57–72% MDD. Compliance was consistent. The combination therapy cohorts tended to have significantly higher ( $p < .05$ ) pharmacy costs than the monotherapy cohorts. The study did not conclusively support differences in medical costs between the cohorts. **CONCLUSION:** Therapy in all cohorts changed before MDD of the original agent was attempted. Patients in each cohort progressed to insulin monotherapy without a recommended trial of combination agents. Although pharmacy and medical costs influence the total cost of diabetic care, there was no significant difference in medical costs identified. Cost differences were driven by pharmacy costs.

SEE PCV8

**DIABETES****PDB1**

**DIABETIC MANAGEMENT THROUGH ORAL GLUCOSE LOWERING AGENTS: TREATMENT PATTERN, COST AND UTILIZATION ANALYSIS**

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**OBJECTIVES:** Assess the treatment progression of Type 2 diabetic patients taking glimepiride, glipizide xl, and/or metformin as initial monotherapy and the impact these agents have on the cost and utilization of health care services. **METHOD:** Medical and pharmacy claims data for 7,585 patients meeting inclusion criteria were collected

**PDB2**

**USING RETROSPECTIVE CLAIMS DATA TO DESIGN CLINICAL SAFETY SURVEILLANCE OF THIAZOLIDINEDIONE DRUGS**

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**HYPOTHESIS:** Prescription patterns for the newer thiazolidinedione (TZD) drugs, pioglitazone and rosiglitazone, will reflect historic prescription patterns for troglitazone. Predicting what drugs are commonly prescribed in combination with pioglitazone and rosiglitazone might help anticipate the most common drug interactions for these drugs, and possible adverse effects due to additive drug toxicity. This information can be used to design surveillance monitoring to detect toxicity due to additive effects early. If this type of toxicity is detected, recommendations for multidrug regimens can be revised appropriately. **METHODS:** This retrospective data analysis used data from Solucient's proprietary Medical Claims Data Warehouse of over 6 million lives. Patients in the troglitazone cohort took troglitazone for at least 4 consecutive months between 9/1/1998 and 6/30/2000, and had at least one other prescription for a diabetic drug written after the last troglitazone prescription. Patients in the pioglitazone and rosiglitazone cohorts took pioglitazone

zone or rosiglitazone for at least 4 consecutive months between 1/1/1999 and 6/30/2000. **RESULTS:** All three TZDs show similar prescription patterns, even though both newer TZDs are approved as monotherapy and troglitazone was not. The combination of TZD and sulfonylurea occurred most commonly (troglitazone 28%, pioglitazone 26% and rosiglitazone 30%), followed by monotherapy (troglitazone 20%, pioglitazone 23% and rosiglitazone 23%). Combination with insulin (troglitazone 20%, pioglitazone 19% and rosiglitazone 16%) ranked third for all. **CONCLUSIONS:** Our results suggest that pioglitazone and rosiglitazone are prescribed in a manner similar to troglitazone. This suggests that physicians should be particularly vigilant for drug interactions between sulfonylureas and TZDs, as well as for additive drug toxicities between from these drugs. This analytic approach could be expanded to other drugs frequently used in patients with type II diabetes, particularly antihypertensives, drugs for congestive cardiac failure and antihyperlipidemics.

**PDB3**

### THE BURDEN OF ILLNESS OF DIABETES MELLITUS TYPE 2 IN GERMANY—A PILOT STUDY

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**OBJECTIVES:** A study was performed to assess the costs of diabetes mellitus type 2 considering costs for co-morbidities and diabetes related complications in Germany. The main objective of this cross-sectional study was to describe the cost structure of the treatment of diabetes mellitus type 2. The study focuses particularly on costs for oral antidiabetic treatment. **METHODS:** The resource utilization of a population of 201 diabetes mellitus patients with type 2 diabetes was retrospectively documented over a period of 2 years in a cross-sectional study. The documentation was performed by general practitioners (GPs) and diabetologists across Germany. Only direct costs were considered (perspective from statutory health insurances). Subgroups were analysed considering diabetes related macro- and microvascular complications. Costs were analysed taking the perspective of the statutory health insurance into consideration. **RESULTS:** Total costs of 201 patients suffering from diabetes mellitus type 2 amounted to DM 1,477,061 over a period of two years, which translates into DM 7,349 per patient. Costs per year were DM 3,674 with a maximum of DM 63,915. The largest cost-driving factor is the hospitalisation representing 34.1 % of the total costs followed by drug acquisition costs (20.4 %). Patients treated with insulin cause the 3,5 times higher costs than patients treated with oral drugs. The amount of costs also correlates with the complication status and the duration of diabetes. The lowest costs are caused by patients treated with oral antidiabetic drugs and/or diet and with-

out complications. **CONCLUSION:** The highest costs were caused by patients with a high complication status, a long duration of diabetes and those treated with insulin. This result emphasises the necessity of an early treatment of diabetes mellitus type 2 preventing expensive diabetes related long-term complications e.g., myocardial infarction, stroke, diabetic foot lesion or dialysis.

**PDB4**

### COST-EFFECTIVENESS AND CARDIOVASCULAR RISK—AN ANALYSIS OF ROSIGLITAZONE COMPARED WITH OTHER ORAL HYPOGLYCEMIC AGENTS IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS

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**BACKGROUND:** Avandia (rosiglitazone) is a novel insulin sensitizing agent. Compared with traditional therapies for type 2 diabetes mellitus (T2DM), it is as efficacious in lowering glycemic parameters with the additional benefit of improving insulin resistance (IR); both of these are linked to increased risk of cardiovascular (CV) events. An evaluation was conducted from a government payer perspective to explore the potential cost-effectiveness of Avandia compared with less costly generic agents, glyburide and metformin. **METHODS:** A Markov model was used to calculate direct medical costs and expected survival. The discount rate was 5%. Long-term outcomes were modeled based on clinical and epidemiologic studies and the 10 year UKPDS data. Costs were obtained from the manufacturer, literature, case costing and provincial sources. The base case analysis considered a 70 y.o. male with T2DM with a risk factor profile representative of the UKPDS cohort. Further analyses of patients with other combinations of CV co-morbidity were conducted to examine the range of cost-effectiveness. **RESULTS:** Avandia, compared to glyburide and metformin, is a potentially attractive option. In the base case Avandia was associated with the highest expected cost but also the greatest survival (\$7,781 and 6.254 years); metformin the lowest cost (\$3,655) and intermediate survival (6.181 years); glyburide was dominated by metformin (\$3,667 and 6.1608 years); the incremental CE ratios for Avandia were \$56,888 and \$44,237 per LY gained vs. metformin and glyburide respectively. For patients with other clusters of risk factors, the CE ratios ranged from \$6,886/LYG (4 additional CV risk factors) up to \$59,947/LYG (0 additional risks). The sensitivity analyses showed that the base case results were robust. **CONCLUSIONS:** While acknowledging the limitations of modeling techniques, the results of this analysis suggest that Avandia, which addresses both dysglycemia and IR, may be a cost-effective alternative for T2DM compared to the conventional therapies.



**PDB5****A COST-MINIMIZATION STUDY TO DETERMINE THE IMPACT OF ADDING GLUCOVANCE TO A COUNTY HOSPITAL FORMULARY**Lal LS<sup>1</sup>, Ogbonnaya KI<sup>2</sup><sup>1</sup>Texas Southern University, College of Pharmacy, Houston, TX, USA; <sup>2</sup>Baylor College of Medicine, Houston, TX, USA

**OBJECTIVE:** This study is conducted to determine the economic impact of the addition of a new diabetic agent, Glucovance (metformin/glyburide) to a county hospital system with over 21,000 diabetic patients. **METHODS:** A cost minimization analysis between Glucovance and metformin plus any of the sulfonylureas is conducted. Initially, a database of all diabetic patients in the county hospital system is created to determine total number of patients who are being treated with metformin alone and in combination with other sulfonylureas, glipizide XL, generic glipizide, glyburide, and glimepiride. Next, the cost difference between treating with Glucovance alone or as a dual therapy with both metformin 500mg plus the most common dose of each sulfonylurea is calculated to determine the incremental cost savings over a year's time of therapy. Only the direct costs of the drugs involved are utilized in this study. **RESULTS:** The results indicate that if all of the 6,622 patients who are on dual therapy with both metformin 500mg and a usual maintenance dose of a sulfonylurea drug are switched to the new combination product, the county system can save over half a million dollars (\$555,566.00) in a year, in direct drug costs alone. **CONCLUSION:** These results illustrate that there is an economic incentive to add the new combination product to the formulary. However, future cost-effectiveness studies are needed to determine the impact of this decision both in terms of clinical and economic outcomes.

**PDB6****AN EARLY LOOK AT TZD USE AMONG TYPE 2 DIABETES PATIENTS**Schabert VF<sup>1</sup>, Guo M<sup>2</sup>, Conklin JE<sup>1</sup>, Neslusan CA<sup>2</sup><sup>1</sup>The MEDSTAT Group, Santa Barbara, CA, USA; <sup>2</sup>R.W. Johnson Pharmaceutical Research Institute, Raritan, NJ, USA

**OBJECTIVE:** One of the newest drug classes used in the treatment of type-2 diabetes is the thiazolidinediones (TZDs). TZDs enhance insulin action in insulin-dependent tissues without stimulating insulin secretion. These drugs are used both as monotherapy and in combination with other anti-diabetic pharmacotherapies. Two TZDs are currently on the market, rosiglitazone and pioglitazone. Both of these compounds were approved in the US mid-year 1999. This study examines the patient characteristics, drug use, and resource utilization of individuals treated with a TZD in the first year following approval. **METHODS:** Patients who received at least one prescription for rosiglitazone or pioglitazone were selected from over 2.3 million employees, retirees, and dependents in the MarketScan® databases. Health plan enrollment

data, medical claims, and pharmacy claims were used to construct the final sample. Descriptive information is presented on patient demographics, inpatient, outpatient and prescription drug use. Comparisons between these variables across the different therapy groups (e.g., monotherapy versus combination therapy) were made using appropriate statistical tests. **RESULTS:** 18,801 patients received at least one prescription for rosiglitazone or pioglitazone during the study period. Mean age is 60.0 years (SD = 11.6 years), including 6,510 who were 65 or older. The sample is almost evenly split between males and females (52.3% and 47.7%, respectively). 54.9% (10,324) of the patients had at least three months follow-up available. Of these, 6.3% (655) were hospitalized within three months of TZD initiation. Patients filled other types of diabetes medications after initiating therapy with a TZD—28.8% (n = 5,417) insulin, 52.0% (n = 9,776) sulfonylureas, 39.8% (n = 7,475) metformin, and 7.1% (n = 1,340) other types of diabetes drugs. **CONCLUSIONS:** Additional TZD-type compounds are being developed. This study provides an early look at the characteristics and subsequent outcomes of patients who are being prescribed this important new type of therapy for diabetes.

**PDB7****COSTS AND EFFECTIVENESS OF INTENSIVE INSULIN THERAPY FOR TYPE 2 DIABETES**

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**OBJECTIVE:** To estimate the lifetime benefits and costs of intensive insulin therapy for type 2 diabetes mellitus (2DM), cost-effectiveness analysis was carried out. **METHODS:** Cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) were carried out to estimate the lifetime benefits and costs of intensive insulin therapy (IIT) for 2DM. A Markov model based on a randomized controlled trial (Kumamoto Study) was developed. As a comparator, conventional therapy (CV) was used. A societal viewpoint was adopted for the estimation of costs, and both direct and indirect costs were evaluated. A Monte Carlo simulation was done to evaluate a confidence interval of cost-effective or cost-utility ratio. Quality of life (utility) was measured by a time-trade off method among 2DM patients. **RESULTS:** At lifetime follow-up among 40 years of men, expected life years (28.7 years) for IIT were longer than those (26.5 years) for CV. On the other hand, expected costs (\$106,500) for IIT were higher than those (\$95,600). The incremental cost per life-year gained for IIT was \$3,020 (discount rate of cost and effectiveness: 5%). The incremental cost per QALY gained was \$3,270. Sensitivity analysis for age, costs, and health outcomes confirmed robustness of these results. **CONCLUSION:** Over lifetime, IIT for 2DM not only reduces complications, but also improves QOL and increases length of life. From a societal perspective, efficiency of IIT is considerably high.

**PDB8****FACTORS ASSOCIATED WITH PRESCRIPTION CLAIMS FOR BLOOD GLUCOSE TEST STRIPS AMONG FEE-FOR-SERVICE NEW MEXICO MEDICAID PATIENTS**

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**OBJECTIVE:** Continuous blood glucose monitoring which requires the use of blood glucose test strips (BGTS) is essential for diabetes management. The objective of this study was to identify predictors of claims for BGTS submitted to the New Mexico Medicaid fee-for-service (NMMFFS) program. **METHODS:** Patients with prescription claims for insulin or oral diabetic medications between December 1, 1999 and November 30, 2000 were identified from the NMMFFS claims database. It was determined if these patients had claims for BGTS. Information on demographic predictors including age, gender, race/ethnicity, insulin use, and area of residence (rural, urban, intermediate) were extracted. A forward stepwise logistic regression analysis using the likelihood-ratio (LR) test, was performed to identify significant predictors of claims for BGTS. **RESULTS:** A total of 5636 diabetic patients, mean age 65.93 (SD = 17.25), were identified. Of these, 38.6% (n = 2178) had claims for BGTS. About 70% (n = 3974) were female, 45.1% (n = 2543) had claims for insulin, and 38.8% (n = 2185) resided in an urban area. Additionally, there were 42.7% (n = 2408) non-Hispanic whites, 30.8% (n = 1738) Hispanics, and 9.2% (n = 519) American Indians. The logistic regression results indicated that younger patients (OR = 0.97, 95% CI = 0.97–0.98) and patients with claims for insulin (OR = 1.88, 95% CI = 1.68–2.11) were more likely to have claims for BGTS. However, males (OR = 0.64, 95% CI = 0.56–0.73), patients who lived in intermediate areas (OR = 0.74, 95% CI = 0.65–0.83), non-Hispanic whites (OR = 0.78, 95% CI = 0.67–0.91), Hispanics (OR = 0.63, 95% CI = 0.53–0.75) and American Indians (OR = 0.40, 95% CI = 0.32–0.51) were all less likely to have claims for BGTS. **CONCLUSIONS:** Elderly patients who are female, non-insulin users, non-Hispanic white, Hispanic or American Indian and live in intermediate areas are less likely to have claims for strips. Therefore, educational interventions are needed to increase claims for BGTS in these patients, thus improving blood glucose monitoring.

**PDB9****COST-EFFECTIVENESS ANALYSIS OF A MULTIDISCIPLINARY DIABETES CARE CLINIC**

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**OBJECTIVES:** Diabetes affects more than 15.7 million people in the United States, resulting in an estimated annual cost of \$98 billion (1997). With numerous compli-

cations, including heart disease, retinopathy, nephropathy, and neuropathy, contributing to the direct and indirect costs of diabetes, control is vital. A cost-effectiveness analysis was performed to compare health care resource utilization related to diabetes care incurred by health plan patients. **METHODS:** Subjects were enrolled in the Diabetes Care Clinic (DCC) for at least one year and were members of the health plan for one year prior to enrollment. Pharmacy and medical claims data from 1997–2000 were analyzed to identify diabetes-related charges incurred one year pre- and post-enrollment in the DCC. Charges were used to estimate costs and were adjusted to year 2000 dollars at a rate of inflation of 3%. Using the electronic medical record and clinic charts, hemoglobin A1c (HgbA1c), cholesterol profile, microalbuminuria, and blood pressure were evaluated. **RESULTS:** 23 diabetic patients met the inclusion criteria. These patients were mostly Type 2 diabetics (91%), female (65%), and Caucasian (70%). The mean age was 58 years. A preliminary analysis of the data indicated that the average HgbA1c decreased from 10.3 to 8.5, with 9 patients attaining glycemic control (defined as HgbA1c < 8.0) after one year of enrollment. Additionally, average blood pressure decreased from 152/80 to 136/73. The average annual cost per patient for diabetes-related care was \$3,090 pre-enrollment and \$4,760 post-enrollment. A marginal cost-effectiveness ratio, in terms of cost to number of patients attaining glycemic control, was calculated. The added cost for glycemic control of one patient was \$186. **CONCLUSIONS:** An analysis of short-term outcomes demonstrated the cost-effectiveness of a diabetes care clinic. By maintaining tight glycemic and blood pressure control, diabetic complications can be reduced with significant savings to the health plan.

**PDB10****THE COST OF NEW ONSET DIABETES MELLITUS AMONG US RENAL TRANSPLANT RECIPIENTS**

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**OBJECTIVES:** Immunosuppressive medications are associated with increased diabetes among kidney transplant recipients. We used data from the USRDS database to estimate the incidence and the average cost to Medicare of new onset diabetes Mellitus (NODM). **METHODS:** The USRDS database merges the UNOS renal transplant registry with Medicare billing and payment records. The USRDS registry recorded 9,541 single-organ, first, kidney transplants in 1996; 5,987 (63%) of these were not diabetic at transplantation. For the 4,515 (75% of 5,987) patients with Medicare claims, we merged all Medicare institutional and physician supplier claims records from 1996 through 1997 with the clinical information from UNOS. We classified patients as newly diabetic if any

ICD-9 diabetes diagnosis (250.00 to 250.79) occurred within one year of the patient's transplant. We then used a Kaplan-Meier-style non-parametric calculation to estimate the average accumulated costs for patients with and without NODM. **RESULTS:** Among the 4,515 transplant recipients studied, 621 (13.7%) reported diabetes diagnoses within the first year post-transplant. By the end of the first post-transplant year, Medicare had paid \$35,288 for each non-diabetic recipient and an extra \$17,614 ( $P = 0.001$ ) for each of the NODM recipients. By two years post-transplant, Medicare had paid an average \$46,869 for each of the non-diabetic recipients and an extra \$26,032 for each of the NODM recipients ( $P = 0.001$ ). **CONCLUSIONS:** Our 13.7% NODM exceeds the 2% to 5% previously reported, and the extra \$26,032 is 55.5% above what Medicare paid for recipients without NODM. New immunosuppressives unassociated with NODM may generate substantial savings worldwide.

**PDB11****ECONOMIC OUTCOMES OF DIABETES AMONG AN EMPLOYED POPULATION**

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**OBJECTIVES:** The two major types of diabetes, Type I and Type II diabetes, can have life-threatening complications, which often lead to significant adverse economic consequences. This study investigates the extent to which Type I and Type II diabetes impose significant financial burdens on an employer. **METHODS:** The data source is a rich administrative claims database from a national, Fortune 100 manufacturer. It includes all medical, pharmaceutical, and disability claims for employees, spouses, dependents, and retirees ( $n > 100,000$ ). The diabetes research sample consists of individuals with at least two medical and/or disability claims for diabetes or at least one prescription drug claim for a hypoglycemic agent. Resource utilization by diabetes patients, who are identified as either Type I or Type II diabetics, is contrasted with that of matched samples from the employer's overall beneficiary population. **RESULTS:** Direct (medical and pharmaceutical) and indirect (disability and sporadic absenteeism) costs of Type I and Type II diabetes are analyzed. The total average per capita annual costs are \$2,612 for the Matched Type I Control sample compared to \$9,397 for Type I diabetics, and \$3,432 for the Matched Type II Control sample compared to \$7,639 for Type II diabetics. While Type I diabetics cost the employer more than Type II diabetics on average, the cost of Type II diabetes patients, who were prescribed insulin, exceeds the cost of Type I diabetes patients. Also, while the costs of both types of diabetes are relatively high, less than 50% of total medical costs for these patients are for the treatment of diabetes or related co-morbid condi-

tions. **CONCLUSIONS:** Diabetes adds a significant financial burden on the employer. The resources used by both types of diabetics are substantial, not only for the treatment of diabetes, but also for the treatment of related co-morbid conditions, as well as other conditions.

**PDB12****A PHARMACOECONOMIC ANALYSIS OF WEIGHT-REDUCTION THERAPY IN A HYPOTHETICAL COHORT OF OBESE CHINESE PATIENTS WITH IMPAIRED GLUCOSE TOLERANCE**

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**OBJECTIVES:** To conduct a pharmacoeconomic analysis to estimate the potential cost avoidance due to reduced rate of incidence of diabetes after weight-reduction therapy in obese Chinese patients with impaired glucose tolerance (IGT). **METHODS:** The incidence of IGT-to-diabetes mellitus (DM) conversion of two hypothetical cohorts of obese Chinese patients with IGT, either managed with diet control ( $n = 100$ ) or diet control plus orlistat ( $n = 100$ ), were projected over a two-year period. The probabilities of IGT-to-DM progression in the orlistat plus diet group and the diet only group were estimated from a published study in a non-Chinese and a westernized Chinese population, respectively. Direct medical costs of management of type 2 diabetes were estimated from a public budget perspective. **RESULTS:** The estimated rates of IGT-to-DM conversion were 1.9% for the orlistat plus diet group and 8% for the diet only group. The total costs of DM management at the end of the first and second years were estimated to be HK\$8,187 and HK\$23,390 (HK\$ 7.8 = \$US 1) for the orlistat group. In the diet only group, the costs of DM management were HK\$34,469 in year one and HK\$100,123 in year two. The cost avoidance associated with orlistat therapy were calculated to be HK\$26,282 and HK\$75,092 per 100 patients at the end of the first and second years, respectively. **CONCLUSIONS:** Results of the present study suggest positive economic impacts of weight-reduction therapy in a hypothetical Chinese population with IGT in the prevention of type 2 diabetes.

**PDB13****OPTIMIZATION OF DIABETES MANAGEMENT IN GERMANY USING A COMPUTER BASED OUTCOME PROGNOSIS MODEL**

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**OBJECTIVES:** Optimization of type 2 diabetes intervention strategies in Germany based on stepwise prognoses

of expected medical and economic outcomes in population subgroups. **METHODS:** A published, editable diabetes model was used to assess the outcomes of different degrees of secondary prevention measures for different diabetes type 2 patient sub-groups in Germany. Clinical data were derived from German diabetes quality of care circles. Incremental cost-effectiveness ratios (ICERs) were calculated as the differences of average lifetime cost divided by the difference of average life expectancy. Optimization was approximated by calculating ICERs for stepwise modified prevention strategies, including screening and complication treatments for variable population risk characteristics. **RESULTS:** Compared to the prognosis of overall life expectancy and cost consequences the more refined stepwise approach generates a series of results for all combinations of intervention strategy and population subgroup. At certain risk levels the ICER based treatment recommendation may change if subgroup prognosis is applied. But for all age groups of diabetes patients secondary prevention of complication is the dominant variant. Medical outcomes and incremental cost-effectiveness are improved by additional secondary prevention measures except for patients with non-reversible risks. The potential savings from improved prevention amount to 10% of total expenditures for diabetes care in Germany, i.e., DEM 3000 million. **CONCLUSIONS:** With the stepwise assessment of subgroup outcomes a treatment optimization and optimal allocation of diabetes management to patient subgroups is feasible. Using average data to calculate overall ICER for the total diabetes population may ignore the best treatment strategy in different population subgroups. Subgroup analysis represents a helpful tool in the health economic evaluation of diabetes treatment strategies when variable population risk characteristics and baseline complications affect the clinical and economic outcome.

**PDB14**

#### **IMPACT OF A DIABETES DISEASE MANAGEMENT PROGRAM: A RETROSPECTIVE CLAIMS-BASED EVALUATION**

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**OBJECTIVE:** Evaluate the impact of a comprehensive diabetes disease management (DM) program on health care costs, quality of life and patient satisfaction. **METHODS:** Diabetes patients targeted by pharmacy claims were invited to enroll in a voluntary payor-sponsored DM program (n = 2,178). Eligible non-enrollees were used for the control group (n = 6,396). Medical and pharmacy claims were combined to determine health care costs. Quality of life and patient satisfaction were also assessed, via patient interview. The analysis timeframe encompassed two years prior and one year following program initiation. **RESULTS:** Enrollees had higher direct health care costs than non-enrollees. We were able to predict accurately the medical spend in our control group in ab-

sence of intervention with standard time series analysis within 4%. Following DM intervention, enrollees' health care spend was lower than their baseline spend and lower than their projected spend (-\$116, -\$1,056). Conversely, health care spend increased in the non-enrollee group from baseline (+\$714) (Table 1). Additionally, enrollee quality of life measures improved from baseline and patient satisfaction with the DM program was high. **CONCLUSIONS:** A comprehensive diabetes DM program can lower health care cost and improve patient reported quality of life while demonstrating consistently high patient satisfaction.

**PDB15**

#### **DOES PATIENT EXPERIENCE MATTER? TYPE II DIABETES PATIENTS' STATED PREFERENCES FOR INSULIN THERAPIES**

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**OBJECTIVES:** Patient preferences for alternative treatments may be affected by health status and experience with the treatment. Randomized Clinical Trials (RCTs) offer a unique opportunity to collect preference data while controlling for patient experience. **METHODS:** Patients with Type II diabetes in a large US RCT answered a series of stated preference (conjoint format) questions regarding attributes of alternative insulin therapies. All patients are insulin-naïve and take insulin as part of the trial. Preference data is collected before the patient begins insulin, after 3 months, and after 6 months of insulin therapy. Insulin attributes include the frequency of insulin injections, method of injection (syringe or pen), glucose control and frequency of hypoglycemia. Personal health data such as glucose control are collected at each administration of the stated preference survey. **RESULTS:** Preferences are analyzed in an ordered probit panel model that controls for individual health status. Insulin administration attributes have the largest importance scores. The importance score of the insulin injection frequency attribute decreases during the later observation points. While few patients experience nighttime hypoglycemia, this attribute is significant and has a larger importance score than glucose control. **CONCLUSIONS:** Patient experience significantly affects patient preferences and the derived pharmacoeconomic measures and should be controlled in preference experiments. Results suggest that some insulin-naïve patients are more averse to insulin injections before they begin insulin therapy. Results also suggest that increased experience with diabetes control measures during the trial affects treatment preferences.

**PDB16****AN OVERVIEW OF PHARMACOECONOMICS IN TURKEY: COST ANALYSIS AND REIMBURSEMENT OF ANTIDIABETIC DRUGS**Sapci AH<sup>1</sup>, Sapci HA<sup>2</sup>, Demirdamar R<sup>3</sup><sup>1</sup>Numune Research Hospital, Ankara, Turkey; <sup>2</sup>Faculty of Medicine, Gazi University, Ankara, Turkey; <sup>3</sup>Faculty of Pharmacy, Hacettepe University, Ankara, Turkey

**OBJECTIVE:** The Turkish health care system is increasingly pressured by costs. In 1980 total health expenditures were 2.1 billions of dollars and in 2000, 8.2 billion dollars. In the present study, we aimed to analyze health insurance system and inpatient expenditures for diabetic prescription drugs. People in Turkey are covered by four different health insurance systems. 1) Emekli Sandigi: retirement foundation for the government employees. 2) Sosyal Sigortalar Kurumu: social security system for laborers. 3) Bag-Kur: governmental free security system. 4) Private insurance companies that cover health care. All these social security systems, namely the government, pay 90–100% of both inpatient and outpatient prescriptions, whereas in other countries this is not the case. Although Turkey is living with a high rate inflation, our country has been spending increasing amounts on health care most of which is reimbursement. However, since there are scarce number of pharmacoeconomic studies, an estimation cannot be made. **METHODS:** Numune Hospital is the biggest governmental hospital with a 1453 active bed capacity. We analyzed prospectively prescription costs per diabetic patient from January between December 2000 at Endocrinology and Diabetes Inpatient Unit. **RESULTS:** Our results revealed that 122.69 dollars are paid per patient. This cost does not include the other treatment costs or the hospital expenditures, it is the amount paid per patient for drugs. **CONCLUSIONS:** For the inpatients, we know that the treatment and prescription is rational. On the other hand our previous research revealed polypharmacy and irrational drug use is a serious problem for outpatients. We therefore conclude that pharmacoeconomic studies should be encouraged and used to evaluate health costs.

**EYE/EAR/SKIN/DENTAL****PEE1****ANTIBIOTIC PRESCRIBING PATTERNS FOR THE TREATMENT OF INITIAL ACUTE OTITIS MEDIA IN CHILDREN ENROLLED IN IOWA MEDICAID FROM 1990 THROUGH 1997**

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**INTRODUCTION:** Otitis media and acute otitis media (AOM) are the most common diseases among children in the US with an annual cost of more than \$3 billion in 1996. Historically, a ten-day course of antibiotics has been the standard treatment for AOM. Providers can

choose first-line antibiotics (Amoxicillin, Trimethoprim-Sulfamethoxazole, and Erythromycin-Sulfisoxazole) or a group of second-line antibiotics. Second-line antibiotics generally have a broader spectrum of activity but are more costly relative to first-line antibiotics. Presently, policy-makers have little evidence to evaluate the increased effectiveness of second-line antibiotics for AOM in practice. **OBJECTIVES:** As a first step to address this question, this study describes the factors related to the choice between first-line and second-line antibiotics for initial AOM in Iowa Medicaid population. **METHODS:** We identified 19,987 Iowa Medicaid eligible children less than 13 year of age who had initial AOM from 1990 through 1997. We estimated the probability of the second-line agent use across the patient demographics (age, sex), previous antibiotic use, year of diagnosis, patient's county, and the specialty of the treating physician. **RESULTS:** Factors of age ( $p < 0.01$ ), county ( $p < 0.01$ ), previous antibiotic use ( $p < 0.01$ ), provider specialty ( $p < 0.01$ ), and year of diagnosis ( $p < 0.01$ ) had statistically significant effects on second-line prescribing. We found that second-line prescribing increased over time. With respect to specialty, general practitioners (OR = 1.33, 95% CI = 1.18–1.49), family practitioners (OR = 1.10, 95% CI = 1.01–1.19), and otolaryngologists (OR = 1.83, 95% CI = 1.53–2.18) were more likely to prescribe second-line antibiotics than pediatricians. In addition, the effect of the timing of previous antibiotic use on second-line prescribing varied with type of antibiotic previously used. Any second-line antibiotic used within the last 180 days was positively related to second-line antibiotic use for initial AOM. However, only first-line antibiotic use within the last 60 days contributed to increased second-line use.

**PEE2****THE COST-EFFECTIVENESS OF GENETIC TESTING FOR PERIODONTAL DISEASE. A PAYER'S PERSPECTIVE**Higashi MK<sup>1</sup>, Veenstra D<sup>1</sup>, del Aguila M<sup>2</sup>, Hujuel P<sup>1</sup><sup>1</sup>University of Washington, Seattle, WA, USA; <sup>2</sup>Washington Dental Service, Seattle, WA, USA

**BACKGROUND:** Genetic testing for disease predisposition is rapidly becoming available for a variety of chronic diseases, but it is not clear how the health insurance industry will make reimbursement decisions for these new diagnostics because the long-term clinical and economic benefits are unclear. A provider of dental health benefits requested assistance in assessing a genetic test for a composite interleukin-1 (IL-1) genotype. This test is being marketed to predict risk for progression of periodontal disease. **OBJECTIVE:** To estimate the incremental clinical and economic outcomes associated with the use of IL-1 testing to identify high-risk patients. **METHODS:** A disease simulation model was developed using decision-analytic and Markov modeling techniques over a 30-year time frame. **RESULTS:** In the base-case analysis, using

the genetic test resulted in an incremental cost-effectiveness ratio was \$32,633 per QALY gained. Sensitivity analysis produced results ranging from increased costs of \$300,430 and 3.6 additional cases of severe periodontitis (per one thousand patients) to cost savings of \$830,140 and 52.8 fewer cases of severe periodontitis. Sources of uncertainty were 1) patient compliance based on test result, 2) effectiveness of non-surgical therapy, and 3) the relative risk for progression based on genotype. **CONCLUSION:** The use of genetic testing to guide treatment for periodontitis may result in a wide range of outcomes under different modeling scenarios. These results range from improved patient health and cost-savings to additional costs and poorer health. Economic modeling has identified the additional data required to determine if IL-1 testing can be implemented in a primary care setting in a cost-effective manner. These methods may be used by the health insurance industry to assess the cost-effectiveness of genetic testing for predisposition towards other diseases.

**PEE3****DRY-EYE RELATED INCREASES IN HEALTH CARE UTILIZATION AND EXPENDITURES**

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**OBJECTIVE:** This study investigates the incremental cost of dry eye disease (keratitis sicca) in a managed care population. **METHODS:** Patients with dry eye diagnoses (ICD-9-CM = 370.33, 375.15, 710.2) or punctal occlusion procedures (CPT-4 = 68760, 68761) during 1997–1998 were identified from PharMetrics' Integrated Outcomes database of 7 million patients. Controls were randomly selected and matched 1:1 to dry eye cases on age category, gender and managed care plan. Costs were calculated for 6 months before and after the first dry eye-related claim for cases, or the midpoint of claims history for controls. **RESULTS:** The prevalence of dry eye disease was 0.48% in 1997 and 0.39% in 1998. Dry eye patients (n = 31,683) were more likely than controls to use ophthalmic medications, many of which are not indicated for dry eye (P < .001). Use of non-ophthalmic medications was similar between cohorts. Total charges rose \$454.79 (22.2%) for dry eye patients, significantly more than for controls (\$289.48 [15.9%]) (P < .001). This was mostly due to a rise in outpatient charges (\$257.40 [28.7%] for cases versus \$76.14 [11.2%] for controls). Dry eye diagnoses/procedures were associated with greater increases in outpatient charges, pharmacy charges, and total medical charges (P < .0001). Dry eye patients experienced a greater average increase in total medical costs than did controls, mostly arising from outpatient charges. **CONCLUSION:** We conclude that a major factor in dry eye-related cost increases is additional physician visits, which may be a consequence of the ineffectiveness of available therapies.

**PEE4****THE FRENCH VERSION OF THE PSORIASIS DISABILITY INDEX**

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**OBJECTIVE:** The objective of our work was to translate the PDI into French, with careful attention to the linguistic aspects and the cultural context of the French patients. **CONTEXT:** The PDI is a scale devised by Prof. A. Finlay of Cardiff to evaluate the impact of psoriasis on the life of the patient. This questionnaire has been used in numerous studies to evaluate the consequences of the disease in daily life or the effects of different treatments. **RESULTS:** With the author's approval, the questionnaire was translated from English to French by two independent translators. The two versions were compared and a few non significant differences were noted. A third translation from English to French was realized with the assistance of the APLCP, psoriasis patient support group. When compared to the first two, this third translation brought out the specificity of the French cultural context and the reality of the disease. To make sure that the translation was consistent with our objective, the questionnaire was sent to five patients and translated from French to English by two independent translators. For a large-scale validation, this questionnaire was sent by post to 5000 psoriasis patients belonging to the APLCP. With the addition of a questionnaire on the patient's behavior in respect to the treatment, "Living With Psoriasis" will make it possible to evaluate every two years the impact and the daily consequences of psoriasis on French patients and thus become a decision support tool. **CONCLUSION:** The novelty of this initiative resides in the involvement of a patient support group at every step on a level rarely attained, not only in the translation but also in the validation of the questionnaire. This close involvement reflects the key role of a patient support group in the management of the disease.

**PEE5****INAPPROPRIATE ANTIBIOTIC PRESCRIBING AND ECONOMIC OUTCOMES FOR PEDIATRIC OTITIS MEDIA**

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**OBJECTIVES:** To examine physician prescribing pattern of antibiotics for otitis media in children and compare them with therapeutic guidelines issued by the American Academy of Pediatrics, Family Physicians, and Otolaryngology, for appropriateness. Also, to calculate the cost savings that could be achieved by adhering to the guide-

lines. **METHODS:** Data from the National Ambulatory Medical Care Survey (NAMCS) 1997 was utilized. Patients with principal diagnosis of otitis media with age less than or equal to 12 years were analyzed using multiple linear and binomial logit regression models. Appropriate antibiotics are defined as those that are recommended by the guidelines. The average wholesale price of recommended antibiotics was compared with the inappropriate antibiotics prescribed. The dosage of antibiotics was confirmed by the IMS health and the advice of a practicing Otolaryngologist. Antibiotics cost was calculated by using the Red Book 1997 and 1998. The weighted average method was used to calculate the average wholesale price of the various quantity packages and dosage forms. This study utilized the methodology of relating a secondary database to an outside source (Red Book) to calculate the cost. **RESULTS:** The average cost of a course of appropriate antibiotic (penicillin and its derivatives) was found to be \$8.07, compared to \$69.56 for expensive antibiotics (difference = \$61.49). Children less than four years of age were prescribed more expensive antibiotics ( $R^2 = 0.287$ ). Pediatricians, and Otolaryngologists prescribed appropriate and less expensive antibiotics than other family physicians ( $R^2 = 0.144$ ). There was no relationship between the physician's specialty and patient's age for inappropriate antibiotics prescribing ( $R^2 = 0.345$ ). **CONCLUSIONS:** Adhering to the guidelines and prescribing of appropriate antibiotics appears to save cost. Inappropriate prescribing of antibiotics for otitis media should be addressed more explicitly in general practice.

**PEE6**

### **COST-EFFECTIVENESS OF ARTIFICIAL SKIN SUBSTITUTE VS ALLOGRAFT FOR BURN PATIENTS**

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**INTRODUCTION:** Healing after a burn injury requires a temporary wound cover until the skin epithelium heals. Traditional wound covering, human cadaver allograft (HCA), is expensive, and limited by availability. **OBJECTIVE:** To determine if artificial skin substitute (Transcyte) wound cover is cost-effective for temporary wound coverage in patients with major total body surface (TBSA) burns. **METHODS:** Incremental cost per quality adjusted life year (QALY) in 2000 US dollars is estimated assuming a base case adult patient who has 40% TBSA burn with no inhalation injury, complications, or facial burn followed for one year after HCA or Transcyte procedure. A societal perspective is used. Utilities were surveyed from burn-unit hospital employees. Other variables are taken from literature. **RESULTS:** Under the base case, Transcyte saves \$3600 over HCA, and adds 0.04 QALYs. Quality of life was significantly greater in the Transcyte group (0.54, 95% CI = 0.48–0.59) vs.

HCA group (0.65, 95% CI = 0.57–0.74,  $p = 0.04$ ) while in the hospital, but not significantly different while recovering at home, after recovery, and at work. The incremental QALY of Transcyte minus HCA must be  $< -0.07$  in order for the ICER to reach a threshold of \$50,000. Sensitivity analysis shows that a 33% increase in Transcyte price will reach the threshold ICER of \$50,000. In addition, this model is highly sensitive to utility at work; a 22% decrease of at-work utility with Transcyte will result in an ICER greater than \$50,000. **CONCLUSIONS:** The results show that use of Transcyte as a temporary wound covering for 40% TBSA burns is a dominant strategy relative to standard HCA. Use of this artificial skin results in cost savings, due to faster healing and less operation room time. A gain in QALYs is seen with Transcyte, due to less scarring and pain during the healing process.

**PEE7**

### **A COST COMPARISON STUDY OF COMMON PRACTICE AND BEST PRACTICE TREATMENT FOR PRIMARY OPEN-ANGLE GLAUCOMA IN THE UNITED STATES**

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**OBJECTIVE:** To compare the total, drug, and medical care costs of common practice and best practice management of primary open-angle glaucoma (POAG). **METHODS:** A Delphi panel of ophthalmologists specialized in glaucoma management was convened in order to delineate practice patterns representative of community physicians (common practice), and to characterize the ideal or optimal standards of care (best practice). A decision analytic approach was used to depict and economically quantify the clinical sequelae under each scenario for POAG patients initiated on medical therapy. Common and best practice decision trees were developed for prototypic agents of the most commonly used first-line classes of medications. Percentage likelihood of drug usage was determined based upon physician consensus whereas drug and surgical efficacy rates were determined based upon a composite of published data. Typical drug dosing regimens and number of medical visits, as determined by physician consensus, were used to estimate the cost of treatment. **RESULTS:** The total average annual cost of treatment per eye was estimated at \$733.85 for common practice and \$732.09 for best practice. Drug costs were estimated at \$358.66 for common practice and \$341.38 for best practice. Costs of medical care were estimated at \$375.19 for common practice and \$390.71 for best practice. Surgical costs comprised a larger proportion of medical care costs in best practice as compared to common practice (17.84% vs. 14.29%). In comparing best practice and common practice decision analyses, non-selective beta-blockers were used less often whereas alpha-2 ago-

nists were used more often as first-line medical therapy. The probability of first-line success has been estimated at 71.2% for common practice and 72.3% for best practice. **CONCLUSION:** Despite higher surgical costs and improved outcomes associated with best practice management of POAG as compared with common practice, total, drug, and medical care costs of best practice were comparable to those of common practice.

**PEE8**

#### **FOUR YEAR COST-EFFECTIVENESS OF INITIAL TRABECULECTOMY VERSUS CONVENTIONAL THERAPY IN PRIMARY OPEN-ANGLE GLAUCOMA (POAG)**

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**OBJECTIVES:** To determine the cost-effectiveness of the primary treatment of primary open-angle glaucoma (POAG) with trabeculectomy versus conventional therapy. **METHODS:** A four-year incremental cost/quality-adjusted life year (QALY) model (year 2000 US dollars) of POAG using a societal perspective; including direct and indirect costs with a 3% annual discount rate for the base case. In the Glasgow trial, patients newly diagnosed with POAG with an intraocular pressure of 26mmHg and/or with glaucomatous field defects were randomized to trabeculectomy or conventional therapy (up to three medications). In the trabeculectomy branch, patients would either be 1) controlled without extra medication, 2) controlled with extra medication or 3) die from natural causes. Annual chance nodes for the conventional were 1) controlled by medication, 2) surgery or 3) death from natural causes. QALYs were calculated assuming a decline in utility would accompany loss in visual field. A 65-year old patient with a 5% rate of decline in utility was used as the base case. Sensitivity analyses were performed on the rate of utility decline, cost of medications, trabeculectomy cost, and discount rate. **RESULTS:** For the base case, the cost of initial trabeculectomy was \$8316 versus \$6339 for conventional therapy. The incremental cost was \$1977 and the incremental QALY was 0.08, with ICE ratio of \$24,830/QALY. **CONCLUSIONS:** Initial trabeculectomy is cost-effective for POAG. The model was most sensitive to the rate of decline in utility (<2%) and robust to changes in the costs of medications and trabeculectomy. Limitations include the lack of long-term clinical and QALY data on glaucoma patients with different treatments. Currently the standard of practice in the US is to start with conventional therapy for patients with moderate or severe glaucoma. Our results indicate that trabeculectomy may be a cost-effective option for these patients.

**GASTROINTESTINAL DISORDERS****PGI1**

#### **EFFECTS ON HEALTH CARE CONTACTS AND DAYS ABSENT FROM WORK WITH BUDESONIDE CIR CAPSULES IN THE MAINTENANCE TREATMENT OF CROHN'S DISEASE IN A US SETTING**

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**INTRODUCTION:** Crohn's disease (CD) is a debilitating chronic disease. It also has economic implications (both for patient and society). Reduced work (or school) attendance and continuous need for health care contacts are two important aspects. Data comparing the impact of different treatment approaches are scarce. **OBJECTIVE:** To assess health care utilisation and absence for work (or school) in a US setting of patients treated with budesonide CIR maintenance therapy compared to patients with no maintenance treatment (placebo). A societal perspective was adopted. **METHODS:** Data was collected in a double-blind randomised clinical trial comparing budesonide CIR 6 mg daily with placebo for a one year period. Patients, 55 in each group, had CD localised to the distal ileum and/or the ascending colon and were between the ages of 18 and 73 (mean 40.3 and 40.5 years). The collected data included physician visits, different minor procedures (e.g., radiographic, endoscopic), medications, hospitalisations and surgical procedures. Number of days of absence due to symptoms or treatment of the disease was also collected. All resource utilisation related to the design of the clinical trial was excluded in order not to overestimate real health care use and productivity losses. **RESULTS:** The budesonide CIR treatment group had 26.3% fewer physician visits (87.14 vs. 118.27 ns) and 27% fewer days absent from work or school (311.73 vs. 427.23 days ns). Numerical differences in other variables were smaller but in favour of budesonide CIR. **CONCLUSION:** Treatment with budesonide CIR capsules suggests benefits in terms of reduced health care resource utilisation and absence from work (school), that also could represent favourable cost implications in the delivery of health care.

**PGI2**

#### **ALTERNATIVE MANAGEMENT STRATEGIES FOR DYSPEPSIA**

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**OBJECTIVE:** To compare the cost-effectiveness of alternative dyspepsia management strategies: (1) H. pylori testing; if seropositive, providing H. pylori eradication treatment using oral omeprazole, clarithromycin, and amoxicillin; (2) empiric antisecretory therapy using omeprazole. **METHODS:** Decision analytical models compared cost/QALY for alternative strategies in patients



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. **RESULTS:** 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.

**PG13**

**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 post-procedure 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.

**PG14**

**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 IBSQOL 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 dif-

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

**PG15**

### 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.

**PG16**

### 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.

**PG17**

### 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

these in terms of health care resource use and associated costs, e.g., costs of hospitalisations, diagnostic and surgical procedures, outpatient care and drug consumption. Panel and literature data was used for events not investigated in the clinical trials. Cost inputs were derived from Tampere University Hospital for year 1998. Days in remission and relapse were translated into Quality Adjusted Life Years (QALYs) using CD specific health-state utility data from the literature. **RESULTS:** The outcomes of the clinical trials were reflected in the model as a 26.4% reduction in annual number of relapses for the average patient in the budesonide CIR treatment group. Mean annual health care cost per patient was 17,740 FIM (2,000 USD) for the budesonide CIR patient and 16,608 FIM (1,877 USD) for the NMT patient. The difference between the groups amounted to a cost per gained QALY of 68,610 FIM (7,753 USD), which is well in line with what is considered a cost-effective treatment strategy. **CONCLUSION:** Budesonide CIR means fewer relapses per average patient and is a cost-effective treatment strategy for the treatment of Crohn's disease in Finland.

**PG18**

**RAPID IMPACT OF RABEPRAZOLE ON SYMPTOM DISTRESS AMONG PATIENTS WITH GASTROESOPHAGEAL REFLUX DISEASE**

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**OBJECTIVES:** Gastroesophageal reflux disease (GERD) is a common condition associated with a variety of symptoms, particularly heartburn. The purpose of this study was to assess patient-reported symptom distress in a randomized trial of rabeprazole (RAB), a proton pump inhibitor. **METHODS:** Symptom distress was measured using the Distress subscale of the GERD Symptom Assessment Scale (GSAS) that asks patients about the degree of bother they experience for 15 symptoms. Patients completed the GSAS at baseline and week 4. We evaluated the impact of treatment (RAB 10mg, RAB 20mg, or placebo) on mean change in GSAS Distress scores using an ANCOVA model. We also conducted a relative variability analysis using ANOVA models to determine which of 5 clinical indicators are most useful to explain changes in GSAS Distress scores. Mean change was assessed as a function of baseline daytime heartburn severity, baseline nighttime heartburn severity, time to first 24 hours without heartburn symptoms, complete daytime heartburn relief, and complete nighttime heartburn relief. **RESULTS:** The sample consisted of 169 patients (RAB10mg = 55, RAB 20mg = 56, placebo = 58). Overall, a significant difference in mean change in GSAS Distress scores was observed across treatment groups ( $p = 0.0007$ ). Both the RAB 10mg and RAB 20mg groups reported significantly greater improvements in GSAS Distress scores than the

placebo group ( $p = 0.0036$  and  $p = 0.0004$ , respectively). Of the 5 clinical indicators examined, time to first 24 hours without heartburn explained the greatest amount of variability in GSAS Distress scores. Achieving complete daytime and complete nighttime heartburn relief also were significant factors. **CONCLUSIONS:** In clinical studies, RAB provided fast and consistent (both daytime and nighttime) heartburn relief. Given that speed of heartburn relief as well as achieving complete heartburn relief were significant factors explaining variability in patient-reported symptom distress, the positive impact of RAB on the GSAS distress scale was consistent with its clinical efficacy.

**PG19**

**COST-EFFECTIVENESS OF 'TEST&TREAT' HELICOBACTER PYLORI INFECTED DYSPEPTIC PATIENTS IN A PRIMARY CARE SETTING**

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**OBJECTIVES:** With recent recognition of the primary role of Helicobacter pylori (HP) in peptic ulcer disease, it has been proposed that patients with dyspepsia undergo noninvasive testing for HP, instead of endoscopy, followed by antibiotics if positive. We evaluated cost-effectiveness of 'Test&Treat' strategy versus empirical treatment for HP infection in dyspeptic patients presenting in the primary care setting. **METHODS:** The study was a one-year incremental cost (yr2000 US dollars) per quality-adjusted life year (QALY) model for dyspeptic patients age less than 45 years old in a primary care setting from a societal perspective. With 'Test&Treat' algorithm, patients were tested for HP infection using urea breath test. If positive, eradication was prescribed. Alternatively, patients were given conventional treatment of H2RA for four weeks. If not cured, HP would be eradicated empirically. Both direct and indirect costs were included. The model took into consideration preventing gastric cancer from eradication. Sensitivity analyses were performed on prevalence of HP infection, drug treatment efficacy, laboratory test costs, drug treatment costs, and drug treatment utility loss. **RESULTS:** At baseline, with HP prevalence of 40% and HP antibiotic eradication efficacy of 89%, results showed that 'Test&Treat' had an incremental cost-effective ratio (ICER) of \$31,723/QALY. One-way sensitivity analysis showed that antibiotic treatment efficacies lower than 45–46% would exceed the societal threshold ICER of \$50,000. **CONCLUSIONS:** The model showed that 'Test&Treat' was cost-effective for uncomplicated dyspeptic patients in primary care. Although NIH guidelines state that all ulcer patients with HP infection require eradication regimen, universal endoscopic diagnosis of ulcer causation (HP+/HP-) would not be cost-effective. However, treating all patients empirically could increase antibiotic resistance. The 'Test&Treat' strategy has the benefits of slowing antibiotic resistance while avoiding high endoscopy costs. The model was ro-

bust to changes of most parameters—most sensitive to prevalence and eradication efficacy changes.

**PG110**

### **IRRITABLE BOWEL SYNDROME COSTS SICKNESS FUNDS DM 2.8 BILLION PER YEAR**

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**BACKGROUND:** With a prevalence of up to 20%, Irritable Bowel Syndrome (IBS) could cost the German Sickness Funds (GKV) more than DM 28 billion (10,5% of its total expenditures) per year. Despite these potentially tremendous costs it is still a fairly obscure disease in terms of proper diagnosis and lacking effective treatment. **OBJECTIVE:** To assess diagnosis and treatment options of IBS using strict Rome-II criteria. **METHODS:** Face-to-face interviews of patients (121) and physicians (147 GPs, 53 internists). **RESULTS:** The patient survey (age 14–74 yrs.; strict Rome-II criteria) puts the prevalence of IBS (constipated and alternating type) in Germany at around 2.3% (1.4 million). This figure correlates well with previous findings. The patients responded that they experienced an average of 7 episodes per year, each lasting about 4–5 days. Some 11% of them suffer permanently. Of the physicians questioned, only 73% recognize IBS when given the symptoms; 57% of these actually classify it accordingly while an alternative diagnosis is “irritable colon” (24%). When choosing a drug, daily treatment costs outweigh every other factor of the physicians relevant set (efficacy, onset, side-effects, mode of action etc.) by about 3:1. In consequence a drug treatment is initiated in (only) 40% of the cases. This is also due to a lack of effective and specific treatment which could help to reduce the frequency of episodes. Results of another study put the direct costs of the average IBS patient at around DM 1,729 per year. Combining this with the above findings results in a more realistic figure of around DM 988 million in direct costs per year (0.37% of total GKV expenditures). **CONCLUSION:** These comparably high costs (insulin treated diabetes: DM 1,217 p.a.) could be significantly reduced by DM 247 for each episode prevented through proper diagnosis and consequent treatment with a specific and effective medication.

**PG111**

### **CHARACTERIZATION AND MARKOV MODELING OF GASTROESOPHAGEAL REFLUX DISEASE STATES IN A LARGE HEALTH CARE PLAN**

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**OBJECTIVES:** The objective was to describe the disease state (DS) transition patterns of gastroesophageal reflux disease (GERD) by applying a multi-state model assuming a Markov process. **METHODS:** This retrospective study utilized administrative claims for subjects with GERD from a large Midwest USA health care plan. Subjects were tracked for six, six-month time periods (baseline and five followups). Within each time period, ICD-9 diagnosis codes were used to categorize subjects' GERD into four DS plus a non-symptomatic state: DS0 {no GERD diagnosis}, DS1 {mild esophagitis}, DS2 {reflux esophagitis}, DS3 {esophageal ulceration}, and DS4 {strictures and complications}. GERD transition probabilities and patterns were analyzed in a five-state Markov framework. Disease regressions and progressions were allowed. The effects of patient and provider covariables on transition probabilities were modeled using logistic regression techniques. **RESULTS:** A total of 7575 subjects with GERD were analyzed. In the five followup periods combined, 79% of the subjects were in GERD DS0, 6% in DS1, 8% in DS2, 2% in DS3, and 5% in DS4. For all initial DS, the most frequent transition path was to regress to DS0 (becoming non-symptomatic) and the second most common was to stay in the initial disease state. For subjects ending a time period in DS1, 89% regressed to DS0 in the next time period, while 6% stayed in DS1, 3% progressed to DS2, 1% progressed to DS3, and 1% progressed to DS4. Multivariate modeling of risk factors influencing transitions showed that progressing from DS1 is associated with age >70, a proton pump inhibitor prescription, and absence of a diagnostic procedure. **CONCLUSIONS:** The Markov analysis showed that subjects with GERD commonly have their symptoms regress, with only a small percent progressing. The Markov model is a useful methodology to research disease states in a retrospective database setting within a health care plan.

**PG112**

### **ESTIMATING POTENTIAL UTILIZATION OF ESOMEPRAZOLE BY ASSESSING GERD SYMPTOM CONTROL ON TRADITIONAL PPI'S**

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**OBJECTIVES:** Approximately one-half of the American population experiences weekly symptoms of gastroesophageal reflux disease (GERD). With the hypothesis that not all patients are completely symptom free on proton pump inhibitor's (PPI's), the pharmaceutical industry is formulating more potent anti-secretory drug therapies. In November of 2000 the FDA approved esomeprazole for the treatment of Erosive Esophagitis (EE). Esomeprazole is a more potent inhibitor of gastrin and gastric acid, with clinical studies demonstrating quicker symptom relief with more complete 24-hour acid control. If complete acid control translates into better long-term symptom relief for chronic symptomatic GERD it may play a vital

role in refractory GERD patients. The purpose of this cross-sectional survey study is to estimate the percentage of patients actively treated with PPI's (omeprazole and lansoprazole), who perceive control of their symptoms. The Gastrointestinal Symptom Rating Scale (GSRS), a validated rating scale to assess GERD patients' quality of life, was utilized. The study hypothesis is that 80% of the patients will perceive their symptom control is very good or excellent. **METHODS:** An unblinded self-administered questionnaire, including the GSRS, was mailed to 300 patients who were currently receiving GERD maintenance therapy with a PPI. Patients were asked questions regarding the duration and severity of symptoms, dosing of medication, contributing lifestyle factors and debilitation of disease. **RESULTS:** 153 questionnaires were returned fully completed, a 51% response rate. The surveyed patients were  $60 \pm 14$  years with 89% of respondents being male. Of the PPI's prescribed 86% and 14% were lansoprazole and omeprazole respectively. The median total score of the GSRS was 19, representing mild to moderate patient symptomatology. **CONCLUSIONS:** 66% of respondents treated with currently prescribed PPI's had very good or excellent symptom control, however the need exists for a more effective PPI for adequate symptom control in 34% of patients.

**PG113****FACTORS ASSOCIATED WITH PHYSICIAN KNOWLEDGE OF WHETHER PRESCRIPTION DRUGS ARE ON FORMULARY**

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**OBJECTIVE:** Prescription drug formularies have been used by many pharmacy benefit managers (PBMs) as a tool to control the rising costs of prescription drugs and became increasingly popular since the 1990s. Despite its popularity, little is known about how familiar physicians are with what prescriptions are on formulary. This study examines factors associated with physician knowledge of formulary. **METHODS:** The National Ambulatory Medical Care Survey (NAMCS) is a data series of annual survey of a national representative sample of physician office visits. It provides up to six medications associated with each office visit. The 1998 NAMCS collected information regarding the formulary status (yes, no, do not know, or not applicable) of each medication and provided a unique opportunities to assess physicians' knowledge of formulary. Univariate analyses as well as multivariate logit model were used to examine the association between physician knowledge of formulary and types of visits, physician specialty and practice locations. **RESULTS:** On average, 47% of physicians did not know whether the drug they prescribed was on formulary. Physicians whose patients belonged to an HMO and were

paid by capitation were seven times more likely to know whether a drug was on formulary, compared to those whose patients were neither in an HMO nor capitated. Physicians in the South were 1.7 times more likely to know than those in the West, whereas the odd-ratios was 0.7 for those in the Midwest. Neither physician specialty (primary care physician versus specialist) nor patient history (new versus established patient) was found to be significantly associated with physician knowledge of formulary. **CONCLUSIONS:** It is important for PBMs to find mechanisms to increase physician awareness of whether a patient's medications are on formulary. Improving physicians' understanding of what medications were on formulary could potentially decrease prescription drug costs for health care plans and patients.

**PG114****HOW IMPORTANT IS APPROPRIATE EMPIRICAL ANTIBIOTIC TREATMENT FOR INTRA-ABDOMINAL INFECTIONS?**

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**OBJECTIVES:** To assess the association between hospital costs and the appropriateness of empirical antibiotic treatment for community-acquired intra-abdominal infection. **METHODS:** Patients were identified from hospital discharges from three hospitals for 1993 to 1997. Medical records were obtained to validate the diagnosis and obtain details of antibiotic therapy and its outcome. Valid cases had macroscopic evidence of intra-abdominal infection at operation, therefore all cases had surgical control of infection in addition to antimicrobial therapy. Appropriateness of empirical therapy was assessed from the results of in-vitro sensitivity tests (culture positive cases) and compliance with local antibiotic policies (culture negative cases). **RESULTS:** We identified 294 valid cases of intra-abdominal infection of whom 162 (55%) were culture positive. Appropriate antibiotic treatment was associated with significantly shorter length of stay and lower investigation costs for patients with positive cultures but not for patients with negative cultures or no test/result (data not shown). Culture +ve cases, appropriate (n = 129) vs inappropriate (n = 33): mean length of stay 12 vs 22 days, p = 0.0007 boot strap t test, mean investigation cost £250 vs £409 p = 0.04, mean antibiotic cost £138 vs £128 p = 0.9. A log transformed linear regression analysis was carried out on the cost data for the culture positive cases adjusting for five independent variables. Inappropriate antibiotics, increasing age and a higher number of comorbidities and previous admissions were significantly associated with increased cost of hospital stay but not gender. This model accounted for 34% of the variance in cost of hospital stay. For the cost of investigations inappropriate treatment, increasing age and

number of comorbidities were all significant predictors accounting for 26% of variance in costs. Number of comorbidities was the only variable significantly associated with the cost of antibiotics. **CONCLUSIONS:** Appropriate empirical antibiotic treatment of patients with culture positive intra-abdominal infection is strongly associated with length of stay and hospital costs.

**PG115**

### COMPUTERIZED ASSESSMENT OF COMPLICATIONS FOLLOWING COLORECTAL SURGERY

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**OBJECTIVES:** Historically, complication rates following colorectal surgery were stratified by disease process, type of operation, or anesthesia risk derived after an intensive review of the medical record. Newer computer applications purport to shorten this process and predict the probability of postoperative complications by distinguishing them from comorbidities that are co-mingled on uniform discharge codes. We analyzed CaduCIS software (CareScience, Inc., Philadelphia, PA) which uses discharge codes to see if its predictions of comorbidity and complications accurately track the medical record. **METHODS:** Two-hundred and seventy patients were analyzed using principal and secondary diagnoses coded on discharge. Coding inaccuracies of clinical occurrences were identified by physician review of each medical record. The actual incidences of 17 common preoperative comorbidities and 11 postoperative complications were compared to computerized predictions by applying standard statistical tests. **RESULTS:** The overall incidence of complications obtained by physician (actual) review was 47%, compared to 46% by computer. The computerized predicted distribution of comorbidities was similar to the actual occurrences in 15 of 17 categories. Analysis showed a statistical difference between the computer-predicted and “actual” complication rates in 5 of the 11 categories; however these differences (underestimates) were due to charting and coding inaccuracies, not to computerized errors. The most common preoperative comorbidities and complications were cardiopulmonary (47% and 28%, respectively). **CONCLUSIONS:** The computer-system’s accurate measurement of the overall complication rate supports the claim that aggregate complication estimates derived from readily available administrative data are sufficient for across-the-board comparisons among hospitals. The computerized system can generate such measurements in a fraction of the time it takes to manually review the medical records. As uniform discharge coding of co-mingled comorbidity and complications are increasingly used to rapidly compute surgical outcomes, colon and rectal surgeons need to ensure compatibility of the actual and coded medical record.

**PG116**

### ANALYSIS OF THE LONG-TERM COSTS, SAVINGS AND EFFECTS GENERATED BY INFLIXIMAB TO NORMALIZE QUALITY OF LIFE IN PATIENTS WITH CROHN’S DISEASE

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**OBJECTIVES:** Infliximab (Remicade) (I) 5mg/kg is effective to control refractory Crohn’s disease in 81% and to improve fistulas in 68% of patients, thus greatly improving quality of life (QoL). The objective of this study was to calculate the direct costs and savings generated by I to achieve this improvement of QoL. **METHODS:** This mirror-image study was carried out in 48 patients, of which 22 had fistulas, all responding to therapy. Patients were followed for 6 to 24 months prior and 6 to 24 months after I. All direct costs to the Belgian public payer were recorded separately for every 6 month time period before and after I, in order to control for a bias due to changed management regardless of I. The cost of I was calculated separately. IBDQ scores were recorded before and after I for each period. **RESULTS:** There was an important build up of costs in each period before I: -2-1.5y: 1,002 (±459) Euro; -1.5-1.0y: 1,486 (±459) Euro; -1.0-0.5: 2,114 (±391) Euro; -0.5-0: 2,427 (±302) Euro. After I there was a sharp decrease of the cost of care (excluding the cost of I) to 1,760 (±239) Euro (0+0.5y) and 1,380 (±264) Euro (+0.5+1.0y). The decrease was statistically significant (p=0.016). The average cost of I in the first six months was 4,850 (±327) Euro and in the second six months 1,300 (±280) Euro. The IBDQ increased from 147.8 (SE 8.4) to 187.8 (SE 7.0). The total direct cost of care after I, adjusted for the non-responders, was calculated to be 17.0 Euro per day of normalised QoL. **CONCLUSIONS:** Although the cost of infliximab is substantial, the total direct cost to produce a normal QoL in the entire year after therapy is quite acceptable, providing that patients not responding are not further treated.

**PG117**

### COMPARISON OF GENERIC VERSUS DISEASE SPECIFIC TOOLS FOR THE MEASUREMENT OF HEALTH-RELATED QUALITY OF LIFE IN CROHN’S DISEASE

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Health-related quality of life (HRQoL) research suggests that, due to unique characteristics of a disease state, disease specific tools are better discriminators of health status than generic tools. **OBJECTIVE:** To compare generic (SF-12) versus disease specific (SIBDQ) quality of life tools in a cohort of patients receiving treatment for Crohn’s Disease (CD). **METHODS:** Structural Equation

Modeling techniques were used to evaluate the effectiveness of the SF-12 and the SIBDQ for evaluating health status patients with CD. A cohort of 151 patients with CD receiving drug therapy was administered both instruments via telephone survey. **RESULTS:** The variance explained by the SIBDQ in this population was 11.6% while the SF-12 explained 55.7%. Adapted models of both the SIBDQ and SF-12 resulted in explained variance of 54.8% and 84.1%, respectively. **CONCLUSIONS:** Given these results, the generic HRQoL tool was significantly better than the disease specific tool at measuring and accounting for health status in this population. Patients with moderate or severe CD have previously been shown to have differing clinical response to therapy based upon disease severity, whereby patients with more severe disease have better response. Due to these possible unique clinical outcomes of newer medications such as infliximab, the effectiveness of disease specific tools may be compromised since improving therapies may affect HRQoL in a different manner than therapies previously available. Other innovative therapies, such as biologic response modifiers for rheumatoid arthritis, may have similar findings related to HRQoL measurement. This potential problem with HRQoL measurement is likely to increase as biopharmaceutical and pharmacogenomic research increases the number and rate of new product approvals. These findings have important implications related to measurement of HRQoL in clinical trials and pharmacoeconomic evaluation of medications. This suggests a need for careful reevaluation of disease specific tools given the clinical effects of newer therapies.

## INFECTIOUS DISEASES

PID 1

### EFFICACY OF ZINC LOZENGES ON THE DURATION OF COMMON COLD SYMPTOMS: A META-ANALYSIS REVISITED

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**OBJECTIVE:** Cold symptoms are both common and costly. The effectiveness of zinc lozenges in reducing the duration of common cold symptoms has been investigated in several studies with discrepant results. We therefore performed a meta-analysis in an attempt to clarify these discrepancies and determine the overall effectiveness of zinc lozenges in the treatment of the common cold. **METHODS:** A computerized search of the MEDLINE database from January 1966 to December 2000 was performed to identify randomized controlled trials comparing zinc lozenges to placebo for the common cold. Data were systematically abstracted. The outcome assessed was the duration of cold symptoms. Quantitative

pooling was undertaken using the Dersimonian and Laird random-effects model. **RESULTS:** Five studies met the inclusion criteria and provided sufficient information to calculate the mean duration of cold symptoms. A total of 562 subjects were included in these trials: 283 in the zinc group and 279 in the placebo group. The summary mean duration of cold symptoms in the zinc group was 2.25 days less than that in the placebo group (95% confidence interval [CI], 1.07–3.43). However, there was evidence of statistical heterogeneity among studies ( $P = 0.003$ ). In a subgroup analysis, we found that there were two sets of homogeneous studies with different magnitudes of reduction: 3.6 days (95% CI: 2.77,4.43) and 1.32 days (95% CI: 0.52,2.13). **CONCLUSIONS:** Zinc lozenges appear to be an effective treatment for reducing the duration of cold symptoms. However, further analyses are required to explore the sources of heterogeneity. A formal cost-effectiveness analysis may be necessary to determine whether this intervention is economical.

PID 2

### IMPACT OF CYTOMEGALOVIRUS (CMV)-RELATED READMISSION ON POST HEART TRANSPLANT RESOURCE USE

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**OBJECTIVES:** The incidence and costs associated with the rehospitalization of heart transplant patients for the treatment of CMV infection have not been well documented. Two adult heart transplant centers participated in a Transplant Infection Cost Analysis program that was implemented in several centers covering different solid organ programs. **METHODS:** A retrospective chart review of all patients rehospitalized within two years post-transplant identified the number of such readmissions, hospital costs and charges for the CMV associated readmission, and the length of stay. Data were pooled for analysis. All dollar amounts were standardized to 1997 dollars using the Medical Care component of the Consumer Price Index. **RESULTS:** Between 1994 and 1996, the two hospitals performed a total of 163 heart transplants. There were a total of 34 readmissions (21%) to these hospitals associated with a CMV infection. Total direct hospital costs were \$740,220 (average \$21,771 and range \$1,324–\$349,224). Total related charges were \$1,431,793 (average \$42,111 and range \$2,323–\$698,447). Total days of inpatient care for CMV infection were 371 days (average 10.9 and range 2–95) at an average cost per day of \$1,997. **CONCLUSIONS:** Data from two heart transplant centers demonstrate that CMV infection caused significant readmissions. Use of hospital resources to treat CMV infection one to two years post-transplant was substantial. Total cost of CMV was not captured: readmission to other hospitals, outpatient costs, physician costs, mortality and lost productivity should be included for a complete assessment of the economic burden of CMV infection.

**PID3****TRENDS IN INPATIENT COSTS FOR ACUTE PANCREATITIS IN THE UNITED STATES**

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Although the care of patients with pancreatitis-related complications is estimated to be much more resource-intensive than that provided to other critically-ill patients, information on the cost of acute pancreatitis is limited. **OBJECTIVES:** To examine trends in the incidence and cost of acute pancreatitis-related hospitalizations in the United States, and to ascertain patient disposition at discharge to evaluate the extent to which costs may extend beyond the initial hospitalization. **METHODS:** Data were obtained from the 1995–1997 Health care Cost and Utilization Project database. ICD-9-CM code 577.0 was used to identify hospitalizations with a primary or secondary diagnosis of acute pancreatitis. Patient demographics, length of stay (LOS), total charges (in constant 1995 dollars), and discharge status were assessed. **RESULTS:** Between 1995 and 1997, the number of acute pancreatitis-related hospitalizations increased by 9.1% from 241,178 to 263,136. During that period, the average LOS decreased by 9.5% from 8.4 days to 7.6 days and the mean hospital charges decreased by 4.9% from \$19,222 to \$18,280. Using LOS 15 days as a proxy for severity, severe acute pancreatitis-related hospital discharges decreased from 30,444 in 1995 to 27,839 in 1997. During that period, the average LOS remained constant (28.9–28.4 days) and the mean charges increased from \$77,572 to \$82,043. Nationwide, the projected pancreatitis-related inpatient charges have increased from \$4.6 to \$4.8 billion. Despite representing 12% of admissions, severe acute pancreatitis-related charges represented 49% of all acute pancreatitis-related inpatient charges. 38–41% of patients were discharged to another facility, suggesting that these cost estimates are conservative. **CONCLUSIONS:** Acute pancreatitis is a major financial burden on health care systems due to high inpatient costs and frequent need for medical care that extends beyond the hospital stay. Despite a reduction in charge per case, total inpatient charges of pancreatitis have increased to rising incidence.

**PID4****ECONOMIC COST OF HIV INFECTION IN UNTREATED WORKERS: AN EMPLOYER'S PERSPECTIVE**

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It is necessary to understand the direct and indirect costs of HIV infection in untreated workers in order to estimate the value of aggressive antiretroviral therapies from an employer's perspective. Currently the cost of HIV/

AIDS from an employer's perspective is not well understood. **OBJECTIVES:** To estimate lifetime costs of HIV infection in untreated employees from an employer's perspective. **METHODS:** A simulation model was developed to predict costs of HIV infection in untreated employees from an employer's perspective over a ten-year time frame. This model utilized age, CD4+ cell counts, and plasma HIV-1 RNA level as major predictors of disease progression and expected patient survival to estimate lifetime costs. Major direct cost components were health insurance premium, life insurance premium, short-term disability benefits, long-term disability benefits, and hiring/training expenses. The indirect cost included productivity loss at work. **RESULTS:** For a hypothetical 35-year old HIV-positive employee with CD4+ cell counts at 380 cells/mm<sup>3</sup> and HIV-1 RNA at 22,000 copies/ml, the model estimated that the total direct and indirect costs of HIV infection was \$165,873 from the employer's perspective over a 10-year period. This included \$66,659 for health insurance, \$12,788 for life insurance costs, \$8,580 for short-term and long-term disability benefits, \$25,894 for hiring and training expenses and \$51,952 due to productivity loss. Sensitivity analyses suggested that changes in employee age, CD4+ cell count, HIV-1 RNA viral load, and CD4+ cell decline rate were important parameters that significantly impact the costs of untreated HIV workers to employers. **CONCLUSION:** Without effective antiretroviral therapy, HIV infection could result in significant direct and indirect costs to employers. Therefore, the cost-effectiveness of treatment with advanced antiretroviral regimen should be considered for HIV infected workers.

**PID5****MOXIFLOXACIN VS AMOXICILLIN/CLAVULANATE IN THE TREATMENT OF ACUTE MAXILLARY SINUSITIS (AMS): EFFICACY, SAFETY AND PATIENT-REPORTED OUTCOMES IN PRIMARY CARE**

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**OBJECTIVE:** This study was designed to reflect real-world experience in the treatment of patients with AMS. Efficacy, safety, and patient-reported outcomes variables were compared between moxifloxacin (MXF) and amoxicillin/clavulanate (AC) for the management of AMS in a primary care setting. **METHODS:** In this prospective, multicenter, non-blinded phase IIIb trial, 475 adult patients with symptoms of AMS were randomized to receive a 10-day oral regimen of either MXF (400mg once-daily) or AC (875mg twice-daily). Clinical success at the test-of-cure (TOC) visit (post-therapy days 14–21) was the primary efficacy measure. Secondary outcomes included rate of clinical relapse at follow-up (post-therapy days 26–46) and exploratory evaluation of patient-reported outcomes variables. Safety data was also tabulated from intent-to-treat (ITT) patients. **RESULTS:** Of



471 adults comprising the ITT population (234 MXF, 237 AC), MXF treatment was statistically equivalent to AC at the TOC visit (85.2% vs 81.8%; 95%CI = -6%,13%). Per-protocol analysis also confirmed statistical equivalence between MXF and AC (86.5% vs 83.6%; 95%CI = -7%,13%). Rates of relapse were similar for the ITT (4% MXF, 5% AC) and the per-protocol (4% both) populations. The frequency of drug-related adverse events were similar between MXF (30%) and AC (25%) and were primarily gastrointestinal-related: nausea (11% MXF, 5% AC) and diarrhea (3% MXF, 10% AC). At the TOC visit, significantly more MXF-treated patients (n = 47; 24%) in the ITT population than AC-treated patients (n = 28; 14%) reported symptomatic improvement by day 3 (p < 0.02). No differences existed in terms of lost work hours or time to return to normal activities between treatment groups. **CONCLUSIONS:** In this primary care clinical trial, once-daily MXF was as effective and safe as twice-daily AC in the treatment of AMS. In some patients, MXF was associated with more rapid symptomatic relief, which has potential clinical and socioeconomic implications.

**PID6**

#### **HIV/AIDS HEALTH STATE UTILITIES USING COMMUNITY AND PATIENT PREFERENCE WEIGHTS: WHEN DOES IT MATTER?**

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**OBJECTIVES:** To compare utilities for HIV/AIDS health states derived from community-based preferences with those derived from patients, and to examine the implications of differences for a cost-effectiveness analysis of early versus deferred treatment of HIV patients presenting with CD4 cell counts of 500/ $\mu$ L. **METHODS:** We used data from the HIV Cost and Services Utilization Study (HCSUS), a probability sample of 2,864 HIV-infected adults receiving care in the United States in 1996, to derive utilities for HIV/AIDS health states. Community-based utilities were calculated from the SF-6D responses in the HCSUS survey using algorithms derived by Brazier et al. Patient utilities were calculated from patient self-assessments using a rating scale transformation derived by Torrance et al. We used a computer-based state-transition simulation model of HIV disease to conduct cost-effectiveness analyses using both community and patient utilities. **RESULTS:** Patient utilities were significantly higher (by 4% to 9%, p < 0.001) than community utilities for all disease stages: for asymptomatic HIV patients 0.970 (0.963–0.977) vs. 0.937 (0.926–0.949); for symptomatic HIV patients 0.910 (0.902–0.919) vs. 0.841 (0.826–0.855); and for patients with a history of an AIDS-defining condition 0.845 (0.832–0.858) vs. 0.778

(0.761–0.795). The cost-effectiveness ratio of early therapy (initiated at 500 CD4 cells/ $\mu$ L) versus deferred therapy (initiated at <200 CD4 cells/ $\mu$ L) was \$20,100/QALY using community utilities and \$18,400/QALY using patient utilities. In a sensitivity analysis, when we assumed a 20% reduction in quality of life due to side effects during early therapy but not during deferred therapy, the cost-effectiveness ratio of early versus deferred therapy was \$50,900/QALY using community utilities and \$46,300/QALY using patient utilities. **CONCLUSIONS:** There are differences between community and patient utilities for HIV/AIDS health states. The impact of these differences on HIV/AIDS cost-effectiveness results should be considered when treatment side effects are important.

**PID7**

#### **OBSERVATIONAL EVALUATION OF HEALTH STATE UTILITIES AMONG A COHORT OF SEPSIS PATIENTS**

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**OBJECTIVE:** Among sepsis survivors, during recovery and thereafter, it is not established if patients resume or improve their quality of life. The study objective was to assess change in health status among sepsis survivors over a 6-month period. **METHODS:** This was a prospective, multicenter, cohort study involving 701 patients with severe sepsis of presumed infectious origin from 53 hospitals. Patients' health status was assessed at day 30, 60, 90 and 180 using EuroQoL-5D and a visual analog scale. Instruments were completed by the patient while in hospital and follow-up assessments were performed by telephone interview. **RESULTS:** For this interim analysis, 93 patients had completed health state information for day 30, 60, 90, and 180. Mean (SD) age was 60 + 17 years and 48% were female. The number of patients remaining in the hospital decreased from 56% at day 30 to 7%, thereafter. The average utility score/VAS score at each time point was: 0.53/0.61 (day 30), 0.62/0.68 (day 60), 0.68/0.71 (day 90), 0.69 (p < 0.0001)/0.72 (day 180). Based on patients' subjective assessment of their health status during the last 12 months, 60% had improved or maintained their health. The improvement in utility scores was influenced primarily by changes in mobility, self-care, and usual activities. Pain and anxiety appeared to have a minimal influence on overall improvement in health status. At day 30, 28% of the patients reported no problems in walking, compared to 58% at day 180. Likewise, 48% and 26% of patients reported no problems with self-care and performing usual activities at day 30, respectively, and 67% (self-care) and 47% (usual activities) at day 180. **CONCLUSION:** Sepsis survivors experienced a continual improvement towards population-based normal levels in their health utility scores over a 6-month period. Improvements in physical activity, self-care and usual activities were predominantly associated with improved health utility.

**PID8****COSTS OF HEALTH CARE FOR HEPATITIS C-INFECTED MEMBERS IN A MANAGED CARE ORGANIZATION (MCO)**Schaffer M<sup>1</sup>, Phillips AL<sup>2</sup>, Mansukani S<sup>1</sup><sup>1</sup>Health Partners, Inc, Philadelphia, PA, USA; <sup>2</sup>Thomas Jefferson University, Philadelphia, PA, USA

The current literature provides limited information about the cost-burden of Hepatitis C. **OBJECTIVES:** To identify all medical and pharmacy costs accrued by members with Hepatitis C in a Medicaid MCO during 1999. **METHODS:** Hepatitis C-infected patients were identified from a database of continuously enrolled members from an inner-city Medicaid MCO in Philadelphia during 1999 using ICD-9 codes indicative of Hepatitis C. Medical and pharmacy claims for these identified members during this study period were obtained and analyzed. A subanalysis comparing patients prescribed combination ribavirin/interferon alfa-2b therapy with patients not prescribed combination therapy was performed. Costs were reported as reimbursements paid for medical claims and pharmacy claims (AWP—14.5%). **RESULTS:** From a cohort of 73,869 members, 395 members (0.535%) met inclusion criteria for Hepatitis C. The mean age was 46.5 years (SD = 9.5; range = 4–81) and 213 (53.9%) were male. These members had 17,507 medical claims resulting in payments of \$4,075,082. Inpatient hospital services accounted for 48% of these costs. There were 27,681 pharmacy claims that totaled \$1,495,096. Sixty patients received combination therapy, which totaled \$375,468 in pharmacy claims (n = 444). Comparing patients prescribed combination therapy and patients not prescribed combination therapy, medical costs were \$2,580/member and \$11,702/member, respectively. In addition, pharmacy costs were \$8,610/member and \$2,920/member, respectively. Total costs in 1999 for patients prescribed combination therapy was \$11,190/member and for patients not prescribed combination therapy was \$14,622/member. These results were not adjusted for disease severity. **CONCLUSIONS:** Hepatitis C is a very costly disease. Total health care costs to this Medicaid MCO during 1999 for the 395 members identified with Hepatitis C exceeded \$5.5 million. In addition, total costs were less for members prescribed combination ribavirin/interferon alfa-2b therapy compared with members not prescribed combination therapy. Further investigation is needed to explain the observed differences in health care expenditures between these two populations.

**PID9****COST-EFFECTIVENESS OF INTERFERON ALFA THERAPY FOR CHRONIC HEPATITIS C WITH CIRRHOSIS**

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**OBJECTIVE:** To estimate the lifetime benefits and costs of interferon alfa therapy for active hepatitis C with cirrhosis (HC), cost-effective analysis was carried out. **METHODS:** Cost-effectiveness analysis (CEA) and cost-utility analysis (CUA) were carried out to estimate the lifetime benefits and costs of interferon alfa therapy (IFA) for HC. A Markov model based on a randomized controlled trial was developed. As a comparator, conventional therapy (CV) was used. A societal viewpoint was adopted for the estimation of costs, and both direct and indirect costs were evaluated. A Monte Carlo simulation was done to evaluate a confidence interval of cost-effectiveness or cost-utility ratio. Quality of life (utility) was measured by a time-trade off method among HC patients. **RESULTS:** At lifetime follow-up among 40 years of men, expected life years (15.2 years) for IFA were longer than those (9.0 years) for CT. Moreover, expected QALYs (9.86) for IFA were longer than those (5.30) for CT. On the other hand, expected costs (\$548,500) for IFA were higher than those (\$459,000) for CT. The incremental cost per life-year gained for IFA was \$4,900 (discount rate of cost and effectiveness: 5%). The incremental cost per QALY gained was \$6,240. Sensitivity analysis for age, costs, and health outcomes confirmed robustness of these results. **CONCLUSION:** On the basis of this analysis, IFA for HC should prolong length and quality of life at a reasonable incremental costs, from a societal perspective.

**PID10****EFFECTS OF LINEZOLID ON HOSPITAL LENGTH OF STAY IN METHICILLIN-RESISTANT STAPHYLOCOCCUS INFECTIONS ESTIMATED FROM MULTIVARIATE SURVIVAL ANALYSIS**Willke RJ<sup>1</sup>, Li ZJ<sup>2</sup>, Glick H<sup>3</sup>, Rittenhouse BE<sup>1</sup>, Hafkin B<sup>4</sup><sup>1</sup>Pharmacia, Peapack, NJ, USA; <sup>2</sup>Pharmacia Corporation, Kalamazoo, MI, USA; <sup>3</sup>University of Pennsylvania, Philadelphia, PA, USA; <sup>4</sup>Pharmacia Corporation, Portage, MI, USA

**OBJECTIVES:** To estimate differences in adjusted hospital length of stay (LOS) between linezolid and vancomycin using multivariate survival analysis. Linezolid's bioequivalent IV and oral formulations may enable earlier hospital discharge compared to vancomycin treatment. **METHODS:** 460 hospitalized patients with suspected/confirmed methicillin-resistant Staphylococcus infections were treated with either linezolid (LZD) or vancomycin (VAN) in a randomized controlled trial. Covariate imbalances between treatment groups were tested using t-tests and chi-square tests. Multivariate Cox proportional hazards and several parametric models for LOS were tested for best fit using the Akaike Information Criteria and log-likelihood ratio statistics. The Cox proportional hazards assumption was rejected ( $p < .05$ ); log-logistic survival models fit best. The log-logistic estimates are used to create two alternative adjusted survivorship functions, one based on individual corrections to LOS (Individual correction), and the other based on means of the predicted survivor-

ship function for each individual (Mean survivorship). Adjusted LOS at quartiles of % discharged for each function was compared with unadjusted LOS using Kaplan-Meier method. **RESULTS:** Hospital unit type at randomization and number of comorbidities both differed significantly between groups and significantly affected LOS. With covariate controls in the log-logistic model, linezolid treatment significantly reduced LOS ( $p = .04$ ). Adjusted/unadjusted LOS at quartiles of % discharged were:

% discharged	Adjusted LOS (days)				Unadjusted LOS	
	Individual correction		Mean survivorship		Kaplan-Meier	
	LZD	VAN	LZD	VAN	LZD	VAN
25	6	10	6	9	6	8
50 (median)	14	16	13	16	14	15
75	26	28	28	29	29	29

**CONCLUSIONS:** When adjusted for covariate differences, median LOS for linezolid patients was at least 2 days shorter than for vancomycin patients. Other differences in the LOS distribution are evident and may be important to decision-makers but off-median estimates may be sensitive to the adjustment method used. Methodologic considerations are explored further.

#### PID11

### PEGYLATED (40KDA) INTERFERON ALFA-2A (PEGASYS®) SIGNIFICANTLY IMPROVES TOLERABILITY, QUALITY OF LIFE, AND WORK PRODUCTIVITY IN PATIENTS WITH CHRONIC HEPATITIS C

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**BACKGROUND:** Several studies have demonstrated the negative impact of chronic hepatitis C (CHC) and respective treatments on patient health-related quality of life. Studies suggest PEGASYS provides an improved sustained virological response compared with interferon (IFN) monotherapy (30–39% vs 10–19%) and may provide safety, quality of life (QoL), and work productivity benefits compared with standard interferon/ribavirin (IFN/RBV, REBETRON™) combination therapy. **OBJECTIVE:** To compare the safety and tolerability of treatment with PEGASYS vs REBETRON in previously untreated patients with chronic hepatitis C (CHC). **METHODS:** A 72-week, multicenter study randomized 412 patients to PEGASYS 180 µg qw or REBETRON (IFN-26 3 MIU tiw + RBV 1000-1200 mg qd). Tolerability was assessed by the Hepatitis Quality of Life Questionnaire (HQLQ, assessed at weeks 4, 12, 24, 48, 60, and 72; SF-36 plus 4 Hepatitis-specific domains) and the Work Productivity and Activity Impairment (WPAI) instrument. **RESULTS:** After 12

weeks of treatment, HCV-RNA was negative in 46.8% of PEGASYS and 50.3% of REBETRON patients. Patients on PEGASYS showed a clinically significant difference compared to REBETRON in several AEs: anemia (2.0% vs 32.4%), dyspnea (9.5% vs 18.1%), pruritus (6.7% vs 17.5%). At weeks 4 and 12, patients on PEGASYS compared to REBETRON had significantly better work productivity (Estimated Wkly Work Productivity Lost: \$32.10, PEGASYS; \$86.60, REBETRON) in 7 of 7 domains. Week 4 and 12 HQLQ assessments indicated patients on PEGASYS vs those on REBETRON had clinically and statistically better QoL scores in 8 of 8 SF-36 domains, both physical and mental summary scores, and 4 CHC-specific domains ( $P < 0.05$ ). **CONCLUSIONS:** The 12-week data demonstrate that patients treated with PEGASYS had a superior tolerance to therapy, were more productive as measured by the WPAI, and had better health related quality of life profiles compared with patients treated with REBETRON, while maintaining similar virological response.

#### PID12

### AVERTING FUTURE AIDS CASES: MODELING COSTS OF INTERVENTIONS WITH OUT-OF-TREATMENT SUBSTANCE ABUSERS

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**OBJECTIVE:** The North Carolina Cooperative Agreement (NCCoOp) for AIDS Intervention Research implemented an AIDS intervention in an urban, high-risk, primarily African-American, crack and injection drug-using population. Estimated costs for the standard intervention are \$242 per person. How many future AIDS cases will be averted by making this expenditure? **METHODS:** We constructed an epidemic model to assess the long-term impacts of intervention related changes on HIV incidence and prevalence. Our model is a dynamic compartment model focusing on 8 distinct sexual and drug use risk groups within the community. Cost data are available from existing intervention analyses. **RESULTS:** 778 persons were enrolled in the NCCoOp intervention in Wake and Durham counties, NC. Of these, 80 (11.5%) were HIV positive. Using data collected prior to intervention, our model predicts that HIV prevalence will rise to 18% of the NCCoOp population in five years. The epidemic is driven predominantly by high-frequency needle users (HFNU), primary needle users (PNU), and primary crack users (PCU) who account for 79% of new infections over this time period. Using data collected after intervention, our model predicts HIV prevalence will decline to 7% of the NCCoOp population in five years. However, HFNU, PNU, and PCU account for 89% of new infections in this case. Risky drug use and sexual behaviors were dramatically reduced by intervention and this accounts for most of the reduction in HIV prevalence. Other factors influencing the reduction in HIV prevalence are AIDS mortality and growth in the drug using population. **CONCLU-**

**SIONS:** Our model provides evidence that an effective AIDS intervention in a high-risk population of out-of-treatment substance abusers can avert significant numbers of new HIV infections, which may offset initial costs.

**PID 13****ECONOMIC EVALUATION OF ROTAVIRUS VACCINATION FOR THE NETHERLANDS**

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**OBJECTIVES:** To estimate the cost-effectiveness of a national rotavirus (RV) vaccination program for the Netherlands, from a societal perspective. **METHODS:** Three RV-vaccine doses are administered to infants as part of the routine schedule of childhood immunizations. Based on clinical trials we assume a vaccine protection duration of 4 years and a vaccine effectiveness of 55% against mild RV-diarrhea, 65% against moderate RV-diarrhea (outpatient treatment), and 80% against severe RV-diarrhea (inpatient treatment). Resource consumption caused by RV-diarrhea is derived from recent national studies and the findings of expert panels and valued according to the Dutch costing guidelines. Direct medical (e.g., for vaccine administration or RV-tests) and non-medical costs (e.g., for transportation or extra diapers) are considered. Indirect costs include the productivity loss of paid (friction cost method) and unpaid work (substitution approach) caused by parents caring for their sick child. Costs are presented in 1998 EUR and both future costs and effects are discounted at 4%. A decision analysis model is employed to calculate the health outcomes and costs of the vaccination program. **RESULTS:** RV-vaccination would avoid 34,300 cases of gastroenteritis and 2,300 hospitalizations per year. The break-even dose price of the vaccine is EUR 4 or EUR 9, depending on the exclusion or inclusion of the productivity loss of unpaid work. However, at a dose price of the 1999 withdrawn RV-vaccine (EUR 30) the program would yield costs of EUR 15,000 (paid work only) or EUR 12,100 (paid and unpaid work) per avoided hospitalization. These results are sensitive to the incidence of RV-gastroenteritis, the vaccine effectiveness, the length of hospitalization, and the productivity loss caused by RV-gastroenteritis while variations in outpatient care and direct non-medical costs have limited influence. **CONCLUSIONS:** Depending on its price the RV-vaccine might be a promising candidate for the Dutch national immunization program.

**PID 14****PREDICTORS OF THE MENTAL (MHS) AND PHYSICAL HEALTH SUMMARY (PHS) SCORES OF THE MOS-HIV IN A SAMPLE OF HIV-INFECTED PATIENTS**

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**OBJECTIVE:** Studies evaluating predictors of health-related quality-of-life (HRQOL) in patients infected with HIV have primarily been limited to clinical, sociodemographic, and psychological factors. Little is known about the relationship between HRQOL and behaviors such as medication adherence or complementary and alternative medicine (CAM) use. The purpose of this study was to determine the clinical, sociodemographic, and behavioral predictors of HRQOL. **METHODS:** A sample of 242 HIV-infected patients was recruited. Data were collected using a self-administered instrument containing the Medical Outcomes Study (MOS)-HIV Health Survey and items relating to CAM use, medication adherence, and sociodemographic characteristics. Clinical information was abstracted from medical records. Independent associations of the Mental (MHS) and Physical Health Summary (PHS) scores with CD4 cell counts, HIV-1 viral loads, CAM use, self-reported medication adherence, antiretroviral use, and sociodemographic characteristics were assessed. Linear regression models were created for each score. Variables independently associated ( $p < 0.05$ ) with a score were entered into that model. **RESULTS:** The mean MHS and PHS scores were 46.6 and 42.8, respectively. Education, income, CAM use, and self-reported adherence to HIV medication regimens were independently associated ( $p < 0.03$ ) with MHS scores. PHS scores were independently associated ( $p < 0.003$ ) with age, income, HIV-1 viral load, CD4 count, and CAM use. In the multivariate analyses, income and self-reported adherence were found to be significant ( $p < 0.005$ ) predictors of the MHS scores (Adj.  $R^2 = 0.197$ ); age, income, CD4 counts, and CAM use were found to be significant ( $p < 0.03$ ) predictors of PHS scores (Adj.  $R^2 = 0.182$ ). **CONCLUSIONS:** Our research suggests that, along with clinical and sociodemographic characteristics, self-reported behaviors are important predictors of HRQOL among HIV-infected patients.

**PID 15****MANAGING AIDS IN THE ERA OF ANTIRETROVIRAL THERAPY: CHANGES IN THE RATE AND COST OF HOSPITALIZATIONS**

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**BACKGROUND:** Clinical trials have shown that highly active antiretroviral therapy (HAART) alters the natural progression of HIV. This study was undertaken to determine if, apart from the beneficial clinical impact, there has been a change in the cost of AIDS-related care. **METHODS:** Data from the Massachusetts (MA) Department of Public Health and hospital discharge databases for 1995–1998 were used to examine changes in hospital admission and discharge patterns, and hospital costs for adults with AIDS across the four years. Analyses involved log transformation to address highly skewed distributions, ANOVA to compare continuous variables and Chi-Square to compare the proportions. Hospital costs in-

clude all accommodations and ancillaries. Cost estimates, adjusted for medical inflation and cost-to-charge ratios, are reported in 1998 US\$. **RESULTS:** From 1995 to 1998, the rate of hospital admissions for MA residents with AIDS declined substantially. In 1995, 86% of the 3,162 AIDS patients were admitted at least once during the year compared to 31% of the 5,636 patients in 1998. The mean number of annual admissions per patient dropped from 2 to 1.76 and the inpatient case fatality rate fell from 6.7% to 4.6%. The mean LOS per AIDS admission fell by 1.3 days; a greater decline than the 0.4 day average observed in MA over the same period. The mean hospital stay cost decreased from \$8,070 to \$7,538. These changes accounted for a \$2,900 drop in the mean annual hospitalization cost per AIDS patient during that time. Discharge to sub-acute inpatient and home health services fell by 8.6% in this period. All changes reported are statistically significant ( $p < 0.05$ ). **CONCLUSIONS:** The change in LOS is not the result of post-discharge resource use shifting. The decrease in resource use and costs observed after the introduction of HAART are consistent with an economically beneficial impact of these agents.

**PID16****COST BURDEN OF VARICELLA-ZOSTER VIRUS INFECTION IN A MANAGED CARE SETTING**

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Although information exists in the form of projected costs, limited data are available on the overall cost of illness resulting from varicella-zoster virus (VZV) infection. VZV is usually a benign childhood illness, but reactivation of latent VZV can lead to serious complications. **OBJECTIVE:** To assess via medical claims the costs associated with VZV infection and its resultant complications from the payers' perspective. **METHODS:** We conducted a retrospective database analysis of 73,869 managed care members continuously enrolled throughout calendar year 1999. Records of members with a diagnosis code of either primary varicella (ICD9-052) or herpes zoster (ICD-053) were selected. Data was extracted and cost information was tallied for all medical claims including inpatient hospitalizations, primary care visits, specialist visits, emergency department visits, and specialty procedures. Cost data are reported in 1999 US dollars. **RESULTS:** In 1999, a total of 119 patients were diagnosed with varicella (52%) and herpes zoster (48%). The mean cost to the payer was \$496.77/patient. The average amount paid out for members with varicella was \$181.87. The average cost per member with herpes zoster was \$786.27. Sixty-two (52%) VZV afflicted members were diagnosed with varicella while 57 were diagnosed with herpes zoster. The amount paid for members over age 19 ( $n = 56$ ) was \$640.30/patient. Of these patients, 14% were classified with varicella infection, whereas 86% were classified as

having zoster. For members aged  $<19$  ( $n = 63$ ), the mean amount paid was \$369.18/patient. In this group, 78% were diagnosed with varicella infection, whereas 22% were diagnosed with zoster. **CONCLUSION:** The above costs document for the first time the true cost of VZV infection from the payers' perspective. Further efforts to expand vaccination programs should take these costs into consideration.

**PID17****ECONOMIC EVALUATION OF OSELTAMIVIR FOR INFLUENZA PATIENTS IN JAPAN**

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**OBJECTIVES:** The aim of this analysis is to estimate the economic impacts of oseltamivir treatment for influenza in Japan. **METHODS:** A decision tree with endpoints of occurrences of pneumonia was constructed to compare two treatment strategies, oseltamivir treatment and conventional treatment, for otherwise healthy adult (over 16) patients with influenza like illness in Japan. Drug consumption data (e.g., acetaminophen, antibiotics, and palliative drugs for influenza like illness related symptoms) were collected prospectively as well as work absenteeism data as part of the Japanese placebo-controlled double-blind multicenter study by oseltamivir that included 316 patients. Parameters used in the decision tree were mainly derived from this study and combined with published data. Sensitivity analyses were also performed to examine the robustness of the results. **RESULTS:** Expected total medical cost per patient was 14,100 yen and 14,412 yen for oseltamivir treatment and conventional treatment, respectively. Expected cost including production loss was 56,654 yen and 63,485 yen, for oseltamivir treatment and conventional treatment, respectively. Based on the results of basic analyses, the savings that could be expected in Japanese nationwide health care costs with widespread use of oseltamivir ranged from 1.1 billion yen to 3.4 billion yen. **CONCLUSION:** This study suggested that oseltamivir treatment for patients with flu-like symptoms can be attractive from the societal perspective in Japan.

**PID18****METHICILLIN-RESISTANT STAPHYLOCOCCUS SPECIES TREATMENT PATTERNS IN CANADA**

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Antibiotic resistance is of growing importance to the Canadian health care system due to the morbidity, mortality, and financial costs of certain pathogens for which there are limited therapeutic options. Among the resistant organisms, the incidence of methicillin-resistant *Staphylococcus* species (MRSS) is rising and is posing an increasing burden to health care systems. **OBJECTIVE:** To characterize MRSS treatment patterns in patients with

complicated and uncomplicated skin and soft tissue infections (SSTIs). **METHODS:** Five infectious disease experts from across Canada were interviewed to understand their current treatment practices. The interview responses were used to design a chart review of 100 patients from three acute-care facilities who were hospitalized for a SSTI caused by MRSS. **RESULTS:** Approximately 60–100% of SSTIs caused by MRSS are currently being treated with vancomycin and, in the majority of these patients, the entire treatment course (approximately 5–28 days) is received via IV infusion. Other therapies included fusidic acid and clindamycin. In all cases, IV therapy is initiated in hospital, although approximately 20–60% of patients are eventually able to be discharged to complete their IV therapy with the assistance of home care. Additional data collected in the survey include duration of intravenous (IV) therapy, frequency of switch to oral therapy, and length of oral therapy, hospital stay, and home IV care. **CONCLUSIONS:** Despite the proven economic benefits and wide acceptance of switch therapy, a large portion of patients with SSTIs caused by MRSS are currently completing their entire treatment course via IV infusion. The major reason cited is the lack of an effective oral therapeutic alternative. An oral antibiotic that is effective at treating these types of infections, therefore, represents cost-savings to hospitals by potentially reducing drug administration costs, hospital length of stay due to early discharge, and costs associated with home IV care.

**PID19****AN ECONOMIC ANALYSIS OF CEFDINIR VERSUS LORACARBEF FOR TREATMENT OF ACUTE EXACERBATIONS OF CHRONIC BRONCHITIS**

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**OBJECTIVE:** To perform an economic analysis for the treatment of Acute Exacerbations of Chronic Bronchitis (AECB) comparing cefdinir 300mg twice a day for five days to loracarbef 400mg twice a day for seven days. **METHODS:** A randomized double-blind controlled trial conducted in twenty-four US centers between October 1995 and June 1997 collected data whether patients became cured or not after treatment with cefdinir or loracarbef as well as hospitalizations, clinic visits, and medications not related to the study medication. The final analysis is reported from a third party payer perspective. A total of 585 patients were randomized into two groups, 290 patients receiving cefdinir and 295 patients receiving loracarbef. Symptoms for inclusion criteria were cough and mucopurulent or purulent sputum production for three consecutive months. History or clinical evidence of other diseases and concomitant infections requiring systemic antimicrobial therapy were among the exclusion factors. **RESULTS:** The unadjusted cure rates for cefdinir and loracarbef were very similar at 82.4% (239/290) and 80% (236/295) using ANOVA. Comparable efficacy was

further supported through a probit regression showing an insignificantly higher cure rate for cefdinir of 10.3% ( $p = 0.4903$ ). The unadjusted mean medical costs per case for loracarbef were \$345.03, 27.5 percent higher than cefdinir (\$270.60). An ordinary least squares regression, including patient characteristics as covariates, showed a cost savings of \$74.43 ( $p < 0.001$ ) associated with cefdinir. **CONCLUSIONS:** The key findings of the economic analysis showed a significant cost savings by treating AECB with cefdinir 300mg twice a day for five days as compared with loracarbef 400mg twice a day for seven days. Furthermore, patients taking cefdinir had four less doses, resulting in a higher state of compliance and convenience.

**PID20****TARGETING POPULATIONS AT-RISK FOR URINARY TRACT INFECTION COMPLICATION**

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**OBJECTIVES:** Urinary Tract Infection (UTI) was identified as the second most frequent complication at a large hospital, occurring in 3% of patients admitted, and contributing to \$1.4 million in costs, during the study period October 1998 to September 1999. This project was designed to increase hospital awareness concerning UTI complication, identify patient populations at-risk, and evaluate treatments. **METHODS:** Risk adjustment developed at the University of Pennsylvania School of Medicine was used to predict patients' hospitalization complications. Complication rates were compared between patients with and without UTI as a secondary diagnosis. Laboratory data were analyzed to identify whether patients with a secondary diagnosis of UTI met CDC laboratory diagnosis criteria. Differentiating patients by day of onset identified potentially nosocomial UTI's. Such patients were differentiated by DRG. Finally, the distribution of antibiotic treatments was determined. **RESULTS:** While the predicted complication rate for patients with UTI as a secondary diagnosis was 55.0%, their actual rate was 79.2% ( $p < .001$ ). 55% of such patients met CDC laboratory diagnosis criteria; of these patients, 36% were diagnosed >3 days from admission, i.e., had potentially nosocomial UTI's. Four DRG's—Tracheostomy, PTCA, CHF, and Hip & Knee Replacement—accounted for 40% of all patients with UTI as a secondary diagnosis, but 80% of potentially nosocomial UTI patients. Treatment for all UTI patients showed widespread Levofloxacin use, regardless of DRG. Of note, most UTI's were related to E. Coli, which can be treated more cost-effectively with trimethoprim sulfamethoxazole. **CONCLUSIONS:** Based on this investigation, the hospital re-initiated the National Nosocomial Infections Surveillance System program for UTI's, evaluated Levofloxacin use, developed physician guidelines for UTI diagnosis and treatment, and increased nursing education concerning catheter care and maintenance protocols.

**PIB21****THE COST-EFFECTIVENESS ANALYSIS OF LAMIVUDINE IN THE TREATMENT OF CHRONIC HEPATITIS B IN POLAND**

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**OBJECTIVES:** To estimate the C/E of lamivudine in the treatment of chronic hepatitis B (CHB) in Poland. **METHODS:** Model for the Polish health-care context was developed, based on the use of clinical data from literature and local data on health-care resource utilisation and unit cost. Costs and effects of a population of CHB patients were modelled using 4 scenarios, which attempt to reflect real-life practice, in which patients may receive any of the treatment options available and a proportion of patients may still receive no treatment because therapy is not suitable. Scenario A and B assumed the availability of both treatment options: the first choice of treatment is in A-lamivudine and in B-INFa. In scenario C the only approved treatment is INFa, in scenario D patient received no antiviral treatment. The measure of outcomes were: HBeAg seroconversion and nonprogression to cirrhosis. Only direct medical costs were analysed. The perspective of health-care payers and time horizon of 1 year were taken. The one-way sensitivity analysis and extreme scenario analysis were performed. **RESULTS:** The best results in terms of seroconversion and nonprogression to cirrhosis were achieved in scenario A, costs were lowest in scenario D. Mean cost/HBeAg seroconversion and mean cost/cirrhosis avoided were (in PLN, 1 USD = 4 PLN): for A—35238 and 6480, for B—72654 and 16289, for C—49370 and 8689, for D—20985 and 1474. The incremental analysis vs scenario D indicated, that A is a more cost-effective alternative than B and C. Changing in value of key drivers for sensitivity analysis did not have any significant effect on the ICER. **CONCLUSIONS:** Lamivudine as the first choice treatment of CHB (scenario A) allows to receive the best results in terms of seroconversion and nonprogression to cirrhosis. This is the most cost-effective alternative to “no treatment” (scenario D).

**PIB22****AN APPRAISAL OF HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS FOR USE IN PATIENTS DIAGNOSED WITH HUMAN IMMUNODEFICIENCY VIRUS (HIV) DISEASE**

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**OBJECTIVES:** The increasing effectiveness of medical treatments for HIV (Human Immunodeficiency Virus) has increased survival time of patients infected with the virus. Because of the high incidence of side effects and the burden of complex medication regimens, an increased emphasis has been placed on the assessment of health-

related quality of life (HRQL) in HIV patients. The purpose of this study is to review and compare instruments used for measuring HRQL in HIV patients. **METHODS:** Clinical trials involving HIV patients were identified through the use of MEDLINE and AIDSLINE. The HRQL instruments used in these trials included: 1) generic instruments such as the Medical Outcomes Study (MOS) Short-Form (SF-36), Sickness Impact Profile, Nottingham Health Profile; 2) utility-based measures such as the Quality of Well-Being Scale and the Q-TWIST (Quality adjusted Time Without Symptoms of disease and Toxicity); and 3) disease-specific instruments such as the Multidimensional Quality of Life questionnaire for HIV (MQoL-HIV), Functional Assessment of HIV Infection (FAHI) scale, HIV/AIDS-Targeted Quality of Life Instrument (HAT-QoL), HIV Overview of Problem/Evaluation System (HOPES) instrument, HIV Patient Reported Status and Experience (HIV-PARSE) scale, and the MOS-HIV scale. Criteria for evaluating the instruments included: comprehensiveness, respondent burden, internal consistency of scales, test-retest reliability, clinical validity, and responsiveness to change. **RESULTS:** No instrument was found to be completely devoid of ceiling effects. Although none of the instruments demonstrated perfect psychometric properties, overall, the MOS-HIV instrument fared better than all its counterparts. The instrument has minimal respondent burden and has shown evidence of internal consistency, test-retest reliability, validity, and is responsive to changes over time. The instrument has been widely used in clinical trials and has been translated into 14 other languages, and translated forms have been validated. **CONCLUSIONS:** The MOS-HIV scale appears to be most optimal for HRQL measurement in clinical trials involving HIV patients.

**PIB23****PATTERNS OF ANTIBIOTIC USE AND COSTS ASSOCIATED WITH EPISODES OF TREATMENT FOR COMMON OUTPATIENT RESPIRATORY-TRACT INFECTIONS: AN ANALYSIS OF MANAGED-CARE DATA**Edelman-Lewis B<sup>1</sup>, Menzin J<sup>2</sup>, Boulanger L<sup>2</sup>, Leung M<sup>2</sup>, Friedman M<sup>2</sup>, Hurley JS<sup>3</sup>, Harnett J<sup>4</sup>, Wilson J<sup>4</sup><sup>1</sup>Focus Managed Research, Inc, Worcester, MA, USA; <sup>2</sup>Boston Health Economics, Inc, Waltham, MA, USA; <sup>3</sup>Lovelace Respiratory Research Institute, Albuquerque, NM, USA; <sup>4</sup>Pfizer Inc, New York, NY, USA

**OBJECTIVE:** The objective of this study was to understand the prescribing patterns and economic burden of several common respiratory tract infections (RTIs) treated in primary care. **METHODS:** Using eligibility and claims data from the Lovelace Health Systems of Albuquerque, New Mexico, we selected all outpatients treated with a single antibiotic within 3 days of diagnosis between December 1997 and March 1999 for one of the following 4 RTIs: sinusitis, otitis media (OM), pharyngitis, and bronchitis. The patient's index episode, the focus of this anal-

ysis, was defined as the first infection identified following a gap of at least 30 days in antibiotic use. The treatment episode ended when there were no additional antibiotics prescribed or infection-related outpatient medical visits for 21 consecutive days. The costs of antibiotics, visits, and tests were documented over the course of the episode. **RESULTS:** A total of 30,562 patients (11,798 with sinusitis, 5,636 with otitis media, 7,310 with pharyngitis, and 5,818 with bronchitis) met the study inclusion criteria. For sinusitis, OM, and pharyngitis, penicillins were the most widely prescribed antibiotics, followed by macrolides, sulfonamides, cephalosporins, penicillin/B-lactamase inhibitors, tetracyclines and fluoroquinolones. Macrolides were the most commonly used antibiotic for bronchitis (48% of patients). For patients requiring a switch to a different antibiotic, macrolides were the most frequent choice. The overall costs per episode were \$97 for pharyngitis, \$114 for both OM and sinusitis, and \$133 for bronchitis. The proportion of total costs related to follow-up treatment ranged from 19% for pharyngitis to 32% for OM. Antibiotics accounted for 19% (for pharyngitis) to 29% (for sinusitis) of overall costs. **CONCLUSIONS:** The costs of treatment episodes for RTIs are fairly substantial and vary by condition. While the initial encounter accounts for the majority of the costs, the expenses associated with the need for additional treatment are important to consider.

**PID24**

**COST COMPARISON OF GATIFLOXACIN VERSUS LEVOFLOXACIN IN THE TREATMENT OF COMMUNITY-ACQUIRED PNEUMONIA IN AN OUTPATIENT POPULATION**

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**OBJECTIVE:** In addition to information about efficacy and safety, decision-makers are interested in information about the impact of new drug treatments on health care costs. The objective is to determine the impact of using gatifloxacin versus levofloxacin on total costs among outpatient adults with community-acquired pneumonia (CAP). **METHODS:** Patients were randomized to receive either gatifloxacin (GAT) or levofloxacin (LEV) once daily. Data were collected on efficacy, safety, and medical care resource use from 163 GAT and 176 LEV clinically evaluable patients. Medical care resource use information included the dose and duration of the study and concomitant medications, duration of intensive care unit (ICU) and non-ICU hospital stay, and number of outpatient physician visits. We used a multivariate regression analysis to determine the impact of treatment on total costs. The dependent variable was the logarithm of total costs to adjust for the left skewness found in the cost data. The regression analysis controlled for disease severity, admission to the hospital on the day of (or before)

randomization, and prognostic factors (including age, presence of comorbidities, and a previous CAP episode within the last 12 months). **RESULTS:** GAT achieved a cure rate of 96% compared to 94% for LEV. Based on results from the multivariate regression analysis, patients in the GAT arm could expect total costs that were approximately 8% lower (on average) than the total costs incurred by patients in the LEV arm. Patients admitted to the hospital on the day of (or before) randomization could expect total costs that were nearly 51 times higher. Hospital admission on the day of (or before) randomization was the only statistically significant driver of expected total cost. **CONCLUSION:** GAT shows a trend to be less costly and have a higher cure rate than LEV for outpatients with CAP.

**PID25**

**ECONOMIC EVALUATION OF MACROLIDES AND FLUOROQUINOLONES FOR THE TREATMENT OF RESPIRATORY TRACT INFECTIONS**

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**BACKGROUND:** In the field of respiratory tract infections (RTI), concern about the efficiency of various treatments has increased with the introduction of newer antibiotics often associated with higher acquisition costs. These include second-generation macrolides and fluoroquinolones, which constitute alternative strategies to amoxicillin and erythromycin. **OBJECTIVES:** To evaluate, from a cost-efficacy standpoint, how these newer agents compare with each other in the treatment of community acquired RTI in adults. **METHODS:** Cost-efficacy analyses were done using decision-analysis techniques based on efficacy and safety data of published clinical trials. The analyses were performed from the perspective of a provincial third-party payer. Costs considered were those of antibiotics, physicians and pharmacists services and diagnostic procedures. RTI for which analyses were performed are: bronchitis, community acquired pneumonia, otitis media, pharyngitis and sinusitis. Specific antibiotics compared were: azithromycin, ciprofloxacin, clarithromycin, grepafloxacin, levofloxacin and ofloxacin. **RESULTS:** Following a review of the literature using Medline and Current Contents, 98 articles published between January 1986 and December 1999 met the inclusion criteria and provided efficacy and safety data for the analyses. Efficacy rates for each antibiotic did not differ strikingly and various dosages did not necessarily have an impact on efficacy rates. Cost-efficacy analyses indicate that, among the antibiotics studied, the lowest cost-efficacy ratios were associated with either azithromycin or clarithromycin at a dose of 250mg twice daily. Azithromycin represented the preferred strategy for the ambulatory treatment of community-acquired pneumonia and otitis media, while clarithromycin at a dose of



250 mg twice daily would be preferable for bronchitis, pharyngitis and sinusitis. The studied fluoroquinolones and clarithromycin at a dose of 500 mg twice daily were dominated strategies for each of the studied RTI. **CONCLUSION:** From a cost-efficacy standpoint clarithromycin and azithromycin would be preferable to fluoroquinolones when an alternate strategy to amoxicillin or erythromycin is needed.

**PIB26**

**PHARMACOECONOMIC EVALUATION OF CEFUROXIME IN ABDOMINAL HYSTERECTOMY**

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**OBJECTIVES:** The prophylaxis of infection in hysterectomy is necessary because it decreases the amount of postoperative complications. It has been shown that cefuroxime is an effective antibiotic for prevention of infectious complications after abdominal hysterectomy. It has a bactericidal activity against most pathogens which can lead to wound failure and prolonged the duration of hospitalization. But pharmacoeconomic evaluation is not performed in the numerous investigations. **METHODS:** 40 women were randomized in equal groups to receive cefuroxime 1,5 g i.v. before start of hysterectomy (group I) and combination of ampicillin 4,0 g/day i.m. and gentamycin 5 mg/kg/day i.m. during 5 days after hysterectomy (group II). The last method is commonly used in city gynecological departments. General condition, temperature, pulse, condition of postoperative wounds, vaginal discharges were evaluated every day by means of a score scale. The sum of scores was performed as total clinical score (TCS). Cost-minimization analysis was performed for evaluation of economic outcomes of the treatment. **RESULTS:** Clinical efficacy of the studied regimens was equal because the dynamic of TCS coincided in both groups (100% and 95% accordingly). Condition of wounds was excellent and pathogenic microorganisms were not performed. But in group II were detected skin rash (3 cases) and infectious infiltrate in the place of injection (1 case). Duration of hospitalization was similar in both groups. But total cost in group I was less by 17.7% than in group II ( $p < 0.05$ ) because acquisition cost was more in group II. **CONCLUSIONS:** Prophylaxis of infectious complications in hysterectomy by cefuroxime is as effective as combination postoperative treatment with ampicillin plus gentamycin. Cefuroxime has an economic advantage and less danger for patients. This simple method of prophylaxis indicates more compliance and less cost and may be recommended for most cases of hysterectomy.

**PIB27**

**DOES A DAY STILL MAKE A DIFFERENCE? A DECISION ANALYSIS OF ADULT STREPTOCOCCAL PHARYNGITIS**

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**OBJECTIVES:** Adults presenting with acute sore throats is one of the most common complaints encountered by primary care clinicians, yet the proper management of adult patients with pharyngitis is still somewhat controversial. This study proposes to identify the appropriate clinical management of adult pharyngitis using both cost-benefit analysis and cost-effectiveness analysis. **METHODS:** Cost-Benefit Analysis and Cost-Effectiveness Analysis. Six management strategies were considered in these analyses: empiric treatment, performing a rapid test, obtaining a bacterial culture, empiric treatment with a confirmatory bacterial culture, or a combination of the rapid test with a bacterial culture of negative rapid tests. In addition, the study incorporates differing probabilities of streptococcal disease based upon on previously published symptomatically derived logistic regression scores. Using an internet-based survey, information is collected on undergraduate and graduate students' willingness-to-pay and time trade-off of presented health states. **RESULTS:** Preliminary results indicate that patients presenting with 3 or more indicative symptoms (3 days of fever  $>39^{\circ}\text{C}$ , tender anterior cervical nodes, enlarged tonsils with purulent exudates, and lack of cough) should be treated empirically. Those adult patients that complain of only two symptoms should be managed by a combination of a rapid diagnostic test with a bacterial culture on those rapid tests with negative results. **CONCLUSIONS:** This study presents findings that should provide clinicians with a better guide in the treatment of adult patients with pharyngitis. Performing normative analyses of currently accepted clinical management, the study employs adult's preferences as well as variation in severity of symptoms.

**PIB28**

**COMPARING DIFFERENCES IN CLINICAL EFFECTIVENESS, NEPHROTOXICITY, AND COST-EFFECTIVENESS OF AMINOGLYCOSIDE THERAPY BETWEEN ALTERNATIVE DOSING PROTOCOLS**

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**OBJECTIVE:** The objective of this study was to develop a pharmacoeconomic model which compared the difference in cost-effectiveness (CE) between a Multiple-daily-dosing (MDD) protocol of aminoglycosides (AG) managed by a Clinical Pharmacokinetic Dosing Service (CPS) and a protocol for Once-daily-dosing (ODD), from the perspective of a Managed Care Organization. **METHOD:** Event rates for both clinical effectiveness and aminogly-

coside-associated-nephrotoxicity (ANN) for MDD were determined by a retrospective chart review of 262 randomly sampled patients who received gentamicin for the treatment of serious gram-negative bacterial infections between January 1, 1990 and March 30, 1998. The incidence of ANN was 3.1%. Event rates for ODD protocol for both clinical effectiveness and ANN were determined to be 82.2% and 5.8%, respectively based on an extensive review of the current literature. Time-in-motion studies were performed to determine personnel costs for all nursing and pharmacy activities. Decision analysis was used to determine the CE of the two protocols. **RESULTS:** The results were unexpected based on reports in the literature predicting substantial cost savings with the use of ODD programs. In the base case analysis the expected per patient cost value for MDD with CPS and ODD protocols was \$241 and \$237 respectively. However, MDD with CPS was determined to be more cost-effective than ODD due to slightly increased rate of clinical effectiveness and a decrease in the rate of ANN (average CE ratios = \$281 versus \$287, respectively). Both one-way and two-way sensitivity analyses were performed by varying the two key parameters of clinical effectiveness and ANN. The model was robust to alterations in these key parameters. **CONCLUSION:** This CE analysis questions the benefit of implementing an ODD program when compared to a more traditional MDD protocol managed by a CPS for aminoglycoside dosing.

## MENTAL HEALTH

### SHOULD THE 51 ITEMS OF THE SCHIZOPHRENIA OUTCOMES ASSESSMENT PROJECT (SOAP-51) BE WEIGHTED?

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**OBJECTIVES:** To determine if the 51 items in the Schizophrenia Outcomes Assessment Project (SOAP-51) instrument should be scored using weighted or unweighted items. **METHODS:** 193 community-based individuals with schizophrenia (average age 46.3yr, 46.6% female) rated the importance of each item in the SOAP-51 twice, 4 weeks apart, using a 10cm verbally anchored ("not important to me" to "very important to me"), horizontal line with a numerical scale progressing in units of 10 from 0 (not)–100 (most). **RESULTS:** Results are based on 180 valid and complete surveys in the first administration; there were also 171 in the second. The items ranged from a low of  $56.7 \pm 35.5$  (How important is it for you to have sexual relationships in your life?) to a high of  $89.1 \pm 18.4$  (How important is it for you that your medication helps you?): 1 item scored in the 50s, 2 in the 60s, 16 in the 70s, and 33 in the 80s. Six of 8 average item factor scores (self-concept, work/role, mental

health, medication effects, activities of daily living, and physical functioning) had weights in the 80s ranging from  $80.4 \pm 18.7$  to  $85.1 \pm 13.3$ ; however, two were in the 70s:  $79.1 \pm 15.5$  (satisfaction) and 75.4 (interpersonal). There was no difference between the importance weights of the 8 factors nor the 51 items ( $p > 0.05$ ). **CONCLUSIONS:** It is appropriate to use an unweighted summary for calculating the factor scores in the SOAP-51. It is apparent that in the SOAP item reduction process, items considered to be of import to the clients were retained in the final instrument.

## PMH2

### TREATMENT COURSE AND CHARGES FOR DEPRESSED PATIENTS TREATED WITH SERTRALINE, VENLAFAXINE, AND VENLAFAXINE XR IN THE MANAGED CARE SETTING

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**OBJECTIVES:** Little information is available comparing the treatment course and charges of newly diagnosed patients with depression treated with either sertraline (SER), venlafaxine (VEN) or venlafaxine sustained-release (VXR) in the managed care setting. This analysis aimed to determine the impact on treatment course and depression-related charges of selecting SER, VEN or VXR as first-line pharmacotherapy for newly diagnosed patients. **METHODS:** Retrospective intent-to-treat analysis of an integrated database of medical and pharmacy charges (PharMetric's Integrated Outcomes database 07/98–06/99) including patients aged 18–65 who were diagnosed with depression [ICD-9: 296.2, 296.3, 300.4, 311] and who initiated SER, VEN or VXR therapy within the same 30-day period. Patients with documented previous mental disorders/treatment were excluded. Depression-related treatment charges for the 6-month period following treatment initiation were compared using log-linear regression. Cohorts were comparable with respect to prescribing physician (psychiatry vs. other). **RESULTS:** 19,129 patients were included in the analysis (SER = 15,222; VEN = 1032; VXR = 2875). VXR patients were more likely to augment therapy compared to VEN or SER (18% vs. 13% and 12%;  $p < 0.05$ ). VEN patients were more likely to switch to other medications than VXR or SER (33% vs. 21% and 16%;  $p < 0.05$ ). After controlling for differences in age, gender, managed care plan, pre-treatment history of resource utilization, physician specialty type, index RX year, and switching/augmentation, VEN and VXR patients incurred 13% and 30% higher depression-related charges, respectively, than patients initiated on SER ( $p < 0.05$  for both comparisons). **CONCLUSIONS:** Treatment of depression with sertraline was associated with significantly less augmentation/switching, and lower depression-related charges than ven-

lafaxine or sustained release venlafaxine. The results of this study lend insight useful in making prescribing/formulary decisions for patients with newly diagnosed depression.

**PMH3**

### IS DEPRESSION THE MAJOR CAUSE OF IMPAIRED QUALITY OF LIFE IN SCHIZOPHRENIC PATIENTS?

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**OBJECTIVES:** Schizophrenia is a complex and invalidating disease with a wide range of symptoms and often social exclusion. Patients' quality of life is heavily impaired. The associations between the different symptoms and the QoL, as well as the possible impact of the patient management are still not well known. Our objective was to study the associations between health status, quality of life, general functioning and patient management in schizophrenic patients. **METHODS:** 238 schizophrenic patients were assessed in a cross sectional study with the Lehman QoL scale, EuroQoL, SF-36, Calgary Depression Scale, CGI, GAF and PANSS. At the same time the patient management was assessed. A progressive approach using graphical chain models was adopted to determine the strength of the associations between the different variables. **RESULTS:** Depression was strongly associated with the subjective dimensions of QoL, the utility of EuroQoL and with the mental health sub-score of SF-36. The schizophrenic symptoms (PANSS) seem to have no direct impact on the QoL, but only through their association to depression and impaired functioning (GAF). Other factors that seem to have an impact on the QoL are recent hospitalisation and the type of antipsychotic drug prescribed, atypical antipsychotics seem more favourable compared to typical. **CONCLUSIONS:** Depression seems to be the major factor impairing the quality of life of schizophrenic patients.

**PMH4**

### ASSESSMENT OF PATIENTS' ATTITUDES TOWARD ANTIPSYCHOTIC TREATMENT IN A 40-WEEK RANDOMIZED, CONTROLLED TRIAL

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**OBJECTIVES:** Pharmacotherapy can reduce or prevent symptom relapse among schizophrenics, thereby providing long-term benefits. Relapse is common following noncompliance or discontinuation of antipsychotic medication, and dissatisfaction with medication may lead to noncompliance resulting in symptom relapse and increased health care expenditures. We assessed how schizophrenic patients view the use of antipsychotics. **METHODS:** The Drug Attitude Inventory (DAI), com-

prised of 10 "yes/no" questions about efficacy, side effects and satisfaction, was used to characterize patients' attitudes and subjective responses to antipsychotic treatment. The DAI was administered to subjects with chronic or subchronic schizophrenia or schizoaffective disorder in a forty-week, double-blind, randomized, parallel-group, flexible-dose study of two regimens of ziprasidone (80 to 120 mg QD or 40 to 80 BID) and one regimen of haloperidol (5 to 20 mg daily). A score was calculated as the sum of the responses to all questionnaire items, and the subsets of six subjective and four attitudinal questions. A categorical linear model was used to analyze the marginal probabilities of favorable responses to the questions. **RESULTS:** For total, subjective and attitudinal items, DAI scores at baseline were comparable between treatment groups. Overall item response significantly favored ziprasidone at week 40 ( $p = 0.0016$ ; 7/10 questions showed a higher percentage of positive responses for ziprasidone, and the magnitude of differences per question ranged from +14.2% to -3.7%). This difference was primarily due to positive responses to the subjective questions ( $p = 0.0006$ ; 4/6 questions showed a higher percentage of positive responses for ziprasidone, and the magnitude of differences per question ranged from +14.2% to -3.2%). **CONCLUSIONS:** Patients in the ziprasidone groups had a significantly more positive attitude regarding their medication than those in the haloperidol group over 40 weeks of treatment. These findings have implications for greater patient compliance with ziprasidone treatment, which may lead to decreases in relapse rates, hospitalizations, and other health care resource use.

**PMH5**

### FROM FIRST TO SECOND: IMPACT OF PARTICIPANT CHARACTERISTICS ON THE TIME TO FIRST SWITCH IN A SCHIZOPHRENIA POPULATION

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**OBJECTIVE:** Examine which participant level factors impact the time to switch from first- to second-generation agents among participants in the Schizophrenia Care and Assessment Project (SCAP). **METHODS:** Baseline data identified participants not receiving second generation agents ( $n = 520$ ). Accelerated failure time (AFT) modeling (Weibull distribution error) applied. Number of years between disease onset and study initiation included. Dependent variable: days between study initiation and first switch to second-generation. Right censoring addressed through dichotomous censor variable (1 = switch during window). **RESULTS:** About one-fourth ( $n = 133$ ) experienced switch (mean time to switch = 171.08 days). Working hypothesis: persons with higher side effect and symptom scores and lower functioning would exhibit shorter time to switch. Persons with higher side effect scores (AIMS) experienced longer interval until

switch (1.08;  $p = 0.01$ ) and those with higher depression scores (MADRS) experienced shorter time to switch (0.97;  $p = 0.02$ ). Those receiving service through university hospital experienced longer interval (3.19;  $p = 0.01$ ). The computed hazard rate ( $-0.68$ ) indicates the risk of switch is decreasing over time. **CONCLUSIONS:** Findings indicate that symptoms and type of service delivery site are significant in determining the switch from older to newer agents. The shorter interval for those with higher depression scores is expected and is probably reflective of clinical intervention aimed toward the amelioration of negative symptoms. Interestingly, the longer interval for those with higher side effect scores was contrary to expectation and may indicate that the motivating influence to change is more related to the presentation of primary disease state, rather than the reduction of secondary symptoms associated with the first generation medications. The longer interval for those receiving care in a university hospital setting is perplexing since it is usually expected that medication adjustment will occur during hospital stays. Further investigation of this phenomenon may be aided by the inclusion of physician level information, which is anticipated in upcoming analyses.

**PMH6**

**CHANGE IN INSTRUMENTAL ACTIVITIES OF DAILY LIVING ASSOCIATED WITH ANTIDEPRESSANTS IN OLDER DEPRESSED PATIENTS**

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**OBJECTIVES:** While most current antidepressant agents, such as SSRIs and dual action agents are reasonably effective in ameliorating depressive symptomatology in older patients, less is known about their impact on concurrent instrumental activities of daily living (IADL's). This study examines change in IADL's, such as the capacity to use the telephone, travel, shop, cook, do housework, handle money, or take medicine, from admission to three-month post-discharge follow-up in geropsychiatric patients (age 55 and older) with major depression (ICD-9-CM codes 296.20-296.36) treated with fluoxetine ( $n = 77$ ), mirtazapine ( $n = 36$ ), sertraline ( $n = 145$ ), or venlafaxine ( $n = 56$ ). **METHODS:** Data were obtained from the CQI+SM Outcomes Measurement System, which tracked patients admitted to geropsychiatric inpatient programs in 111 general hospitals across 33 states between 1997–1999. IADL's were measured by selected items from the Duke OARS Multidimensional Functional Assessment Questionnaire (Lawton & Brody, 1969). A Medication Usage Questionnaire was used to track medications prescribed. One-way Analyses of Variance and if significant, Tukey's pairwise comparisons were used to compare medication groups. **RESULTS:** At admission, patients exhibited moderate to severe inability

to independently carry out IADL's (Mean score of 14 to 15 out of 21). Medication groups were indistinguishable on change scores in overall IADL's from time of admission to follow-up. On average, patients showed no change in their ability to carry out IADL's during this time period, despite an improvement in level of depression, as measured by the collateral version of the Geriatric Depression Scale (Nitcher, Burke, Roccaforte, & Wengel, 1993). **CONCLUSIONS:** Antidepressant agents in this analysis were associated with modest improvement in IADL's as assessed by the Duke OARS Multidimensional Functional Assessment in Older Adults. New treatment modalities that improve IADL's along with depressive symptomatology in older patients would be beneficial. Further controlled studies are needed to better understand these findings.

**PMH7**

**CHANGE IN MALADAPTIVE BEHAVIORS ASSOCIATED WITH ANTIDEPRESSANTS IN OLDER DEPRESSED PATIENTS**

Jensik SE<sup>1</sup>, Mayo KW<sup>2</sup>, Bailey KL<sup>2</sup>, Sandoval RP<sup>2</sup>, Edell WS<sup>1</sup>, Adams BE<sup>1</sup>

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**OBJECTIVES:** Numerous antidepressant agents are available to treat geropsychiatric patients with depression. While most current agents are reasonably effective in ameliorating depressive symptomatology, less is known about the impact of these agents on concurrent maladaptive behaviors. This study examines change in sixteen such behaviors from admission to discharge to three-month post-discharge follow-up in geropsychiatric patients (age 55 and older) with major depression (ICD-9-CM codes 296.20-296.36) treated with fluoxetine ( $n = 292$ ), mirtazapine ( $n = 288$ ), sertraline ( $n = 744$ ), or venlafaxine ( $n = 289$ ). **METHODS:** Data were obtained from the CQI+SM Outcomes Measurement System, which tracked patients admitted to geropsychiatric inpatient programs in 111 general hospitals across 33 states between 1997–1999. Maladaptive behaviors were measured by the Psychogeriatric Dependency Rating Scale (PGDRS) (Wilkinson & Graham-White, 1980) and a Medication Usage Questionnaire was used to track medications prescribed at admission, discharge, and follow-up. One-way Analyses of Variance and if significant, Tukey's pairwise comparisons were used to compare medication groups. **RESULTS:** At admission, patients exhibited mild to moderate evidence of maladaptive behaviors (Mean PGDRS overall score of 20 out of 48). Medication groups were indistinguishable on change scores in overall maladaptive behaviors from time of admission to discharge (average length of stay around 16 days), discharge to follow-up, or admission to follow-up. On average, patients showed a very modest improvement (1–2 points) on the PGDRS from admission to discharge, modest decline from discharge to follow-up (0–2 points),

and no change to modest improvement from admission to follow-up (0–1 points). **CONCLUSIONS:** Antidepressant agents in this analysis were associated with modest improvement in maladaptive behavior as assessed by the PDGRS. New treatment modalities that improve maladaptive behavior along with depressive symptomatology in older patients would be beneficial. Further controlled studies are needed to better understand these findings.

**PMH8**

### **IMPACT OF CURRENT ANTIDEPRESSANTS ON COGNITION IN OLDER PATIENTS WITH DEPRESSION**

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**OBJECTIVES:** An array of antidepressant agents are available in the treatment of geropsychiatric patients with depression. While most current agents, such as the selective serotonin reuptake inhibitors (SSRI's) (e.g., fluoxetine; sertraline) and agents acting upon both serotonin and norepinephrine (e.g., mirtazapine; venlafaxine), are reasonably effective in ameliorating depressive symptomatology, less is known about the impact of these agents on other common areas of deficit in older depressed patients, such as cognition. This study examines change in cognitive functioning in geropsychiatric patients (age 55 and older) with major depression (ICD-9-CM codes 296.20-296.36) treated with fluoxetine (n = 269), mirtazapine (n = 275), sertraline (n = 713), or venlafaxine (n = 259). **METHODS:** Data were obtained from the CQI+SM Outcomes Measurement System, a Joint Commission of Accredited Hospital Organizations (JCAHO) ORYX accepted performance improvement system, which tracked patients admitted to geropsychiatric inpatient programs in 111 general hospitals across 33 states between 1997–1999. Cognitive functioning was measured at admission and discharge using the Mini-Mental State Examination (MMSE) (Folstein, Folstein, & McHugh, 1975). A Medication Usage Questionnaire was used to track medications prescribed to patients just prior to admission and at discharge. One-way Analyses of Variance and if significant, Tukey's pairwise comparisons, were used to compare medication groups. **RESULTS:** At admission, patients exhibited moderate evidence of cognitive impairment (Mean MMSE score of 21 out of 30). Medication groups were indistinguishable on change scores in cognitive functioning from time of admission to discharge (average length of stay around 16 days). The average change score on the MMSE was 1.1 to 1.6 points, suggesting very mild improvement. **CONCLUSIONS:** Antidepressant agents in this analysis were associated with modest improvement in cognitive functioning as assessed by the MMSE. New treatment modalities that improve cognition along with depressive symptomatology in older patients would be beneficial.

**PMH9**

### **HEALTH CARE UTILIZATION AND COSTS IN SCHIZOPHRENIC PATIENTS TAKING RISPERIDONE VERSUS OLANZAPINE IN A VETERANS ADMINISTRATION POPULATION**

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**OBJECTIVES:** To compare the change in health care utilization and costs from one year before (preperiod) and one year after (postperiod) starting treatment with risperidone or olanzapine in schizophrenia patients in a Veterans Administration population. **METHODS:** Patients with a diagnosis of schizophrenia (ICD-9 CM code 295) in the preperiod, who had an initial prescription for risperidone or olanzapine dispensed between 3/97 and 3/99, were included. Patients who received any atypical antipsychotic in the preperiod were excluded. Comparisons of average change in utilization and cost from the preperiod to the postperiod were made between the groups for: inpatient hospitalizations, outpatient clinic visits, medications, and total health care cost. Analysis of covariance was used to analyze the data using age, gender, and race as covariates. **RESULTS:** 304 patients in the olanzapine group and 344 in the risperidone group were included. The olanzapine group had significantly more inpatient admissions per patient (0.09 vs. -0.24, p = 0.026), longer inpatient lengths of stay (4.3 days vs. -4.2 days, p = 0.004), and higher cost of inpatient admissions (\$2735 vs. -\$3226, p = 0.003) than the risperidone group. There was a significantly lower cost of antipsychotic for the risperidone group than for the olanzapine group (\$650 vs. \$1660, p < 0.001). The mean daily doses were 3.4 mg of risperidone and 12.0 mg of olanzapine. The olanzapine group also had a significantly higher change in cost for all drugs (\$1492 vs. \$683, p < 0.001) and all health care costs (\$5,665 vs. -\$1,167, p < 0.001) than the risperidone group. **CONCLUSIONS:** The changes in total health care costs, number, length of stay, and cost of inpatient admissions, and medication costs for risperidone-treated patients were significantly lower compared with olanzapine-treated patients.

**PMH10**

### **HEALTH OUTCOMES OF CHILDHOOD ATTENTION-DEFICIT/HYPERACTIVITY DISORDER (ADHD): HEALTH CARE USE AND WORK STATUS OF CAREGIVERS**

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**OBJECTIVES:** Attention-deficit/hyperactivity disorder (ADHD) is the most commonly diagnosed psychiatric disorder among children in the US. However, the social

and economic costs of ADHD are not well understood. We sought to examine the impact of childhood ADHD on caregivers' work status and work productivity, and patients' health care use. **METHODS:** We conducted a telephone survey of 154 caregivers of ADHD-diagnosed children. Caregivers were identified from membership in CHADD (Children and Adults with Attention-Deficit/Hyperactivity Disorder). **RESULTS:** The mean number of ADHD-diagnosed children per caregiver was 1.3 (range 1–4); 60% of children were in 6th grade or lower. The reported mean number of prior year ADHD-related visits to pediatricians, psychiatrists, psychologists, and counselors was 2.0, 3.7, 2.9, and 6.6 visits, respectively. In the 3 months prior to telephone survey, 18% of visits were for unscheduled emergencies—63% of caregivers reported some change in their work status as a result of their child's ADHD. Of these, 15% changed type of job, 46% reduced hours worked per week, and 11% stopped working completely. During the 4 weeks prior to survey, caregivers reported having lost an average of 0.8 days from work and being 25% less productive, for an average of 2.4 days attributed to their child's ADHD—this is equivalent to 39 days reduced caregiver productivity per year. **CONCLUSIONS:** Childhood ADHD adversely affects caregiver work status and work productivity. ADHD also results in frequent unscheduled emergency visits. Effective disease management of childhood ADHD may ultimately mitigate substantial costs borne by employers and health care systems.

**PMH 11**

**SCHIZOPHRENIA CARE AND ASSESSMENT PROGRAM (SCAP): THE IMPACT OF CLINICAL SYNDROME, ANTIPSYCHOTIC MEDICATION TREATMENT AND ADHERENCE ON OUTPATIENT PSYCHIATRIC UTILIZATION**

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**OBJECTIVE:** To examine the impact of clinical syndrome, type of medication and adherence on outpatient utilization. **METHODS:** Baseline data predicted 6-month outpatient utilization (n = 985). Psychotherapy, clinic visits (specimen collection), and total number of outpatient visits were examined. Presence of medication (15 first-generation; 5 novel; both) was coded. Adherence reflected the 4-weeks prior to assessment. Clinical syndrome variables: deficit, hallucinations/delusions, and disorganization. Negative binomial regression (adjusted standard errors). **RESULTS:** Psychotherapy Visits: Positive effect observed for higher hallucinations/delusions and use of both first- and second-generations. Clinic Visits: The probability of visit was positively impacted by higher disorganization, adherence, education less than high school graduation, and CHAMPUS. Negative effect noted for use of novel agents and having Medicare only. Number of visits higher for those with higher disorganization. Total Outpatient Visits: Positive effect observed

for adherence at both periods and treatment with novel agents alone or in combination with first-generation agents. The clinical syndrome variables did not achieve significance. **CONCLUSIONS:** The positive correlation of medication adherence at both baseline and 6 months with clinic visits and total visits is an important driver in outpatient services utilization. The type of medication positively impacts the number of visits, however, a negative association was observed between type of medication and the probability of a clinic visit. It may be possible that some persons using novel agents achieve improvement through outpatient medication management (psychotherapy visits) and may require less frequent clinic visits (for specimen collection), suggesting that the favorable adverse event profile of second-generation agents may promote community functioning. Positive symptoms and disorganization drive the occurrence and number of visits while the presence of deficit syndrome did not achieve significance. These findings suggest that as treatment costs vary by method, payers could benefit by assessing clinical syndrome in order to estimate disease-related payments accurately.

**PMH 12**

**PREVALENCE OF COMORBID ANXIETY AND DEPRESSION AMONG PATIENTS PRESCRIBED SSRI MONOTHERAPY**

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**OBJECTIVE:** To examine the distribution of mental health conditions comorbid to depression, especially anxiety, among patients treated for 1–6 months or 7–12 months with an SSRI. **METHODS:** The study comprised a retrospective review of integrated medical and pharmacy claims from a national managed care organization. Continuously enrolled patients between the ages of 18 and 65 years were identified from the 1.9M claims underlying six IPA model plans for 1997–1998. Patients placed on SSRI therapy following a 4 month period without drugs were stratified according to underlying mental health conditions and length of SSRI monotherapy. **RESULTS:** Overall, between 47% and 52% of patients placed on SSRI monotherapy had a history of depression; an additional 5–12% had histories of anxiety without depression. Greater proportions of patients for whom paroxetine was prescribed rather than either fluoxetine or sertraline had anxiety comorbid to depression in the year prior to initiating drug therapy (11.5%, 6.5%, 7.9%, respectively) (Chi-square <.001). The 40 or more percent of patients without depression or anxiety in their histories—12 months preceding initiation of drug therapy and month of initiation—but treated with SSRIs often had diagnoses for other mental health conditions, specifically neurotic disorders, affective psychoses, nondependent abuse of drugs and adjustment reaction. These diagnoses persisted when patients were subset according to persistence of therapy, i.e., SSRI therapy for greater or

fewer than 6 months. **CONCLUSIONS:** These results support the common belief that physicians differentially prescribe SSRIs according to comorbid symptoms. Observed differences in the prevalence of diagnoses across SSRI therapies are consistent with differences in the range of approved indications across drugs and preferential prescribing of paroxetine for patients with comorbid anxiety disorders.

**PMH 13**

**PRE-TREATMENT PATIENT DIFFERENCES:  
CHOICE OF DRUG THERAPY  
WITHIN SCHIZOPHRENIA**

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**OBJECTIVE:** To examine pre-treatment differences in characteristics of patients with schizophrenia treated with olanzapine and risperidone, as reported in epidemiologic studies. **METHOD:** All 15 non-randomized studies with olanzapine and risperidone cited in Medline or presented at major conferences (APA, ECNP, WPA, ISPOR) through 1999 were included. The direction, magnitude, and statistical significance from all comparisons of pre-treatment characteristics for schizophrenia patients initiating therapy on olanzapine or risperidone are summarized. **RESULTS:** Several studies found olanzapine patients were more likely to be younger and male. One of six studies found younger mean age at onset, though prior duration of illness results had no consistent direction. Other specific comparisons were included in only one or two studies. History of hospital admission results were mixed, though olanzapine patients had significantly higher prior hospitalization costs in the one study with that measure. Patients initiated on olanzapine were more likely to have prior use of clozapine, depot antipsychotics, and/or antidepressants, whereas patients initiated on risperidone were more likely to have anticholinergic use at therapy start. In one study, patients initiated on olanzapine had mean CGI scores and/or GAF scores indicative of greater severity. **CONCLUSIONS:** When evaluated, significant pre-treatment patient differences were often found. Physicians may be choosing olanzapine therapy for more complicated schizophrenic patients, indicated by prior hospitalization cost, medication use, and clinical assessment scores.

**PMH 14**

**DEFICIT SYNDROME AND DRUG USE  
PATTERNS IN COMMUNITY-BASED  
SCHIZOPHRENIA CARE**

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**OBJECTIVE:** To determine how deficit syndrome relates to patterns of antipsychotic drug use among persons with

schizophrenia receiving community-based care. **METHODS:** Study participants were enrolled in the US Schizophrenia Care and Assessment Program (SCAP). Data were obtained from participants who completed the baseline and 6-month assessments and were using antipsychotic medications at baseline (n = 1019). Presence of deficit syndrome was assigned based on proxy methods using clinical data (Kirkpatrick B., et al., 1989). Antipsychotics were categorized as first-generation, second-generation, or other. Few participants received antipsychotics in the 'other' category (2%) and were not included in these analyses. Baseline characteristics and the presence of deficit syndrome were used to predict two outcomes: (1) the likelihood of receiving first-generation antipsychotics at the initial assessment, and (2) the likelihood of switching from one antipsychotic class to another between assessments. Covariates included demographic (gender, race, age, marital status, education, insurance), clinical (GAF, hallucinations/delusions, disorganization), medication adherence, and site variables. Logistic regression was applied. **RESULTS:** Deficit syndrome was not significantly related to use of a 1st-generation agent at baseline. A positive association was found for African Americans (.0004), lower hallucination/delusion scores (.02), and several site indicators (<.05) (Orlando, Denver, Baltimore, and San Diego). The probability of switching antipsychotic classes between assessments was significantly related to one site indicator (.01) (Orlando); weak evidence (.08) of lower GAF scores being associated with a switch was observed. The presence of deficit syndrome did not achieve significance in either model. **CONCLUSIONS:** The deficit syndrome has been studied extensively in its relation to neurological function and course of illness. In the SCAP population of patients receiving community-based care at diverse settings, we do not find a relation between deficit syndrome and two measures of antipsychotic drug assignment. Further research may include evaluation of the relationship between deficit syndrome and drug assignment patterns over time.

**PMH 15**

**A RETROSPECTIVE ECONOMIC EVALUATION  
OF OLANZAPINE VERSUS RISPERIDONE IN THE  
TREATMENT OF SCHIZOPHRENIA**

Zhao Z

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**OBJECTIVES:** The purpose of this study was to assess the one-year direct schizophrenia-related treatment costs, mental health care costs and total health care costs for patients diagnosed with schizophrenia and initiating therapy with either olanzapine or risperidone. **METHODS:** A retrospective analysis of the integrated medical and pharmacy claims of a large, geographically diverse, commercially insured population was conducted. A previously validated algorithm to identify schizophrenics was used for patient selection. The confirmed schizophrenia pa-

tients who began treatment with either olanzapine or risperidone were included. Treatment course and associated schizophrenia-related, mental health care and total health care costs during the subsequent 12-month period were examined using univariate and multivariate methods. **RESULTS:** Nine hundred eighty-five (985) patients initiated on risperidone and 348 initiated on olanzapine met inclusion criteria. The mean dose was 4.02 and 10.49 for risperidone and olanzapine patients, respectively. Patients taking olanzapine versus risperidone stayed on therapy longer during the 12-month observation period (217 days versus 181 days,  $p < 0.0001$ ). Although pharmaceutical costs were significantly higher for olanzapine patients, their medical costs were significantly lower than those on risperidone. After adjusting for differences in patient demographics, disease severity and comorbidities, olanzapine patients had significantly lower mental health care costs including drug costs (\$1,827 less,  $p < 0.05$ ) and lower total health care costs (\$1,834 less,  $p < 0.05$ ). The schizophrenia-related costs (including drug costs) were not statistically significantly different, though numerically the risperidone patients incurred \$740 more per patient than patients on olanzapine ( $p = 0.26$ ). **CONCLUSIONS:** The findings in this study suggest that the initial selection of atypical antipsychotic for the treatment of schizophrenia matters, as olanzapine offset its acquisition cost by reducing medical costs and demonstrated significant mental and total health care cost savings over risperidone.

**PMH 16****USE OF RASCH MODELS FOR VALIDATION OF INSTRUMENTS USED IN MENTAL HEALTH EVALUATION**

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**OBJECTIVES:** The Positive And Negative Syndrome Scale (PANSS) and Calgary Depression Scale for Schizophrenics (CDSS) are widely used in the evaluation of schizophrenia. Their internal validity have already been evaluated with classical methods (multitrait and confirmatory analyses). During the last two decades, Item Response Theory has been developed to deal with latent traits. As part of it, Rasch models are commonly used in Quality of Life research but not yet for other outcome questionnaires. **METHODS:** 458 schizophrenic patients were evaluated with the PANSS and CDSS. Rasch models for polytomous items were fitted to the data in order to assess: 1) unidimensionality of the CDSS and the PANSS subscales, i.e. their ability to measure one latent trait (degree of depression/degree of positive, negative, general schizophrenic symptoms); infit and outfit statistics were used and residuals studied; 2) invariance of comparisons, implying that the parameter characterizing an item does not depend on the latent trait distribution of the population; item parameters estimates were compared for two

subgroups of the population. **RESULTS:** Unidimensionality and invariance of comparisons are globally satisfactory for the CDSS, although the appropriateness of two items (items four and seven) may be questionable. Results do not support the three-dimensional structure for the PANSS, which is commonly used as the reference. **CONCLUSIONS:** Further investigation of the factorial structure of PANSS (e.g five-factors structures, which have been proposed by several authors) is necessary. Rasch models provide a powerful approach to evaluate internal validity of mental health scales, enabling to investigate invariance of comparisons, which constitutes the major distinction from classical methods.

**PMH 17****TYPICAL AND ATYPICAL ANTIPSYCHOTICS IN THE TREATMENT OF SCHIZOPHRENIA: ASSESSMENT OF CLINICAL AND ECONOMIC OUTCOMES USING A MARKOV MODEL**

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**OBJECTIVES:** Health economic assessment of cost-effectiveness parameters for the comparison of typical (Haloperidol), partially atypical depot (Flupentixol) and atypical neuroleptics (Olanzapin, Risperidon) in the treatment of schizophrenia from the perspective of German health insurance. **METHODS:** A published markov model was rebuilt and calibrated with DATA®, taking into consideration relapse rates, extrapyramidal symptoms (EPS) and other prognostic symptoms. All data were derived from published sources where available. Besides the comparison of monotherapy, a stepwise treatment scenario was simulated, starting with three months Olanzapin treatment followed by Flupentixol. Over the 5-year simulation period cumulated complication rates (percentage of relapse, positive and negative symptoms), patient related outcomes (Brief Psychiatric Rating Score "BPRS") and cost parameters (medication, EPS-cost and total costs) were assessed. A cost-effectiveness analysis was performed. **RESULTS:** Olanzapin/Flupentixol in combination had the lowest relapse rate (42.9 %), followed by Flupentixol (44.4%), Olanzapin (44.8%), Risperidon (48.0 %) and Haloperidol (57.6%). Olanzapin treatment showed the highest BPRS score (3.13), followed by Risperidon (3.07), Olanzapin/Flupentixol (2.52), Flupentixol (2.42) and Haloperidol (2.37). The most cost-effective treatment measured by cost in DEM per relapse free patient was Olanzapin/Flupentixol (200,000), followed by Olanzapin (211,000), Flupentixol (212,000), Risperidon (231,000) and Haloperidol (287,000). The best cost-effectiveness (expressed in DEM/BPRS) was observed in Olanzapin (37,100), followed by Risperidon (39,100), Olanzapin/Flupentixol (45,500), Flupentixol (48,600) and Haloperidol (51,400). Total 5-year drug cost (DEM)



were 24,600, 26,800, 3,800, 2,700 and 3,210 respectively. **CONCLUSIONS:** In terms of relapse rates Olanzapin and Flupentixol lead to better clinical outcome and better cost-effectiveness results as compared to alternative typical or atypical neuroleptic therapy. With Olanzapin and Risperidon most favorable BPRS scores were achieved. Flupentixol depot as monotherapy or following initial Olanzapin treatment is a cost-effective alternative to atypical neuroleptics at low drug cost and low relapse rates.

**PMH18****HEALTH CARE UTILIZATION IN PATIENTS WITH TREATMENT RESISTANT DEPRESSION**

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**OBJECTIVES:** Approximately one-half of patients with an episode of major depression will have a recurrent episode during their lifetime. Recent studies indicate that approximately 20% of depressed patients are resistant to traditional antidepressant treatments. This study utilizes medical and prescription claims data from the 1995–1998 MarketScan® Databases to profile the characteristics and health care utilization of patients with treatment-resistant depression. **METHODS:** Depression-diagnosed patients with adequate antidepressant dosing and treatment duration are selected. Patients are classified as treatment-resistant if they have switched/augmented their initial medication with other antidepressants twice, or if they have switched/augmented their initial medication and have claims for depression-related hospitalizations or suicide attempts. Depression-diagnosed patients meeting selection criteria but not classified as treatment-resistant by the above criteria are used as a comparison group. **RESULTS:** Patients with treatment-resistant depression are at least twice as likely to be diagnosed with bipolar disorder, at least 1.5 times as likely to be diagnosed with comorbid anxiety disorders, and at least 1.5 times as likely to be diagnosed with substance-related disorders than the comparison group (p-values <0.01). Patients with treatment-resistant depression have 30% higher mean number of psychiatric diagnostic groupings (PDG) and 9% higher mean number of major diagnostic categories (MDC) than the comparison group (p-values <0.01). Furthermore, patients with treatment-resistant depression are at least twice as likely to be hospitalized (depression and non-depression related), and have 41% more outpatient visits than the comparison group (p-values <0.01). Finally, patients with treatment-resistant depression use 2 to 3 times more psychotropic medications (in addition to antidepressants) than the comparison group (p-values <0.01). **CONCLUSIONS:** Treatment-resistant patients are higher utilizers of both depression-related and general medical services. This finding underscores the importance of early identification and effective treat-

ment of treatment-resistant patients to prevent future depressive episodes and to mitigate health care utilization.

**PMH19****RISK OF HOSPITALIZATION FOR PATIENTS WITH BIPOLAR DISORDER**

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**OBJECTIVES:** Health care utilization for patients with bipolar disorder has received limited attention. This study utilizes medical and prescription claims data from the 1998 to mid-2000 MarketScan Databases to examine the risks of hospitalization, a major cost driver in treating bipolar patients. Hospitalizations are associated with a relapse of bipolar symptoms (often due to treatment ineffectiveness or discontinuation). **METHODS:** Bipolar patients are identified using diagnosis codes and prescription drug claims. An ‘intent-to-treat’ framework for classifying drug cohorts by initial bipolar prescription is used. Prescription claims are studied over a minimum of a six-month time period to analyze drug use patterns (e.g., switching and augmenting treatment). Descriptive profiles of the bipolar patients are presented. Cox proportional hazard models are used to examine the relationships among observable patient characteristics, drug choice, drug use patterns, and hospitalizations. This method accounts for the potential bias in parameter estimates due to data censoring. **RESULTS:** Among patients with at least 6-months of follow-up data (n = 6,536), the mean age is 43 years old and 63.3% are female. The majority of patients are initially observed on antimanic medications, with lesser percentages on other common pharmacological therapies (typical and atypical antipsychotics, and antiepileptics). During the 6-month follow-up, 14.5% of patients have at least one hospitalization and 7.2% have at least one bipolar-related hospitalization. During a 12-month follow-up, 23.3% have at least one hospitalization of any type and 11.5% have at least one bipolar-related hospitalization. The unadjusted risk of hospitalization increases over time, at a decreasing rate. **CONCLUSION:** The high incidence of hospitalization demonstrates the need for effective treatment options. This study also illustrates the importance of accounting for censored data to obtain unbiased estimates of factors associated with the risk of hospitalization.

**PMH20****DOSING OF BENZODIAZEPINE HYPNOTICS IN ELDERLY PATIENTS**

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**OBJECTIVES:** Use of benzodiazepines in elderly patients has been associated with adverse outcomes including mo-

tor vehicle accidents and hip fractures from falls. Evidence exists showing greater risk of adverse outcomes with higher doses of these drugs regardless of drug half-life. Initial administration of lower doses to elderly and debilitated patients is generally recommended for benzodiazepine hypnotics. We analyzed whether these recommendations are generally followed when prescribing these drugs to inpatients. **METHODS:** Demographic and hospital information for all patients receiving flurazepam, triazolam, or temazepam between January 1998 and June 2000 was extracted from Solucient's Projected Inpatient International Classification of Clinical Services (pICCS) database. This database contains demographic, hospital, clinical, and detailed service level information for inpatients from over 150 short-term, non-federal, US hospitals. The percent of elderly patients (over age 65) receiving the recommended dose was determined. The relationship of patient age, hospital teaching status, bed size, and geographic region on the likelihood of following dosing recommendations was analyzed. **RESULTS:** We extracted information for 14,929 inpatients receiving flurazepam, 8,147 inpatients receiving triazolam, and 125,625 patients receiving temazepam. Among elderly patients receiving one of these drugs, 72.1% of patients receiving flurazepam, 49.8% of patients receiving temazepam, and 7.1% of patients receiving triazolam received the recommended dose. For all three drugs, patient age was directly correlated with the likelihood of receiving the recommended dose. There was no consistent relationship between teaching status, hospital bed size, or geographic region and the likelihood of receiving the recommended dose, although teaching hospitals were much more likely than non-teaching hospitals to provide the recommended dose for temazepam and triazolam (OR 5.3 CI 4.9–5.8 for temazepam; OR 2.7 CI 2.2–3.2 for triazolam). **CONCLUSIONS:** Many elderly inpatients are prescribed higher than recommended doses of hypnotic benzodiazepines, suggesting need for systemic interventions to avert adverse outcomes.

**PMH2 I**

**QUALITY OF LIFE OF NON-INSTITUTIONAL CAREGIVERS OF SCHIZOPHRENIC PATIENTS: CONTRIBUTION OF QUALITATIVE INTERVIEWS TO QUESTIONNAIRE GENERATION**

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**OBJECTIVES:** The detrimental effects of hospitalisation and developments in psychopharmaceutical, psychotherapeutic and social treatments led to deinstitutionalization. Proxies of patients, relatives or friends, have had to learn to cope with caregiving tasks. Facilitating the coping of the caregivers should ensure a better quality of caregiving, notably in terms of therapeutical observance. An exhaustive literature review found 9 instruments for

caregivers of schizophrenic patients. Five of them are self administered, but none of those covering mental, psychological and social fields have been widely validated and accepted within the scientific community, none are available in French. We report the first step of development of a specific, multidimensional, self-administered instrument measuring the quality of life of non-institutional caregivers of schizophrenic patients. **METHODS:** Face-to-face interviews were conducted with non-institutional caregivers of schizophrenic patients. Their content was analysed to generate a large number of candidate items covering all-important aspects of caregivers' quality of life. Eighteen interviews were performed: 11 mothers and 7 fathers aged from 48 years to 71. **RESULTS:** Content analysis identified topics covering mental (worrying, emotional over-involvement, and suffering, guilt, fair of stigma, of future, loneliness, disillusion, anxiety, feeling of usefulness, self esteem . . . ) physical (fatigue, disruption of sleep . . . ) and social (relationships with the patient, friends, relatives, health workers, occupation, leisure . . . ) fields. Negative as well as positive impact was identified. **CONCLUSIONS:** These results were compared to the domains described in the literature. This step led to the generation of about 100 questions and the validity of this questionnaire will be studied on 400 caregivers.

**PMH22**

**PATTERNS OF ANTIDEPRESSANT USE AND HEALTH CARE COSTS IN DEPRESSED PATIENTS WHO RECEIVED SSRI THERAPY**

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**OBJECTIVES:** To assess differences in the health care resource use of patients who received selective serotonin reuptake inhibitor (SSRI) antidepressants. **METHODS:** Retrospective analysis of administrative medical claims from 1/97–12/99 was conducted using Protocare Sciences' Managed Care Database. Patients were categorized as early discontinued or continued (<6 months vs. ≥6 months therapy), then as non-switched or switched (one agent vs. >one agent). Total health care costs were compared across these categories. **RESULTS:** Under half (48%) of the 11,119 SSRI users studied continued antidepressant therapy for at least 6 months. Two-thirds of all patients received monotherapy; 19% switched agents (44% of switches were in the first three months of therapy); 15% used multiple agents. Eight percent of patients who discontinued early had switched agents within the specified 6 month period; 90% of these switches occurred in the first three months. For patients who continued therapy for ≥6 months, the average total health care charges per patient per month (PPPM) during the first three therapy months were \$906 (switch by third month), \$568 (switch by sixth month), \$496 (switch by twelfth month) and \$375 (switch after twelfth month). PPPM charges in the first six

therapy months ranged from \$452–\$921 for discontinued patients and from \$423–\$483 for non-switched, continued patients. **CONCLUSIONS:** Patients who discontinued SSRI therapy early tended to have higher costs than patients who continued therapy. It is unclear whether these increased costs stem from treatment of medication side effects or increased utilization related to lack of efficacy of the initial antidepressant. Alternatively, early switchers may simply be more clinically complex patients.

**PMH23**

**DEINSTITUTIONALIZATION OF SCHIZOPHRENIC PATIENTS: COST-CONSEQUENCES AND POLICY IMPLICATION OF INTENSIVE CASE MANAGEMENT VERSUS STANDARD CASE MANAGEMENT**

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**OBJECTIVES:** In France a large part of acute hospitalisation beds are occupied by long-term hospitalisation of schizophrenic patients. A model was developed to compare Intensive Case Management (ICM) to Standard Case Management (SCM) for long-term hospitalised chronic schizophrenic patients. **METHODS:** A model was used to evaluate the number of patients that are either successfully dechynchronized, experiencing failure, or are readmitted to hospital within a year for a cohort of 100 chronic schizophrenic patients. With these figures, it was possible to estimate the needs in terms of number of beds and employees in the catchment area of Clermont-Ferrand in France, for the 1st, 2nd and 3rd year after the ICM strategy have been implemented. **RESULTS:** At the beginning of the first year, 100 hospitalisation beds, 30 nurses, 10 psychologists and 5 psychiatrists were needed. After 1 year these numbers were respectively reduced to 50, 15, 10 and 2.5 due to the success of the ICM strategy. This positive trend is also recorded for the second year of implementation. At the end of the 3rd year a steady point level is nevertheless reached with the model, due to the fact that there will always be patients that can not be dechynchronized; the numbers at this point will be 11 beds, 3 nurses, 1 psychologist and a half-time psychiatrist. **CONCLUSIONS:** Due to the important caseload of ICM, it remains more costly than SCM at implementation, but will reduce cost from year 1, and be less costly than SCM from year 3. This model can therefore evaluate the economic impact of creating a dechynchronization unit in a catchment area and make budgetary prevision for large-scale implementation of ICM in France.

**PMH24**

**THE COST OF ACUTE HOSPITALIZATION FOR ANOREXIA NERVOSA AND BULIMIA**

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**BACKGROUND:** It has been reported that approximately 1% of young women have anorexia nervosa and 4% bulimia. Managing eating disorders requires a multi-disciplinary approach including acute hospitalization, when necessary. This study was undertaken to assess the cost of acute hospital care for these disorders. **METHODS:** Inpatient cost estimates, adjusted for medical inflation and cost-to-charge ratios, were developed using data from all-payer 1998 discharge databases from five states, supplemented with national fee schedules. ICD9 codes were used to identify those with a principal diagnosis of anorexia (307.1) or bulimia (307.51). Cases where both diagnoses were coded are excluded from results reported here. Log transformation was used to address highly skewed distributions. Length-of-stay (LOS), disposition and psychiatric unit care (PSYU) were also examined. Hospital costs (i.e., accommodation, ancillary, physician) are reported in 2000 US\$. **RESULTS:** The state databases yielded 641 cases of anorexia and 326 of bulimia. The overwhelming majority (>96%) were females. For anorexia: the mean age was 25 years (45% <20 years); mean LOS was 13; 24% received care in a PSYU; 87% were discharged home; 7% went to a rehab or mental health facility (MHF) and 3% left against medical advice (AMA). For bulimia, the mean age was 27 years (25% <20 years); mean LOS was 9; 39% received care in a PSYU; 90% were discharged home; 4% to rehab or MHF; 3% left AMA. The mean total cost per hospital stay was \$12,390 for anorexia and \$9,120 for bulimia. On average, the number of annual admissions was 1.6 and 1.2 for anorexia and bulimia, respectively. Managed care was the largest primary payer. **CONCLUSIONS:** Although hospitalization is not the primary site of medical care for managing serious eating disorders, it's sometimes required. We believe that this information provides an essential piece in understanding the economic consequences of these conditions.

**PMH25**

**A MODEL COMPARING OLANZAPINE AND ZIPRASIDONE IN PATIENTS WITH SCHIZOPHRENIA**

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**OBJECTIVE:** To estimate and compare the efficacy, treatment-emergent adverse events, costs and outcomes of olanzapine and ziprasidone for treatment of schizophrenia. **METHODS:** A decision-analytic model was used to determine outcomes for patients treated over a 1-year period. Model parameters were based on clinical trial data and published medical literature. Data from different trials were compared only when patient populations were similar. Comparative studies were available for weight gain and cardiovascular events. For essential parameters with no relevant study results, assumptions were made that the medications would be similar. **RE-**

**SULTS:** Compared to patients treated with ziprasidone, data seem to suggest that olanzapine patients had a higher response rate, a higher incidence of weight gain, and a lower incidence of QTc prolongation. Total medical cost was higher for ziprasidone patients when the medication cost of ziprasidone was assumed to be more than half the price than that of olanzapine. The olanzapine group's costs were more sensitive to changes in drug costs, whereas the ziprasidone group's costs were more sensitive to the response rate of the medication used for those patients not responsive to ziprasidone. **CONCLUSIONS:** Compared to ziprasidone patients, olanzapine patients may have a higher response rate, a higher incidence of weight gain, and a lower incidence of QTc prolongation, with lower total costs as long as ziprasidone is more than half the price of olanzapine.

**PMH26**

**OUTPATIENT ANTIPSYCHOTIC USE:  
COMPARING ATYPICAL AND CONVENTIONAL  
ANTIPSYCHOTIC ADHERENCE USING A  
NATIONAL RETAIL PHARMACY DATA BASE**

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**OBJECTIVES:** We report on trends in medication adherence for patients who received conventional and atypical antipsychotics under routine outpatient care during a 9-month period in 1998–9. **METHODS:** Refill records were analyzed for over 25,000 patients at a national retail pharmacy chain. Persistence was defined as a patient's possession of medication at 30 day intervals from a patient's initial prescription. Persistence was taken as a proxy for medication adherence. **RESULTS:** The percentage of patients adhering to therapy at nine months was 44.4% for atypical agents; 47.6% for conventional agents; and 71.1% for clozapine. **CONCLUSIONS:** Improved clozapine adherence was associated with a closely supervised medication administration process that ensured patient tracking and frequent and sustained patient-provider contact. Atypical agents, with their improved side-effect profile relative to conventional agents, were not associated with better adherence. These results suggest that improved side-effect profiles alone may not insure higher levels of medication adherence and that improved medication administration processes may facilitate higher levels of outpatient medication adherence for patients with major mental illness.

**PMH27**

**COST-UTILITY ANALYSIS OF QUETIAPINE  
COMPARED TO RISPERIDONE IN THE  
TREATMENT OF PATIENTS WITH  
SCHIZOPHRENIA OR OTHER  
PSYCHOTIC DISORDERS**

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**OBJECTIVE:** Comparative cost-effectiveness was assessed in an open-label, randomized trial (QUEST) that compared the efficacy and safety of quetiapine with risperidone in a outpatient population with schizophrenia or other psychotic disorders. **METHOD:** Based on the overall Positive And Negative Syndrome Scale (PANSS) scores, patients in QUEST were categorized into one of three health states—mild (PANSS  $\leq 74.5$ ), moderate (PANSS  $> 74.5$  and  $\leq 106.5$ ), or severe (PANSS score  $> 106.5$ )—at baseline and at 2 months and 4 months. Utilities and expected utilities from baseline were calculated. **RESULTS:** At baseline, 297 (54.0%), 206 (37.5%), and 47 (8.5%) quetiapine patients, had mild, moderate or severe symptoms compared to 102 (59.0%), 55 (31.8%), and 16 (9.2%) in the risperidone group. For patients in the mild or moderate states at baseline, improvements were seen in both treatment groups. For severe patients, more quetiapine patients improved: 21.2% versus 7.7% in the mild state and 60.6% versus 30.8% in the moderate state ( $p = 0.020$ ) at 2 months and 46.9% versus 0.0% in the mild state and 40.6% versus 62.5% in the moderate state ( $p = 0.023$ ) at 4 months. Overall, when weighted by utilities, quetiapine treated patients attained greater gains in health state utilities at each follow-up visit for the mild ( $0.61 \pm 0.069$ ), moderate ( $0.36 \pm 0.073$ ) and severe ( $0.29 \pm 0.071$ ) states. At 2-months, quetiapine patients enjoyed a gain of 0.239 from their baseline level compared to 0.175 for the risperidone group. At 4-months, the gains were 0.329 versus 0.184 for the quetiapine and risperidone groups ( $p < 0.05$ ). Average daily doses were 253.9mg quetiapine and 4.4mg risperidone, yielding average daily costs to US consumers of \$6.38 and \$7.85. At average retail costs to consumers in the US, quetiapine reduces costs by \$1.47/day or \$536.55 annually. **CONCLUSION:** Patients with schizophrenia or other psychotic disorders, treatment with quetiapine resulted in significant effectiveness and cost savings compared with risperidone.

**PMH28**

**DEPRESSION AND HOMELESSNESS,  
A FRENCH INITIATIVE**

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**CONTEXT:** So-called chronic depression, a limiting factor in terms of social reinsertion, must be diagnosed to enable its management and to prevent a decline towards a profound, desocialised state. **OBJECTIVE:** To determine the incidence of depression in populations of the homeless, who are users of the Samu Social de Paris—Paris Social Emergencies Unit—(SSP). **METHOD:** Once an individual had been assessed and a response found to his or her need, it was suggested that patients calling the SSP free-phone number should agree to complete the CES-D questionnaire. Developed in the US by Randloff (1977), this questionnaire enables the detection of depressive symptoms in a given population. Its use over the

telephone has been validated. **RESULTS:** Mean age: 43 years. Sex ratio: 84% men, 16% women, this being in line with the ratio of users of the SSP. In 54% of our sample, the period of homelessness was longer than 2 years; 92% were single, 64% had maintained contacts with their family and 36% declared they had no income. 70% of those questioned had a score of 17 or higher on the CES-D scale, indicative of depressive symptoms, mean score: 22.4; the prevalence of possible depression was 69% and that of probable was 60%. Although no significant difference was seen in terms of the duration of homelessness, two peaks were nonetheless observed: at 28 for those on the street for more than one month and less than 6 months, and 22.8 for those homeless for more than two years. **CONCLUSION:** By “turning the spotlight” on a poorly understood population, this study provides relevant results, which demonstrate the need to act very rapidly to help these populations living in considerable need, before the homeless sink into a state of permanent poverty.

**PMH29**

### **COST ANALYSIS OF OLANZAPINE VERSUS RISPERIDONE IN THE TREATMENT OF UNCONTROLLED SCHIZOPHRENIA**

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**OBJECTIVES:** This study compares the one-year direct schizophrenia-related treatment costs, mental health care costs and total health care costs of uncontrolled schizophrenia patients initiated on olanzapine versus risperidone. **METHODS:** The integrated medical and pharmacy claims of a large, geographically diverse, commercially insured population were used to conduct this analysis. Patients who initiated treatment with either olanzapine or risperidone and had one inpatient or two outpatient services for schizophrenia within 30 days prior to initiation of drug of interest were included in this analysis. Treatment course and associated schizophrenia-related, mental health care and total health care costs during the subsequent 12-month period were examined using univariate and multivariate methods. **RESULTS:** Four hundred thirty-one (431) patients initiated on risperidone and 142 initiated on olanzapine met inclusion criteria. The mean dose was 4.34 and 11 for risperidone and olanzapine patients, respectively. During the one-year period after initiation of drug of interest, olanzapine patients (compared with risperidone patients) were less likely to be hospitalized and had shorter mean length of hospital stays for schizophrenia-related causes, mental health care causes and all causes. Although pharmaceutical costs were significantly higher, medical costs were significantly lower for patients on olanzapine compared to those on risperidone. Univariate and multivariate analyses (controlling for potential confounding factors such as patient demographics, disease severity and comorbidities) consistently demonstrated that olanzapine patients had

significantly lower schizophrenia-related costs (\$2,839 less,  $p < 0.05$ ), lower mental health care costs (\$3,744 less,  $p < 0.005$ ) and lower total health care costs (\$4,674 less,  $p < 0.001$ ) than those patients initiated on risperidone. **CONCLUSIONS:** The findings revealed significant differences between olanzapine and risperidone in the treatment of uncontrolled schizophrenics in clinical practice. Olanzapine patients incurred lower costs (lower schizophrenia-related, mental health care and total health care costs). The lower costs were inpatient driven by fewer hospitalizations and shorter length of hospital stays in the olanzapine treatment group.

**PMH30**

### **DIFFERENCES IN HEALTH CARE EXPENDITURES AMONG PATIENTS TREATED FOR DEPRESSION WITH OR WITHOUT ANXIETY**

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**OBJECTIVE:** To compare health care expenditures of treatment with SNRIs and SSRIs in depressed patients with or without anxiety. **METHOD:** Using administrative claims from the MEDSTAT MarketScan database, we identified patients with a new episode of depression enrolled in a participating health plan from 1994 to 1998. Patients included for analysis had both a diagnosis of depression (ICD-9-CM criteria) and a prescription for either an SNRI (venlafaxine [n = 290], venlafaxine XR [n = 63]) or an SSRI (fluoxetine [n = 2854], paroxetine [n = 1772], sertraline [n = 2580], fluvoxamine [n = 124]) antidepressant. **RESULTS:** The SNRIs (n = 353) had lower inpatient non-mental health costs (\$206 vs \$472;  $P = 0.02$ ) and lower antidepressant medication costs (\$302 vs \$338;  $P = 0.01$ ) compared with the SSRIs (n = 7330). In particular, venlafaxine (n = 290) costs were lower than fluoxetine (n = 2854) costs (\$281 vs \$395;  $P < 0.05$ ). Among patients with depression and anxiety, SNRIs (n = 219) had lower inpatient non-mental health costs (\$273 vs \$635;  $P = 0.04$ ) and lower antidepressant medication costs (\$304 vs \$350;  $P = 0.01$ ) than SSRIs (n = 4351). Among depressed patients without anxiety, SNRIs (n = 134) had lower inpatient non-mental health costs (\$96 vs \$234;  $P = 0.05$ ) and lower inpatient mental health costs among users of inpatient mental health services (\$2,301 vs \$4,847;  $P = 0.02$ ) relative to SSRIs (n = 2979). **CONCLUSION:** Patients receiving SNRIs appear to have lower health care expenditures in some areas compared with SSRIs among depressed patients with or without anxiety. Further research is needed to determine whether patients treated with SNRIs can be shown to accrue more favorable economic benefits over time relative to patients treated with SSRIs.

**PMH31****PHARMACOECONOMIC EVALUATION OF THE TREATMENT WITH OLANZAPINE IN “REVOLVING DOOR” SCHIZOPHRENIC PATIENTS**

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**OBJECTIVES:** We aimed to evaluate the clinical, societal and economic outcomes of olanzapine treatment compared to treatment with standard antipsychotics in outpatients with multiple schizophrenic episodes and subsequent yearly rehospitalizations. **METHODS:** The present study comprised two stages. Within the first (clinical) stage a mirror image 24-week cost-effectiveness study was performed. Data were evaluated from 30 schizophrenic patients (ICD-10). Drug efficacy assessment included PANSS. Social functioning was evaluated with the original checklist. Economic analysis based on resource utilization data. Within the second stage a Markov simulation model over a hypothetical 5-year period has been developed to compare the overall costs and cost-effectiveness of olanzapine with those of standard treatment. **RESULTS:** During the maintenance phase of the study, olanzapine-treated patients achieved a statistically significant greater improvement than ones treated with standard antipsychotics on overall measures of effectiveness. In spite of high acquisition cost of olanzapine, total medical costs were not significantly more (nearly 10 %). Incremental cost-effectiveness ratio for olanzapine of 5 roubles (1998 values) per disability-free day gained over the trial period. The direct cost per patient was calculated to be 56000 roubles higher for 5-year therapy with olanzapine. However the net savings per olanzapine-treated patient was 40.000 roubles from societal perspective by significantly increasing productivity and producing more time in a disability-free state. The results of analysis were not robust in a sensitivity analysis, including variations in the frequency, duration and/or cost of hospitalization and/or acquisition cost of olanzapine. **CONCLUSIONS:** Olanzapine offered an economically justifiable therapeutic option in the long-term management of the special subpopulation of patients with frequent rehospitalizations.

**PMH32****BARRIERS TO THE USE OF MEDICATIONS TO TREAT ALCOHOLISM**Mark TL<sup>1</sup>, Kranzler HR<sup>2</sup>, Poole VH<sup>1</sup>, Hagen CA<sup>3</sup>, McLeod C<sup>3</sup>, Crosse SE<sup>3</sup><sup>1</sup>The MEDSTAT Group, Washington, DC, USA; <sup>2</sup>University of Connecticut School of Medicine, Farmington, CT, USA;<sup>3</sup>Westat, Rockville, MD, USA

In December 1994, naltrexone, marketed under the brand name Revia, became the first adjunctive medication in almost 50 years approved by the FDA for treat-

ment of alcoholism. Despite the evidence of its efficacy in randomized clinical trials, the use of naltrexone is not widespread. **OBJECTIVE:** To identify possible barriers to the use of naltrexone and other new medications in the treatment of alcoholism. **METHODS:** Focus groups were conducted in Washington, DC. The first comprised physicians who treat substance abuse, recruited nationally through a professional association and physician consultant referrals. The second comprised individuals who had been treated for alcoholism in the past three years and were in recovery, recruited locally through a newspaper advertisement. The physician group was taped and transcribed; the patient group was not taped in order to protect confidentiality. **RESULTS:** Public and provider lack of information were identified as key reasons why naltrexone has not been used more widely. Patients also pointed out medication side effects, the philosophy of Alcoholics Anonymous (AA), the high price of naltrexone, and stigma as barriers. In addition, physicians noted lack of evidence of efficacy in practice, difficulty measuring efficacy in practice, lack of physician time for patient management, patient reluctance to take medication, uncertainty in identifying appropriate patients for naltrexone, and lack of knowledge of and attitudes toward the use of medications among counselors as barriers. The findings will be used to inform the design of a national survey of providers. **CONCLUSIONS:** The findings suggest that physicians will not adopt innovations based solely on the clinical literature. While millions of dollars have been invested in the development of new alcoholism medications, licensing medications may not result in significant changes in treatment without educational and marketing efforts to promote the medications through the diverse members of the alcoholism treatment community.

**PMH33****OLANZAPINE VERSUS RISPERIDONE IN THE TREATMENT OF SCHIZOPHRENIA: A COMPARISON OF COSTS AMONG TEXAS MEDICAID PATIENTS**Rascati KL<sup>1</sup>, Johnsrud M<sup>1</sup>, Crismon ML<sup>1</sup>, Barber BL<sup>2</sup>, Lage MJ<sup>2</sup><sup>1</sup>The Center for Pharmacoeconomic Studies—The University of Texas, Austin, TX, USA; <sup>2</sup>Eli Lilly and Co, Indianapolis, IN, USA

**OBJECTIVE:** The purpose of this retrospective study is to examine both schizophrenia-related direct costs and total (schizophrenia plus non-schizophrenia) direct costs among Texas Medicaid patients who have been diagnosed with a schizophrenic disorder and have been initiated on one of two atypical antipsychotics (olanzapine or risperidone). **METHODS:** Services and prescription utilization and cost data were retrieved for 3,072 patients with schizophrenia who were initiated on olanzapine or risperidone between 1997 and 1998. Each patient was followed for one year from initiation of therapy. Multivariate analysis was used to control for a wide range of factors (drug choice, patient demographics, pre-utiliza-

tion costs, region, health conditions, and treatment patterns) that may influence schizophrenia-related costs and total costs. Estimation was conducted via a two-stage instrumental variable model. **RESULTS:** The mean unadjusted total schizophrenia-related cost per patient per year was \$4,973, and the total unadjusted health care cost per patient per year was \$7,335. Although the daily drug costs associated with olanzapine were higher than risperidone, and patients taking olanzapine on average stayed on therapy longer than those taking risperidone, when looking at total schizophrenia-related costs (services plus prescription utilization), there was no significant difference between drug groups (olanzapine \$81 lower,  $p = 0.7534$ ). Additionally, when total health care costs were analyzed, there was no significant difference in drug groups (olanzapine \$530 lower,  $p = 0.1050$ ). Sensitivity analyses found similar results. **CONCLUSION:** This naturalistic study used data from a Texas Medicaid population to examine the schizophrenia-related costs (and total costs) for patients who received olanzapine versus risperidone. No differences in direct costs were found for patients receiving olanzapine versus risperidone.

**PMH34**

#### **SWITCHING AND AUGMENTATION OF ANTIDEPRESSANTS IN OLDER DEPRESSED PATIENTS**

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Newer antidepressants are often prescribed to geriatric patients with depression because older agents often have side effects that may be problematic in the elderly. Less well-understood are the prescribing patterns of clinicians when such first-line agents are switched or augmented. **OBJECTIVE:** To examine switching and augmentation patterns used during the inpatient and post-discharge period in geriatric patients with major depression (ICD-9-CM codes 296.20-296.36) treated initially with fluoxetine, mirtazapine, sertraline, or venlafaxine. **METHOD:** Data were obtained from the CQI+SM Outcomes Measurement System, an ORYX (JCAHO) accepted performance improvement system, which tracked patients admitted to geropsychiatric inpatient programs in 111 general hospitals across 33 states between 1997–1999. A Medication Usage Questionnaire was used to track medications prescribed just prior to admission, at time of discharge, and at three-month post-discharge follow-up. **RESULTS:** From admission to discharge, over one-third to one-half (37.4–52.1%) of patients switched or augmented specific antidepressant agent. Switching and augmenting rates decreased somewhat from discharge to follow-up (10.5–29.6%) and from admission to follow-up (30.5–38.9%). Remarkably, over twenty distinct antidepressant agents were used when switching occurred, and

fifteen distinct antidepressant agents were used to augment the initial antidepressant agent. **CONCLUSIONS:** A significant number of patients do not appear to improve adequately on their agent of first choice. The great variety of treatment combinations suggests there is no clearly preferred treatment strategy for partial and non-responders. Practice guidelines for treatment strategies to augment and switch in older patients with depression would be beneficial for both clinicians and patients.

**PMH35**

#### **PATTERNS OF ANTIDEPRESSANT AND ANTIPSYCHOTIC MEDICATION USE IN MEDICAID, 1995–1999**

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**OBJECTIVES:** This study sought to: 1) analyze trends in utilization of antidepressant and antipsychotic medications in Medicaid between 1995 and 1999; 2) gauge the utilization and diffusion of new generation, branded antidepressants and antipsychotics during this period. **METHODS:** The study was based on a time-series analysis of quarterly, state-level, Medicaid pharmaceutical claims, as administered by HCFA. Data from 45 states were suitable for analysis. **RESULTS:** In 1998, antidepressants and antipsychotics accounted for 9% of Medicaid prescriptions, but 19% of expenditures. From 1995 to 1998, Medicaid prescriptions for antidepressant and antipsychotic medications grew by 40% and 20%, respectively; corresponding expenditures grew by 96% and 160%. The growth rate in both prescriptions and expenditures for antidepressants and antipsychotics outpaces that observed in Medicaid pharmacy benefits as a whole by more than two-fold. In 1995, new generation antidepressants and antipsychotics accounted for 44% and 17.5% of all prescriptions for Medicaid antidepressants and antipsychotics, respectively. By 1998, these new generation drugs had accounted for 62% and 51% of all Medicaid prescriptions for antidepressants and antipsychotics. **CONCLUSIONS:** Antidepressants and antipsychotics account for a large proportion of Medicaid pharmaceutical prescriptions and reimbursements. The total Medicaid market for antidepressants and antipsychotics grew dramatically over this four-year period. The impact of newer antidepressants and antipsychotics on expenditures is disproportionate to the number of prescriptions for these agents. New generation antidepressants and antipsychotics have been accepted into common use within Medicaid programs. Increased Medicaid expenditures for antidepressants have been driven both by the uptake of new generation agents and by increased overall prescription volume. Increased Medicaid expenditures for antipsychotics have been driven by increased utilization of atypical antipsychotics. Utilization of new-generation antidepressants and antipsychotics varies among the states; not all states have adopted new generation agents as quickly as others.

**PMH36****DOSING OF BENZODIAZEPINE HYPNOTICS IN ELDERLY PATIENTS**

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**OBJECTIVES:** Use of benzodiazepines in elderly patients has been associated with adverse outcomes including motor vehicle accidents and hip fractures from falls. Evidence exists showing greater risk of adverse outcomes with higher doses of these drugs regardless of drug half-life. Initial administration of lower doses to elderly and debilitated patients is generally recommended for benzodiazepine hypnotics. We analyzed whether these recommendations are generally followed when prescribing these drugs to inpatients. **METHODS:** Demographic and hospital information for all patients receiving flurazepam, triazolam, or temazepam between January 1998 and June 2000 was extracted from Solucient's Projected Inpatient International Classification of Clinical Services (pICCS) database. This database contains demographic, hospital, clinical, and detailed service level information for inpatients from over 150 short-term, non-federal, US hospitals. The percent of elderly patients (over age 65) receiving the recommended dose was determined. The relationship of patient age, hospital teaching status, bed size, and geographic region on the likelihood of following dosing recommendations was analyzed. **RESULTS:** We extracted information for 14,929 inpatients receiving flurazepam, 8,147 inpatients receiving triazolam, and 125,625 patients receiving temazepam. Among elderly patients receiving one of these drugs, 72.1% of patients receiving flurazepam, 49.8% of patients receiving temazepam, and 7.1% of patients receiving triazolam received the recommended dose. For all three drugs, patient age was directly correlated with the likelihood of receiving the recommended dose. There was no consistent relationship between teaching status, hospital bed size, or geographic region and the likelihood of receiving the recommended dose, although teaching hospitals were much more likely than non-teaching hospitals to provide the recommended dose for temazepam and triazolam (OR 5.3 CI 4.9–5.8 for temazepam; OR 2.7 CI 2.2–3.2 for triazolam). **CONCLUSIONS:** Many elderly inpatients are prescribed higher than recommended doses of hypnotic benzodiazepines, suggesting need for systemic interventions to avert adverse outcomes.

**PAIN & NEUROLOGIC DISORDERS****PPN1****AN INTERNET STUDY OF WTP FOR MIGRAINE PHARMACOTHERAPIES**

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**BACKGROUND:** There are a wide range of therapeutic options for migraine headaches that have different costs

and benefits, and little is known about the cost-effectiveness of specific therapies. **OBJECTIVE:** Assess patients' preferences for outcomes of treatment of migraine headache based on their marginal willingness to pay (WTP) for treatment attributes. **METHODS:** In an Internet-based study, we used computer software to measure importance ratings of attributes of pharmacological migraine therapies, then elicited their WTP for an ideal drug (one that was 100% effective, worked quickly, and had no adverse effects) and for "less than ideal" drugs with relatively poor performance in one specific attribute of performance. Patients: 429 self-identified migraineurs recruited via an Internet web site. **RESULTS:** A high proportion of patients in the study had symptoms consistent with migraine etiology of headache (91% in enrollees, 99% of patients providing WTP ratings). Expert review confirmed a large proportion of symptom profiles as being consistent with migraine (90% of the first 109 enrollees). Median WTP for an ideal migraine therapy was 4.1% of estimated monthly income or \$130 (US), and was associated with severity of pain, frequency of headaches, and the types of medications used in the past. WTP was reduced when pharmaceuticals offered less benefit (median reductions of a \$75 per month for 50% chance of causing a rebound headache; \$62 for rendering user unable to work, \$50 for a two-hour delay in effect; and \$15 for failure to relieve nausea). Reductions in WTP were largely consistent with importance ratings for attributes except for "speed of relief," which was more highly valued. **CONCLUSIONS:** Elicitation of patients' WTP for specific attributes of a therapy appears to be a feasible method to quantify patients' preferences for outcomes. Further work is needed to compare this approach to traditional methods for measurement of WTP.

**PPN2****USE OF GALANTAMINE IN THE NETHERLANDS FOR THE TREATMENT OF MILD TO MODERATE ALZHEIMER'S DISEASE**

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**OBJECTIVES:** To estimate the costs and long-term health effects of using galantamine in Dutch patients with mild to moderate Alzheimer's disease (AD). **METHODS:** A pharmacoeconomic model was developed. It consists of two components: an initial module based on two galantamine clinical trials and a subsequent module that uses trial results and equations derived from recently published data to forecast the time until patients require full time care (FTC) or die. The analyses compare treatment with galantamine 24 mg to no pharmacologic treatment. Cost estimates were based on resource use profiles of patients with AD in the Netherlands and are reported in 1998 guilders (NLG) determined from the perspective of a comprehensive care payer. Future costs are dis-



counted at a 5% annual rate. Extensive sensitivity analyses were conducted. **RESULTS:** Over the decade of analysis, a net saving of NLG 3,050 was estimated. The cost of galantamine makes up 5.0% of the total. The model predicts that patients treated with galantamine are expected to spend 10.0% less time receiving home-based FTC and 9.9% less time in a nursing home compared to untreated patients. For every hundred patients starting treatment on galantamine 17.8 person-years of FTC are avoided (14.3 discounted). Secondary analyses of the effect of galantamine on behavioral symptoms estimated an increment in total savings of NLG 4,903. Sensitivity analyses run on key model parameters showed results to be robust. **CONCLUSION:** On average, treatment with galantamine not only provides a considerable health benefit but is also expected to yield savings in the costs associated with mild to moderate AD in the Netherlands.

**PPN3****THE IMPACT OF DEMENTIA ON CAREGIVER QUALITY OF LIFE**

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**BACKGROUND:** The prevalence of Alzheimer's disease (AD) and vascular dementia (VD) is expected to rise substantially in the coming decades. As well, the impact of these conditions on caregiver burden and quality of life (QOL) is also expected to increase. **OBJECTIVES:** To (1) determine how the characteristics of patients and their caregivers affects caregiver's QOL, and (2) identify subsets of caregivers disproportionately affected by their patient's disease. **METHODS:** Data were collected cross-sectionally at baseline on 912 pairs of AD/VD patients and their primary caregivers as part of a multinational prospective longitudinal clinical trial. Patient and caregiver demographics, patient CDR and DAD scores were collected, as were caregiver EuroQol (EQ-5D) scores and time spent on caregiving activities. Univariate and multivariate analyses were conducted to determine patient and caregiver characteristics that were particularly associated with low caregiver QOL. **RESULTS:** Patient severity as measured by CDR score was moderately related to caregiver EuroQol score ( $p < .05$ ). Specifically, caregiver EuroQol scores were .84, .78, .76, and .74 for questionable, mild, moderate, and severe dementia (on the CDR), respectively. In a main-effects only regression model, a 4-point and a 7-point reduction in caregiver's EuroQol score was associated with the caregiver being a woman and being a spouse/partner of the patient, respectively. When an interaction term between these two variables was introduced into the regression, the main effects of caregiver gender and being a spouse/partner of the patient became insignificant. However, the interaction term, being a woman spouse caring for a patient, was associated with a significant 12-point reduction in EuroQol

score. **CONCLUSIONS:** Worse caregiver QOL is associated with more severe patient disease stage and with being a woman caring for a demented spouse. Interventions should thus be planned with special consideration given this potentially more vulnerable set of caregivers.

**PPN4****UTILITY ASSESSMENTS OF OPIOID TREATMENT IN THE US, CANADA AND AUSTRALIA FOR PATIENTS WITH CHRONIC NON-MALIGNANT PAIN**

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**BACKGROUND:** Optimal treatment for chronic non-malignant pain (CNMP) is largely a function of patient preferences in balancing pain control with treatment tolerability. **OBJECTIVE:** To estimate utilities for health states associated with CNMP and its treatment with opioids. **METHODS:** 96 CNMP patients (31 Canadian, 33 US, 32 Australian) completed the SF-36<sup>TM</sup> and assessed health state descriptions and their own current health using the visual analog scale and computer-assisted adaptive conjoint analysis (ACA). The health state descriptions included combinations of: presence/absence of 7 side effects (3 severity levels for each); pain control (5 severity levels); and 2 opioid administration routes. **RESULTS:** On average, subjects were 47 ( $\pm 13$ ) years, white (95%), female (63%), not living alone (74%), and unemployed (74%). Approximately 75% of subjects in each country were currently experiencing mild to moderate pain; most had arthritic or low back pain. All SF-36<sup>TM</sup> subscale scores by country were significantly lower than US age- and gender-equivalent norms ( $p < 0.05$ ). Mean utilities did not vary substantially between oral vs. transdermal opioid administration. Overall, mean ( $\pm$ SE) utilities ranged from a maximum of  $0.87 \pm 0.02$  (no pain or side effects) to a minimum of  $0.18 \pm 0.02$  (uncontrolled pain with severe respiratory depression or severe vomiting). Mean utilities for controlled pain with moderate side effects ranged from  $0.62 \pm 0.02$  (mood changes, vomiting, or respiratory depression) to  $0.74 \pm 0.02$  (sweating). Uncontrolled pain without side effects ( $0.64 \pm 0.02$ ) was preferred to well-controlled pain with severe side effects (range:  $0.41 \pm 0.03$  [mood changes, vomiting, or respiratory depression] to  $0.54 \pm 0.03$  [sweating]). **CONCLUSIONS:** Results indicate a patient preference for opioid therapy that causes fewer side effects. Although pain may be extremely debilitating, tolerating pain to avoid opioid side effects may be preferable to controlling pain and experiencing certain opioid side effects. Opioid side effects combined with poorly-controlled pain may result in very low health utility.

**PPM5****COMPARISON OF COSTS AND COST-EFFECTIVENESS OF OXCARBAZEPINE AND SODIUM VALPROATE FOR NEW/RECENT ONSET PARTIAL SEIZURES**Bazalo G<sup>1</sup>, Sachdeo R<sup>2</sup>, Graham S<sup>3</sup>, Chang S<sup>3</sup>, Cohen A<sup>3</sup><sup>1</sup>Bazalo Consulting, Scottsdale, AZ, USA; <sup>2</sup>Robert Wood Johnson Medical School, New Brunswick, NJ, USA; <sup>3</sup>Novartis Pharmaceuticals, East Hanover, NJ, USA

**OBJECTIVE:** to determine the comparative costs and cost-effectiveness of oxcarbazepine and sodium valproate in the treatment of new and recent onset partial epileptic seizures. **METHODS:** Low, moderate and high dose maintenance regimens were determined for each drug based upon prescription audit information captured in the prescribing physician's office. Unit drug costs based on wholesale acquisition costs were then used to compute a daily drug cost for each dosage level. A decision-analysis model using a Monte Carlo simulation was developed to evaluate the cost-effectiveness of oxcarbazepine and sodium valproate. The model contained the computed daily drug costs along with direct payer costs associated with initiation and maintenance of therapy, treatment of adverse events and switching from one drug to another due to poor seizure control or adverse events. The probabilities of maintaining seizure control and of experiencing adverse events were obtained from double-blind clinical trials comparing oxcarbazepine and sodium valproate. **RESULTS:** The average daily drug costs weighted over the three dosage levels were \$4.72 (\$1.49 to \$7.66) for oxcarbazepine and \$3.17 (\$2.45 to \$3.87) for sodium valproate. Total one year costs for oxcarbazepine, including costs of adverse events and costs of switching drugs due to poor seizure control or adverse events were \$3,511 for oxcarbazepine and \$5,931 for sodium valproate. The computed number of months on initial therapy was 9.95 for oxcarbazepine and 9.66 for sodium valproate. The analysis was carried out to four years using the same probabilities for adverse events and seizure control. The four-year costs were \$17,949 and \$23,144 with 25.8 and 24.3 months of therapy for oxcarbazepine and sodium valproate respectively. **CONCLUSION:** These findings suggest that oxcarbazepine results in lower expected total costs compared to sodium valproate when drug costs, evaluation and management, adverse events and costs of switching therapies are taken into account.

**PPM6****VALIDATION OF THE 24 HOUR HEADACHE DISABILITY QUESTIONNAIRE (DISQ-24) IN A SAMPLE OF HEADACHE SUFFERERS**

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**OBJECTIVES:** The Disq-24 was developed to measure headache disability on a 24-hour basis and was first utilized in a sample of migraine subjects who experienced

chronic daily headaches. The purpose of this study was to evaluate this instrument's psychometric properties. **METHODS:** The Disq-24 is a 14-item questionnaire with a 6-point Likert-type scale that measures disability with regards to three hypothesized dimensions: family/social (4-item), work activities (5-item), and emotions/feelings (5-item). This instrument was administered in a prospective, multicenter, randomized, double-blind, placebo-controlled, parallel group trial of 170 transformed migraine sufferers. Four scaling assumptions of summated rating scales (equal variances, equal weights, item-internal consistency and discriminant validity) and scale-level reliability were examined using the baseline data. **RESULTS:** The means and standard deviations of items within each scale were similar. However, item evaluation demonstrated a floor effect in all items ranging from 22% to 66%. Item internal consistency was generally high and ranged from 0.62 to 0.90. Cronbach's alpha ranged from 0.93 to 0.95 for the three dimensions and was 0.97 for the total score, exceeding the generally acceptable criteria of 0.70. Although each item was highly correlated with the hypothesized scale, the item-scale correlations did not discriminate significantly with other scales. **CONCLUSIONS:** Although the Disq-24 satisfied the equal variance, equal weights, and internal consistency assumptions of summated rating scales, item discriminant validity was not supported in the above analysis. This lack of support could be due to the small sample size and/or the existence of a unidimensional structure. The validity of the instrument warrants further testing in a headache population which is not restricted to chronic daily headache patients.

**PPM7****A MODEL FOR PREDICTING THE INCIDENCE OF MIGRAINE IN THE IDAHO MEDICAID POPULATION**Shaw J<sup>1</sup>, Joish V<sup>1</sup>, Cady PS<sup>2</sup><sup>1</sup>The University of Arizona, Tucson, AZ, USA; <sup>2</sup>Idaho State University, Pocatello, ID, USA

**BACKGROUND:** Migraine headache affects approximately 9 million Americans. It is a chronic disease and is often associated with a high rate of disability. **OBJECTIVE:** The purpose of this research was to develop a model for predicting the incident number of migraine cases in the Idaho Medicaid population over a 5-year period. **METHODS:** Incident migraine cases between January 1994 and December 1998 were identified from the Idaho Medicaid claims database using migraine-specific ICD-9-CM codes or migraine-specific pharmacy claims. Data were collected on the total number of new migraine cases according to age, race, gender, and year. A negative binomial model was developed to predict incident migraine cases from the other variables. All model independent variables were treated as categorical variables. Two hundred sixty-six Medicaid recipients between the ages of 5 and 104 were included in the analysis. **RESULTS:** A test for

overdispersion revealed that use of a negative binomial model was appropriate. Age, race, gender, and year were all determined to be significant effects by likelihood-ratio test. The greatest incidence of migraine was observed among persons 30–34 years of age. Controlling for other effects, the incidence of migraine fell with increasing age >34 or decreasing age <30. The estimated mean number of new cases was greater among Caucasians than non-Caucasians (46.2 vs. 3.7) and was greater among females than males (41.9 vs. 8.0). The estimated incidence of migraine was lowest in 1994 and generally rose each year from 1996 onward. Using a pseudo-R<sup>2</sup> measure developed by Nagelkerke, the model explained 87.2% of the variance in incident migraine cases. **CONCLUSIONS:** The findings of this investigation with regard to age, race, and gender are consistent with those of previous studies. Our estimates for the impact of time on the incidence of migraine suggest that costs associated with migraine treatment will continue to rise for the Idaho Medicaid program.

**PPN8**

**PSYCHOMETRIC EVALUATION OF WIDELY USED PAIN MEASURES FOR PURPOSE OF COMPUTERIZED DYNAMIC PAIN ASSESSMENT**

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**OBJECTIVES:** The aim of this study was to test the unidimensionality of 65 items from nine widely used pain questionnaires in preparation for computerized adaptive pain assessment. **METHODS:** Random samples of adults were contacted on the internet (N = 782) and telephone (N = 750). 65 items were selected mainly from Brief Pain Inventory, MOS Pain Measures, Oswestry Low Back Pain Disability Questionnaire, Nottingham Health Profile, McGill Pain Questionnaire, Health Disability Index, Migraine-Specific Questionnaire, Aberdeen Back Pain Scale, and Headache Impact Test. Mplus software was used to perform confirmatory and exploratory factor analyses of polychoric correlations among the items. Model was examined through eigenvalue analysis, inter-factor correlations, and root mean square residuals. **RESULTS:** Confirmatory factor loadings ranged from 0.53 to 0.92 with 90% of them higher than 0.7. Three factors were rotated to an oblique solution. Examination of exploratory factor analysis revealed two subdimensions of pain based upon item content: pain severity and pain impact. The third dimension observed in the three-factor solution, interpreted as current pain, was defined by questions without recall period. Eigenvalue analyses showed that the first factor explained more than 65 percent of the total variance in all pain item scores. Three factors explained 74% of the variance. The interfactor correlations were high, ranged from 0.64 to 0.67. Root mean square residuals were low, 0.07 for one-factor solution and

0.05, 0.03 for two- and three-factor solution respectively. **CONCLUSION:** Most items from widely used questionnaires measure one single underlying construct of pain sufficiently to meet the assumption of Item Response Theory. Items selected will be calibrated on a standard metric to estimate scores at patient's specific pain level. Further investigation on the application of IRT methods and computer technology in pain assessment is warranted.

**PPN9**

**HOW IS PAIN FELT ACROSS COUNTRIES? THE SHORT-FORM MCGILL PAIN QUESTIONNAIRE (SF-MPQ) IN 10 LANGUAGES**

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**OBJECTIVES:** Measuring Health-Related Quality of Life (HRQoL) has become a vital part of assessing pain in international studies. The SF-MPQ is one of the most widely used tests for the measurement of pain. It consists of 15 descriptors (11 sensory; 4 affective) rated on an intensity scale from 0 (none) to 3 (severe), a Present Pain Intensity (PPI) Index and a visual analogue scale (VAS). Prior to use in international trials the measure underwent linguistic validation in 10 languages. **METHODS:** A HRQoL specialist coordinated the translation process in each target country using the following methodology: 1) two forward translations by professional translators, native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by a HRQoL specialist and translators; 3) backward translation by a native English speaker; 4) comparison of the source and backward versions; 5) comprehension test in a sample target population and finalization. **RESULTS:** Linguistic and conceptual issues emerged during the translation process. The adjective “aching” was redundant in most languages, equivalents were found such as “discomforting”/“not very intense”. The adjective “tender” used alone was not found descriptive; the equivalent “sensitive to touch” was therefore preferred. The term “punishing” was found to have a strong religious connotation, the notions of “violent” or “torturing” were used instead. Concerning the PPI Index, the terms used to describe pain had an affective component such as “distressing”, “horrible”. An intensity scale was favored in translations. **CONCLUSIONS:** A rigorous translation methodology of the original SF-MPQ was performed to ensure conceptual equivalence and acceptability of translations. The issues encountered during linguistic validation highlight the value of international input in instrument design. Future psychometric testing will be conducted to ensure reliability and validity of each translation, appropriateness of the questionnaire in each country, and comparability of data across countries.

## PPN10

**SURVIVAL AND NURSING HOME FREE SURVIVAL (NHFS) OF AD PATIENTS**

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**OBJECTIVE:** To model survival and NHFS of Alzheimer Disease (AD) patients. To justify the Mini-Mental Status Examination (MMSE) score as an important predictor of patient survival and nursing home utilization. **METHODS:** Survival models were applied to analyze the Minimum Uniform Data Set (MUDS), developed and maintained by Alzheimer Research Centers of California (ARCC). The study sample included 3150 AD patients, who enrolled in ARCC between Oct. 1992 and Jan. 1999. Cox regression models with and without time-dependent covariates were used in the analysis. Results were adjusted by comorbidities. **RESULTS:** The MMSE score was shown to be a strong predictor of both AD patients' survival and NHFS. One-unit increase of MMSE score (on a 30-point scale) corresponds to a 5.5% hazard reduction. That is to say, if a patient's 5-year survival probability is 0.500, with his MMSE score increased by one unit, the probability will be increased to 0.520. One unit increase of MMSE also corresponds to 6.4% hazard reduction in future nursing home utilization, which means a NHFS probability of 0.500 will be increased to 0.523. Female, black, and Hispanic had higher survival probability. Older age, longer education, and history of major psychosis in patient's primary relatives caused lower survival rate. Marriage and female gender increased NHFS; high value in Body mass index decreased NHFS. All the above results were significant at 0.01 or 0.05 level. **CONCLUSIONS:** The study showed MMSE was a strong predictor of patient survival and NHFS. Further study should be conducted to explore the possibility that MMSE score can be used as a clinical indicator for treating AD patients. It is also interesting that, older age doesn't have significant impact on NHFS although it is a strong predictor of survival. On the other hand, marriage has a significant impact on NHFS, but not on survival.

## PPN11

**THE MIGRAINE IN FRANCE IN 2000: EPIDEMIOLOGICAL DATA**Henry P<sup>1</sup>, Auray JP<sup>2</sup>, Duru G<sup>3</sup>, Chazot G<sup>3</sup>, Dartigues JF<sup>4</sup>, Lanteri-Minet M<sup>5</sup>, Lucas C<sup>6</sup>, Pradalier A<sup>7</sup>, El Hasnaoui A<sup>8</sup>, Gaudin AF<sup>9</sup>

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**OBJECTIVE:** A French national epidemiological study on migraine was presented 10 years ago at the Migraine

trust. It was the first study to cover an entire country (HENRY P. et al.: Migraine prevalence in France. In *New advances in headache research*: 2. Ed. Clifford Rose 1991 Smith Gordon—pp. : 11–14). This study has provided also data on the burden of migraine in terms of its economic and social impact. We would like today to update the data. **METHODS:** 1486 persons, aged over 15 and suffering from headaches were randomly selected from a large representative sample of the French population. They were asked to complete a questionnaire, which allowed discriminating sufferers of migraine according to IHS criteria. **RESULTS:** Among the 1486 headache sufferers, we find 880 migrainous people (1-1, 1-2 and 1-7 IHS criteria), 454 without migrainous headache and 152 with chronic daily headache. If we compare the results of the certain migraine group (1-1 and 1-2 IHS) we find that they are identical (8,1% (1989) versus 8,2% (1999)). However, if we include the migrainous disorder group fulfilling all criteria but one (1-7 IHS), the prevalence rate for migraine headache in France between 1989 and 1999 seems to show a clear increase, rising from 12,1% to 17,3% because of less restrictive criteria than those applied ten years ago. Regarding the prevalence in general population for chronic daily headache the rate is around 3% with 1,8% for men and 3,9% for women in 1999.

## PPN12

**DIFFERENCES IN HEALTH-RELATED QUALITY OF LIFE BETWEEN MIGRAINEURS WITH AND WITHOUT PROPHYLACTIC MEDICATION USE**

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In a previous study, sumatriptan therapy was associated with improvements in Health Related Quality of Life (HRQoL). Using the same population, the present study explores additional changes in HRQoL between patients who did and did not receive migraine prophylaxis medication. **OBJECTIVES:** To compare the difference in HRQoL of migraineurs who did and did not receive migraine prophylactic medication. **METHODS:** A retrospective database analysis was conducted using pharmacy claims and HRQoL data. Study patients were from a managed care organization, were diagnosed with migraine, and were initiated on sumatriptan (baseline). The SF-36 and Migraine-Specific Quality of Life Questionnaire-Version 1.0 (MSQ) surveys were administered at baseline, 3 and 6 months after initiation of sumatriptan. Patients were identified for the prophylaxis group if they received any medication from a previously developed list of possible migraine prophylaxis medications: 1) within 30 days prior to baseline and 2) at least 4 out of the 6 months after baseline. A two-way repeated measures ANOVA was performed comparing differences in HRQoL between the groups from baseline to 6 months. **RESULTS:** Of 178 patients, 40 were in the prophylaxis group and 138 in the non-prophylaxis group. Statistically significant increases were found in the MSQ Role Function-Restricted

tive, and the SF-36 Role-Physical, Bodily Pain domains in the non-prophylaxis group compared with the prophylaxis group (p-value <0.05). A statistically significant increase was found in the SF-36 Physical Functioning domain in the prophylaxis group compared with the non-prophylaxis group (p-value <0.05). **CONCLUSION:** Although sumatriptan has been shown to improve HRQoL of migraineurs, concurrent use of prophylaxis medication for migraineurs shows mixed results of any additional benefit in HRQoL.

#### PPN13

### DELAYS IN NURSING HOME PLACEMENT FOR PATIENTS WITH ALZHEIMER'S DISEASE ASSOCIATED WITH TREATMENT WITH DONEPEZIL MAY HAVE HEALTH CARE COST-SAVING IMPLICATIONS

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**OBJECTIVES:** Donepezil, an anti-dementia drug, has been associated with delays in nursing home placement (NHP) for patients with Alzheimer's disease (AD). This analysis explores the health care cost-saving implications of such treatment. **METHODS:** Information on the dates and reasons for NHP was obtained through follow-up interviews with caregivers and chart reviews of 763 AD patients who participated in three randomized, double-blind, placebo-controlled clinical trials and two subsequent open-label studies of donepezil. Patients were categorized according to their experiences in utilizing donepezil during the clinical trials and extension studies. Cox proportional hazards models (adjusted for age, gender, baseline Mini-Mental Status Examination scores, caregiver status and post clinical study use of cholinesterase inhibitors) were used to estimate adjusted survival functions from which median times to NHP were estimated for each donepezil use category. Analyses of the relationship between donepezil use and time to NHP were completed for both first dementia-related placement (data reported here) and for permanent placement (data similar). Standard nursing home cost data were applied to these results. **RESULTS:** For the least exposure group (dose <5 mg/day and/or used drug for less than 8 weeks total; n = 95), the median time to first dementia-related NHP was 43 months. Compared with this group, patients who received at least 5 mg/day of donepezil for 8 weeks or more had a significantly (p < 0.05) longer time to first dementia-related NHP. For patients who received donepezil for at least 36 weeks (12 weeks of double blind and 24 weeks of open-label treatment, for example), the median time was 73 months to first dementia-related NHP (RR = 0.458, p < 0.01). **CONCLUSIONS:** Because nursing home care has been reported as the principal cost driver in the care of AD patients, these delays to the time of entry into a nurs-

ing home associated with donepezil treatment may have important health care cost-saving implications.

#### PPN14

### A PROGNOSTIC MODEL TO PREDICT QUALITY OF LIFE CHANCES AFTER SUBARACHNOID HEMORRHAGE

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**OBJECTIVES:** Traditionally, mainly survival chances are considered at clinical decisions before major operations. This study looked at the potential ability of the most commonly used pre-operation estimators to predict health related quality of life of subarachnoid hemorrhage (SAH) patients one year after surgery. **METHODS:** 173 patients underwent intracranial aneurysm surgery within 72 hours after SAH at the National Institute of Neurosurgery in 1998 and 1999. Before surgery health status assessment included Hunt-Hess (HH) grade as a measure of neurological status, ASA physical status score, and CT examination that determines the presence of intracerebral hemorrhage (ICH) and Fisher scale. 12 months after the surgery, patients were interviewed either by phone or post by using the EQ-5D generic quality of life questionnaire. The relationship between the pre-operation health status/risk estimators and one-year QoL values was examined by differences in mean EQ-5D index values and by developing a regression model. F-statistics and student-t tests have been used to test statistical significance. **RESULTS:** Patients with ICH had lower EQ-5D index values (0.32 vs. 0.70, p < 0.001). Patients with Fisher scores >3 had lower QoL than those with scores below (0.35 vs. 0.68, p < 0.001). HH grade >3 lead to lower QoL values (0.05 vs. 0.66, p < 0.001). Patients with ASA scores >2 had also significantly lower QoL (0.18 vs. 0.66, p < 0.001). Due to similar meaning and high correlation between ICH status and Fisher score, Fisher score was dropped from the prognostic model. Regression model included: EQ-5D index = 1.04 °V 0.38fx(ASA > 2) °V 0.24fxICH °V 0.30fx(HH > 3) °V 0.006fxAGE. The overall model showed an R<sup>2</sup> = 0.412, and p-value <0.001. P-values for individual coefficients were 0.0001, 0.0001, 0.0001, 0.002, and 0.012, respectively. **CONCLUSIONS:** Pre-operation health status/risk assessment can predict future quality of life to an important extent. It is argued that QoL chances should also be considered in addition to survival chances. These results can be useful in sub-group analyses in modeling studies.

**PPN15****MULTIPLE PAIN RELIEF ASSESSMENT IN WOMEN UNDERGOING NATURAL VERSUS EPIDURAL DELIVERY WITH ROPIVACAIN OR BUPIVACAIN**Szende A<sup>1</sup>, Kincses ZS<sup>2</sup>, Zimanyi M<sup>3</sup>, Kadar Z<sup>4</sup>, Zorenyi G<sup>1</sup><sup>1</sup>AstraZeneca, Torokbalint, Hungary; <sup>2</sup>Semmelweis University, Budapest, Hungary; <sup>3</sup>Albert Szentgyorgyi Medical University, Szeged, Hungary; <sup>4</sup>Diosgyor City Hospital, Diosgyor, Hungary

**OBJECTIVES:** To compare level of pain and pain relief by using different outcome measurement techniques in women undergoing natural and epidural delivery. To identify the relationship between categorical self-assessment and continuous VAS measures in painless delivery. **METHODS:** 300 women at 10 centres in Hungary undergoing natural, epidural (ropivacain), or epidural (bupivacain) delivery were involved in this non-randomized, open study. To avoid selection bias, patients were recruited consecutively and natural delivery patients came from centres where epidural delivery was not offered. Pain was measured by 10cm visual analogue scale and by categorical self-assessment questions before pain relief, at 15, 30 minutes, and then hourly afterwards. Patient's preferred choice for possible future delivery was also recorded. ANOVA method was used to test statistical significance. **RESULTS:** Initial average pain level measured by VAS was 6.9 cm. Initial pain level did not differ across groups. Changes in pain between the two epidural groups were not statistically significant. Decrease in VAS scores was 3.3, 5.3, and 5.1 cm at 15, 30, and 60 minutes after drug administration, respectively. Changes assessed by patients as some, good, and excellent pain relief was associated with an average change of 1.80; 3.75; and 5.67 cm in VAS, respectively. Good or excellent pain relief was experienced in 91% of epidural patients. All of the epidural group and 70% of the natural group would choose painless delivery at a possible future occasion. Most reasons related to decreased pain, less tiredness, better compliance with doctors, and more attention to the baby. P values were less than 0.05. **CONCLUSIONS:** Large decrease in pain level can be achieved in epidural groups at small additional costs and this is reflected in patients' preferences. Validation of the VAS method in painless delivery by assessment of importance of change can be highly useful in future VAS studies.

**PPN16****ECONOMIC BURDEN AND LOSS IN QUALITY OF LIFE DUE TO LOW BACK PAIN**Szende A<sup>1</sup>, Lovas K<sup>2</sup>, Szebenyi B<sup>3</sup>, Bálint G<sup>3</sup>, Héjj G<sup>3</sup><sup>1</sup>AstraZeneca, Torokbalint, Hungary; <sup>2</sup>Semmelweis University, Budapest, Hungary; <sup>3</sup>National Institute of Rheumatology and Physiotherapy, Budapest, Hungary

**OBJECTIVES:** Low back pain is a common health problem in the population but its impact on quality of life and societal costs is not well identified yet. The objective of

this study was to measure quality of life and costs related to LBP and to understand the relationship among these measurements. **METHODS:** 87 LBP patients (56 females) of mean age of 55 were recruited within a musculoskeletal study in both primary care and rheumatology outpatient settings in Hungary in 2000. Patients filled in the generic EQ-5D quality of life and the disease specific Oswestry questionnaires and reported health care utilization. Mean quality of life and utilization values were analysed and correlation coefficients between different measurements were reported. **RESULTS:** Average EQ-5Dindex, EQ-5Dvas, and Oswestry score were 0.48; 0.52; 40, respectively. QoL did not differ significantly across sub-diagnoses (i.e. discopathia, lumboschialgia, osteoporosis, spondylitis ankylopoetica, and other) groups of LBP. Average annual number of physiotherapy and spa/pool treatment occasions was 8.9 and 2, respectively. Average number of GP and specialist visits were 7.5 and 4. Patients spent a mean of 2.9 days in hospital and they spent 12.7 days in bed due to LBP. Active workers reported 16.6 days spent on sick leave. Statistically significant correlation was observed between EQ-5Dindex and EQ-5Dvas; EQ-5Dindex and Oswestry; EQ-5Dvas and Oswestry; days in bed and EQ-5Dindex; days in bed and EQ-5Dvas; days in bed and Oswestry. Corresponding correlation coefficients were 0.71; -0.74; -0.67; -0.55; -0.36; 0.4 (p < 0.01). **CONCLUSIONS:** Results showed that LBP leads to substantial loss in quality of life, important direct medical costs, and substantial productivity costs among active patients. Different health status measures correlated strongly to each other but the most important cost driver, i.e. days on sick leave did not show any correlation with these.

**PPN17****ADDRESSING PARADOXES IN ECONOMIC EVALUATIONS (EES). AN EXAMPLE USING MOTOR NEURON DISEASE (MND)**Bose UK<sup>1</sup>, Burrell A<sup>1</sup>, Ward J<sup>2</sup><sup>1</sup>Aventis Pharma, West Malling, UK; <sup>2</sup>Evidence Research Unit, Macclesfield, UK

**BACKGROUND:** MND results in progressive degeneration of the motor neurons, with intellect remaining largely unaffected. Average life expectancy from diagnosis to death is 2–5 years. Riluzole is the only treatment which has been shown to extend life in MND, though its cost-effectiveness has been questioned. In recent years, there has been a large increase in the number of EEs. Many have been criticised due to methodological deficiencies. Using MND as an example, it is clear that EEs can provide either valuable or misleading information in a decision-making context. **METHODS:** Systematic search for, and critical appraisal of, available EEs of riluzole therapy for MND. **RESULTS:** The methodological quality of the six identified studies was variable. The study with the greatest validity concluded that riluzole is a cost-

effective intervention. Flaws in other studies related to the identification and measurement of costs, and to the extrapolation of benefits. Overall there was a range in the estimates of cost-effectiveness. For example, Messori et al (1999) calculated the incremental cost per life year gained to be approximately £41,000, whereas analysis by Tavakoli, et al. (1999) used Markov modeling to incorporate the importance of implications on quality of life in the remaining months. This methodology revealed that the incremental cost per life year gained was £8,587, and therefore identified riluzole as a cost-effective therapy. **CONCLUSION:** Clear presentation and use of perspective and relevant disease end-points are vital in economic evaluation to avoid paradoxes in results of studies assessing similar interventions. For therapies such as riluzole, where length of life and quality of life are key variables, different end-points can provide contradictory results.

**PPN18**

**COST SAVINGS IN MIGRAINE ASSOCIATED WITH LESS CHEST PAIN ON NEW TRIPTAN THERAPY**

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**OBJECTIVES:** To build an economic model estimating the costs of care for chest pain in migraine patients when treated with almotriptan instead of sumatriptan. **METHODS:** We conducted a population-based retrospective cohort study from the MEDSTAT MarketScan database. Patients were continuously enrolled for any two consecutive years between 1996 and 1998 and had a first prescription for oral sumatriptan between July 1, 1996 and June 30, 1998. Exclusion criteria included contraindications or risk factors for coronary artery disease. The baseline and treatment periods were defined as five months before and after the date of the first prescription minus 15 days (since most patients receive samples). Patients with chest pain-related diagnoses and procedures were compared between periods using the McNemar test. The cost of chest pain-related care was used to build a model estimating costs based on rates of chest pain from clinical trials. **RESULTS:** Of 1,759 patients meeting inclusion criteria, 369 were excluded. The final cohort of 1,390 migraine patients showed a statistically significant increase in the number experiencing chest pain after treatment with sumatriptan (compared to the baseline period) from 110 to 158 ( $p = 0.003$ ), a 43.6% increase. Associated costs increased from \$22,713 to \$30,234. The model estimated annual cost savings of \$11,215 per 1,000 patients for migraine treated with almotriptan instead of sumatriptan due to lower rates of chest pain (0.3% vs. 2.2%,  $p = 0.004$ ). **CONCLUSIONS:** Direct medical cost savings are predicted for health plans from migraine patients switched from sumatriptan to almotriptan based on the lower rate of chest pain.

**PPN19**

**COMPARISON OF HUI2 AND HUI3 SCORES FOR PATIENTS WITH ALZHEIMER'S DISEASE**

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**OBJECTIVES:** To examine the difference between the Japanese versions of the Health Utilities Index (HUI) Mark2 and the HUI Mark3 scores of patients with Alzheimer's Disease (AD) in order to undertake the pharmacoeconomic evaluation of AD drugs. **METHODS:** We conducted a cross-sectional study of AD patients at four sites (three in outpatient and one in institutional settings) using the combined HUI2/HUI3 questionnaire. For those who were not able to make self-evaluations, proxy evaluations were made by caregivers in outpatient settings and by the nursing staff in institutional settings. Severity of dementia was measured by Clinical Dementia Rating (CDR). **RESULTS:** With the HUI2, the mean (SD) utility scores of the 63 outpatients with mild AD ( $n = 19$ ), moderate AD ( $n = 29$ ), and severe AD ( $n = 12$ ) were 0.61(0.16), 0.50(0.25), 0.38(0.18), respectively. The corresponding scores with HUI3 were 0.33(0.23), 0.17(0.29), and 0.02(0.25), respectively. For inpatient ( $n = 12$ ), it was 0.37(0.21) for those with severe AD ( $n = 10$ ) with the HUI2, and 0.04 (0.20) with the HUI3. The single scores for each attribute of the HUI2 and 3 tended to decrease as the CDR level became more severe. **CONCLUSIONS:** Compared with the HUI2, the HUI3 yields significantly lower global utility scores for patients with AD. Based on our results, there appears to be a need to further evaluate the validity of the HUI2 and HUI3.

**PPN20**

**ESTIMATED RESOURCE USE AND COST OF MITOXANTRONE VS PLACEBO IN PATIENTS WITH PROGRESSIVE-RELAPSING AND SECONDARY-PROGRESSIVE MULTIPLE SCLEROSIS: RESULTS FROM THE MIMS TRIAL**

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**OBJECTIVE:** To evaluate the pharmacoeconomics of mitoxantrone (m) therapy in patients with progressive-relapsing and secondary-progressive multiple sclerosis (MS). **METHODS:** The MIMS trial showed that m improves several outcomes in patients with progressive-relapsing and secondary-progressive multiple sclerosis (MS). Patients receiving m 12 mg/m<sup>2</sup> every three months had fewer relapses and hospitalizations, less progression of neurologic disability, and improved quality of life and functionality. A pharmacoeconomic analysis was undertaken to compare resource consumption in the m and placebo (p) groups. Major cost drivers were identified as follows: drug therapy, including acquisition, administration, and monitoring (primarily m, IV corticosteroids, and antibiotics); hospitalizations (5 days/occurrence); physician visits (1/relapse); days lost from work (2/docu-

mented relapse, 3 additional for relapse requiring IV corticosteroids, and 7/hospitalization). Standard costs were assigned as follows: m (\$1000/cycle); IV corticosteroids used to treat relapses (\$1250/occurrence); antibiotics used to treat infections (\$300/occurrence); hospitalizations (\$1850/day); physician visits (\$100/occurrence); wages (\$160/day). **RESULTS:** A cost-minimization analysis was done and the cost per patient per year was found to be as follows: m therapy (m = \$4000, p = \$0); IV corticosteroid therapy (m = \$250, p = \$750); antibiotic therapy (m = \$96, p = \$39); hospitalization (m = \$1850, p = \$3145); physician visits (m = \$40, p = \$100); lost wages (m = \$448, p = \$989). The total annual cost per patient was \$6684 in the m group and \$5023 in the p group. The annual cost of m (\$4000) was substantially offset by a reduction in other costs associated with p for a total annual incremental m cost of \$1661. **CONCLUSIONS:** MS is a chronic, debilitating disease associated with considerable costs. Pharmacoeconomic analyses suggest that m compares favorably with other disease-modifying therapies for MS. Additional data will be presented using remaining direct and indirect cost drivers. The results of cost-effectiveness analyses incorporating patient outcome measures will also be presented.

**PPN2 I****MIGRAINE IN FRANCE IN 2000 :  
THERAPEUTICAL DATA**

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**OBJECTIVE:** GRIM 200 is an epidemiology survey on migraine that was performed in France in 2000, ten years after the first one (GRIM). The goal of this study was to estimate the evolution of epidemiological data since ten years, and to assess the impact of triptans on the disease management and social repercussions of migraine. **METHODS:** The survey was carried out by I.S.L, a national institute, on a representative sample of 10,585 subjects in France aged 15 years and older according to the quota method. There were 2 successive home interviews. Persons suffering from headache were selected during the first interview, or screening. They were then contacted for a second interview with a validated questionnaire for diagnosis of migraine. This questionnaire was the same used in 1989 with supplementary questions concerning triptans. **RESULTS:** We found a 8.2% prevalence of certain migraines (1-1 and 1-2 IHS) and a 17.3% prevalence of certain migraines and migraine disorder (1-7 IHS). Only 5.65% of headache sufferers (n = 1486) were

treated by triptans. Of the 5.65% of patients using triptans, we found 4.23% were migraine sufferers, 0.2% had tension-type headache and 1.2% had chronic daily headache. We found that 2.96% of the general population were chronic daily headache patients (n = 152). Of these, 18 patients were triptans abusers (11.8%). **CONCLUSION:** This study confirmed that triptans use by migraine patients is very low in France in general population. Overuse of triptans seems to be low in comparison with other drugs.

**PPN22**


SEE PPN5



## URINARY & KIDNEY DISORDERS

### HEALTH STATUS OF ELDERLY DIALYSIS PATIENTS

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**OBJECTIVES:** The elderly comprise approximately half of new patients undergoing dialysis, an expensive, lifesaving treatment. We report the health status of 3 elderly age groups, including novel information about patients  $\geq 85$  years, hypothesizing that as age increases health status will decrease. **METHODS:** This retrospective analysis reports on 6154 patients treated by one dialysis chain (48.4% male, 61.5% white, 39.1% diabetes as primary diagnosis). Health status is reported by a single administration of the SF-36 between 10/30/90 and 10/30/00. **RESULTS:** Although not statistically significant at  $p < .01$ , with increasing age, there are trends to lower Physical Function and Role Physical scores. The Physical Component Score shows a statistically significant difference between groups 1 and 2. Group 3, the very elderly, are not significantly different from groups 1 or 2. Other scales show no change. **CONCLUSIONS:** As hypothesized, physical health of dialysis patients appears vulnerable to age. However, other domains of health status remain robust. The very elderly receiving dialysis maintain their mental health when compared to patients in the 2 younger age groups. (See table below.)

#### PUR1

study using the General Practice Research Database (GPRD) containing medical records from 550 of 686 general practices in the UK. The baseline period included the year in which a patient's first OAB symptom or diagnosis record occurred and the following year. The follow-up period was six years. A total of 9,706 patients, aged 40 years or older met the criteria. Transition rates from frequency/urgency to incontinence, and from urge incontinence to frequency/urgency were calculated. Logistic regression was used to examine the impact of risk factors on symptom transition, and its effect on a patient's risk of depression and accidental fall. **RESULTS:** Of female patients with OAB, 23.4% had "frequency/urgency" at baseline and developed "incontinence" in the follow-up period—potentially reflecting progression of the condition. Factors associated with progression of OAB included older patients (70 to 90 years), female gender, urgency, accidental falls, multiple sclerosis, and epilepsy. Controlling for these factors, patients with progression showed an increased risk of depression and accidental fall compared to patients who had no change in symptoms (adjusted odds ratios 1.44 and 1.35, respectively;  $p = 0.0001$  for both). **CONCLUSION:** OAB appears to be a progressive disease. A significant proportion of patients progressed from "dry" to "wet" symptoms. This may imply that some patients with OAB, if left untreated, will develop progression of OAB over time. The risks of depression and accidental falls were significantly increased in those patients whose OAB condition worsened. Further research is required to determine whether treatment can prevent, reduce, or delay the progression of OAB syndrome.

### EVIDENCE OF DISEASE PROGRESSION IN ADULT PATIENTS WITH AN OVERACTIVE BLADDER (OAB)

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**OBJECTIVES.** This study examined patterns of transition of bladder symptoms in adult patients with an overactive bladder, identified risk factors for such transitions, and assessed the impact of symptom transition on patient outcomes of depression and accidental falls. **METHODS:** This study was a retrospective, population based cohort

#### PUR2

### PERSISTENCE OF THERAPY WITH DRUGS FOR OVERACTIVE BLADDER

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**OBJECTIVE:** This study evaluates the real world persistence of therapy for overactive bladder (OAB), comparing tolterodine, oxybutynin and flavoxate head-to-head in a large sample extracted from a US drug claim database. Clinical trials have shown tolterodine has equal efficacy to oxybutynin in reduction of OAB symptoms and

#### PUR3

**Table for PUR1** Mean SF-36 SCORE (SD)

1652	Physical Function	Role Physical	Bodily Pain	General Health	Vitality	Social Function	Role Emotional	Mental Health	Physical Component Score*	Mental Component Score
Group 1 65–74	36.9 (27.8) n = 3687	29.3 (37.9) n = 3609	58.5 (29.0) n = 3674	43.2 (20.1) n = 3587	42.7 (22.8) n = 3635	62.8 (28.8) n = 3687	55.7 (43.6) n = 3577	69.2 (20.0) n = 3621	31.8 (10.1) n = 3445	48.3 (11.3) n = 3445
Group 2 75–84	32.4 (26.2) n = 2117	26.8 (36.4) n = 2059	58.1 (28.4) n = 2111	44.2 (20.0) n = 2073	40.8 (22.4) n = 2098	61.3 (30.0) n = 2119	54.2 (43.9) n = 2038	69.5 (20.1) n = 2089	30.9 (9.4) n = 1957	48.4 (11.6) n = 1957
Group 3 $\geq 85$	30.0 (27.1) n = 267	26.8 (37.5) n = 257	58.7 (58.7) n = 266	46.8 (21.1) n = 254	42.1 (23.0) n = 261	63.5 (30.1) n = 267	53.6 (44.5) n = 257	71.5 (19.1) n = 258	30.7 (10.0) n = 244	49.5 (11.0) n = 244

\* =  $p < .01$

a significantly better side-effect profile. **METHOD:** A longitudinal study was conducted using drug claims from PCS Health Systems. The study cohort consists of 4602 “naïve tolterodine users”, 7291 “naïve oxybutynin users” and 2127 “naïve flavoxate users.” Survival analysis was used to estimate the “persistence rate”—defined as the proportion of patients who are still on a drug treatment during or after a defined period of continuous treatment for the drug. A Cox-regression model was used to assess the net effect of using tolterodine or oxybutynin on the persistence of drug therapy controlling for differences in the patients’ demographics, comorbid conditions, and other factors. **RESULTS:** The persistence on tolterodine was 30% higher than that on oxybutynin on continuous treatment periods of 31–60 days, and 90% higher for 301–360 days of therapy. The persistence on tolterodine was 430% higher than that on flavoxate for treatment periods of 30–60 days and 340% higher for 301–360 days of therapy. The average length of continuous treatment for naïve tolterodine users was the longest of the three drugs: 143(3.9) days compared to 91(2.6) days for oxybutynin and 41(4.6) days for flavoxate. The adjusted odds-ratio of terminating drug treatment for tolterodine vs. oxybutynin users was 0.66 ( $p > 0.001$ ). **CONCLUSIONS:** Patients using tolterodine were significantly more likely to continue their treatment than those choosing other OAB drugs. The better persistence for tolterodine users should result in longer symptom relief for patients, particularly for those who are in need of long-term treatment but are distressed by side effects.

**PUR4**

#### **ANALYSIS OF COMORBIDITY IN OVERACTIVE BLADDER AND URINARY INCONTINENCE IN A MANAGED CARE ORGANIZATION**

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**OBJECTIVE:** The primary objectives of this study are to examine the costs of overactive bladder and urinary incontinence (OAB/UI) and evaluate for the presence of depression and falls and fractures as comorbid conditions from a managed care perspective. **METHOD:** Retrospective computerized claims records from a managed care organization were analyzed. Patients were included if they had an ICD-9 code consistent with OAB or UI, were under treatment and were continuously eligible between 1/1/99 and 12/31/99 ( $N = 445$ ). Randomly sampled control patients from the general membership were matched on age and gender with the OAB/UI group at a ratio of 5:1 ( $N = 2,220$ ). Diagnoses of depression and of falls, fractures and contusions were collected and a Charlson comorbidity index was developed for all study patients. Depression-related costs and falls & fracture-related costs included those directly related to treatment. **RESULTS:** Seventeen (0.77%) of the control patients had a diagnosis of depression compared to 2.02% of the OAB/UI patients ( $P < 0.0001$ ). Of the OAB/UI patients, 13.93%

were diagnosed with a fall or fracture compared to 8.11% of the control patients ( $P < 0.0001$ ). The mean Charlson score of the OAB/UI group was 0.51 (SD 1.10) compared to 0.37 (SD 1.00) for the control group ( $P < 0.01$ ). The mean cost of treating depression was \$33 (SD \$605) for the control group and \$42 (SD \$138) for the OAB/UI group ( $P < 0.0001$ ). The average cost of treating falls & fractures was \$154 (SD \$1,922) for the control group and \$434 (SD \$4,946) for the OAB/UI group ( $P < 0.0001$ ). **CONCLUSION:** Compared to the general population, patients with a diagnosis of OAB/UI are significantly more likely to experience a fall or fracture or experience depression. They also tend to have a significantly higher burden of comorbidity. The average cost of fall & fracture treatment and treatment of depression is significantly higher among OAB/UI patients.

**PUR5**

#### **THE IMPACT OF PHARMACOTHERAPY ON OVERACTIVE BLADDER SYMPTOM IMPROVEMENT AND RESOURCE UTILIZATION**

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**OBJECTIVES:** To examine the effects of drug treatment on overactive bladder (OAB) symptom improvement and resource utilization. **METHODS:** We conducted an observational study of 217 OAB patients enrolled by 31 physicians nationwide. One hundred twenty-two patients have been tracked through 3 months to determine symptom improvement, change(s) in treatment, and resource utilization. The impact of medication on OAB symptom improvement was modeled using stepwise logistic regression adjusting for patient age, sex, symptom duration, symptom severity, incontinence, frequency of leakage accidents, and frequency of urinations. **RESULTS:** Participants averaged 60.7 years old (S.D. = 15.7), 85.2% were female, and the mean duration of OAB symptoms was 8.1 years. On average, patients experienced 11.0 urinations per day (S.D. = 4.7) and 2.2 accidents per day (S.D. = 3.4). Treatment with medication increased the odds of symptom improvement by four-fold (odds ratio (O.R.) = 4.3, 95% confidence interval (CI) 1.8–9.9). Patients with incontinence were significantly more likely to report improvement in symptoms compared with patients with urinary frequency alone (O.R. = 3.2, 95%CI 1.2–8.4). Nineteen of 72 (26%) patients not started on medication at baseline began medication within the first 3 months, consuming an average of 1.16 office visits per patient. In contrast, 11 of 50 patients (22%) who were started on medication at baseline discontinued within the first 3 months, consuming an average of 0.64 office visits per patient. Patients staying on medication (39/50, 78%) consumed on average the fewest office visits per patient (0.15), while patients who managed symptoms without medication (53/72, 73%) consumed an average of 0.26 office visits. **CONCLUSIONS:** Pharmacotherapy signifi-

cantly improves OAB symptoms and is associated with less office visit utilization. Thus, initiating patients on medication, rather than trying a step-wise care approach, may be a cost-effective means to manage symptoms of OAB.

**PUR6****THE RELIABILITY AND VALIDITY OF A NEW OAB-SPECIFIC HRQL QUESTIONNAIRE (OAB-Q)**

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**OBJECTIVES:** Most health-related quality-of-life (HRQL) bladder questionnaires address the impact of incontinence; however, OAB includes frequency and urgency symptoms without incontinence. Thus, a questionnaire was developed to assess the impact of OAB on HRQL in patients with and without incontinence. **METHODS:** The 61-item self-administered OAB-q contains a symptom and HRQL scale. Both the OAB-q and the SF-36 were completed by participants recruited from: 1) a community sample who screened positive for OAB in a telephone survey and participated in a clinical validation study (n = 254); 2) a clinical study for those seeking treatment for OAB symptoms (baseline)(n = 736). Item analysis and exploratory factor analysis (EFA) were performed to assess factor structure. Psychometric evaluation was conducted to assess internal reliability and validity. **RESULTS:** Of the 911 participants, the clinical diagnoses were: normal = 130, OAB with incontinence (OAB-I) = 552, OAB without incontinence (OAB-C) = 229. Mean age = 59.5; 74.4% were women. EFA revealed 1 domain for symptom distress and 4 domains for HRQL: coping, concern/emotional, sleep and social interactions. Both OAB-I and OAB-C participants reported significantly greater symptom distress and HRQL impact than normals. Significant differences between OAB-I and OAB-C participants were present in all OAB-q subscales except sleep where both groups were highly affected. Internal consistency reliability of the symptom distress scale was 0.86 and the HRQL subscales ranged from 0.88–0.94. The OAB-q subscales correlated moderately well with the SF-36 subscales (r = 0.17–0.52) providing validity evidence. The OAB-q was reduced to 34 items: 8 symptom distress and 26 HRQL items. **CONCLUSIONS:** The OAB-q is a reliable and valid instrument that can discriminate between clinically-diagnosed normal, OAB-I and OAB-C participants. As the first OAB-specific HRQL questionnaire, the OAB-q demonstrates that OAB with and without incontinence causes significant symptom distress and has a negative impact on HRQL.

**PUR7****CLINICAL CORRELATES WITH HEALTH-RELATED QUALITY OF LIFE SCORES AND SUBSCALES AMONG CONSULTING AND NON-CONSULTING INDIVIDUALS WITH STRESS URINARY INCONTINENCE**

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**OBJECTIVES:** To measure clinical parameters and health-related quality of life using the incontinence quality of life (I-QOL) instrument among consulting and non-consulting stress urinary incontinence (SUI) patients. **METHODS:** The I-QOL is a self-administered instrument that contains 22 items yielding a total score as well as three subscale scores (avoidance and limiting behaviors, psychosocial and social embarrassment). Physicians and consulting patients were identified in the UK, Germany, France, Italy, Netherlands and the US. Study participants completed questionnaires to obtain diagnostic and treatment information for patients and to also gather details on demographics, symptoms and quality of life. The non-consulting patients (those who did not consult a doctor) were also asked to complete questionnaires regarding their symptoms and quality of life. Statistical analysis included t-tests and multiple regressions, adjusting for multiple comparisons using Hochberg's method. The analysis consisted of associations between I-QOL measures and treatment variables, diagnostic tests and severity of symptoms among consulting and non-consulting SUI patients. **RESULTS:** A sample of 2174 SUI consulting patients and 809 SUI non-consulting patients participated. Multivariate analysis showed that pad use among consulting patients was a predictor of the psychosocial subscale score (t = -3.52, p < 0.01) whereas leakage during exercise predicted the avoidance and limiting behaviors subscale scores among non-consulting SUI patients (t = -4.47, p < 0.05). The non-consulting SUI patients were younger than the consulting SUI patients (t = -8.99, p < 0.0001). There were no statistically significant differences in employment and marital status between the two groups. **CONCLUSIONS:** There were differences in association between the I-QOL subscores and symptom severity among consulting and non-consulting SUI patients. There was a significant age difference between the non-consulting and consulting SUI patients. Evaluation of I-QOL differences between consulting and non-consulting patients will require additional study.

**PUR8****THE INFLUENCE OF RACE ON SF-36 SCORES OF DIALYSIS PATIENTS**

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**OBJECTIVES:** African-Americans represent one-third of dialysis patients and are known to live longer than Cau-

casian dialysis patients. Previous reports suggest they also have better health status. The health status of African-Americans and Caucasians has not been compared using the SF-36. We hypothesize that SF-36 scores for African-Americans will be better than for Caucasians. **METHODS:** This retrospective analysis compares 6509 African-Americans (mean age 55 years, 48% male, 34% diabetes as primary diagnosis) to 7715 white patients (mean age 60 years, 56% male, 37% diabetes as primary diagnosis) from one dialysis chain. Health status is measured by a single administration of the SF-36 between 10/30/90 and 10/30/00. Clinical variables are assessed. **RESULTS:** For all domains except Role Emotional, African-Americans report better health status, despite univariate analysis showing significantly worse hematocrit, dialysis adequacy (Kt/V), creatinine, hypertension, and socioeconomic status (all:  $p < .01$ ). **CONCLUSIONS:** Despite worse results on clinical parameters and lower socioeconomic status, African-American dialysis patients report better SF-36 scores than Caucasians. Health status has been shown to be an independent predictor of dialysis patient survival. Our results may partially explain the increase in survival observed for African-American dialysis patients. Further investigation is necessary to determine if these differences remain after case-mix adjustment. (See table below.)

were identified. Eligible infants were required to be continuously enrolled in the plan during the birth hospitalization, have complete claims histories, and have prescription drug benefits. A secondary analysis of resource utilization during the first 30 days post-initial hospital discharge was conducted among surviving infants who were continuously enrolled during that 30 day period. Costs reflect payments by the plan, patient deductibles, and co-payments for all covered medical services. **RESULTS:** In 1998, 1,208 births to enrollees were premature and eligible for study; 28% were multiple births. Twenty-one infants (1.7%) died during the birth hospitalization. The total direct medical cost of the birth hospitalization was \$35.5 million. During the first 30 days post discharge, 133 (12.4%) of the remaining eligible infants ( $n = 1,076$ ) had claims for inpatient services. Total direct cost of all covered medical services during this period was an additional \$1.2 million. **CONCLUSION:** Even in a relatively low risk population, the direct medical costs associated with premature birth were very high (nearly \$37 million for about 1,000 infants) and need for acute medical care continued in the first month post-discharge. Appropriate medical management of this high risk population may be cost-effective.

**WOMEN'S & MEN'S HEALTH**

**PWM1**

**PREMATURE BIRTH AND RESOURCE UTILIZATION IN A LARGE EMPLOYMENT BASED INDEPENDENT PRACTICE ASSOCIATION (IPA)**

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**OBJECTIVES:** While premature birth is one of the costliest hospital events, the total direct medical cost of care associated with the birth of a premature infant has not been documented from a societal perspective. **METHODS:** Retrospective analysis of administrative claims data from a large, employment based IPA covering a total of 3 million members in 1998 was conducted. All infants born in calendar year 1998 with a birth diagnosis of prematurity (<38 weeks gestation) and low birth weight (<2500 grams) [ICD 9-CM codes 765.0x and 765.1x]

**PWM2**

**A COST-MINIMIZATION ANALYSIS COMPARING MIRENA® WITH ORAL CONTRACEPTIVES**

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**OBJECTIVES:** To validate the economic advantages of Mirena, a new hormone releasing contraceptive system that can be inserted in the uterus for 5 years, compared to oral contraceptives (OC) in Canada. Mirena and OC offer equivalent contraceptive efficacy with a similar safety profile. **METHODS:** A cost-minimization analysis with a third-party payer perspective and a 5-year horizon. Three major scenarios were analysed. In the first scenario, only the drug acquisition cost of both treatments was used. Mean cost of OC was calculated based on the amount reimbursed in the April 2000 list of the Régie de l'assurance-maladie du Québec (RAMQ). In the second scenario, the pharmacy's dispensing fee (Quebec RAMQ fee) was added. In the third scenario, real-life conditions of use of Mirena were applied, i.e. an expulsion rate of

**Table for PUR8**

	Physical Function*	Role Physical*	Bodily Pain*	General Health*	Vitality*	Social Function*	Role Emotional	Mental Health*	Physical Component Score*	Mental Component Score*
African-American	46.9 (28.8) n = 6427	37.3 (40.4) n = 6283	60.3 (28.5) n = 6401	45.3 (20.6) n = 6235	49.5 (22.1) n = 6332	66.1 (27.9) n = 6416	58.7 (43.1) n = 6216	69.8 (20.1) n = 6302	34.9 (10.3) n = 5981	48.6 (11.3) n = 5981
Caucasian	41.6 (29.5) n = 7655	29.1 (37.7) n = 7512	57.0 (28.2) n = 7614	41.3 (21.0) n = 7536	40.3 (22.8) n = 7590	61.1 (29.1) n = 7660	57.6 (43.4) n = 7458	67.7 (21.0) n = 7569	32.4 (10.5) n = 7264	47.2 (11.7) n = 7264

\* $p < .01$

6% and estimated continuation rate of 56% and 65% after 5 years. Sensitivity analysis was performed on OC cost using the lowest and highest costs from the RAMQ list. Discounting was performed at 0%, 3% and 5% over 65 time-periods (13 cycles  $\times$  5 years) for OC. No discount rate was applied to Mirena since acquisition cost is paid once at treatment start. **RESULTS:** The mean cost of an OC is determined to be \$11 per cycle, while drug acquisition cost of Mirena is \$290. All scenarios favour Mirena. With a 5% discount rate, Mirena offered a mean saving of \$346 over 5 years. When the pharmacist's dispensing fee was included Mirena offered a mean saving of \$750. In real life conditions, with a 5% discount rate, the use of Mirena resulted in a mean saving of at least 30% (i.e., between \$194 and \$221). **CONCLUSION:** Mirena represents a less expensive alternative to long-term contraception when compared to OC and this, in all proposed scenarios.

**PWM3****ERECTILE DYSFUNCTION: A PROSPECTIVE STUDY OF PATIENTS SEEKING THERAPY**

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**OBJECTIVES:** To describe erectile dysfunction (ED) patient demographics, comorbidities, treatment seeking behavior, and patient-reported use and outcomes of therapy. **METHODS:** A self-administered questionnaire was developed and pilot tested. The final survey instrument included selected demographics, questions regarding when patients first experienced ED symptoms, when patients first sought treatment for ED, patients' experience with ED treatments, patients' rating of how well a particular ED therapy worked, and comorbid conditions. Patients evaluated their experience with ED therapies on a Likert-type scale. **RESULTS:** During May and June of 1997, 285 questionnaires were given to patients while they waited to see their urologist for ED treatment. A total of 59.4 percent (n = 168) of respondents (n = 283) listed "Caucasian, White" as their race. Age of the survey respondents ranged from 31 to 82 years with a mean age of 59.5 years (sd = 11.2). A total of 27.1 percent of survey respondents completed 4 years or more of college. A total of 31.4 percent of respondents reported 1996 household income of \$30,001–\$50,000. A total of 58.1 percent (n = 165) of the respondents listed "Married/long-term partner" as their marital status. A total of 76.5 percent (n = 218) of respondents reported currently being treated by a physician for health problems in addition to ED. Respondents reported a mean of 2.9 years (sd = 5.1 years, range = < 1 year to 34 years) between first noticing the symptoms of ED and seeking professional medical treatment for those symptoms. A total of 239

(83.9%) respondents reported having tried at least one therapy option to treat their ED. The ED therapy mentioned most often was "an injectable drug" with a mean rating of 3.8 (sd = 1.2). **CONCLUSION:** This multi-site, prospective study gives insight into patient demographics, comorbidities, experience with ED and its treatment and allows a better understanding of therapy health outcomes for this important medical condition.

**PWM4****PHARMACIST-INITIATED EMERGENCY CONTRACEPTION IN BRITISH COLUMBIA**

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**BACKGROUND:** As of December 1 2000, the Province of British Columbia launched a program of expanded access to emergency contraceptive pills (ECPs) authorizing pharmacists with special training to provide ECPs to women without a prescription from their physicians. **OBJECTIVES:** To determine whether the expanded access program (EAP) will increase the utilization of ECPs and reduce pregnancy and abortion rates among women in B.C. **METHODS:** This research utilizes a province-wide prescription database (PharmaNet) that documents prescription transactions for all residents. PharmaNet data will be linked, in a manner insuring researchers are blinded to patient identity, to information in other provincial health-care databases including physician visits, hospitalizations, and birth and abortion records. Data for all women with an index prescription for an ECP from a pharmacist or a physician for the 2-year period prior to and for the 2-year period after initiation of the EAP will be included in the analyses. **RESULTS:** Four weeks after the program launch, 50% of the province's 2400 pharmacists have been certified and half of those are registered providers. Currently, 340 of the province's 760 community pharmacies have one or more pharmacists certified and registered to prescribe ECPs. To date, 316 patients (mean age 26 years; range, 15 to 48) have received pharmacist-initiated ECPs in 19 of the province's 20 health regions; 58% of the pharmacist-initiated ECP prescriptions occurred on weeknights or weekends; the average interval between unprotected intercourse and arrival in the pharmacy has been 24 hours; and 53% of the women stated that the reason for need was due to birth control failure. At time of presentation, these data will be updated for the first five months of this study. **CONCLUSIONS:** Despite limited publicity to date, participation by pharmacists and access by women have been notable during the first four weeks of the program.

**PWM5****HEALTH CARE USE ATTRIBUTABLE TO PROSTATE NON-SELECTIVE ALPHA-1 ANTAGONIST INITIATION FOR BENIGN PROSTATIC HYPERPLASIA (BPH)**Chrischilles EA<sup>1</sup>, Rubenstein LM<sup>1</sup>, Gilden D<sup>2</sup>, Shah H<sup>3</sup><sup>1</sup>University of Iowa, Iowa City, IA, USA; <sup>2</sup>Jen Associates, Inc, Cambridge, MA, USA; <sup>3</sup>Boehringer Ingelheim Pharmaceuticals, Inc, Ridgefield, CT, USA

**OBJECTIVE:** The prescription of prostate non-selective alpha-1 antagonists (terazosin, doxazosin, prazosin) may require extra health care visits for dose titration and for monitoring treatment safety and effectiveness. From a retrospective cohort study using pension related fee-for-service supplementary Medigap health claims data, we estimated the impact of alpha-1 antagonist initiation on health care use and costs for men with BPH. **METHODS:** Claims data from a two year period included medical and prescription drug information for 53,824 men with BPH. We compared men who initiated alpha-1 antagonists with a random sample of nonusers. Inpatient and outpatient costs were calculated as the sum of the Medicare paid amount, the Medigap co-pay amount, and the Medigap deductible amount. Comparisons used generalized estimating equation (GEE) or Poisson regression methods to estimate the change from four months pre- to four months post-initiation and an imputed date for non-users. This period coincided with the recommended time for treatment titration and a period of increased hypotensive event risk in this population. **RESULTS:** Adjusting for baseline health care use, age, and co-morbidity, alpha-1 antagonist initiators had a mean of 4.2 more physician visits post-initiation than men who did not initiate among those who did not use other antihypertensives and 5.8 more visits among men who did use antihypertensives ( $p < 0.05$ ). The corresponding adjusted difference in cost of physician visits was \$176 per man for those who did not use other antihypertensives and \$267 for those who did use other antihypertensives ( $p < 0.05$ ). Initiation was also significantly associated with an increase of 0.15 hospital stays per 1,000 person-days among non-users of other antihypertensives and an increase of 0.24 hospital stays per 1,000 person-days among users of other antihypertensives. **CONCLUSION:** The increased number of physician visits, hospital stays, and physician visit costs post-initiation should be considered in cost-effectiveness analyses of BPH treatments.

**PWM6****COST-EFFECTIVENESS OF INTRAVAGINAL PROSTAGLANDIN E2 GEL AND INTRAVAGINAL MISOPROSTOL FOR PREINDUCTION CERVICAL RIPENING**

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**OBJECTIVES:** To compare the cost-effectiveness of intravaginal prostaglandin E2 gel and intravaginal miso-

prostol tablets for preinduction cervical ripening. **METHODS:** This study was a modeled cost-effectiveness analysis from the hospital perspective. A decision analysis was used to estimate costs and percentage of women achieving vaginal delivery with either intravaginal prostaglandin E2 or intravaginal misoprostol. Costs were assessed in 1999 dollars and obtained from Brigham and Women's Hospital in Boston, Massachusetts. Probabilities and percentage of patients achieving vaginal delivery within 24 hours were obtained by meta-analysis of published trials. Health resources used for the rate of delivery after each dose of the study agents were obtained through an expert physician panel. **RESULTS:** The primary outcome measures were direct medical costs, in 1999 dollars, and effect was measured as percentage of patients achieving successful cervical ripening, leading to labor induction and vaginal delivery before use of an alternative method. The meta-analysis included a total of 9 trials incorporating 1,056 patients. Direct medical costs for prostaglandin E2 was \$1,852.14 and \$1,941.51 for misoprostol. Eighty-five percent of patients receiving misoprostol and 71% of patients receiving prostaglandin E2 achieved vaginal delivery before the use of an alternative method. **CONCLUSION:** Though misoprostol is less expensive per dose compared to prostaglandin E2, the overall treatment costs are higher when encompassing costs associated with adverse effects. Therefore, an incremental cost analysis demonstrates that if the hospital is willing to pay \$638 more per patient, there will be a 1% greater chance of achieving vaginal delivery.

**PWM7****THE EFFECT AND ECONOMIC IMPACT OF STANDARDIZED ORDERS ON THE PREVENTION AND TREATMENT OF PONV IN HOSPITALIZED GYNECOLOGICAL SURGERY PATIENTS**

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**OBJECTIVES:** The risk of post-operative nausea and vomiting (PONV) following gynecological surgery remains high despite effective prophylactic medications. Thus, the objectives of this study were to determine if standardized orders for the prophylaxis and treatment of PONV in gynecological surgery patients: 1) reduce PONV occurrence; 2) reduce total costs; and 3) influence the choice of medications used for PONV prophylaxis and treatment. **METHODS:** A retrospective design was employed in which a random sample of 200 patients was selected from each of the two 6 month phases before (pre) and after (post) the implementation of standardized orders for PONV prophylaxis and treatment. The primary outcome was the occurrence of any PONV episode. Logistic regression was used to adjust for potential confounding factors. **RESULTS:** Characteristics were similar except for surgical and anesthesia length between phases. The proportion of patients receiving PONV prophylaxis increased from 31% (pre) to 47% (post,  $p = 0.002$ ).

There was a reduction in the risk of a PONV event in the post phase (OR = 0.67, 95% CI 0.67 to 0.97,  $p = 0.04$ ). The risk of PONV was significantly reduced with the administration of prophylactic medications (OR = 0.46, 95% CI 0.46 to 0.67). There was a reduction in the mean number of PONV episodes in the post phase (1.81 events) versus the pre phase (1.47 events,  $p = 0.02$ ). A reduction in mean PONV management costs was observed in the post phase (\$8.31, SD 8.50) as compared to the pre-phase (\$10.23, SD 8.25,  $p = 0.02$ ). For mean prophylactic costs, these were significantly higher in the post-implementation phase when compared to the pre-implementation phase (\$1.64, SD 3.36 vs. \$0.91, SD 2.43,  $p = 0.013$ ). Univariate sensitivity analyses revealed that the economic results were sensitive to several parameters. **CONCLUSION:** The implementation of pre-printed order forms for PONV prophylaxis and treatment appears to be an effective and economically attractive strategy.

**PWM8****QUALITY OF LIFE IN POST-MENOPAUSAL WOMEN IN FIVE EUROPEAN COUNTRIES**

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**OBJECTIVES:** Whilst differences between Caucasian, African and Asian menopausal women have been well documented, the aim of this study is to explore the relationship between menopause, HRT use and aspects of quality of life (QoL) across five European countries. **METHODS:** A large-scale observational study of women's health in France, Germany, Italy, Poland, UK was conducted with 7806 women, aged 45–65, and consulting gynecologists or primary care physicians ( $n = 530$ ). QoL was assessed with the Women's Health Questionnaire (vasomotor, depressed mood and sexual behavior scales). **RESULTS:** Mean age (range 52.5 to 54.7) and time since menopause were similar across all countries. Findings suggested differential use of HRT across Europe (current or lapsed): high in Germany (68%), low in France (50%) and Italy (49%) (chi-square = 139,  $P < 0.001$ ). We compared aspects of QoL between users and non-users (stratified by time since menopause). Within 5 years of menopause HRT users experienced: significantly fewer vasomotor symptoms than non-HRT users across all countries ( $z = -15.9$ ,  $p < 0.001$ ); significantly less depression ( $z = -10.5$ ,  $P < 0.001$ ) across all countries except the UK, and significantly better sexual functioning in Italy and Germany ( $z = -7.6$ ,  $p < 0.001$ ). For women experiencing menopause over 5 years ago, HRT users had better scores in sexual ( $z = -12.2$ ,  $P < 0.001$ ) and mood ( $z = -3.0$ ,  $P \leq 0.002$ ) domains than non-users in all countries, but no differences were observed for vasomotor symptoms. **CONCLUSIONS:** Within 5 years of menopause, HRT improves those aspects of menopausal symptoms which are most important to women at that

time in their lives (vasomotor symptoms, mood) irrespective of country. After 5 years, across countries, the impact of vasomotor symptoms on women naturally decreases and thus HRT users no longer experience a benefit over non-users. However, the benefits of HRT on sexual functioning and mood continue. These findings suggest that pooling European WHQ data may be appropriate.

**NO SPECIFIC OR MULTIPLE DISEASES-HEALTH POLICY****PHP1****THE ECONOMICS OF PARALLEL TRADE IN PHARMACEUTICALS: EXPERIENCES FROM SWEDEN**

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**OBJECTIVES:** To analyse the impact of parallel trade of pharmaceuticals on welfare and innovation in the long run and to estimate the impact of costs for pharmaceuticals in some therapeutic areas in the short run. **METHODS:** Identify arguments for and against parallel trade by use of literature review and by interviewing agents involved in parallel trade of pharmaceuticals. Official data of prices and sales of pharmaceuticals are used to estimate the impact of parallel trade on the drug bill. **RESULTS:** In Europe the principle of free trade and the harmonization of registration requirements for pharmaceuticals tend to force price convergence across markets, i.e. a uniform 'Euro price'. Parallel trade have reduced annual costs for pharmaceuticals for treating ulcer related diseases by about 19 percent and for the treatment of inhaled steroids of about 8 percent in Sweden. These cost savings are compared with the excess costs for the distribution and storage of parallel-imported products. Comparison shows net cost savings for the ulcer related diseases and inhaled steroids in the short run. **CONCLUSIONS:** There is a conflict between the principle of free trade and the principle of intellectual property rights (e.g., patent, brand-names, etc.). The purpose of intellectual property rights is to provide economic incentives for the innovative industry to develop new medicines. New medicines are products with relatively high R&D costs, difficult to finance without patent protection and price discrimination.

**PHP2****ATTITUDE OF PHYSICIANS TOWARD FORMULARIES AND SERVICES PROVIDED BY PHARMACIST**

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**OBJECTIVE:** This study evaluated attitude of physicians toward formularies as well as services provided by the pharmacy department in a large independent practice association (IPA). **METHODS:** Surveys ( $n = 280$ ) were sent to all practitioners in the IPA. The survey requested information on physician use of and satisfaction with the existing printed formulary quick list, their satisfaction with the pharmacy services, and their attitude towards formularies in general using a five-point strongly agree-strongly disagree scale. We received 90 completed surveys with a response rate of 32%. **RESULTS:** Majority of respondents were staff physicians (87%). Around 31% indicated pediatrics as their specialization followed by family medicine (17%) and internal medicine (17%). Practitioners who indicated that they had received the formulary quick list (37%) were highly satisfied ( $3.44 \pm 0.84$ ) with it. Practitioners were very satisfied with the performance ( $4.27 \pm 0.79$ ), interaction ( $4.35 \pm 0.81$ ), and services offered ( $4.21 \pm 0.79$ ) by the pharmacies. Their attitude towards pharmacist playing a more active role in patient care was positive ( $3.54 \pm 0.98$ ). However, their attitude towards formularies in general was negative. They agreed that formularies increased the amount of time spent making drug choices ( $4.01 \pm 1.1$ ), limited access to the best medicines for patients ( $3.63 \pm 0.88$ ), resulted in less-effective medicines ( $3.01 \pm 0.99$ ), compromised the quality of drugs prescribed ( $3.36 \pm 0.92$ ), and reduced the opportunities to offer the best medication for patients ( $3.43 \pm 0.82$ ). **CONCLUSION:** Physicians had negative attitude towards formularies in general. However, they were satisfied with the services offered by pharmacists, and they were positive towards more patient care involvement by the pharmacists. Physicians were also satisfied with the formulary quick list offered by the pharmacy department. A plan was developed to provide practitioners with an interactive, intranet-based reference of medications that would assist in prescribing decisions.

**PHP3****PHARMACOECONOMIC FELLOWSHIPS: STRUCTURE, PROCESS, AND OUTCOMES**

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The escalating demand for pharmacoeconomic research has exceeded the supply of available researchers. Post-graduate pharmacoeconomic fellowships emerged to train and produce quality independent researchers to meet these growing educational needs. However, even after more than ten years in existence, the effectiveness of these programs has not been formally evaluated. In order to determine their effectiveness, first, a set of measures for pharmacoeconomic fellowship programs needs to be developed. **OBJECTIVE:** To construct a framework to examine the potential structure, process, and outcome measures for pharmacoeconomic fellowship programs. **METHODS:** Using the Donabedian model, we discuss

the structures, processes, and outcomes of pharmacoeconomic fellowship programs. **RESULTS:** We begin by focusing on the structure of these programs, including facilities, qualification of the teaching staff, and operations of the institution. The types of settings involved in pharmacoeconomic fellowships are illustrated, and the experience and skills of preceptors and fellowship applicants are defined. The processes of pharmacoeconomic fellowships are reviewed, and the different characteristics of these programs such as the research and the educational components are discussed. Potential outcome measures of pharmacoeconomic fellowship programs are discussed. **CONCLUSION:** A framework for examining the structure, process, and outcome measures for pharmacoeconomic fellowship programs is given. Measures evaluating the outcomes of fellowship programs need to be developed. Further research is needed to determine the effectiveness of pharmacoeconomic fellowship programs.

**PHP4****DEVELOPING A COMPREHENSIVE PERFORMANCE MEASUREMENT DATA SET FOR PHARMACEUTICAL BENEFIT MANAGEMENT PROGRAMS**

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Pharmaceutical benefit management (PBM) programs are key to the provision of prescription drugs among those enrolled in health plans. A recent survey of HMOs revealed 600 of 604 HMOs had a drug benefit; and only 57 HMOs of the 600 with a drug benefit did not provide prescription drug coverage through a PBM (PBMI, 2000). Several proposals have advocated use of PBMs to administer outpatient prescription drug benefits for Medicare enrollees. Thus, the demand for accountability and a means to evaluate performance of PBM programs is growing; yet a set of standardized indicators for evaluating PBM performance does not yet exist. **OBJECTIVE:** Explore the array of functions performed by PBMs and measures used to evaluate PBM performance. Recommend additional measures that should be considered toward development of a comprehensive measurement set for evaluating PBM activities. **METHODS:** MEDLINE and web searches were conducted to develop a summary of PBM functions and existing PBM-related indicators. Measures used in other performance measurement activities that could be modified to assess PBM performance also were identified. **RESULTS:** PBM activities fall into four major categories: (1) administrative and management, (2) drug use control, (3) cost containment, and (4) disease management. Monitoring costs and savings of using drug management programs is the main focus of PBM performance measurement to date. Several entities have participated in efforts to develop measures for evaluating pharmaceutical care, but none has defined a comprehensive set of performance measures. Additional measures



that could be included in a comprehensive measurement set, falling into the four major categories of PBM activities, are suggested. **CONCLUSIONS:** A standardized, comprehensive set of performance indicators should be developed to enable public and private sector purchasing organizations to evaluate PBM services and the impact of these activities on quality of care and consumer satisfaction.

**PHP5**

**POLISH GUIDELINES FOR CONDUCTING PHARMACOECONOMIC EVALUATIONS IN COMPARISON TO INTERNATIONAL HEALTH ECONOMIC GUIDELINES**

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**OBJECTIVES:** Poland is the next European country, which is in the process of drafting country-specific guidelines for economic evaluation of pharmaceuticals. The aim of the study was to compare Polish pharmacoeconomic guidelines with international health economic guidelines, highlighting areas of agreement and dissent. **METHODS:** Existing documents from 18 countries were reviewed, analyzed and a comparison was undertaken. The following topics were considered: objective, use of pharmacoeconomic analyses, responsibility in their conduct and target audience, methodology and ethical code of practice while conducting and publishing results of pharmacoeconomic analysis. The explanation of differences was taken. **RESULTS:** For a number of issues recommendations are consistent between Poland and other countries. For the purpose of the Polish pharmacoeconomic research guidelines, the Canadian, Australian, Dutch and Belgian guidelines have, in some parts, been specially adopted to the Polish situation. In some parts it was possible to combine certain aspects; in the other, due to the unique local circumstances, there was a need to develop the methodological guidelines on a pure national level. For example there is a lack of consensus concerning costing and utility measurement. **CONCLUSIONS:** The guidelines for conducting pharmacoeconomic evaluations are linked to existing health care system and approaches to the pricing and reimbursement of pharmaceuticals. This is the purpose of differences between international health economic guidelines. To reach an optimal degree of the use of pharmacoeconomic studies in decision-making process it is essential to take into account local situation and create country-specific guidelines.

**PHP6**

**ACTIVITIES, FUNCTIONS AND STRUCTURE OF PHARMACY AND THERAPEUTICS COMMITTEES IN ISRAELI HOSPITALS**

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**OBJECTIVES:** The pharmacoeconomic literature shows that one of the means available to HMOs for wisely using the medical budget is the Pharmacy and Therapeutics Committee (PTC). The present procedure for the hospital PTCs was written by the Ministry of Health in 1978. The aim of the study was to investigate the Israeli hospitals PTCs work. **METHODS:** This study was based upon a questionnaire which included subjects from the PTCs procedure and also subjects that the PTC dealt with in the late nineties. The questionnaire was sent in October 1999 to 51 hospitals. The information was processed on Excel software. **RESULTS:** Hospital responses were 41/51 (80.4%). Thirty one hospitals reported having PTC and answered the questionnaire, ten hospitals reported not-having PTC at all. The PTCs chairperson appointed is a department director as demanded by the Ministry Procedure by 12 (41%) of the hospitals, the deputy chairperson nomination matched by 2 (7%) hospitals, organizer of the PTC nomination matched by 20 (69%) of the hospitals. The attending doctors specialities are: intern, pediatrics, surgery, gynecology, infection diseases, anesthesiology and mental health. Nine (31%) hospitals reported having a PTC procedure, 28 (97%) hospitals are checking requests for enlarging the local formulary and just 25 (86%) recommend of formulary reduction; 20 (69%) hospital PTCs recommended 50 guidelines to the local management and 28 of them were adopted. **CONCLUSION:** From the returned questionnaires it seems that no PTC keeps the entire procedure. In 1999, the local PTCs reported adding 494 medicines and decreasing 48, which means a total of 446 medicines added. One hundred seventy nine members of PTCs formed 50 guidelines; 28 of them were accepted by the local management. There is no control of the Ministry of Health on the PTCs procedures implementation; the procedure has not been upgraded since 1978 and it is not familiar to most of the hospitals.

**PHP7**

**APPLICATION OF HEALTH ECONOMICS IN THE CANADIAN PHARMACEUTICAL INDUSTRY**

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**OBJECTIVES:** The field of health economics (HE) has undergone vast growth over the last decade. One continually evolving main factor is the motivation for performing HE studies, in particular in Canada because of changing requirements for provincial formulary submissions. The objective of this study was to determine how HE data is being applied by the Canadian pharmaceutical industry to date. **METHODS:** A survey was sent to key personnel working in HE in the Canadian pharmaceutical industry and followed-up. Data from returned surveys were compiled in a database, tabulated, and evaluated. **RESULTS:** Twenty-one (84%) of 25 surveys sent to companies reporting previous experience with HE were re-

turned; 90% of these companies were firms with more than 100 full-time employees. Of the respondents, 67% currently have a department or unit whose sole responsibility is HE, up from 12% reported in a previous study for 1995. The application of HE information by Canadian pharmaceutical companies is most often for provincial formulary submissions (100%), marketing (86%) and pricing (81%). It is also used by 62% of respondents for internal training and medical education programs. Relatively few Canadian companies apply HE information to managed care decision-making (38%) and patient education (24%). Health economic research data was published by 3/4 of the respondents in the form of scientific posters or conference presentations and by 2/3 in the biomedical, peer-reviewed literature. Ninety percent of respondents cited plans for new HE studies in Canada within the next year. **CONCLUSION:** Canadian companies have expanded their use of HE data in recent years. The focus has shifted from preferential internal use (pricing and marketing) to more external purposes such as provincial and hospital formulary submissions. Health economic research data also find a place in training within pharmaceutical companies and in medical education.

**PHP8****PRACTICE USE OF PHARMACOECONOMICS DATA IN HOSPITAL FORMULARY DECISIONS**

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**OBJECTIVES:** The use of formulary system can ensure high quality and control cost if the formulary decision is based on appropriate clinical and economic considerations. We explored use of pharmacoeconomic data in hospitals for formulary decisions. **METHODS:** Study design was cross-sectional telephone survey using a structured survey instrument. Participants were pharmacists who are P&T committee members of Florida hospitals. **RESULTS:** Data were collected from 73 hospitals. Most hospitals make formulary decisions at the local level (82%). Thirty-three percent indicate that pharmacoeconomic data is used "all the time" when formulary decisions are made with only six percent stating that it is rarely or never used. Pharmacoeconomic data is rated by 62% of participants to be "very important" in formulary decisions. The usual sources of pharmacoeconomic data listed by participants are in-house data (73%), published literature (55%), and pharmaceutical industry studies (15%). When asked to rank order 10 criteria in making formulary decisions, the mean ratings of participants suggested the following order of importance: Efficacy, Toxicity, Side Effects, Acquisition Cost, Costs weighed by Benefits, Extent of Drug Monitoring, Availability of Oral Therapy, In-house data, Average Hospital LOS, Avoiding use of Home Infusion. Most participants reported that someone with pharmacoeconomic skills is employed by

the hospital (one has a Masters degree, one has residency training, 31 with practical experience and 15 have informal training). Based on a pharmacoeconomic case study comparing a new drug B to a current drug A, most of the participants would add drug B to the formulary if it is a new class of drug with no pre-existing resistance, has the advantage of reduced IV use, or has a consistent reduction in hospital LOS. **CONCLUSIONS:** Results of this study confirms that most hospitals consider pharmacoeconomic data invaluable in formulary decisions.

**PHP9****COMPARISON OF TECHNOLOGY ASSESSMENT IN LARGE MEDICAL GROUPS AND HEALTH MAINTENANCE ORGANIZATIONS (HMOs)**

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**OBJECTIVES:** This analysis compares the characteristics and processes of technology assessment (TA) in large medical groups and HMOs. **METHODS:** The survey populations were large medical groups and large HMOs (at financial risk for lives >100,000). Mail and telephone questionnaires were implemented. **RESULTS:** Survey response rate among medical groups was 54% (39/73). Response rate among HMOs was 43% (41/96). In responding medical groups, TA involves physicians (100%), finance staff (85%), and quality improvement staff (77%). In responding HMOs, medical functions (91%) and pharmacy functions (83%) participate in TA. Medical groups most frequently conduct TA when technology is adopted into clinical practice (88% of respondents) and use TA to help develop guidelines (84%). HMOs conduct TA throughout the product lifecycle and use TA for coverage determinations. Medical groups and HMOs conduct TA on injectable biotechnology products more than any other type of drug. 44% of medical group respondents and 90% of HMO respondents seek outside assistance for TA, with the Agency for Health care Research and Quality (AHRQ) as a leading source for medical groups and private TA vendors as leading sources for HMOs. Both medical groups and HMOs consider expert opinion and peer-reviewed journals as the most valuable information sources. **CONCLUSIONS:** The need to manage legal and financial risk while focusing on clinical practice and patient care drives TA in medical groups. A need to define legally defensible benefits drives TA in HMOs.

**PHP10****THE POTENTIAL BENEFITS AND DRAWBACKS OF ALLOWING DIRECT-TO-CONSUMER ADVERTISING OF PHARMACEUTICALS IN EUROPE**

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Whether to legalise direct-to-consumer advertising (DTCA), the authorised advertising of prescription drugs direct to the consumer, within the European Union (EU) is often discussed. But how would allowing DTCA help EU governments looking for solutions to rising costs, rising patient expectations, loss of public confidence and ageing populations? This poster summarises the main arguments for and against the EU legalising DTCA. **OBJECTIVES:** To explore the arguments for and against allowing the use of DTCA in EU states; to determine the validity of the propounded arguments, by evaluating actual data which highlights the effects of introducing DTCA in the US and New Zealand. **METHODS:** Using PubMed and a within-literature search, a literature review of published information on the arguments for and against DTCA, and DTCA's associated costs was undertaken. **RESULTS:** Advocates believe DTCA will enable the pharmaceutical industry to significantly improve the effectiveness of its marketing campaigns. DTCA's opponents argue that health care providers' ability to ration health care based on clinical need will be destroyed. US data indicates that DTCA rose 38.5% in 1999 to \$US1.8bn, whilst in New Zealand expenditure rose 47.1% in 2000 to \$US21.5m. DTCA has caused US retail spending on prescriptions to soar. Yet in New Zealand DTCA is credited with improving awareness, choice and treatment of previously neglected conditions. **CONCLUSIONS:** DTCA's ability to allow the pharmaceutical industry to connect with its ultimate consumers (patients) would lead to increased strains on European health systems. But, the increased awareness that DTCA will bring to currently neglected conditions (such as osteoarthritis in men) could lead to huge benefits to patients quality-of-lives and help refocus changing health systems towards patients needs. As such, DTCA could be part of the solution to Europe's health care crisis, but its introduction will bring to EU states as many headaches as it solves.

**PHPII**

**USE OF THE ANDERSEN HEALTH CARE SERVICES UTILIZATION BEHAVIORAL MODEL TO UNDERSTAND THE RELATIONSHIP BETWEEN HEALTH INSURANCE COVERAGE AND HEALTH CARE SERVICES UTILIZATION AMONG THE ELDERLY**

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**OBJECTIVES:** The purpose of this study was to determine the relationship between health insurance coverage (Medicare, Medicaid, other public, employer-sponsored, and other private) and health care services utilization (i.e., physician visits, hospitalizations, and the ability to get needed prescription medications) among the elderly. **METHODS:** The 1996 National Health Interview Survey and its supplements were utilized as the data sources. Elderly persons (>65 years) who had Medicare coverage (N = 27,727,536) were included in the study. The

Andersen Health Care Services Utilization Behavioral Model provided the study framework and was used to understand the effect of health insurance coverage on health care services utilization while controlling for other variables. The framework models the relationship between predisposing (age, gender, living status, race, and education), enabling (income, health insurance coverage, usual source of care, geographic location, and out-of-pocket spending), and need for care (health status, activity limitation, restricted bed days, and comorbidities) factors and health care services utilization. **RESULTS:** Elderly persons with additional public health insurance coverage (Medicare plus Medicaid or Medicare plus other public health insurance) had significantly more physician visits than those with Medicare only ( $p = 0.0159$  and  $0.0258$ , respectively). Elderly persons who had Medicare plus other public health insurance and Medicare plus other private health insurance were significantly more likely to be hospitalized than those who had Medicare only ( $p = 0.0341$  and  $0.0327$ , respectively). Elderly persons with Medicare plus employer-sponsored insurance were more likely to get needed prescription medication(s) ( $p = 0.0076$ ) than those with Medicare only. **CONCLUSIONS:** Elderly persons who had additional health insurance coverage (i.e., in addition to Medicare) were more likely to have more physician visits, hospitalizations, and they were more likely to obtain needed prescription medications. Additional health insurance coverage may be beneficial in increasing access to health care services among the elderly.

**PHPI2**

**ACUTE CARE ELDERLY UNITS: THEIR PREVALENCE, CHARACTERISTICS AND DETERMINANTS**

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**BACKGROUND:** The acutely ill hospitalized elderly patients face the risk of functional decline and poor quality care. To improve the outcomes of hospitalization, various intervention models have been used. However, the contributors to the functional loss and quality of care are interrelated and warrant a multidimensional intervention. The Acute Care for Elders (ACE) unit is a one such promising model of care for elderly to minimize adverse outcomes of hospitalization. **OBJECTIVE:** To analyze the determinants, prevalence and characteristics of ACE units. **METHODS:** We surveyed all established Geriatric Medicine Divisions ( $n = 100$ ) across US to determine presence of ACE unit. Data on demographics, resource, structure, administration, and patient care was obtained via a questionnaire. Hospital data regarding number of beds, revenue, number of medicare inpatients, and average length of stay was obtained from Annual Survey data of the American Hospital Association. Descriptive analysis and step-wise logistic regression were used to analyze the characteristics and determinants of ACE units. **RE-**

**SULTS:** Of the 82 responding geriatric divisions, 15 had an active ACE unit. Average daily census on ACE units ranged from 5 to 25, average length of stay was 5.2 days and the average nurse to patient ratio was 1:6. Community dwelling was the most common pre-admission living setting. Two most common admitting diagnoses were congestive heart failure and pneumonia. T-test showed significant difference ( $<.05$ ) between hospitals with ACE unit and hospitals without, with respect to number of beds and total revenue. The step-wise logistic regression indicated that total hospital revenue was the only significant factor in determining the presence of an ACE unit. **CONCLUSIONS:** Thus, application of the ACE unit model remains modest given the paucity of information regarding its long and short-term benefits and cost-effectiveness. Further research in this direction can facilitate informed policy decisions.

**PHPI 3**

**INDICES FOR EVALUATION OF DRUG COST/UTILIZATION: EVERY SILVER LINING HAS A GRAY CLOUD**

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**OBJECTIVE:** Given the high cost of pharmaceuticals, particularly “blockbuster” drugs such as the COX-II inhibitors, the issue of value-for-dollar is an increasingly important one for managed care decision-makers. Due to the complexity of conducting full economic evaluations, it is often tempting to try to reduce such analyses to the most simplistic methods possible—either by assuming equal effectiveness of two drugs and performing a cost-minimization analysis, or by using an index of drug cost/utilization such as DDD (number of defined daily doses of a drug used in a population), PMPM (per member per month cost/utilization), PPPM (per patient per month cost/utilization), ADC (average daily cost of drug therapy), or DACON (daily average consumption of a drug in a population). If a partial economic evaluation based on drug cost/utilization is necessary or preferred, decision-makers should bear in mind the relative strengths and limitations of these approaches prior to making policy decisions. The objectives of this paper are: (1) to describe several indices of drug cost/utilization, (2) to discuss their strengths and limitations, (3) to provide illustrations of their use, and (4) to offer suggestions for appropriate interpretation. **METHODS:** Using numerical examples focusing on COX-II inhibitors, several indices of drug cost/utilization are described and compared, including DDD, PMPM, PPPM, ADC, and DACON. General limitations and assumptions of “partial” economic evaluations based solely upon cost/utilization data are discussed, including assumptions of equal effectiveness, compliance, continuation and safety; as well as confounding by indication, severity of illness and time on market. **RESULTS:** Depending upon the index used, results (data) on drug cost/utilization for COX-II inhibitors

vary. **CONCLUSION:** Numerous indices are used to describe and evaluate drug cost/utilization. Each has its own strengths and limitations, and must be interpreted in the appropriate context to best inform pharmaceutical policy decision-making.

**PHPI 4**

**COST ANALYSIS OF PHARMACEUTICAL SERVICES IN A TEACHING INSTITUTION**

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**OBJECTIVES:** The study purpose was to describe and quantify annual costs of pharmaceutical services per category (5) and clientele (5) in a 452 bed mother and child teaching institution. **METHODS:** Based on a daily diary completed by each pharmacist, we calculated costs of pharmaceutical services in five categories in 1999–2000: distribution, management, clinical, teaching and research. Pharmacists were requested to provide a description of their activities, including the number of new patients/follow-up, verbal and written requests and number/type of interventions. Costs ratios were calculated. **RESULTS:** 1999–2000 fiscal year showed 21,330 admissions, 115,961 patient-days and 275,000 outpatient visits. Pharmacists represented 47% of total worked hours. Pharmacists’ total hours reported represented 89,6 % of accounting data. Hours were dedicated to distribution (53%), clinical (29%), management (12%), teaching (5%) and research (1%) services. Pharmacists answered 26 491 questions while providing 26 065 interventions among 5 clientele (intensive care, pediatrics, multi-specialties, mother and child and haematology/oncology). We calculated a ratio of interventions/worked hours with an average of 0,61 (min 0,015–max 1,35). An analysis of these differences will be provided. Pharmacists’ total annual costs represented \$1,453,000.00 CDN including social benefits. Assuming our pharmacy model optimizes the number of potential interventions in our setting and that 100 % of pharmacist’s paid time is required to materialize them, we calculated an average cost of \$54.92 CDN/intervention (min \$24.80 CDN–max \$2,233.00 CDN). Differences were calculated between 1998–1999 and 1999–2000 showing an average of 104% difference (min 68%–max 197%). Differences can be explained by pharmacist expertise evolution, management decisions and changes in activity volumes. **CONCLUSION:** There are little data available to allow benchmarking in the costs of pharmaceutical services. Further studies are required to identify the most useful ratios to monitor such costs as well as relevant outcomes.

**PHPI 5****A SURVEY OF PUBLIC HOSPITAL PHARMACISTS IN SINGAPORE ON THEIR VIEWS ABOUT 'THE FORMULARY' AND ITS DECISION-MAKING PROCESS**

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**OUR PREMISE:** If the expectation is “A formulary must help control drug costs but not just promote cheap drugs (i.e., compromise on quality of care)”, there clearly exists a need for pharmacoeconomics in formulary decision-making. **OBJECTIVES:** To understand if such expectation and need exist in Singapore, and how confident pharmacists would be if asked to use pharmacoeconomics to aid their decision-making. **METHOD:** After having obtained consent from the respective pharmacy managers, survey forms were circulated to all pharmacists in the 5 major public hospitals of Singapore. If after 2–3 weeks, the response rate was lower than 50% a reminder (via e-mail) and a second circulation of the questionnaire was made. In the event of any clarification(s) being required, the respondent was contacted over phone. **RESULTS AND CONCLUSION:** With a response rate that ranged from 50% to 85% in the individual hospitals and an overall average of ~64% (70 of 110 identified pharmacists responded) our findings delineated the following picture in Singapore. Formulary restriction is the best method to control drug costs (57%). However, it should not be a list of cheapest alternatives (90 %) but should ideally promote the use of the best drug (71%) while also controlling the hospital budget (57%). Though what factors are involved in the current formulary decision-making process are not known (49% have no knowledge), drug effectiveness (64%) as opposed to acquisition cost (5%) will be considered as the most important factor by the pharmacists if they were to decide on the formulary. However, only 1% felt very confident about being able to use pharmacoeconomics to aid their decision-making, if asked to do so. There is therefore, a definite but unstated need for use of pharmacoeconomics in the formulary setting; however, there is clearly a lack of capability to fulfill the need.

**PHPI 6****THE VALUE OF VARIOUS FORMS OF EVIDENCE IN DRUG FORMULARY DECISION MAKING**Morris L<sup>1</sup>, Aikin K<sup>2</sup><sup>1</sup>Louis A. Morris & Associates, Dix Hills, NY, USA; <sup>2</sup>Food and Drug Administration, Rockville, MD, USA

**INTRODUCTION:** The study examined the perceived value of different forms of evidence (i.e., randomized controlled trials and retrospective cohort analyses study designs) among physicians and pharmacists (N = 780). Research participants read three abstracts (for each of three fictitious drugs) that varied type of claim (cost, cost-effectiveness, and effectiveness) and study design.

They rated the perceived value of the study in determining formulary recommendations on seven items. **METHODS:** Factor analysis was used to derive weights for a single measure of value that ranged from 0.735 (low value) to 5.145 (high value). **RESULTS:** Four-way ANOVAs indicated that cost-effectiveness (mean = 3.19) and effectiveness (mean = 3.11) data were of more value than cost data (mean = 2.84,  $p < .0001$ ). Also, formulary-affiliated physicians (mean = 3.10) found the studies to be of more value than hospital pharmacy directors (mean = 2.93,  $p < .02$ ). A significant two-way interaction indicated that pharmacy directors valued retrospective cohort analyses more than randomized trials regardless of type of claim. In contrast, physicians valued randomized trials more than retrospective cohort analyses ( $p < .001$ ). Manipulation checks indicated some difficulty identifying the purpose of individual studies. While most respondents could correctly identify cost-effectiveness and effectiveness studies (between 77% and 92% correctly identified these studies), there was confusion regarding cost studies. Almost half of the participants (between 42% and 57%) characterized these studies (which were described as “cost-minimization” analyses) as cost-effectiveness studies. Pharmacy directors (49%) were more likely to mischaracterize the cost-minimization studies compared to the physician groups (approximately 40% of these groups) (chi square = 20.29,  $p < .02$ ). **CONCLUSIONS:** The results suggest that the multidisciplinary make-up of formulary committees is important to assure the incorporation of multiple forms of evidence in decision-making. Also, more attention to the study design is essential to evaluate the value of various forms of evidence for formulary decisions.

**PHPI 7****PATIENT OUTCOMES IN THE SEDATED ICU PATIENT**Kamath T<sup>1</sup>, Hopefl A<sup>2</sup>, Chaikledkaew U<sup>1</sup>, Johnson KA<sup>1</sup><sup>1</sup>University of Southern California, Los Angeles, CA, USA;<sup>2</sup>AmeriNet, St. Louis, MO, USA

**OBJECTIVE:** This study compares patient outcomes in the mechanically ventilated ICU patient by patient demographics, hospital characteristics and drug therapy. **METHODS:** Data collected from 42 hospitals included patient demographics, disease severity, sedatives/analgesics administered, hospital type/size, days hospitalized and discharge status. **RESULTS:** 622 patients were studied (48% female, mean APACHE score = 21.7, 31% with care plans). Only 50% of patient episodes for ICU sedation greater than 24 hours were treated with lorazepam (guideline recommended drug for long-term sedation). 94% of patients received recommended analgesics. Patients in community hospitals had fewer ICU days (9.31 versus 11.05) and total hospital days (14.14 versus 16.96) compared to teaching hospitals. Patients receiving midazolam or orazepam had shorter hospital stays (13.7 and 15.5 days respectively) compared to propofol pa-

tients. Patients receiving midazolam had higher mortality rates (31.7%) compared to patients on lorazepam (29.2%). However, these results were not confirmed when controlling for disease severity and other factors. Multivariate regression analysis revealed that type of sedative/analgesic drug treatment and whether the hospital had a care plan were not associated with shorter ICU and total hospital stays when controlling for patient demographics and disease severity. In fact, patients admitted to hospitals with care plans had longer total hospital stays. More severe patients had shorter total hospital stays, probably due to higher mortality. Higher mortality was associated with older patients and higher disease severity. **CONCLUSION:** There is much discussion about treatment guidelines and use of care plans to improve quality of care and reduce hospitalization costs. In this study, the type of sedation and analgesia treatment in mechanically ventilated ICU patients and whether the patient had a care plan did not influence days in ICU or mortality. Whether following treatment guidelines and care plans reduces total costs, needs further evaluation.

**PHP18**

**A MODEL FOR COMPARING COSTS ASSOCIATED WITH PRESCRIPTION WASTAGE WITH APPLICATION TO VA PRESCRIPTION DATA**

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**OBJECTIVE:** The objective of this study was to determine the frequency and cost of prescription switches for 90-day vs. 30-day outpatient prescriptions dispensed by a VA pharmacy and to develop a model to determine the prescription fill policy with the lowest total costs. **METHODS:** VA outpatient prescription records for one year for simvastatin and lovastatin (30 or 90-days) were analyzed to determine the frequency, quantity and cost of medication wasted due to medication switches. The quantity wasted was defined as the difference between the quantity dispensed and the quantity of drug used before changing to a new drug or dosage. Differences in dispensing costs for a given time-period were also included. Sensitivity analyses were conducted for quantity wasted, drug costs, and dispensing costs. **RESULTS:** A total of 16,990 prescriptions were analyzed. The quantity and costs of medication wasted were higher for 90-day prescriptions than for 30-day prescriptions. However, average costs to the VA pharmacy were \$2.45 higher per prescription for the 30-day supply because of additional dispensing costs for the 30-day fill. The model and sensitivity analyses show that a 90-day supply policy results in lower total pharmacy costs under several scenarios. Only in the case of high drug costs was the 30-day policy favorable to the 90-day policy in terms of total costs. **CONCLUSION:** Prescriptions given in a 90-day supply resulted in lower total costs. The projected cost savings of having a 90-day versus a 30-day policy would hold true

for prescriptions with similar drug costs and similar rates of wastage that result from changes that physicians make to patients' prescriptions. In addition, the model provides a flexible framework for pharmacy administrators to assess refill policies in terms of excess or unnecessary cost for different classes of drugs, given patient and/or physician behavior.

**PHP19**

**USING FINANCIAL RATIOS TO COMPARE PHARMACY SPENDING IN THE DEPARTMENT OF VETERANS AFFAIRS**

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**OBJECTIVE:** To understand how pharmacy spending varies across the VA Medical Centers in the United States. Pharmacy costs continue to rise. From 1990 to 1994 pharmacy expenditures were reported to be 6% of the total Veteran's Health Association (VHA) budget. In 1995 and 1996 it was 7%. In 1997 it was 8% and in 1998 it was 9%. Then in 1999 it went to 11%. Future projections are for a continued increase in budget spending. **METHODS:** Ratios of yearly Pharmacy to Medical Center expenditures were compared. These ratios were ranked and compared with geographical location. The years of 1997 and 1998 were studied. **RESULTS:** The majority of the highest ratios were located in the Midwest, Southwest, and Southern regions of the United States. **CONCLUSIONS:** Financial ratios can demonstrate variations in expenditures and identify areas that may require further inquiry.

**PHP20**

**THE LAG BETWEEN EFFECTIVENESS AND COST-EFFECTIVENESS EVIDENCE OF NEW DRUGS AND DECISION-MAKING IN HEALTH CARE**

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**BACKGROUND:** A new drug is approved for use if its effectiveness has been demonstrated. Recently decision-makers in a number of countries have begun to account for both the effectiveness and cost-effectiveness of new drugs. However, cost-effectiveness evidence lags behind the effectiveness data. **OBJECTIVE:** To explore the timeliness of delivering cost-effectiveness information about new drugs with established effectiveness and significant financial impact. **METHODS:** New drugs were identified, based on guidance documents and reports published by the National Institute for Clinical Excellence of England and Wales, and the following data were collected: dates of publication of first effectiveness and cost-effectiveness evidence, methodology of the cost-effectiveness analysis, funding of the research, etc. **RESULTS:** Guidance documents for the following new drugs/drug groups have been published by NICE by the end of 2000: tax-

anes for ovarian and breast cancer, proton pump inhibitors in the treatment of dyspepsia, glycoprotein IIb/IIIa inhibitors, methylphenidate for hyperactivity in childhood, zanamivir, and rosiglitazone for type II Diabetes Mellitus. The analysis of the evidence shows that the effectiveness of these drugs has been demonstrated in the last 12 years. However, cost-effectiveness evidence has been published for 70% of the drugs with an average delay of 3 years (range 0–10). The cost-effectiveness of those, introduced after 1995 (80% of all included drugs/drug groups), has been demonstrated using models only, if at all. **CONCLUSIONS:** Cost-effectiveness evidence is produced with a lag behind the effectiveness evidence. As a result, decision-makers are in a position of awaiting sound evidence while issuing guidance based on current inconclusive research results. The cost to society is discussed, and establishing the cost-effectiveness of new drugs alongside RCTs at an earlier stage of their development is suggested.

**PHP2 1**

**SINGLE EUROPEAN-LEVEL COST-EFFECTIVENESS ANALYSIS: OVER THE FOURTH HURDLE AND INTO THE DITCH?**

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**BACKGROUND:** As more European governments require economic data to support reimbursement applications the potential burden of multiple economic evaluations is being seen as a problem by industry. Placing responsibility for cost-effectiveness assessment at the European level using standardised methods has been proposed as a solution. **OBJECTIVE:** To review the feasibility of a European level cost-effectiveness test for new drugs, from conceptual, practical and political viewpoints. **METHODS:** The issues are examined first from the theoretical perspective—does a European level economic evaluation have any inherent logic. Secondly, the practical issues of how such an evaluation might be conducted are examined. Could it be based on a phase III clinical trial? The political issues relate to who would regulate the production of such cost-effectiveness data; who would use the data to assist in what decision(s)? Different regulatory models are assessed using the analogy of drug licensing. **DISCUSSION:** The position generally taken by economists is that a generalised cost-effectiveness result is neither possible nor useful. Differences in the price structures, treatment patterns and provider incentives between systems make generalisations of cost-effectiveness of questionable relevance. How fast will European integration produce a single health market? Moves towards a single European price for each drug are relevant as in the willingness of European states to allow the EU to play a bigger role in health care financing and organisation. Will countries accept each others' assessments or will an EU agency like EMEA be required? **CONCLUSIONS:**

Long-term political and economic changes may well create a true European market in which cost-effectiveness at the European level will have meaning and relevance. Meanwhile, individual country health care systems seem more concerned with short-term budget impact when making new drugs available. The pharmaceutical industry should not anticipate a reduction in the overall demand for locally targeted economic information.

**PHP2 2**

**PATIENT ADHERENCE TO DRUG THERAPY IN A THREE-TIER COPAYMENT STRUCTURE**

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**BACKGROUND:** The three-tier copayment plan is designed to reduce the cost of pharmacy benefits to the insurer or payer while maintaining patient choice. Because the patient pays a larger portion of the cost of middle- and high-tier drugs, some have argued that this plan design may adversely impact patient drug utilization for chronic medications. **OBJECTIVE:** To determine whether a three-tier copayment structure adversely affects patient drug utilization for middle- and upper-tier drugs for diabetes and depression. **METHODS:** We conducted a longitudinal, retrospective claims database study using claims data from a national pharmaceutical benefits management company. Claims for two chronic conditions, depression and oral diabetes, were examined for patients on three-tier copayment plans and for patients on an open formulary plan with the same copayment for every drug. Average rates of patient adherence, number of prescriptions filled, and days of therapy were calculated. **RESULTS:** There were statistically significant differences in rates of patient adherence, number of prescriptions filled, days of therapy, amount of copay, and payer costs among patients using drugs in the lower, middle, or upper tier of the three-tier structure. In addition, average patient adherence, number of prescriptions filled, and days of therapy did differ significantly for patients on an open formulary compared to patients on a three-tier copayment structure. These differences were largely a function of sample size, and may be of little practical utility. **CONCLUSIONS:** The larger patient copayment for medications in the middle and upper tiers of a three-tier copayment structure have only a minimal impact on drug utilization in the antidepressant and oral diabetes drug categories. Further research is needed to determine whether these findings would be replicated when applied to other therapeutic classes.

**PHP2 3**

**DRUG REIMBURSEMENT PROGRAM FOR INDIGENT PATIENTS: AN ECONOMIC IMPACT ON THE HOSPITAL ADMINISTRATION BUDGET**

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All patients are entitled to equal access to health care resources. The Department of Pharmacoeconomics at University of Texas MD Anderson Cancer Center (UTMDACC) administers a Patient Assistance Program (PAP) that provides assistance to indigent patients with free pharmaceuticals for their therapy. Drug cost is recovered through a drug reimbursement program offered by pharmaceutical companies. **OBJECTIVE:** The objective of this report is to examine trends in drug cost savings to indigent patients at UTMDACC using the PAP model. **METHODS:** A retrospective study using data from September 1996 to August 2000 was conducted to determine the value of the program. Patients were enrolled in this program if they qualified based on the Financial Classification Scale. Uninsured patients as well as under-insured patients were considered in this study. Data was analyzed to evaluate the trend in cost savings for the three fiscal years. **RESULTS:** Over \$334 million was spent on drug cost over the period. There was an average increase of 22% per year in drug cost. The indigent patients accounted for 9% of the total patient population at UTMDACC. An estimated \$33 million was spent on drugs for indigent patients during that period. The PAP system recovered a total of \$16.8 million; \$4.1M (1997), \$4.3M (1998), \$3.5M (1999), and \$4.9M (2000). This accounts for 51% in drug cost recovery through this program. The fluctuation in cost saving was attributed to changes in the number of programs, number of patients enrolled, and product mix. **CONCLUSION:** The PAP system has provided free drugs to patients without financial resources and reduced the economic burden of this population on the health care institution. The program has created goodwill between the pharmaceutical companies, the health care institution, the patients and the community.

#### **NO SPECIFIC OR MULTIPLE DISEASES-QUALITY OF LIFE & PREFERENCE-BASED MEASURES**

**PQP 1**

#### **LESSONS LEARNED FROM DEVELOPING A PSYCHOMETRICALLY BASED SEDATION QUESTIONNAIRE IN PHARMACOLOGICALLY PARALYZED CRITICALLY ILL PATIENTS**

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**OBJECTIVE:** To share lessons learned from developing a reliable and valid questionnaire for adequacy of sedation in pharmacologically paralyzed critically ill patients. **METHODS:** In phase 1, seven experts listed 21 characteristics describing anxiety in pharmacologically paralyzed patients. In phase 2, two scenarios were created illustrating the experience of paralysis: one with and one without receiving a sedative. A convenience sample of 30 people evaluated scenarios to determine the importance of characteristics obtained from phase 1 using a five-point scale. Items were reduced to the 10 most important characteristics (mean  $\geq 3$ ). Based on these results, the fi-

nal instrument consisted of 12 questions: 2 categorical addressing memory of the experience and 10 referred to characteristics of anxiety. In phase 3, two groups of critically ill patients were administered the questionnaire: 1) sedated only and 2) sedated and pharmacologically paralyzed. The questionnaire was administered twice for reliability. Questionnaire results were compared to subjective and objective sedation monitoring tools for validity. Calculated sample size was 20 for each group. **RESULTS:** During six months, 21 patients consented to participate. Twelve patients died and nine patients (6 sedated, 3 sedated/paralyzed) were administered questionnaires. Five patients (3 sedated, 2 sedated/paralyzed) did not remember the intensive care unit experience. Two of three patients in the sedated group who answered the questionnaire found it difficult to remember over time. One sedated/paralyzed patient who answered the questionnaire received a sedative without amnesic properties and felt anxious during therapy. The distressful feeling of this patient was comparable to findings of the objective sedation tool. **CONCLUSIONS:** Mortality in this critically ill patient population was high. Due to amnesic properties of sedatives most patients did not remember the experience. Of patients who remembered, their memory deteriorated over time. Based on lessons learned, it may require 2–3 years to achieve the necessary sample size.

**PQP 2**

#### **ROLE OF HEALTH RELATED QUALITY OF LIFE OUTCOMES IN THE EUROPEAN DRUG REGULATORY PROCESS: A REVIEW OF THE EMEA DOCUMENTS**

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**INTRODUCTION:** The ERIQA Group aims to create guidance for European regulatory authorities on the assessment of the quality of HRQL studies in clinical trials and to evaluate the validity of HRQL claims. **OBJECTIVES:** To identify disease or drugs in which a formal HRQL assessment is recommended. To identify measures and methods recommended. To evaluate the reliability of recommendations across documents. **METHODS:** Informations were searched on the EMEA website ([www.eudra.org/emea.html](http://www.eudra.org/emea.html)). A research was performed with the two key words: "Quality of life" and "QoL". All the documents retrieved were reviewed. **RESULTS:** 133 documents were retrieved excluding duplicates (129: Quality of Life, 25: QoL). 19 documents derived from the Efficacy Working Parties (EWP) including nine notes for guidance (Weight Control, Cancer, Chronic Peripheral Arterial Occlusive Disease, Cardiac Failure, Stable Angina Pectoris, Antiarrhythmics, Parkinson, Alzheimer, Multiple Sclerosis), concept paper (3), points to consider (5) and position statements (2). Only one document was a note for guidance for ICH. 104 European Public Assessment Report (EPAR) were retrieved, representing 26 products. Nine miscellaneous documents were found in-



cluding minute reports, workshop, letters (5), assessment/opinion (2) from the CPMP and 2 documents were produced by the CVMP. **CONCLUSIONS:** The recommendations from the EMEA are vague in most cases, too generic, inconsistent between each other and reveal in some cases a lack of knowledge of the field. These recommendations are not up-dated and do not exist in relevant diseases (HIV/AIDS, HBP). Nevertheless, recommendations do exist showing a real interest in HRQL and recognition of HRQL as a valuable endpoint (mainly secondary).

**PQP3****DEFINING CLINICALLY MEANINGFUL CHANGE IN HEALTH-RELATED QUALITY OF LIFE**

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**OBJECTIVES:** This paper reviews current approaches to defining clinically meaningful change in health-related quality of life (HRQOL). **METHODS:** Definitions of clinically meaningful change are discussed. Psychometric properties of HRQOL instruments necessary for identifying clinically meaningful change are identified. Two broad methods for identifying clinically meaningful change are contrasted: anchor-based methods and distribution-based methods. Anchor-based methods include forced-choice paradigms, global change ratings, receiver operating characteristic techniques, goal attainment scaling and external event methods. Distribution-based methods include individual effect size, the Guyatt responsiveness index, the Jacobson-Traux reliable-change index (and subsequent variations), standard error of measurement, and hierarchical linear modeling. Strategies for validating clinically meaningful change measures are discussed. **RESULTS:** Anchor-based and distribution-based methods have both advantages and limitations, and neither appears superior to the other. Anchor-based methods provide a source for external validation, but are dependent on the specific anchors being used. Distribution-based methods provide a statistical basis for decision-making, but may vary on the basis of sample characteristics. **CONCLUSIONS:** The use of multiple methods to define clinically meaningful change is strongly recommended. Factors to consider in defining clinically meaningful change include the severity of the baseline value, the direction of change, and the importance of the change to the individual.

**PQP4****CROSS-CULTURAL VARIATIONS IN SF-12 SCORES AMONG INDIVIDUALS WITH VARIOUS HEALTH CONDITIONS**

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**OBJECTIVE:** To examine the cross-cultural differences of health-related quality of life among people with various health conditions across four countries. **METHODS:** Analyses were based on 12-page questionnaires mailed to adults in 2000. A total of 38,677 responses were received from France, Germany, Great Britain, and the US Results were subsequently weighted and projected to the national populations of these four countries. Weighting was based on gender, age, and region for the European countries and gender, age, race, and region for the US Participants reported whether they were diagnosed with the following: arthritis, asthma, depression, diabetes, GERD, high blood pressure, high cholesterol, migraines, nasal allergies, or osteoporosis. Physical and mental health status were defined by summary measures of the SF-12 scale. **RESULTS:** The French reported lower mental health status but better physical health status than people in Germany, Great Britain, and the US, regardless of diagnosed health conditions. The opposite was found among arthritis, asthma, and GERD sufferers in Germany, who reported the best mental health status but the lowest physical health. Respondents from Great Britain and the US generally reported SF-12 scores that fell between those of France and Germany, with three notable exceptions. Among people diagnosed with depression, those in the US reported better mental health status. Among people diagnosed with high blood pressure or high cholesterol, those in Great Britain reported the lowest physical health status. **CONCLUSION:** Self-reported quality of life varied by country regardless of condition. Researchers should consider cross-cultural variations in self-reported quality of life measures when conducting multinational trials. Collapsing data could obscure effects.

**PQP5****TRANSLATING SF-36 SCORES INTO PREFERENCES: AN EXAMINATION OF THE PERFORMANCE OF TWO PREDICTIVE EQUATIONS**

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Despite widespread use of the SF-36, its use in cost-utility analyses has been precluded by its inability to measure patient preferences. To overcome this obstacle, various investigators have derived equations to estimate preference scores from the SF-36. **OBJECTIVE:** To compare two methods of estimating preference values from SF-36 scores. **METHODS:** A convenience sample of patients completed the SF-36 and EuroQol during their initial visit to a specialty headache center. Preference scores were estimated from the SF-36 using two equations, one developed by Fryback and the other by Brazier. The performance of each equation was assessed by calculating the correlation coefficient between the estimates and actual preference scores from the EuroQol. Mean preference scores from each method were compared using one-way repeated measures ANOVA. **RESULTS:** Forty-seven

patients were enrolled; 45 completed the EuroQol and SF-36. Mean preferences estimated by the Brazier and Fryback equations were 0.815 (SD: 0.110, Range: 0.497–0.971) and 0.655 (SD: 0.060, Range: 0.511–0.791). The mean EuroQol score was 0.553 (SD: 0.347, Range: –0.239–1.000). The correlation coefficient between predicted preferences from Brazier and Fryback's equations and the EuroQol were 0.613 and 0.494, respectively. The mean preference scores produced by the three methods were significantly different ( $F = 24.59$ ,  $p = 0.0001$ ) and both of the predictive equations yielded significantly higher mean values ( $p < 0.05$ ) than the EuroQol. **CONCLUSIONS:** Both equations to estimate a single, preference-based index from the SF-36 produced higher mean scores and a narrower range of values than the EuroQol. Preferences produced by the Brazier equation were more highly correlated with EuroQol scores than preferences from the Fryback equation. The Fryback equation also produced a wider range of scores. Continued development and validation of predictive equations is needed in order to use SF-36 scores in cost-utility analyses.

**PQP6**

**HEALTH UTILITIES INDEX MARK 3:  
AGREEMENT BETWEEN RATERS AND  
BETWEEN MODALITIES OF ADMINISTRATION**

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**OBJECTIVES:** The aim of this study was to evaluate inter-rater and inter-modality agreement in assessing health status using the Health Utilities Index Mark 3 (HUI3). **METHODS:** A random sample from a Dutch cohort of 14-year-old Very Low Birth Weight children and their parents were invited to participate in a HUI3 face-to-face ( $n = 150$ ) or telephone interview ( $n = 150$ ). All 300 participants were also sent a HUI3 questionnaire by mail. Response rate was 68%. **RESULTS:** Inter-rater and inter-modality agreement were high for the physical HUI3 attributes and poor for the psychological attributes. Children and parents reported more dysfunction in the psychological attributes when interviewed than when completing the mailed questionnaire. High agreement on the physical attributes may have resulted from the fact that hardly any dysfunction was reported in these attributes, and poor agreement in the psychological attributes may have been a result of the fact that in these attributes much more dysfunction was reported. **CONCLUSIONS:** In measuring children's health status using the HUI3, the results and their interpretation vary with the source of information and the modality of administration. For maximum comparability between studies, written self-report questionnaires seem the preferred option.

**PQP7**

**IS COMPLIANCE WITH DRUG TREATMENT  
CORRELATED WITH HEALTH RELATED  
QUALITY OF LIFE?**

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**OBJECTIVES:** Compliance with drug treatment and health related quality of life (HRQL) are two distinct concepts. However, we might expect a weak positive relationship between the two, i.e. higher compliance is associated with higher HRQL. The purpose of this study was to assess the relationship between compliance and HRQL. **METHODS:** HRQL was measured using the physical (PCS) and mental (MCS) component summary measures of the MOS Short-Form 12 (SF-12). Compliance was assessed using Morisky's instrument. Three longitudinal datasets were used to investigate the relationship. One dataset ( $n = 100$ ) included hypertensive patients aged between 34 and 80 years. Another dataset ( $n = 199$ ) covered high risk community-dwelling individuals between 27 and 93 years of age. In this dataset, 43% reported taking medication to control blood pressure. The third dataset ( $n = 365$ ) consisted of elderly patients, of whom 57% reported taking medication for pain relief and 47% to control blood pressure. There are two observations per patient in the first dataset and three per patient in the other two. In all datasets, patients were taking at least one prescribed medication. Correlation coefficients established the relationship between PCS, MCS and compliance. **RESULTS:** In all datasets, MCS was positively correlated to compliance. PCS was positively correlated to compliance in the hypertensive and the elderly populations and was negatively correlated to compliance in the high risk population. Correlation between compliance and PCS range from 0.00 ( $p = 0.96$ ) to 0.09 ( $p = 0.03$ ). Correlation between compliance and MCS range from 0.01 ( $p = 0.90$ ) to 0.21 ( $p = 0.00$ ). **CONCLUSIONS:** Correlation between PCS, MCS and compliance was in general positive but typically small or negligible. Further research is needed to establish the relationship between compliance and HRQL.

**PQP8**

**EVALUATING BIAS INTRODUCED BY  
ANNUALIZING UTILIZATION AND  
COST MEASURES**

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**OBJECTIVES:** Administrative databases are often used to investigate patterns of health care resource use and expenditure over time for particular conditions in order to project future costs and to evaluate the cost-effectiveness of interventions. Duration of the period of observation typically varies across individuals due to differences in

enrollment/disenrollment dates, timing of the index event, and the database time span. Projecting expenditure on an annual or per member per month basis requires standardizing these periods of observation. We evaluate bias introduced by a simple method for annualizing utilization and cost measures. **METHODS:** We investigated resource use and costs surrounding an index event; hospital admission with a primary diagnosis of heart failure. For each patient, claims data were available for a pre-event and post-event period ranging from 6 to 24 months. We standardized periods to one year pre- and post-event by first tabulating counts and costs for the actual period observed. We then multiplied these values by the ratio of 365 days to actual days in the period such that values for periods shorter than 365 days were inflated and longer than 365 days deflated. To determine whether this adjustment biased the magnitude of annualized values, we estimated a regression model with annualized cost and adjustment ratio as dependent and independent variables respectively. **RESULTS:** For the pre-event period, there was no significant association between annualized cost and adjustment factor ( $p = 0.72$ ,  $R^2 = 0.00014$ ,  $p = 0.012$ ) indicating absence of bias. While bias was observed in the post-event adjustment factor ( $p = 0.005$ ), the low model explanatory power ( $R^2 = 0.00869$ ) and lack of correlation (Pearson correlation coefficient 0.093) suggest minimal impact on the magnitude of annualized estimates. **CONCLUSION:** We find that a simple approach to standardization was reasonably robust. We compare advantages and disadvantages with more complex regression-based methods.

**PQP9****QUALITY OF LIFE OF PATIENTS WITH FABRY DISEASE**

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**BACKGROUND:** Fabry disease (FD) is a rare genetic disorder of metabolism due to a deficiency of a lysosomal enzyme (alpha-galactosidase A) and the resultant accumulation of globotriacylceramide in the cerebrovascular and cardiovascular systems, kidney, and liver. Symptoms

become manifest during childhood or adolescence and progress to include episodes of extremity pains, renal failure, cardiomyopathy, and/or strokes. **OBJECTIVES:** To better understand quality of life (QOL) in FD patients relative to disease progression, and normatively, compared to other chronic diseases. **METHODS:** Data were collected prospectively from a sample of 85 FD patients contacted through the Fabry Support and Information Group. Subjects responded to a survey that included the SF-36, a symptoms checklist, and extensive demographic questions. Information about SF-36 performance for other populations was collected from the literature. Data on 53 males are reported here. **RESULTS:** Patients with FD have substantially lower QOL across all domains compared to the 25th percentile of the general male population, as well as that observed for patients with Gaucher disease, renal disease, and stroke. There is also a very substantial decrease in QOL from early adulthood through middle age (data not shown here). **CONCLUSIONS:** These data suggest that FD places an increasing and unusually heavy QOL burden on patients, especially related to general health, physical role and vitality. Research is currently underway to determine whether enzyme replacement therapy can alleviate this burden. (See table below.)

**PQP10****NEGATIVE AFFECTIVITY: A SIGNIFICANT CONTAMINANT OF PATIENT REPORTED HEALTH RELATED QUALITY OF LIFE INSTRUMENTS (SF-36)**

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Negative affectivity (NA) has been shown to be strongly and consistently correlated to patient reported, subjective health indicators. Therefore, subjective health indicators may or may not give an accurate assessment of the individual's true health status. NA can be expected to act as a general nuisance factor in health research, one that taps organically spurious variance. The pervasive influence of NA may confound the results and complicate the interpretation of health related quality of life instruments, such as the SF-36. **OBJECTIVE:** The purpose of this study was to evaluate the potential influence of NA on the MOS SF-36. **METHODS:** We used Structural Equa-

**Table for PQP9**

SF-36 Scores	FD Males	General US Male Population (25th Percentile)	Gaucher Disease (Untreated)	Stroke	Renal Disease (Hemodialysis)
Physical Function	52	80	67	65	82
Role Physical	28	75	52	54	68
Bodily Pain	49	62	65	75	70
General Health	28	62	51	64	51
Vitality	35	50	42	55	59
Social Functioning	56	75	71	86	75
Role Emotional	53	67	64	80	75
Mental Health	63	68	65	80	69

tion Modeling (SEM) techniques to evaluate the SF-36 and the impact of NA on the Mental and Physical Components in a sample taken from the 1990 National Survey of Functional Health Status (NHS). **RESULTS:** The percent of shared variance of the Physical Health and Mental Health indicators and the Physical and Mental Health factors combined are physical function (.0603), role physical (.0817), bodily pain (.0720), health perception (.0600), role emotional (.0486), vitality (.0756), general mental health (.5207) and social function (.0811). General mental health (GMH) indicators are virtually identical to NA indicators. The percent of shared variance of the NA/GMH factor and Physical Health and Mental Health is .4422 and .9781 respectively. **CONCLUSIONS:** The present results suggest that about 47 percent of Physical Health and 98 percent of Mental Health is due to the influence of NA/GMH. This may account for the lack of discriminative ability, shown in previous studies, of the Mental Health factor and Mental Component Scale Score.

#### PQP11

### THE HEALTH AND WORK QUESTIONNAIRE (HWQ): AN INSTRUMENT FOR ASSESSING WORKPLACE PRODUCTIVITY IN RELATION TO WORKER HEALTH

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**OBJECTIVE:** Recently, interest has increased in productivity loss associated with medical conditions or health behaviors that do not preclude attendance at work (e.g., migraine, smoking). Commonly, productivity loss is subjectively assessed (asking workers directly to report on the productivity impacts of their medical conditions or health behaviors) which may be problematic because certain illnesses or health behaviors are viewed as socially undesirable. We describe the initial validation of a new instrument, the Health and Work Questionnaire (HWQ) that can be used in studies of worker health and productivity. **METHOD:** The HWQ consists of 24 items assessing work quality, quantity, efficiency, and related factors. To minimize "social desirability" tendencies on the part of respondents, they are asked to rate their work quality, quantity, and efficiency from their supervisor's and their co-worker's perspectives as well as their own. All items have ten-point response scales. The initial questionnaire was pretested by 30 subjects. Based on subject feedback, no wording changes were deemed necessary. The HWQ was administered to 294 employees of a major US airline and was completed at baseline and at three subsequent monthly intervals. Validation included comparisons with two objective productivity measures collected by the airline: Time Lost, the average time a reservation agent is unavailable between calls; and Total Performance Points,

the performance measure used for quarterly employee evaluation. **RESULTS:** Six subscales were identified by factor analyses: productivity, concentration/focus, supervisor relations, impatience/irritability, work satisfaction, and non-work satisfaction. Internal consistency reliability values were high for all scales (0.84–0.96), with the exception of impatience/irritability, displaying adequate reliability (0.72). All HWQ scale scores correlated significantly with the Time Lost measure; two scales correlated significantly with the performance measure. The significant correlations were all modest (0.12 to 0.22). **CONCLUSIONS:** With other measures, the HWQ may be a useful instrument in assessing group differences and evaluating the impact of health interventions on work-place productivity.

### NO SPECIFIC OR MULTIPLE DISEASES-METHODOLOGICAL ADVANCES

#### PMA1

### METHODOLOGICAL ADVANCES IN THE ASSESSMENT OF QUALITY OF LIFE IN CLINICAL TRIALS

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Pharmaceutical science has moved away from focusing exclusively on the impact of medications on physiological parameters to a focus that includes the subject's quality of life (QoL). To date, QoL assessment has relied exclusively on global summaries that ask subjects to recall, summarize, and evaluate their subjective QoL. New science-based methods using handheld technology to gather QoL data can lead to more valid, reliable, and timely QoL data. Many of the components of QoL, from subjective well-being to objective functioning, derive from an interest in understanding a subject's daily and momentary experiences. Rather than relying on broad summaries of experience, a 'bottoms-up' approach to QoL assessment directly measures subjects' momentary QoL in real-time, in the real-world. Until recently, researchers did not have an efficient way to collect valid momentary QoL data from subjects in their natural environment. Recent methodological advances in the science of patient experience, termed Ecological Momentary Assessment (EMA), make it possible to collect real-time QoL data from subjects using electronic patient experience diaries. This 'bottoms-up' approach using EMA methods extends existing QoL measures by providing a unique perspective on the extent to which subjects' evaluations of various moments in their lives reflect QoL changes over time. Recent empirical evidence suggests that this 'bottoms-up' approach may enhance the sensitivity of QoL assessment in clinical trials. The new perspective EMA provides on momentary patient experience represents a promising methodological advancement in the study of QoL. In combination with standard written assessments of QoL, EMA data can provide a new perspective on the relationship between medication effects and QoL.

**PMA2****DEVELOPMENT OF COST-EFFECTIVE WEB-BASED OUTCOMES RESEARCH STUDIES AND DISEASE MANAGEMENT PROGRAMS**

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Innovations in information technology are rapidly changing the health care market. With more and more clinical trials being conducted and managed on the web, the Internet provides an opportunity for conducting effective multi-center outcomes research studies and developing disease management programs. **OBJECTIVES:** This research describes the development of a web-driven application for ongoing collection, analysis, and reporting of outcomes research data. In addition, the web application was developed to gain experience in provision of benchmarking reports to health care providers conducting disease management programs. **METHODS:** Given current privacy regulations a multi-level security system with error checking was developed to assure integrity of data entering the system. Through integration of several programming languages (Visual Basic Script, Java Script, and HTML) into web-based active server pages, a method for immediate data collection, summary, and on-demand reporting was successfully developed. The system was deployed remotely via an Internet Service Provider. A prospective multi-site (10) hospital based infectious disease study of fungal risk and treatment patterns; and a retrospective lipid/cardiology clinic based study of patient care was conducted using the above technology. **RESULTS:** For expenditures of less than \$1,000, secure web applications were developed that provided electronic data capture of all study variables. The customizability of the program allowed for developing applications for differing disease states thereby reducing set-up costs and improving efficiency. Simultaneous multi-site training and minimal data entry errors further reduced costs. The applications also provided real-time reports that enhanced patient-care and reported practice patterns that highlighted national and regional variations. **CONCLUSIONS:** The success of these studies has demonstrated the utility of the internet in providing health care practitioners with a cost-effective tool for efficiently conducting multi-center outcomes research and disease management. Considering the increasing popularity and access to the Internet, this research has significant implications for outcomes research and disease management.

**PMA3****DOES WHERE YOU LIVE AFFECT IF AND HOW YOU DISCOUNT FUTURE COSTS AND BENEFITS IN ECONOMIC EVALUATION? SHOULD IT?**Faulkner LA<sup>1</sup>, Gafni A<sup>2</sup>, O'Brien BJ<sup>1</sup>

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**OBJECTIVES:** An accepted practice with unresolved issues in economic evaluation is the discounting of future costs and benefits. Many people conducting evaluations view discounting as a technical matter and look to guidelines for the proper rate. Therefore, we ask three questions about international guidelines: 1) what discount rate(s) are recommended; 2) do they differ for costs and health outcomes; 3) what is the underlying theory for discounting and rationale for the rate(s)? **METHODS:** We review recommendations about discounting in international guidelines according to underlying theory used to recommend discounting, suggested rates, rationale for particular rates, whether a different rate was suggested for health outcomes, and what literature was cited. **RESULTS/CONCLUSION:** Australia, Canada, and Ontario recommend discounting costs and health outcomes at 5%, the US 3%, New Zealand 10%, and the Netherlands 4%, while the UK recommends 6% for costs and 1.5% for health outcomes. Most countries recognize the controversy, yet remain unconvinced that health outcomes should be discounted at different rates. While the primary stated underlying theory for discounting is time preference, the rationale (if provided) for the particular rates recommended varies across countries. Most often, it relies on empirical estimates of government bond rates and/or notions of international consistency reflecting potentially conflicting principles. Implicit appeals to measure pure time preference also exist; however, this may not be measurable if time and health are inextricably linked. Furthermore, some health outcome measures may already include individuals' time preferences potentially leading to double discounting. Implications will be discussed.

**PMA4****AN ECONOMIC PROOF AND APPLICATION THAT FORMULARY RESTRICTIONS WITHIN DRUG CLASSES ALWAYS RESULT IN HIGHER COSTS**

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Pharmaceutical benefit providers use restrictive formularies to control health care expenditures for drugs. One type of restriction requires the use of one drug before the use of another drug within the same drug. **OBJECTIVE:** Test the hypothesis that restrictive formularies lower expenditures for pharmaceuticals. **METHOD:** We use expected utility theory to derive equations for the restrictive and unrestrictive formulary cases where the equations take into account effectiveness (i.e., the probability of attaining treatment goal and not attaining goal), alternatives if treatment fails and costs of each scenario. Administrative costs are assumed zero. We prove mathematically that restrictive formularies within drug classes always cost more. Moreover, even if all drugs in the therapeutic class are equal in effectiveness and equal in cost,

the restrictive formulary will still always be more costly than the unrestrictive one. We then allow effectiveness and costs to vary and derive equation to calculate the cost of a restrictive formulary in those cases. We derive the equations for patients with various distributions of baseline severity. Last, we apply the equations and actual effectiveness and cost data to the case of atypical antipsychotics where Ontario and British Columbia Provincial formularies have mandated that risperidone be prescribed before quetiapine or olanzapine. **RESULT:** The cost of the restrictive status would range from \$0.87–0.97 per patient per day with mild symptoms treated with risperidone, \$2.65–3.30 for patients with moderate symptoms and \$5.14–5.73 for patients with severe symptoms. The range depends on effectiveness rates. Even if all drug costs were equal and the efficacy rates were all 80 percent, the cost per patient per day for the restrictive status of quetiapine would be \$0.66–0.71, \$1.12–1.41, \$1.67–2.26 for risperidone patient with mild moderate and severe symptoms. **CONCLUSION:** To our knowledge this is the first proof and practical application. Restrictions were removed in both provinces.

**PMA5****A RISK ADJUSTMENT METHODOLOGY FOR CLAIMS DATA**

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**OBJECTIVES:** To develop a risk adjusted outcomes measurement system that compensates for the lack of clinical information in the claims data by dividing diseases into different stages according to the severity at various stages of the disease progression and the presence of other conditions and procedures coded in the claims database. **METHODS:** The data sources used were Medicare and a large employer's claims databases, which covered approximately 12 million and 130 thousand hospitalizations per year respectively. Rigorous data validation processes were applied to ensure data validity. Our methodology was based on the research completed by JS Gonnella, et.al., (1987) "A Clinically Based Approach to Measurement of Disease Severity", sponsored by National Center for Health Services Research, which classified diseases and combinations of diseases into different stages according to severity. Our risk adjustment system applied this approach to the principle diagnosis, secondary diagnoses and procedures coded in the claims data, to derive severity measurements for each hospitalization. In addition, we adjusted for the number of body systems involved, patient age, gender and other factors. Outcomes measurement included mortality, potentially avoidable complications, length of hospital stay, total charges and total cost. For each DRG group, logistic regression and multiple regression models were developed from the Medicare claims data to create risk adjusted norms. Models were checked for statistical and clinical validity. **RESULTS:** The model outputs were applied to the large

employer's claims data to score each patient for each outcome measurement. The results allowed for multi-dimensional comparisons on quality measurements and resource utilization measurements for all the hospitals in the large employer's database. **CONCLUSIONS:** The uniqueness of our methodology was that it adjusted for severity of diseases at various stages and combinations of diseases and number of body systems involved. It provided a more accurate means for risk adjustment than currently available.

**PMA6****THE REDUCTION OF SAMPLE SIZE FOR A COST-EFFECTIVENESS TRIAL USING A NEW METHOD: THE EIGHT CASES IN JAPAN**

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At ISPOR's Third Annual European Conference, we presented a new formula that can naturally extend the traditional formula for sample-size calculation of a clinical trial, considering the cost-effectiveness ratios for two regimens A and B. **OBJECTIVE:** According to the formula, to explore applicability and validity of such a theoretical framework in real clinical trials, and then show the benefit which the new formula brings in terms of designing a prospective cost-effectiveness trial. **METHODS:** We searched and reviewed the published Japanese articles these ten years that reported socioeconomic evaluation of pharmaceuticals based on a clinical trial for two regimens: a new treatment and an old one. Subsequently we assessed the applicability and the validity of our formula in the context of such reviewed articles, and then if the formula could be applied, we calculated two sample sizes: considering effect only vs. cost-effectiveness. **RESULTS:** We reviewed eighteen Japanese articles which conducted cost-effectiveness analysis using modeling or retrospective cost evaluation after clinical trials except one prospective study. Of these eight were selected as applicable for our formula. In all of them we found that the sample size for one regimen, considering effect only vs. cost-effectiveness, can be reduced such as 1534 to 5 at the best, and 632 to 319 at the worst ratio. **CONCLUSION:** In the eight published Japanese studies, the sample size of each clinical trial considering effect only could actually be reduced if such studies are to be designed in advance as a prospective cost-effectiveness trial considering the difference of the cost-effectiveness ratios of two regimens.

**PMA7****CONTROLLING FOR BIASES FROM MEASUREMENT ERRORS IN HEALTH OUTCOMES RESEARCH USING STRUCTURAL EQUATION MODELING**

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**OBJECTIVES:** Measurement errors in independent variables may lead to attenuated estimates of their effects and may contaminate estimates for other covariates in conventional linear regression models (LRM). However, the direction and magnitude of these biases are difficult to determine theoretically. Measurement error is a serious problem in health services research as health status is a latent variable that can only be measured with error using proxy variables. This study empirically evaluated the validity of LRM models in health outcomes research. **METHODS:** SEMs with a latent health construct are proposed and compared with LRM models to examine the bias of measurement errors in general health status using data from a study of the impact of pharmacist's consultation on both health outcomes and costs (KP/USC study). Perceived health status at a given time point was modeled as a latent variable measured by the multiple scales of the SF-36. **RESULTS:** The latent health construct with multiple scales of the SF-36 and its SEMs for health outcomes and costs are empirically supported by the KP/USC data. SEM estimations of the latent health construct in both the measurement model and the structural model were all statistically significant with expected signs. As predicted, LRM estimates for the SF-36 scales were attenuated. However, there is no strong evidence that LRM estimations of treatment effect were contaminated by the measurement errors in the SF-36 or that the simultaneity between health outcomes and costs. **CONCLUSIONS:** Measurement errors in health status variables may result in attenuated estimates of health status effects on patient outcomes. Fortunately, careful study design can eliminate the contamination of treatment effect estimates due to errors in measuring health status. Moreover, SEM methods can be used to control both attenuation and resonance biases.

**PMA8**

### DEVELOPMENT OF A CHRONIC DISEASE INDICATOR USING A MANAGED CARE POPULATION

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**OBJECTIVES:** Accurate determination of disease prevalence in large patient populations is difficult. The objective of this research was to use pharmacy data to develop an index that estimates the presence and number of chronic diseases in a managed care population. **METHODS:** An expert panel evaluated 246 specific medication classes as to their likelihood to be indicative of a chronic disease. Those classes identified were then compared against medical records from two random samples of persons 18 years of age or older continuously enrolled for at least one year in a health maintenance organization. One sample was drawn from all eligible persons (n = 137), while the other sample was restricted to individuals

50 years of age or greater (n = 138). A cumulative number of chronic conditions was designated the chronic disease index (CDI). Sensitivity and specificity were calculated for those conditions with prevalence greater than 10% based upon medical record review. **RESULTS:** The expert panel designated 54 drug classes as containing medications used to treat chronic conditions. A total of 5640 medications were dispensed over a 1 year period for the 275 subjects. The average total number of chronic conditions via medical record review was 2.89 + 2.07, compared to 1.33 + 1.21 chronic conditions estimated by medication use. The CDI correlated well with the number of chronic conditions found via record review (r = 0.735, p < 0.0001). The specificity of pharmacy records to indicate the presence of hypertension, dyslipidemia, depression, and diabetes was 79.9%, 99.0%, 90.2%, and 99.6%, respectively. The sensitivity was 90.9%, 49.9%, 77.5%, and 62.2% for hypertension, dyslipidemia, depression, and diabetes, respectively. **CONCLUSIONS:** The CDI correlates well with documented chronic conditions. Pharmacy data can be useful in identifying persons with diagnoses of hypertension, dyslipidemia, depression, and diabetes.

**PMA9**

### BAYESIAN OR CLASSICAL DESIGN AND ANALYSIS: DOES IT MAKE A DIFFERENCE??

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**INTRODUCTION:** The utility of research results is measured primarily by its effects on decisions. Underpinning research are methods appropriate to the question or hypothesis. The role of Classical and Bayesian approaches remains in dispute in health services research. The goal of this study was to determine if results differ when both analytic techniques are used with the same dataset. **METHOD:** We searched MEDLINE and related databases for English-language articles published 1 January 1978 through 31 August 1999. We combined Bayesian and Classical statistics search terms, and their variants, with randomized control trials (RCTs) and meta-analyses. **RESULTS:** Searches found 18 studies in 14 publications that met all criteria for review—9 RCTs, 8 meta-analyses and 1 epidemiological estimate. Statistical analyses using both methods agreed in 5 RCTs, 4 meta-analyses, and for the epidemiological estimates. For 4 RCTs where results disagreed, Classical analysis the experimental intervention was efficacious compared to the control and Bayesian reanalysis concluded the experimental intervention was not proven efficacious. Classical meta-analyses of the four studies where results disagreed concluded the experimental intervention was not better than the control; Bayesian reanalysis concluded the intervention was efficacious. **CONCLUSION:** The conventional wisdom that Classical and Bayesian methods will give similar answers is not supported by this study. Disagreement on many fundamental beliefs between Classical and Baye-

sian statistics means continuing debate. One way to resolve this debate is for proponents of each technique to decide together the circumstances for use of each method and analytic framework. If the experts do not agree on the methodological requirements, other decision-makers likely will force their own views, driven mainly by other pressures like cost control.

#### PMA10

### DESCRIPTION OF COST/EFFECTIVENESS RATIO DISTRIBUTIONS

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**BACKGROUND:** Health economic evaluation systematically analyzes all inputs and outputs of treatment, and suggests the most effective alternatives for given resources. Results of a cost-effectiveness analysis are summarized in a series of cost-effectiveness (C/E) ratios. Little is known about the distributions of C/E ratio estimates. Hence, there is a lack of statistical tests for the C/E ratios. **OBJECTIVE:** This study is to describe the characteristics of C/E ratio distribution. Since the cost and effect distributions frequently follow the normal, lognormal, and gamma distributions, the ratio distributions are formed by some combination of them. **METHODS:** In describing the ratio distribution, the probability density functions (PDF) of the ratio distributions are derived if they exist. If the closed form of the PDF does not exist, the ratio distributions are presented graphically. **RESULTS:** First, the ratio distributions take on a variety of shapes depending on the coefficient of variation of their denominator distribution. Most of the time, the ratio distributions have the bell shape with, or without, a heavy right tail. However, the ratio distribution could even be bimodal if the coefficient of variation of denominator was very large. Second, the correlation between numerator and denominator of the C/E ratio significantly affects the distribution shapes and locations. Since the numerator and denominator are allowed to be correlated, this derived PDF is more general and practical than the Cauchy distribution. Third, the ratio distributions formed from the combination of gamma and lognormal distributions are all skewed to the right. **CONCLUSIONS:** The C/E ratio distributions are not always bell shape nor symmetric. The ratio distributions take on a variety of shapes depending on the coefficient of variation of their denominator distribution and the correlation coefficients between numerator and denominators.

#### PMA11

### COMPARISON OF STATISTICAL TESTS FOR THE COST/EFFECTIVENESS RATIOS

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**BACKGROUND:** Results of a cost-effectiveness analysis are summarized in a series of cost-effectiveness (C/E) ratios. As with other statistics, the C/E ratio is subject to sampling variation. However, constructing a confidence interval for the cost-effectiveness ratio is complicated because both numerator and denominator of the ratio are stochastic in nature. Several statistical methods have been proposed lately, yet, the systematic method of handling uncertainty is generally underdeveloped in economic evaluation. **OBJECTIVE:** This study is to compare the statistical methods proposed in constructing confidence intervals for the various ratio distributions, for the various correlation coefficients between numerator and denominator, for the various coefficient of variations, and the various sample sizes. **METHODS:** The ratio distributions are formed from the combinations of normal, log normal, and gamma distributions, which frequently arise in cost-effective studies. In evaluation the performance of statistical methods, a simulation study was conducted for the various ratio distributions. For each sample, the confidence intervals were constructed by five statistical procedures; the Box, Taylor's, Fieller's, bootstrap, and jackknife methods. **RESULTS:** First, since the ratio distributions are largely dependent on the distribution of its denominator, none of the statistical tests work if the mean of denominator is close to zero. Second, if the sample size is small, none of the statistical tests perform well enough regardless of correlation and coefficient of variation. Third, for the large sample size, all methods, except the box method, constructed the confidence interval well. Among them, Fieller's method is the first choice of selection for the estimation of the confidence interval. **CONCLUSION:** None of the statistical tests work if the mean of denominator is close to zero. This is problematic for Incremental Cost-effectiveness Ratio (ICER). If the "net effect" of the new procedure is insignificant, then the statistical test for the ICER is not stable.

#### PMA12

### RELATIONSHIP BETWEEN NONPARAMETRIC RECEIVER OPERATING CHARACTERISTIC ANALYSIS AND A LIKELIHOOD-RATIO TEST FOR MODEL SELECTION: I. A MONTE CARLO SIMULATION USING CONTINUOUS DATA

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**BACKGROUND:** Receiver operating characteristic (ROC) analysis is frequently used to assess the accuracy of diagnostic tests. The area under an ROC curve (AUC) is indicative of the extent to which a measure correctly classifies true-positive and true-negative subjects. DeLong et al. (Biometrics 1988; 44: 837-845) have proposed a method for comparing nonparametric ROC curves derived from the same set of cases. In a small study using data from a naturalistic investigation, DeLong's test yielded results that were consistent with those of a likelihood-ratio test for model selection developed by Vuong



(Econometrica 1989; 57: 307–333). **OBJECTIVE:** To confirm our previous findings, a Monte Carlo simulation was undertaken to assess the relative performance of DeLong's and Vuong's tests in samples of varying sizes. **METHODS:** One thousand observations were randomly generated for a Bernoulli dependent variable and 11 normally distributed independent variables. Bootstrapped estimates for AUC and logistic regression model log-likelihood (LL) were derived using 500 replications of sample size 10, 25, 50, 100, 175, 250, and 500. At each sample size, predictors were compared on the basis of AUC using DeLong's test and model LL using Vuong's test. The random number seed was set so that identical samples were compared with each test. **RESULTS:** In general, the two tests yielded similar statistical conclusions. The observed power of Vuong's test was slightly less than that of DeLong's test. There were only two cases in which the tests yielded different results, and these occurred in small samples. **CONCLUSIONS:** Though slightly less powerful than DeLong's test, Vuong's test may be applied in cases where the dependent variable has more than two levels. It is also easier and takes much less time to perform than DeLong's test. Given these advantages, Vuong's test may be preferred to ROC-based tests in larger samples.

**PMA13**

**RELATIONSHIP BETWEEN NONPARAMETRIC RECEIVER OPERATING CHARACTERISTIC ANALYSIS AND A LIKELIHOOD-RATIO TEST FOR MODEL SELECTION: II. A MONTE CARLO SIMULATION USING DISCRETE DATA**

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**BACKGROUND:** In a simulation using continuous data, we compared the performance of DeLong's test for nonparametric receiver operating characteristic (ROC) curves (Biometrics 1988; 44: 837–845) with that of Vuong's test for model selection (Econometrica 1989; 57: 307–333). Both tests were found to yield similar results regardless of sample size. Diagnostic tests are often measured on an ordinal rating scale, and nonparametric methods tend to underestimate the area under the ROC curve (AUC) when used with discrete data. Thus, it was conceivable that level of measurement might influence the performance of DeLong's test. **OBJECTIVE:** A second Monte Carlo simulation was performed to determine whether DeLong's and Vuong's tests behave differently when used with discrete data. **METHODS:** One thousand observations were randomly generated for a Bernoulli dependent variable and 11 binomial independent variables. The independents were generated such that realizations were integers ranging from 1–10. Bootstrapped estimates for AUC and logistic regression model log-likelihood (LL) were derived using 1000 replications of sample size 10, 25, 50, 100, 175, 250, and 500. At each sample size, predictors were compared on the basis of AUC using DeLong's test and model LL using Vuong's test. The random number seed

was set so that identical samples were compared with each test. **RESULTS:** In general, the two tests yielded similar statistical conclusions. Asymptotically, the observed power of Vuong's test was greater than that of DeLong's test. In smaller samples, however, Vuong's test was slightly less powerful. The results of the two tests diverged in only three cases in small samples. **CONCLUSIONS:** The results of this analysis correspond to those of our simulation using continuous data. Though slightly less powerful than DeLong's test, Vuong's test is more flexible and is less time consuming. Given the results of both simulations, Vuong's test appears to present a useful alternative to ROC analysis for comparing the accuracy of diagnostic tests.

**PMA14**

**BAYESIAN DECISION ANALYSIS IN OUTCOME STUDIES WITH SMALL NUMBERS OF EVENTS: A SIMULATION BASED PREDICTION APPROACH**

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**BACKGROUND:** Decisions are often based on relative risk and their asymptotic properties, which is not reliable when the number of events is small. Moreover, clinical decision-making primarily depends on individual risk of adverse outcome rather than relative risk. Bayesian decision analysis predicts individual outcome, is valid for small samples and can include decision-maker's prior knowledge into the analysis. **METHOD:** We analysed data about gastrointestinal adverse events of medium and high doses of ibuprofen in a population of 46,249 patients. We used a Bayesian method based on expected utility with a utility function  $EFF - q L(\text{No. Events})$ . Where EFF is the efficiency, L is a quadratic function representing the risk of Adverse Outcome and q represents relative importance of the risk. Bayesian value of information (VOI) of additional observations of a particular subgroup was calculated. Markov Chain Monte Carlo procedure and software BUGS were used to fit a Poisson regression model to adjust for confounders. **RESULT:** There were 1 and 5 G.I. events in high and medium dose groups (relative risks, RR 5.26 and 2.36 respectively). The Bayesian mean log-RR between high and medium was 0.41 (95%CI -2.72, 2.58). Assuming that the higher dose had 20% higher efficiency, we found that medium dose is preferable when q is larger than 15. VOI of additional observations was calculated for a range of q and showed that additional observations of the higher dose would be most valuable. For example, when  $q = 50$  the VOI of an additional subgroup of 1000 person-years exposure was 15% for high doses but only 3% for medium doses. **CONCLUSION:** In comparison with the classical approach for drug safety or other outcome studies, Bayesian methods provides much more information to assist decision-making, especially when the number of events is small.

**PMA15****CONDUCTING PHARMACOECONOMIC RESEARCH IN THE ABSENCE OF COUNTRY-SPECIFIC DATA**Miller B<sup>1</sup>, Rosner AJ<sup>2</sup>, Becker DL<sup>2</sup><sup>1</sup>Pharmacia Canada, Mississauga, ON, Canada; <sup>2</sup>Innovus Research Inc, Burlington, ON, Canada

In an ideal world, appropriate pharmacoeconomic evidence would be collected to meet the needs of the local reimbursement environment. Unfortunately, due to clinical research limitations and time constraints, we are often faced with a lack of the necessary data. **OBJECTIVE:** Using an anti-infective as our case study, we present an approach that we developed to overcome the challenge of creating an economic argument for Canadian hospital setting in the absence of country-specific data. **METHODS:** Our methodology involved a multi-step approach: (i) hospital formulary committee members were consulted to identify the submission requirements; (ii) a panel of experts were surveyed to understand local treatment patterns; (iii) the survey results were used in a case modeling exercise to determine the applicability of the randomized clinical trial (RCT) protocol to the Canadian environment; and (iv) a chart review was undertaken to validate results of the case modeling exercise. **RESULTS:** Hospital formulary committees preferred Canadian-specific evidence of a new product's economic value. Committee members were generally unfamiliar with pharmacoeconomic concepts and preferred that a complicated economic model not be used. Results of the expert survey indicated that there are important differences between the RCT protocol and Canadian treatment patterns. These differences include restrictive inclusion/exclusion criteria, an excess of protocol-driven tests and procedures, and treatment strategies that are not necessarily reflective of real-life. The case modeling exercise allowed for a structured method to hypothesize on the real-world impact of the product. An ongoing chart review will be used to confirm these hypotheses. **CONCLUSIONS:** It is anticipated that issues surrounding the absence of country-specific data will continue to plague researchers for the foreseeable future. Use of this multi-step approach provides a rigorous method for making conclusions in the absence of locally acquired evidence.

**PMA16****CONFIRMATION OF THE DECISION RULES AND ASSUMPTIONS FOR A MODEL OF DIABETES TREATMENT USING AN EXPERT PANEL**Caro J<sup>1</sup>, Salas M<sup>1</sup>, Ward A<sup>1</sup>, Sung J<sup>2</sup>, Shah A<sup>2</sup><sup>1</sup>Caro Research Institute, Concord, MA, USA; <sup>2</sup>Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA

**OBJECTIVE:** To assess systematically, using a panel of physician experts, the assumptions made for a pharmacoeconomic model regarding the indications, treatment initiation and decision rules for management of type 2 dia-

betics. **METHODS:** The panel consisted of 7 physicians (three family physicians, two internists and two endocrinologists) who were randomly selected from a pool of high-volume prescribers. The panel was contacted by phone and upon acceptance, they were mailed a 63-item questionnaire cover clinical criteria for treatment management, adherence to diabetes guidelines, decision rules for failure treatment, resource use and tests requested for drug-naïve and previously treated patients. The questionnaire was developed based on literature review and pilot-tested between two clinicians for appropriateness. The ratings were done using a 5-item Likert scale ranging from "strongly agree" to "strongly disagree". **RESULTS:** All participating physicians completed the questionnaire. Endocrinologists and internists follow the American Diabetes Association guidelines (ADA). Only two family physicians use the ADA guidelines. The main assumptions for the pharmacoeconomic model coincided with the experts' opinion, such as the initial treatment for a drug-naïve type 2 diabetic patient is monotherapy and after its failure an increased dose followed by addition of another treatment is recommended. Treatment adjustment is based on glycosylated hemoglobin, post-prandial glucose or fasting plasma glucose. For any treatment changes, patient should visit physician office but they are not usually hospitalized. The presence of side effects is an indication to decrease the dose. Number and type of laboratory tests are independent of drug-naïve status. There are no differences in the criteria used for treatment selection and treatment changes between drug-naïve patients and previously treated patients. Furthermore experts do not recommend switching medications. **CONCLUSIONS:** An expert panel is a useful tool to assess model assumptions.

**PMA17****THE EUROPEAN SERVICE MAPPING SCHEDULE (ESMS): A NEW INSTRUMENT FOR MENTAL HEALTH SERVICES RESEARCH, RESULTS OF A FRENCH STUDY**Azorin JM<sup>1</sup>, Goudemand M<sup>2</sup>, Toumi M<sup>3</sup>, Johnson S<sup>4</sup>, Pettersson Å<sup>3</sup><sup>1</sup>CHU Sainte Marguerite, Marseilles, France; <sup>2</sup>Centre Hospitalier USNB, Lille, France; <sup>3</sup>Lundbeck SA, Paris, France; <sup>4</sup>Whittington Hospital, Department of Psychiatry & Behavioural Sciences, London, UK

**OBJECTIVES:** When comparing patient management and patient outcomes, the available services within a catchment area appear to be a major confounding factor. The ESMS aims to classify services and measure their activity in a standardized way, which opens new opportunities to adjust for service offer. The ESMS allows to map the services available in a set of catchment areas and to identify different profiles. In addition we evaluate the accuracy of the French standardized classification of mental health services and the applicability of the instrument in France. **METHODS:** 171 services in 24 catchment areas

were involved in the study, which focused on the French public mental health care system. Each service was classified according to the ESMS and data were collected on service use. The data for each catchment area were aggregated in residential use, structured day activities, continuous out patient care and emergency out patient care, then a cluster analysis was performed. The ESMS classification of the services based on function was compared to the official French description of services. **RESULTS:** Four classes were identified: Class 1 high activity in all services, class 2 low activity in all services, class 3 low activity in continuous ambulatory care, class 4 high activity in continuous ambulatory care. The ESMS confirmed the consistency between the French official description of the services' missions and the actual activity. 10% of the services had at least one additional "non official" function. The study showed that the ESMS was adapted for use in France, but it requires expert supervision for large-scale implementation. **CONCLUSIONS:** The ESMS proves to be useful not only in mental health service research, but can also bring the possibility to adjust for the catchment area's service profile in outcomes research.

PMA 18

**THE AVANDIA WORLDWIDE AWARENESS REGISTRY (AWARE®): AN INTERNET-BASED PROGRAM FOR EVALUATION OF CLINICAL, HUMANISTIC AND ECONOMIC OUTCOMES OF PATIENTS WITH TYPE 2 DIABETES**

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AWARE® is an Internet-based database designed to capture clinical and humanistic outcomes from diabetes practice settings around the world. The main goal of AWARE® is to better understand how patients with type 2 diabetes respond to different treatments in a naturalistic environment. **OBJECTIVE:** To describe an innovative method of collecting clinical, humanistic and economic outcomes of patients with type 2 diabetes in a "real world" practice setting. **METHODS:** The data collection methods involve the electronic linkage of clinical information and humanistic outcomes of patients with type 2 diabetes. Patients at least 18 years of age who are maintained on oral antidiabetic therapy are eligible to participate in AWARE®. As providers enter patients' clinical information into the patient's electronic medical record, the data elements of interest are automatically transmitted to a secure Internet site (Pharmacon EB-Health™) where the data are stored and continuously updated. Data collected in AWARE® include: demographic information, prescription use, HbA1c, fasting plasma glucose, total cholesterol, triglycerides, LDL, HDL, blood pressure, liver function tests, the SF-36, and the Diabetes and Treatment Satisfaction Questionnaire (DTSQ). Every six months, participants use hand-held devices to complete the elec-

tronic versions of the SF-36 and the DTSQ. The results from these surveys are instantaneously transmitted via wireless technology to EB-Health™. **CONCLUSION:** AWARE® permits immediate retrieval of clinical and humanistic information from an Internet-based registry. Information on the patient's clinical progress may be continuously transmitted to EB-Health™, allowing researchers, clinicians and administrators to perform "real time" analyses of the clinical effectiveness of antidiabetic therapy, as well as to determine its impact on patients' quality of life and satisfaction with treatment. As AWARE® is expanded to sites around the US and throughout the world, it will provide valuable information on the impact of the different treatments for type 2 diabetes on patients' clinical, humanistic and economic outcomes.

## CONTRIBUTED WORKSHOP PRESENTATIONS

WW 1

**METHODOLOGICAL COMPLEXITIES IN USING ADMINISTRATIVE CLAIMS DATABASES TO EVALUATE QUALITY OF CARE FOR ATTENTION-DEFICIT/HYPERACTIVITY DISORDER**

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**OBJECTIVES:** Attention-deficit/hyperactivity disorder (ADHD) is one of the most prevalent of childhood mental disorders, and represents the most common reason children are referred to mental health providers.

**PARTICIPANTS WHO WOULD BENEFIT:** Researchers who use large-scale administrative databases to evaluate quality of care for mental disorders and associated patient outcomes. Purchasers of health care who provide health services to patients with psychiatric disorders.

The presence of the disorder is associated with substantial health resource utilization and costs. Although evidence-based guidelines for the pharmacologic treatment of ADHD are widely available, little is known about variation in provider prescribing practices, patient compliance, and attendant patient health outcomes. This is especially problematic because psychostimulants, commonly prescribed for ADHD as a daily regimen, are frequently taken solely on an "as needed" basis to improve behaviors during school hours. We are currently conducting a program of research using large-scale, national, integrated pharmacy benefits and medical claims databases to examine the quality of ADHD pharmacologic care, patient compliance, and associated patient outcomes. The objectives of this workshop are to discuss the complexi-