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Contributed Presentation Abstracts

CONTRIBUTED PODIUM PRESENTATIONS

ECONOMIC METHODOLOGY ISSUES

EM1

RISK ATTITUDE: ASSOCIATION WITH MAGNITUDE OF RISK AND PATIENT CHARACTERISTICS

Singer ME, Beaird H, Miller LAN
Case Western Reserve University, Cleveland, OH, USA

BACKGROUND: Decision analytic models typically compare strategies using expected values, which assumes risk neutrality in all situations for all individuals. **OBJECTIVE:** Examine how risk attitude is affected by the magnitude of the risk involved, and by the sociodemographic characteristics of the patient. **METHODS:** A set of 5 related standard gambles was created. In all of them the patient has an asymptomatic disease that will cause painless death in 5 years. The only treatment is a pill that only works if taken immediately. If successful, the patient will live for 15 years. The 5 scenarios correspond to 0–4 years until death in the event of treatment failure. The probability of failure was varied to establish the break-even point. The expected break-even point was calculated based on expected values. Risk attitude was measured using the Risk Attitude Ratio (RAR), the ratio of the individual's break-even point to the expected break-even point. RAR = 1 indicates perfect risk neutrality, with lower values indicating risk adversity. Regression models for each scenario were constructed for RAR, with regressors based on age, race, sex, education, income and marital status. Additionally, a hierarchical linear model was constructed using data from all 5 scenarios. **RESULTS:** 167 people were surveyed. Significant risk adversity was observed in all scenarios. Mean break-even points ranged from .07–.35. When treatment failure meant immediate death, risk aversity was great with no statistically significant associations. As time until death increased, RAR increased (less risk averse) and was associated with sex, race and marital status. These associations were upheld in the overall model. Males and the previously married were less risk averse. African-Americans were more risk averse. **CONCLUSIONS:** Risk attitude varies according to the specifics of the gamble as well as sociodemographics. Assumptions of risk neutrality may be particularly poor in cases where treatment failure carries a severe penalty.

EM2

THE IMPACT OF HOSPITAL COSTING METHODS ON STATISTICAL POWER IN MULTINATIONAL CLINICAL TRIALS

Reed SD[1], Friedman JY[1], Malenbaum JH[1], Gnanasakthy A[2], Schulman KA[1]
[1]Duke Clinical Research Institute, Durham, NC, USA; [2]Novartis Pharmaceutical Corporation, East Hanover, NJ, USA

OBJECTIVE: In multinational trials, hospital costing is estimated by assigning diagnosis- and country-specific unit cost estimates to hospitalizations. Using this methodology, the standard error for hospitalization costs is underestimated. Our objective is to expand methods for international hospital costing to increase the validity of hospitalization costs and to explore the effects of using different methodologies on statistical power. **METHODS:** In this analysis, 'standard' costing methodology assigns a fixed cost to each hospitalization. The 'expanded' methodology involves: (1) using DRG weights to adjust country-specific cost estimates for diagnoses for which cost data were not collected; (2) differentiating between costs that occur on the day of admission and all remaining hospital days; and (3) adjusting cost estimates by length of stay for each hospitalization. Using data from a subset of placebo-treated patients enrolled in a multinational study of a new treatment for heart failure, we compared estimates of total hospitalization costs using 'standard' and 'expanded' methodologies. **RESULTS:** Total hospitalization costs were estimated for 200 patients who had at least one hospitalization during the follow-up period (mean = 1.42). Using 'standard' and 'expanded' methods, average total costs were $5,911 and $5,881, respectively. The corresponding standard errors were $269 and $417, an increase of 55% resulting in a loss of power. Assuming homoskedasticity, equal sample size, $P = 0.05$, 2-sided t-test, and a $500 difference in costs, one would have 25.7% power using 'standard' costing methods but only 13.5% when using 'expanded' methods. With a $1,000 difference, one would have 74.5% and 39.3% power, respectively. **CONCLUSIONS:** The results of a cost comparison between treatment strategies can be affected by the methodology used to calculate costs. Studies that consider the intensity of hospital care, or that consider the variability in resource utilization, require a larger sample size than studies that don't consider these issues to have equal power.

EM3

RESPONSE BIAS AMONG LIKELY CLINICAL TRIAL PARTICIPANTS

McDonnell DD, Donohue JA
Consumer Health Sciences, Princeton, NJ, USA

OBJECTIVE: To understand the demographic, attitudinal, behavioral, and clinical characteristics of people who are likely to participate in clinical trials. **METHODS:** Analyses were based on a 12-page questionnaire mailed to U.S. adults in 2000. A total of 21,986 responses were received. Respondents were nationally representative based on gender, age, race, and geographic region; results were subsequently weighted and projected to the U.S. population. Participants were asked if they had ever participated in a clinical trial and whether they would ever consider participating in one. **RESULTS:** Among those who never participated in a clinical trial, 33% said they would strongly consider participating in the future. This group differed in some dramatic ways from the 26% who said they would definitely not consider participating in a clinical trial. For example, those who would participate were more likely to be female (55% v. 49%), younger (43 v. 47 years), and white (77% v. 70%). Behaviorally, likely participants were more likely to drink alcohol (64% v. 55%), smoke (27% v. 22%), visit physicians (4.0 v. 3.6 visits in six months), and use the internet for health care information (13% v. 6%). Attitudinally, those willing to participate were more likely to harbor alternative health care attitudes (e.g., "would try acupuncture" 38% v. 17%) and less likely to be satisfied with their current medical care (39% v. 47%). Clinically, they were more likely to be diagnosed with a range of comorbid medical conditions such as depression (15% v. 6%), migraines (16% v. 8%), and nasal allergies (32% v. 21%). **CONCLUSION:** People who are likely to participate in clinical trials look, think, and behave differently than those who are not likely to participate. Trail design and analysis should consider these differences and their possible impact on clinical, economic, and humanistic outcomes.

EM4

CAN UNIT COSTS BE COMPARED ACROSS WESTERN EUROPEAN COUNTRIES?

Brown R[1], Hutton J[2], Nuijten M[3]
[1]MEDTAP International Inc, Bethesda, MD, USA; [2]MEDTAP International Inc, London, UK; [3]MEDTAP International, Jisp, Netherlands

OBJECTIVE: It is well documented that resource consumption and costs vary across settings. Unit costs can also vary. Using consistent cost-finding methods across and within five Western European (WE) countries unit costs of cardiovascular procedures were compared to examine the degree and impact of variation. **METHODS:** Unit cost data were collected from fee schedules, national averages and selected individual institutions. A bottom-up costing approach was used in hospitals based upon a definition of resources consumed for procedures. Hospital daily rates were calculated from an allocation of overhead accounts and a basic package of services such as nursing, housekeeping, dietary and pharmacy services. Costs were obtained in the local currency and converted directly to Euros. **RESULTS:** Unit cost variation was observed within and across countries. UK costs for percutaneous transluminal coronary angioplasty (PTCA) in 13 centers ranged between 1380 and 2700 Euros, 0.75–1.5 times the median. Inter-country cost variation for the same procedure ranged between 1850–4000 Euros, 0.60–1.3 times the median. Daily hospital general ward rates vary inter-country between 0.8 and 1.6 times the median, comparable to within country variation. Physician ambulatory visit costs from fee schedules that may not reflect actual costs were standard within country but varied across countries (0.5–1.2 times the median of 18 Euros). When applied to a consistent set of resources, differences in costs resulted in widely varying cost-effectiveness (CE) ratios by country. **CONCLUSIONS:** Obtaining comparable unit costs within countries is difficult. Center-specific costing is most reliable, but expensive and must be representative for submissions to national level health authorities. With standardized costing methods, the differences observed here cannot be explained by differences in accounting. Extreme care must be taken when transferring the results of CE analyses between centers, especially between countries.

MEDICAL DEVICE & DIAGNOSTICS

MD1

COST-EFFECTIVENESS OF AIRLINE DEFIBRILLATORS: IS PEACE OF MIND MORE IMPORTANT THAN SAVING LIVES?

Cram P[1], Vijan S[1], Wolbrink AM[2], Fendrick AM[1]
[1]University of Michigan, Ann Arbor, MI, USA; [2]Federal Aviation Administration, Oklahoma City, OK, USA

OBJECTIVES: Airline passengers are particularly vulnerable to the effects of cardiac arrest due to a lack of access to emergency medical services. To offset this isolation, airlines are installing automated external defibrillators (AEDs) on aircraft. Our objective was to measure the cost-effectiveness of airline AED programs and estimate their value to the flying public. **METHODS:** A decision analytic model was constructed to estimate the clinical and economic effects of airline AEDs. Inputs were obtained from published data and the FAA. Utility estimates were derived from cardiac arrest survivors. Sensitivity analyses evaluated changes in AED cost and probability of cardiac arrest. Since AEDs may provide utility gains through "peace of mind" for passengers not experiencing a medical event, the impact of this added passenger confidence was also evaluated. **RESULTS:** AEDs on commercial aircraft cost an incremental $5.16 per flight. AED deployment resulted in an estimated ad-

ditional $162,000 per QALY gained (16 quality-adjusted minutes per flight). Sensitivity analysis of event probabilities and cost inputs did not substantially change the results. However, the cost-effectiveness of AEDs was significantly enhanced by the inclusion of utility gain experienced by passengers from increased peace of mind. While the magnitude of this benefit is unknown, an incremental increase of .003 in utility over the flight duration would reduce the incremental cost-effectiveness of AEDs to less than $50,000 per QALY gained. **CONCLUSIONS:** Our model estimated that when the benefits of on-board AEDs are limited to patients experiencing medical events, the incremental cost-effectiveness is inferior to most recommended medical interventions. However, if passengers gain utility from knowing an AED is on the aircraft, then these incremental expenditures may be justified. Utility gains from "peace of mind" may have significant implications in determining the value of health care interventions. Further research should be conducted into this potentially important area.

MD2

ANALYSIS OF THE IMPACT OF ASSISTIVE LIVING DEVICES ON SELF-ASSESSED HEALTH STATUS RATING

Rodney AB, Xiao H, Robertson T
Florida A&M University, Tallahassee, FL, USA

OBJECTIVE: Persons with limitations in Activities of Daily Living (ADLs) generally report a greater sense of independence when they have the use of assistive devices. Insurance companies have traditionally been reluctant to cover the cost of such devices, considering them to be non-essential equipment. Although the economic cost savings associated with a decrease in the need for external caregivers and institutionalization are calculable, the psychological benefits arising from this greater degree of independence seen in patients who use assistive devices tends to be overlooked. Therefore the main objective of this project was to determine the impact of assistive living devices on patients self-rated health status. **METHOD:** Medical Expenditure Panel Survey (MEPS) Household Component file 1998 P2R3/P3R1 was utilized for this project. The initial pool of 25,000 cases was narrowed using the inclusion criteria whereby all subjects must be 65 years or older, and have coded that they possessed one or more physical disabilities or limitations. This led to a final sample size of 1,025. Information on demographics, socioeconomic status and level of disability was extracted from the database for these patients. Multiple regression analysis was conducted with self-rating of health status serving as the dependent variable. The primary independent variable of interest was use or non-use of assistive living devices. Secondary independent variables included: marital status, sex, age, race, educational level, physical disabilities and limitations, and social limitations. **RESULTS:** Use of assistive devices, race, age, some forms of physical limitations and levels of education were significant in this model ($p < 0.05$). Marital status and gender proved to be insignificant factors. **CONCLUSIONS:** Use of assistive devices does have an impact on the way in which individuals with limitations and disabilities view their health status and therefore may be important contributors to their overall quality of life.

MD3

THE DIAGNOSTIC ACCURACY OF 18FDG-PET IN PATIENTS WITH RECURRENT PAPILLARY OR FOLLICULAR THYROID CANCER: A SYSTEMATIC REVIEW

Hooft L, Hoekstra OS
University Hospital Vrije Universiteit, Amsterdam, Netherlands

OBJECTIVES. Positron Emission Tomography with 18F-fluorodeoxyglucose (FDG-PET) is a new nuclear imaging technique that can detect recurrent or metastatic thyroid carcinomas. We conducted a systematic review to determine the diagnostic accuracy of FDG-PET in patients with papillary and follicular thyroid carcinoma. **METHODS.** Two unblinded reviewers independently selected, extracted and assessed data from relevant literature. Included studies were prospective or retrospective with 10 human subjects or more that evaluated the accuracy of FDG-PET in follicular and papillary thyroid cancer. Reviews, case reports, editorials, letters, and comments were excluded. The methodological quality of the included studies was assessed by the criteria for diagnostic tests recommended by the Cochrane Methods Group on Screening and Diagnostic Tests. A qualitative analyse was conducted to assess the value of FDG-PET in thyroid carcinoma. The rating system consisted of four levels of scientific evidence (1 = best; 4 = worst). **RESULTS.** Two of the fourteen included studies were considered of level 3 evidence. The other twelve studies provided level 4 evidence. Most prevalent methodological flaws regarded validity of reference tests and blinding of test interpretation. The overall conclusion in these studies was that FDG-PET appeared beneficial in patients with elevated thyroglobulin levels and negative 131I WBS. **CONCLUSIONS.** In conclusion, although FDG-PET may solve clinical problems in selected patients suspected of recurrent thyroid cancer, the present evidence does not allow for implementation of a routine diagnostic algorithm. Future studies should be designed to avoid the limitations presented in this review.

MD4

INCLUSION OF INDIRECT COST IN ECONOMIC OUTCOMES ANALYSES OF MEDICAL DEVICES: HOW IMPORTANT IS IT?

Subramanian S, Justason BJ
Boston Scientific Corporation, Natick, MA, USA

OBJECTIVE: To evaluate the impact of indirect cost (due to absence from work, disability, mortality) in economic evaluations comparing minimally invasive proce-

dures using devices to conventional open surgery. Indirect cost savings benefit patients, employers and society as a whole and therefore are important costs to consider. **METHODS:** We searched the literature and identified studies in which "indirect cost", "convalescence" or "work loss" were included in the analysis. All articles published since 1990 on menorrhagia (laparoscopic hysterectomy/endometrial ablation versus open hysterectomy), Gastroesophageal Reflux Disease (GERD) (laparoscopic versus open Nissen fundoplication), and coronary artery disease (Percutaneous Transluminal Coronary Angioplasty (PTCA) versus Coronary Artery Bypass Graft (CABG) surgery) were reviewed. Key information abstracted included: days of work lost, direct and indirect cost estimates, costing methodology, and follow-up period. The percentage impact, measured as the change in the difference between the total cost of open surgery compared to the less-invasive procedure due to the inclusion of indirect cost, was calculated. **RESULTS:** The review produced 11 articles on menorrhagia, 5 on GERD, and 5 on coronary artery disease. There were large differences in the average days of work loss between open surgery and less-invasive procedures; 21 days for laparoscopic versus 40 days for open hysterectomy, 15 days for laparoscopic versus 35 days for open fundoplication, and 27 days for PTCA versus 74 days for CABG. The percentage impact or difference in total cost due to the inclusion of indirect cost was on average 32.8% (4.4%–69.4%). **CONCLUSIONS:** Cost savings associated with minimally invasive surgery compared to open surgery are significantly increased when indirect costs are included in the assessment. Future economic outcome studies should attempt to include indirect cost measures to fully capture the benefits of devices and minimally invasive procedures.

QUALITY OF LIFE & PREFERENCE-BASED MEASURES

QL1

DOES SOCIOECONOMIC STATUS AFFECT THE VALUATION OF HEALTH?

Asada Y[1], Stout NK[1], Kind P[2]
[1]University of Wisconsin, Madison, WI, USA, [2]University of York, York, UK

OBJECTIVE: The issue of whose values count in the evaluation of health interventions is central to decision-making in all health care systems. Within the health services research community there is a degree of consensus that population-based preference weights should be used as the quality-adjustment factor in determining the value of health outcomes. However, previous research indicates an inverse, graded relationship between socioeconomic status (SES) and an individual's own health. If SES is also found to influence the valuation of hypothetical health states, then this could prove to have significant consequences for the evaluation of treatment. **METHODS:** Values for hypothetical health states defined by EQ-5D (a generic measure of health-related quality of life) were collected from a representative survey of the UK general population. 2,997 individuals used time trade-off (TTO) methods to value these EQ-5D health states. Information on each respondent included age, gender, social class and educational attainment. TTO values were bounded and non-normally distributed necessitating methods such as ordered logistic regression in addition to OLS to analyze these data. **RESULTS:** Education and social class as proxies for SES were significant predictors of the mean values for hypothetical health states. Their influence on health state valuation appears to act through their interaction with the mobility and self-care dimensions of the EQ-5D. This relationship persists after adjustment for respondent demographic characteristics. **CONCLUSIONS:** Valuation of hypothetical health states appears related to SES. This has implications for cost-effectiveness analysis since valuations from one population with a particular SES distribution may not be applicable for health policy and medical decision-making in other populations. The relationships between SES and health state valuation merit further investigation, in particular to examine the impact of non-health consequences such as income on values.

QL2

LOGICAL CONSISTENCY AND THE VALUATION OF HEALTH: AN ANALYSIS OF US SURVEY DATA

Craig BM[1], Kind P[2]
[1]University of Wisconsin, Madison, WI, USA; [2]University of York, York, UK

OBJECTIVES: It is widely held that values of the general public should be used in the evaluation of health care. Surveys designed to record such values involve the participation of individuals with different health experiences and with different socioeconomic backgrounds. The technical performance of these participants is likely to vary as a function of these factors, for example the logical consistency of responses is often associated with socioeconomic status. This paper examines the relationship between logical consistency and respondent health using US survey data designed to capture values for states defined by the EQ-5D classification. **METHODS:** A standardised questionnaire was used to elicit valuations for EQ-5D health states in a postal survey conducted by Johnson et al (1998, Pharmacoeconomics) in Arizona in which US respondents (N = 905) rated eight states along a visual analog scale from best to worst imaginable health. A logical ordering is defined for 23 unique pairs of states in that one state dominates the other over all 5 dimension of the EQ-5D. A logical inconsistency was noted when a respondent assigned a lower value to the "better" state in such a pair. Censored regression models were used to assess the relationship between consistency and respondent health. We tested the robustness of these findings using survey data from Wisconsin, which applied the same

questionnaire (N = 222). **RESULTS:** From the best imaginable state, each 20-point decrement in respondent's self-rated health status yielded significantly greater inconsistency in their valuation of EQ-5D health states controlling for age and sex. Inclusion of education and income reduced this effect slightly, yet it remained statistically significant. **CONCLUSIONS:** Respondents in poor health demonstrate greater difficult in valuing health states in a logically consistent manner. Censoring survey data to remove inconsistent respondents may violate the principle of using representative population values in evaluating cost-effectiveness of health care.

QL3

QUALITY OF LIFE IN PRODUCT LABELING: A REVIEW OF MARKETED DRUG PRODUCTS

Chopra T[1], Shah SN[1,2], McLaughlin-Miley C[2], Hinton J[2]
[1]University of Michigan, Ann Arbor, MI, USA;
[2]Pfizer Pharmaceuticals Group, Ann Arbor, MI, USA

Increasingly over the past several years, quality of life and patient-reported outcomes data have been submitted as part of NDA and sNDA packages to US and International regulatory agencies. These data provide important information to prescribing clinicians and patients regarding therapeutic and humanistic benefits of drug therapy. **OBJECTIVES:** To evaluate the marketed drugs with the terminology 'quality-of-life' in the product labeling. **METHODS:** A search of the Physician Desk Reference database was conducted to identify those products that included the term "quality-of-life" (QoL) within the Physician Package Insert. The Summary Basis of Approval (SBA) of each product was reviewed to evaluate the research processes followed, use of psychometrically validated instruments, and the final resulting language attained within the labeling with respect to QoL. **RESULTS:** Twenty-two products referencing the term "quality-of-life" in the product labeling were identified. FDA approval of these products occurred mainly in the years from 1982 to 2000 with increasing frequency of QoL inclusion in recent years. Upon SBA review we found the majority of the products (13/22) utilized a validated instrument during clinical investigations. Only one of the 22 SBAs specifically described and discussed the issue of instrument validation. In the early years approved labeling claims included more broad, sweeping terminology when describing QoL results. In more recent, cases, approved QoL labeling claims were more narrowly defined and more rigorously worded with respect to trial results and specific patient-reported instruments. **CONCLUSION:** Over the course of the time, the approach has become more rigorous resulting in a more refined QoL research process. These findings have demonstrated that the use of QoL descriptive data has increased, particularly a greater degree of comprehensive information pertaining to QoL instruments, research, and data can be found in the SBAs. Hence, more relevant and specific QoL information is claimed in the Physician Package Insert.

QL4

QUALITY OF LIFE MESSAGES IN PRESCRIPTION DRUG ADVERTISEMENTS IN LEADING MEDICAL JOURNALS, 1990–99

Zivin K, Neumann P
Harvard School of Public Health, Boston, MA, USA

OBJECTIVES: The use of health-related quality of life (HRQL) claims in drug promotions is under active discussion by the pharmaceutical industry, the FDA, and other stakeholders. However, the extent to which pharmaceutical companies have previously promoted HRQL messages in advertisements in medical journals, and the nature of those messages, has not been quantified. **METHODS:** We performed a content analysis of all pharmaceutical advertisements appearing in three general medical journals (AIM, JAMA, and NEJM), and three specialty journals (Circulation, Gastroenterology, and Neurology) in January, July, and October annually from 1990–1999. Two reviewers analyzed each advertisement for the presence and type of HRQL content, and for supporting evidence. We distinguished explicit HRQL claims, which used words, such as "quality of life or "patient satisfaction," from implicit claims, which we defined broadly as pictures implying improved physical, emotional/mental, or social functioning. **RESULTS:** We judged that HRQL messages appeared in 520 (24.3%) of 2142 advertisements examined. Advertisements with HRQL content increased from 1990–94 to 1995–99 (19.9% vs. 29.6%, $p < 0.0001$). 56% of HRQL contained implicit messages only, followed by ads that used both implicit and explicit messages (35%), and ads containing explicit messages alone (9%). Overall, few ads (12%) contained any clear supporting evidence. Messages that implied or stated improved overall well-being or mental health were most common (78% of all HRQL ads), followed by enhanced physical or social functioning (63% and 25%, respectively) (numbers add to >100%, because a single ad could contain multiple messages). **CONCLUSIONS:** Advertisements conveying HRQL messages are used frequently by drug manufacturers in medical journals, and are increasing over time. In the future, researchers should better define HRQL, and probe more deeply into what comprises substantiating evidence, perhaps by incorporating the concept of "patient-reported outcomes."

HEALTH POLICY

HP1

ETHNIC DISPARITY OF COMBINATION RIBAVIRIN/INTERFERON ALFA-2B PRESCRIBING AMONG HEPATITIS C-INFECTED MEMBERS IN A MANAGED CARE ORGANIZATION (MCO)

Phillips AL[1], Schaffer M[2], Mansukani S[2]
[1]Thomas Jefferson University, Philadelphia, PA, USA;
[2]Health Partners Inc, Philadelphia, PA, USA

Approximately 2.7 million Americans have active Hepatitis C infection. Combination therapy with ribavirin and interferon alfa-2b has emerged as the treatment of choice for Hepatitis C. **OBJECTIVES:** To determine if the prescribing of combination therapy differed among ethnic groups in Hepatitis C-infected members during calendar year 1999 in a Medicaid MCO. **METHODS:** Hepatitis C-infected patients were identified from a database of continuously enrolled members of an inner-city Medicaid MCO in Philadelphia using ICD-9 codes indicative of Hepatitis C (070.41, 070.44, 070.51, 070.54, 571.40, 571.41, V02.60, V02.62). From this population, members who received combination therapy with ribavirin and interferon alfa-2b were identified and demographic information was obtained. Variation in the prescribing of combination therapy among ethnic groups was assessed using a Chi-square test. **RESULTS:** From a cohort of 73,869 members, 395 members (0.535%) had an ICD-9 code for Hepatitis C. Of those, 60 members had pharmacy claims for combination therapy during 1999. These members aged from 23 to 64 years (mean age = 45.0 yrs; SD = 7.6). Based on the ethnic distribution of the 395 members with an ICD-9 code for Hepatitis C, 8.4% (16/191) of African-Americans were prescribed combination therapy compared with 23% (28/122) of Caucasians, 22.7% (15/66) of Latinos and 14.3% (1/7) of Asian-Americans. A statistically significant difference in the prescribing of combination therapy was noted among ethnic groups ($p < 0.05$). **CONCLUSIONS:** Within this Medicaid MCO, a disproportionately low percentage of African–American members received combination therapy for Hepatitis C during 1999. It is unknown whether this was due to a disproportionate number of contraindications in this group, inequitable prescribing habits of physicians, cultural barriers preventing consent for treatment, or noncompliance with obtaining the medication. Further investigation is needed to determine why this disparity exists so that differences in treatment among ethnic groups may be minimized.

HP2

THE ROLE OF OUTLIER PAYMENTS IN MEDICARE PATIENTS WITH SEVERE SEPSIS

Cooper LM[1], Linde-Zwirble WT[2]
[1]Eli Lilly and Company, Indianapolis, IN, USA; [2]Health Process Management, Owings Mills, MD, USA

INTRODUCTION: Medicare is required to set outlier threshold so that outlier payments are between 5 and 6 percent of total DRG payments to offset extraordinarily high-cost cases. Severe sepsis (SS) is a condition affecting patients in many DRGs. High mortality and resource use in SS patients increases the likelihood of reimbursement under the outlier mechanism. We explore the role of outlier payments for SS in Medicare. **METHODS:** We examined all 1999 Medicare discharges age 65+ in prospective payment hospitals. Cost, reimbursement, and outlier payments were identified for each discharge. SS was identified by the presence of ICD-9-CM codes for acute organ failure and bacterial or fungal infection. DRGs were classified into six groups by post-operative status (medical and surgical) and by frequency of SS (high risk, high volume, remaining). **RESULTS:** Of 9,248,277 records, 384,680 (4%) were reimbursed through the outlier mechanism, reflecting 6% of total payments. SS patients represent 25% of all outliers, with an average cost per outlier case of $44,724. The average cost for non-sepsis outliers per case is $35,098. Twenty-two percent of all sepsis cases are reimbursed as outliers. While overall cases are reimbursed at 95% of reported costs, SS cases are reimbursed at only 85% of costs. SS outliers are reimbursed at only 70% of reported costs with especially low reimbursements for high volume medical SS outlier cases (54%). Overall, SS high risk medical and surgical cases are reimbursed at higher levels (103% and 78% respectively). **CONCLUSIONS:** While severe sepsis cases are only 4.7% of all Medicare discharges, almost one in four are outliers. Current outlier payments do not adequately compensate for the cost of care of most SS patients.

HP3

INCORPORATING CLINICAL OUTCOMES AND ECONOMIC CONSEQUENCES INTO DRUG FORMULARY DECISIONS: EVALUATION OF 30 MONTHS OF EXPERIENCE

Atherly DE[1], Sullivan SD[1], Fullerton DS[2], Sturm LL[2]
[1]University of Washington, Seattle, WA, USA; [2]Regence BlueShield, Seattle, WA, USA

BACKGROUND: In January 1998, Regence BlueShield, a 1.2 million-member health plan, implemented a novel formulary submission process intended to improve clinical decision-making. The process requires pharmaceutical manufacturers to submit dossiers that include clinical and health outcomes data as well as an economic model that will demonstrate the impact of introducing the product to the health plan. Since implementation, the process has not been evaluated. **OBJECTIVE:** To evaluate the scope and content of submission dossiers received from January 1998 to June 2000. **METHODS:** All dossiers received from January 1998 to June 2000 were collected and reviewed. They were evaluated for compliance with the Regence Formulary Submission Guidelines. Data were entered into a spreadsheet for analysis. **RESULTS:** A total of 50 dossiers were reviewed. 25 (50%) were received in year 1, 16 (32%) in year 2, and 9 (18%) in the first six months of year 3. An economic model was provided in 31 dossiers, increasing from 55% to 78% of dossiers over the three years. Only 10 models were cost-effectiveness analyses. The remaining models were budget impact analyses. Complete clinical information was included in 48%, 63% and 78% of submissions in years 1, 2 and 3 respectively. Dossiers were prepared by one of three sources: Staff at the manufacturer's headquarters (68%), an outside vendor (10%) or a local manufacturer's representative (22%). Unpublished studies, which were specif-

ically requested, were included in 18 dossiers, and off-label information was included in 7. Of the 50 products submitted, 24 (48%) were added to Formulary. **CONCLUSIONS:** Compliance with the guidelines has improved over the past 30 months. Overall, a majority of the submissions included complete clinical information and some type of economic analysis. There remains, however, significant opportunity for improvement, particularly in the presentation of economic evaluation data and the dissemination of unpublished studies.

HP4

ASSESSING LIFESTYLE DRUGS FOR DRUG BENEFIT FORMULARIES: A COST-UTILITY ANALYSIS OF ORLISTAT AND SIBUTRAMINE FOR THE TREATMENT OF OBESITY IN ADULTS

Trakas K[1], Oh PI[2], Leiter L[3], Shear NH[2]
[1]University of Toronto, Toronto, ON, Canada; [2]Sunnybrook and Women's College Health Science Centre, Toronto, ON, Canada; [3]St. Michael's Hospital, Toronto, ON, Canada

Obesity is now recognized as a chronic health condition instead of a cosmetic or lifestyle issue. Orlistat and sibutramine are effective weight-loss/weight-maintenance agents. Insurers argue that the high prevalence of obesity (i.e., body mass index (BMI)[3] 30kg/m^2), questionable long-term health benefits, and cost of these drugs make it unfeasible to cover them. Proponents claim decreases in obesity's comorbidities would offset acquisition costs. **OBJECTIVES:** To provide evidence for a rational reimbursement policy for pharmacological treatments of obesity in adults. **METHODS:** A Markov decision analytic model was used to evaluate the cost-effectiveness of orlistat (120mg TID) and sibutramine (5–20mg QD) relative to diet and exercise alone. The model analyzed a hypothetical population of obese, but otherwise healthy 30 year olds over their lifetime. Estimates of efficacy and tolerance were derived from a meta-analysis of randomized, placebo-controlled trials of orlistat and sibutramine. The Framingham Study was used to derive risk-adjusted equations for the incidence of hypertension, dyslipidemia, and DM as well as the incidence of CV events, CV-attributable death, and non-CV death. Equations were adjusted for known risk factors, including BMI. The reference case analysis used the societal perspective and included both direct and indirect costs (discount rate, 3%). Costs were derived from the literature and inflated to year 2000 Canadian dollars (CDN$). Utilities were derived from a Canadian health survey and from the literature. Decision index: incremental cost per quality adjusted life year ($/QALY). A Monte Carlo simulation will be used to perform a sensitivity analyses around: estimated weight-loss, estimated dropout rates, estimated weight regain, cost of treatment, and major clinical events. **RESULTS:** Results for the base case (i.e., societal viewpoint) and third party payer (i.e., Ministry of Health) perspectives will be presented and discussed. Emphasis will be placed on the decision model approach for informing formulary decisions on "lifestyle" drugs.

CANCER

CN1

UTILITIES OF METASTATIC BREAST CANCER PATIENTS (PT) TREATED WITH TAXANES COMPARED TO UTILITIES OF ONCOLOGY NURSES (NUR)

Hauser R[1,3], Theriault R[2], Wilson J[3], Shepherd M[3], Lawson K[3], Koeller J[3]
[1]Abt Associates Clinical Trials, Cambridge, MA, USA; [2]University of Texas M.D. Anderson Cancer Center, Houston, TX, USA; [3]University of Texas, Austin, TX, USA

Cost-utility analysis is rapidly becoming the standard pharmacoeconomic measure in oncology. In a recent report (JCO, 2000;18:3302), data from 40 published cost-utility studies were presented in a league table format. Most of those studies utilized nurses or physicians as proxies for the pt. in determining utility. **OBJECTIVE:** To determine if there is a difference between utility scores obtained from metastatic breast cancer pt. and oncology nurses. **METHODS:** Using eight modified Markov modeled health states (Pharmacoeconomics, 1996; 60:504) describing metastatic breast cancer; the standard gamble procedure was utilized to obtain utility scores from 45 patients and 57 oncology nurses. Utility values were measured on a scale between 0.0 and 1.0. Independent t-tests were used to test for differences between groups using an alpha level of 0.05 (2-sided). **RESULTS:** Significant differences were found on all eight modeled health states:

Modeled Disease State	Mean Utility Score (SD) Patients/Nurses (n = 45; n = 57)	P Value	95% Confidence Intervals
Partial Response (PR)	.84 (.11)/.71 (.22)	.0001	.06–.20
PR with Severe Peripheral Edema	.78 (.17)/.63 (.24)	.0001	.08–.24
PR with Severe Peripheral Neuropathy	.76 (.13)/.56 (.24)	.0001	.12–.28
Before Second Line Treatment Begins	.73 (.16)/.59 (.22)	.0001	.06–.22
Stable Disease	.72 (.15)/.54 (.22)	.0001	.11–.26
Late Progressive Disease	.63 (.18)/.45 (.25)	.0001	.10–.27
Terminal Disease	.40 (.26)/.19 (.21)	.0001	.13–.31
Sepsis	.39 (.25)/.20 (.23)	.0001	.09–.28

CONCLUSION: These results show that patients have a higher utility for health than perceived by nurses. These data leads to the question of whose utility values should be used for cost-utility analysis in oncology.

CN2

EFFECT OF INCLUDING (VERSUS EXCLUDING) FATES WORSE THAN DEATH ON UTILITY MEASUREMENT

Franic DM[1], Pathak DS[2]
[1]The University of Georgia, Athens, GA, USA; [2]The Ohio State University, Columbus, OH, USA

OBJECTIVE: To test impact of including (versus excluding) health states perceived to be worse than death on utility measurement using standard gamble (SG) and visual analogue scale (VAS) methods. **METHODS:** Face-to-face interviews were conducted in a convenience sample of women aged 22 to 50 years with no history of breast cancer or cancer requiring chemotherapy (n = 119). Data were collected between March 2000 and June 2000 at a Midwestern University in the US. Subjects were asked to rate their utility if faced with three hypothetical breast cancer health states: cure, treatment and recurrence. Utility weights were estimated using SG top-down titration and VAS methods scaled from zero (death) to one (perfect health). Linear transformation was used to allow for negative preference weights for health states worse than death. **RESULTS:** Unpaired t-test analysis showed statistically significant greater change in SG (n = 16) and VAS (n = 17) utilities for respondents perceiving cancer recurrence as worse than death than those perceiving death as least desirable health state ($p < 0.05$). Mean change in SG (VAS) utility allowing for health states worse than death for breast cancer cure versus treatment, treatment versus recurrence, and cure versus recurrence were 0.066(0.226), 0.335(0.339), and 0.401(0.564), respectively (n = 119). Excluding negative utilities from study resulted in statistically
significant lower mean changes in utility weights (SG n = 103, VAS n = 102). **CONCLUSION:** Most studies typically measure health preferences excluding health states perceived as worse than death. Similar to Patrick et al (1994) results of this study indicate health preference elicitation methods can be successfully adapted to acquire negative utilities. Regardless of metric used, both SG and VAS yield higher changes in weight estimates when negative utilities are permitted. Addressing negative utilities in studies could significantly affect QALY estimates in economic analyses.

CN3

COST-EFFECTIVENESS ANALYSIS OF IRINOTECAN+5FU/FA ALONE AS FIRST-LINE THERAPY IN ADVANCED COLORECTAL CANCER IN THE UK

Brown R[1], Sorensen S[1], Burrell A[2], Bearne A[2]
[1]MEDTAP International Inc, Bethesda, MD, USA; [2]Aventis Pharma, Kent, UK

OBJECTIVES: This study aims to estimate the cost-effectiveness (CE) of irinotecan+5FU/FA versus 5FU/FA alone in the first line treatment of advanced metastatic colorectal cancer from the perspective of the UK National Health Service. **METHODS:** A decision tree model was designed in Excel to track patients through the course of advanced colorectal disease based upon trial data from first line management and estimating average survival and associated resource use. A systematic review and meta analysis were undertaken for first line treatment with irinotecan and 5FU/FA and 5FU/FA alone to provide data on response rate, time to progression, survival rates (median survival 67.5 weeks versus 55 weeks), drop out from toxicities, and major adverse events. Medication costs were based on the British National Formulary and allow for wastage. Resource utilization for routine treatment and monitoring, adverse event management, use of second line chemotherapy, palliative care and other clinical parameters was elicited from a survey of five UK oncologists experienced with the therapies. Wherever possible, acquisition costs from published sources were applied to the resources. **RESULTS:** The total costs including drug, treatment administration, management of toxicity and of disease progression amounted to £23,825 per patient treated with CPT-11+5FU/FA and £18,795 per patient treated with 5FU/FA alone. When the difference in cost is related to the clinical benefit of irinotecan, the cost per life year gained was estimated as £20,948. Sensitivity analysis showed that the analysis was robust as the CE ratios did not widely vary. **CONCLUSION:** In the treatment of advanced metastatic colorectal cancer in the UK, irinotecan+5FU/FA extends survival and the cost remains within the limits currently accepted for new chemotherapeutic agents.

CN4

ECONOMIC EVALUATION OF GEMZAR/ CISPLATIN RELATIVE TO OTHER CISPLATIN BASED TREATMENTS FOR NON SMALL CELL LUNG (NSCLC) CANCER IN THE UK

Botwood N[1], McKendrick J[1], Aristides M[2], Lees M[2], Maniadakis N[3], Wein W[3], Stephenson D[1]
[1]Eli Lilly, Basingstoke, UK; [2]M-TAG, London, UK; [3]Eli Lilly, Windlesham Surrey, UK

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 and not consistent across geographical regions. This study reports on an economic evaluation of Gemzar/cisplatin (GC) relative to: mitomycin/ifosfamide/cisplatin (MIC), etoposide/cisplatin (PE) and itomycin/vinblastine/cisplatin (MVP). These represent standard platinum-containing regimens that are currently used in the UK. **METHODS:** The study perspective is that of the UK-NHS. Data were derived from comparative clinical trials (Crino et al 1999, Cardenal et al. 1997, Costa 2000). Costing is based on: chemotherapy, infusion, hospitalisations, visits to health care professionals and concomitant medications. Resource utilisation from the trials was combined with unit cost data from various UK sources. Costs correspond to 2000. Time horizon for the estimation of costs is one year; hence discounting was unnecessary. Treatment effectiveness is measured by overall survival and objective tumour response. **RESULTS:** In the first setting the cost-per-patient on GC was £5,101 and on MIC £4,481. Overall tumour response rates were 39.6% and 27.6% respectively. Thus, the incremental cost-per-tumour-response of GC was £5,169. In the second setting, the cost on GC

was £4,142 compared to £3,762 on PE. Overall tumour response was 40.6% and 21.9% respectively and progression-free life years 0.575 and 0.358. Thus, the incremental cost-per-tumour-response of GC was £2,032 and the incremental cost-per-progression-free-life-year £1,751. In the final setting, the cost of GC was £5,084 and of MVP £4,004. Overall tumour response was 54.0% and 36.7% and one year survival 36% and 17% respectively. The incremental cost-per-tumour-response of GC was £6,240 and the incremental cost-per-survivor-at-one-year was £5,681. In extreme changes to underlying variables the above ratios vary from dominance to a maximum of £14,000. **CONCLUSIONS:** These results demonstrate that Gemzar/cisplatin represents a relatively cost-effective treatment for NSCLC with ratios comparable of below those of therapies currently in use within the NHS.

CARDIOVASCULAR DISEASE

CV1

THE VALUE OF COMPLIANCE: EVIDENCE FROM TWO PATIENT COHORTS

McGuigan KA, Sokol M, Yao J, Haynes J, Qian Q, Boscarino J, Epstein R
Merck-Medco Managed Care, LLC, Franklin Lakes, NJ, USA

OBJECTIVES: To identify the association between compliance and the direct costs of care for two different clinical patient cohorts. **METHODS:** Using administrative claims data from Medstat MarketScan (tm) we assessed the association between prescription drug compliance and direct costs of care for two patient groups: a cohort of non-Medicare patients diagnosed as diabetics (N = 9960) and second cohort of non-Medicare patients diagnosed with congestive heart failure (CHF)(N = 935). Since patients who are more compliant tend to be older and have a greater number of comorbidities, and our goal was to isolate the association between compliance and medical care costs, we statistically controlled for differences in potential confounding variables using OLS regression. Covariates included age, gender, comorbidity indices (Chronic Disease Score and Charlson-Deyo), and ICD-9-based severity of illness indicators. Compliance was defined by calculating % days supply over a period of one year. Compliance was then converted to 7 ordinal categories in the regression model in order to identify dose-response associations or threshold/inflection points. **RESULTS:** Among diabetics, those who did not use any prescription medication showed the lowest total costs of care. However, among those patients who needed prescription medication to manage their illness, increased prescription drug costs among the most compliant are more than offset by decreases in medical care costs, for an estimated return on investment (ROI) of more than two-fold. A similar, but stronger, pattern was found among patients with CHF where the estimated ROI was three-fold or greater. **CONCLUSIONS:** For some medical conditions, the additional costs associated with increased compliance may be offset by lower medical costs, resulting in an ROI greater than one.

CV2

INDIRECT COMPARISONS OF DRUGS USING META-ANALYSIS: VALIDATION OF RESULTS

Ross SD[1], Klawansky S[1], Allen IE[2]
[1]MetaWorks, Medford, MA, USA; [2]Babson College, Wellesley, MA, USA

OBJECTIVES: Health care decision-makers need more head-to-head drug comparison trials. Industry rarely sponsors such studies, preferring placebo comparators. We present an example of using meta-analysis for an indirect comparison of 2 drugs, with the results subsequently validated in a direct comparison trial. **METHODS:** The drugs for comparison were abciximab and tirofiban, both GPIIb/IIIa inhibitors used in patients with acute coronary syndromes undergoing percutaneous coronary interventions (PCI). A class effect has been assumed for these agents, although they differ in molecular structure and duration of action. We identified all placebo-controlled trials of each drug in PCI patients, and meta-analysed the odds ratios (OR) for death or MI (D/MI) at 30 days for each set of studies. These ORs were then compared using a general linear model. **RESULTS:** For D/MI at 30 days, the results of the meta-analysis of the 6 abciximab studies [OR = 0.52 (0.43, 0.63)] appeared superior to the results of the 3 tirofiban studies [OR = 0.73 (0.55, 0.96)], although the differences did not reach significance. In the model, a non-significant ($p = 0.10$) abciximab advantage was observed. The ratio of the ORs of tirofiban/placebo and abciximab/placebo meta-analyses was 1.4, suggesting a higher risk of D/MI at 30 days for tirofiban relative to abciximab. After completion of these analyses, the results of a randomized comparison trial of tirofiban vs. abciximab in PCI patients were announced (for D/MI at 30days OR = 1.26, $p = 0.04$). The results demonstrated an advantage for abciximab, in keeping with our meta-analysis result. The magnitude of the efficacy difference was similar to that we had predicted. **CONCLUSIONS:** This is the first time an indirect comparison of drugs using meta-analytic techniques has been validated with a contemporaneous RCT. This method should be used to predict results of direct comparisons of drugs anytime such a trial is contemplated.

CV3

DO SHORT-ACTING OPIATES IN OFF-PUMP BYPASS SURGERY REDUCE LENGTH OF STAY OR TOTAL HOSPITAL COSTS?

Reddy P[1], Feret B[2], Kulicki L[2], Jordan S[2], Donahue S[2], Quercia R[2]
[1]University of Connecticut, Storrs, CT, USA; [2]Hartford Hospital, Hartford, CT, USA

OBJECTIVES: The cost of remifentanil, a short-acting opiate, is approximately 10 times higher than fentanyl, a

longer-acting opiate. Short-acting opiates, however, have the potential to reduce time to extubation (TTE) and may, therefore, decrease length of stay (LOS) and hospital costs. Remifentanil was added to our institution's formulary for use during off-pump bypass surgery. The objective of this analysis was to compare TTE, LOS and total hospital costs between patients who received remifentanil and fentanyl during off-pump bypass surgery. **METHODS:** The study was prospective and observational in design. Consecutive patients who underwent off-pump cardiac bypass surgery and received either remifentanil or fentanyl from September 1998 to August 1999 were included. Patient charges were converted to costs using cost-to-charge ratios. The percent of patients extubated in the operating room (OR), LOS and hospital costs were compared between the groups. **RESULTS:** Baseline demographics, including age, female patients, co-morbidities and intraoperative variables were similar between the remifentanil (n = 39) and fentanyl (n = 20) groups. Patients given remifentanil during surgery were significantly more likely to be extubated in the OR than patients given fentanyl (64% vs. 15%; $p < 0.001$). The mean LOS was similar in both groups (7.3 ± 3.1d vs. 8.3 ± 2.7d; $p = 0.27$). Patients who received remifentanil incurred lower ward ($3,973 ± 1,719 vs. $4,808 ± 1,794; $p = 0.09$), recovery room ($31 ± 40 vs. $65 ± 33; $p = 0.002$) and pulmonary function testing costs ($0 ± 0 vs. $34 ± 103; $p = 0.045$) than patients who received fentanyl. Anesthesia costs were higher among patients who received remifentanil ($476 ± 102 vs. $416 ± 130; $p = 0.06$). Medical and surgical supplies, OR, ICU, cardiac catheterization, laboratory, respiratory therapy, pharmacy, radiology and transfusion costs were similar between the 2 groups ($p > 0.05$). The total cost was $15,272 ± 5,556 and $15,616 ± 4,169 in the remifentanil and fentanyl groups, respectively ($p = 0.81$). **CONCLUSION:** Remifentanil, when used in off-pump bypass surgery, increases the likelihood of extubation in the OR. However, LOS and total hospital costs remain unchanged.

CV4

USING UK OBSERVATIONAL DATA TO IDENTIFY POSSIBILITIES FOR THE COST-EFFECTIVE IMPROVEMENT OF THE TREATMENT OF ATRIAL FIBRILLATION

Piercy J[1], James P[2], Baum D[3], Kuester L[3]
[1]Mapi Values, Macclesfield, UK; [2]CHKS Ltd, Alcester, UK; [3]Solvay Pharmaceuticals, Hannover, Germany

BACKGROUND: Atrial Fibrillation (AF) is the most frequent type of arrhythmia. Termination of acute AF is generally undertaken in a hospital setting. Available drugs for termination of acute AF have severe side effects and complicated dose regimens. There is a need for new drugs with a high conversion rate, favourable safety profile and easier dosing. **OBJECTIVES:** To describe the characteristics and hospital treatment patterns of patients with AF. To investigate the requirements for an improved cost-effective anti-arrhythmic therapy. **METHODS:** A database was used containing aggregated and anonymised diagnostic information, hospital experience (e.g., length of stay), and demographic data for over 80 million inpatient episodes in the UK over ten years. The database contains 28,524 hospital admissions of patients (65 and over) with a diagnosis of AF during 1999/2000. 53.3% are female, with mean length of stay (LOS) 6.1 days; 46.7% are male with LOS 4.3 days. Controlling for age, the gender LOS difference is significant ($p < 0.01$). **RESULTS:** Comorbid Conditions. 17.5% of AF patients also had a diagnosis of chronic ischaemic heart disease (IHD), a further 7.5% had myocardial ischaemia, and 19.5%, congestive heart failure. Furthermore, 24.2% of CHF patients and 16.9% of all angina patients also had clinically significant AF. Cardioversion. Cardioversion (defibrillation) is used when pharmacological therapy fails to terminate acute AF. However, significant numbers (35%) of cardioversion procedures were undertaken on an elective day case basis. We are currently investigating and will report on the resource consequences in acute AF. **CONCLUSIONS:** There is a clear unmet medical need for improved anti-arrhythmic drugs. Using the dataset, we identify two potentially cost-effective possibilities for improved anti-arrhythmic treatment: an agent which can simultaneously demonstrate effectiveness in associated cardiovascular conditions such as IHD or CHF; or an agent reducing the need for cardioversion in acute AF.

CV5

THE COST-EFFECTIVENESS OF LIFETIME FACTOR VIII PROPHYLAXIS IN THE TREATMENT OF SEVERE HEMOPHILIA A

Charles RA[1], Hay J[2]
[1]University of Southern California, School of Pharmacy, Los Angeles, CA, USA; [2]University of Southern California, Los Angeles, CA, USA

Prophylactic infusion of factor VIII has been shown to markedly reduce arthropathy in patients with severe hemophilia A. **OBJECTIVE:** The purpose of this model is to investigate the cost-effectiveness of prophylactic infusion of factor VIII relative to on-demand infusion therapy in patients with severe hemophilia A. **METHODS:** Two hypothetical cohorts were modeled; one cohort receiving prophylactic and the other on-demand infusions. Factor VIII infusion therapy begins at age 1 and continues unchanged over a patient's lifetime. A recursive Markov model is used to estimate the expected costs and QALYs associated with each cohort. Costs and QALYs are calculated using backward induction in 5-year intervals incorporating the DEALE method. Data inputs are estimated from published literature. The analysis is completed from a societal perspective, uses a 3% discount rate, with costs in year 2000 U.S. dollars, and has a time horizon of 50 years. **RESULTS:** According to the model, patients re-

ceiving prophylactic therapy experience both higher lifetime costs ($3,542,357) and higher QALYs (18.95) than patients receiving on-demand therapy ($2,455,268, 15.31). The ICER was determined to be $298,531/QALY. In the sensitivity analysis, the ICER was sensitive to the number of units/kg/yr of factor used per patient, the probability of arthropathy in years 1 through 5, and the utilities assigned. Varying these parameter estimates resulted in an ICER ranging from $8,315 to $616,158/QALY. **CONCLUSION:** Results from the baseline model indicate that lifetime prophylactic infusion of factor VIII in patients with hemophilia is above the generally accepted threshold for cost-effectiveness of $50,000 per QALY. Due to the model's sensitivity to the amount of factor used, it is recommended that pharmacokinetic dosing be explored to reduce the amount of factor needed to achieve therapeutic levels. Research to determine more accurate utilities for persons with hemophilia with and without arthropathy are also needed.

CV6

ECONOMIC EVALUATION OF DALTEPARIN, ENOXAPARIN AND UNFRACTIONATED HEPARIN IN THE TREATMENT OF DEEP VEIN THROMBOSIS

Risebrough NA, Mittmann N
HOPE Research Centre, Toronto, ON, Canada

OBJECTIVES: As low molecular weight heparins (LMWH)s such as enoxaparin (ENOX) and dalteparin (DALT) add drug acquisition cost, yet eliminate the need for activated prothrombin time (aPPT) monitoring compared to unfractionated heparin (UFH), we developed an economic model to quantify the value of DALT, or ENOX compared to UFH as cost per clinical event avoided from an health management organization perspective. **METHODS:** With a hypothetical patient cohort with confirmed DVT, treatment and clinical outcomes were modeled using a conventional decision tree over a 6 month timeframe. Treatment with LMWH or UFH continued for an average of 5 days. Possible clinical events included thrombocytopenia, major bleed, recurrent VTE, or death from any cause. Inpatient treatment with UFH was necessary due to the IV route of administration and need for apt monitoring. Subcutaneous administration of LMWHs facilitate early discharge from hospital or treatment in the outpatient setting for the duration. Based on published sources, we assumed the proportion of patients receiving LMWH as inpatients, outpatients or with early discharge were 45%, 30% and 25%, respectively. Drug efficacy was obtained from a meta-analysis of published clinical trials. Resource use data associated with drugs and inpatient and outpatient medical care were obtained from published sources, treatment guidelines and an expert physician panel. Medical unit costs (2000 $US) were obtained from published sources. **RESULTS:** The baseline analysis showed DALT and ENOX prevented 28 and 17 clinical events respectively per 1000 patients compared to UFH. The total medical cost per patient treated with DALT, ENOX and UFH was $3199, $3347, and $5104, (US$) respectively. Compared to UFH, cost savings with use of LMWH was attributed to reduced clinical events and fewer hospital days. Sensitivity analysis showed results were robust. **CONCLUSIONS:** These figures indicate that LMWHs provide important improvements with medical cost savings and thus are attractive both clinically and economically.

CV7

COST-EFFECTIVENESS OF CARDIOVASCULAR DISEASE (CVD) PREVENTION BY REDUCING POSTPRANDIAL HYPERGLYCEMIA

Glick H[1], Qiao Q[2], Grueger J[3]
[1]University of Pennsylvania, Philadelphia, PA, USA; [2]National Public Health Institute, Helsinki, Finland; [3]Novartis Pharmaceuticals AG, Basel, Switzerland

OBJECTIVES: To estimate the cost-effectiveness of the insulinotropic agent nateglinide vs. metformin using an epidemiologic risk model that quantifies the relationship between glucose spikes as measured by 2 hour postprandial blood glucose (2h-BG) and risks for all cause mortality, acute myocardial infarction (AMI), and stroke in diabetic patients. **METHODS:** We used data from the DECODE study database (N = 22,474, with up 25 years of follow-up) to estimate parametric failure time models predicting the risk for death, AMI, and stroke for 2h-BG, and other CVD risk factors. The risk equations were used to develop a decision model that projected risks, costs, and years of life for up to 40 years for men and women with and without an intervention specifically to control 2h-BG (results for men with 2h-BG >11 mmol/L reported below). Costs included the intervention and the costs of CVD events. All costs are expressed in Swiss francs (CHF), and were discounted at 3%. Clinical efficacy was taken from a randomised clinical trial of nateglinide versus metformin. **RESULTS:** When results were projected for 15, 25, and 40 years, incremental costs were 9,137, 10,047, 10,133 CHF, respectively (1 CHF $\sim$ $0.60). Discounted years of life saved for these same intervals were 0.15, 0.24, and 0.26. The ratios of cost per year of life saved were 59,600, 41,500, 38,400 CHF. **CONCLUSIONS:** Initial modeling suggests that therapy with nateglinide among individuals with elevated levels of 2h-BG reduces the risk for death and CVD events and has acceptable cost-effectiveness ratios compared to metformin.

CV8

WORK-RELATED OUTCOMES OF PATIENTS SIX MONTHS AFTER MYOCARDIAL INFARCTION

Erickson SR[1], McBurney CR[1,2], Kline-Rogers EM[1], Cooper JV[1], Mani OCM[1], Eagle KA[1]
[1]University of Michigan, Ann Arbor, MI, USA; [2]Pfizer Inc., Ann Arbor, MI, USA

OBJECTIVES: To determine the rate of return to work post-MI; and for returnees, self-reported work performance and number of days absent. **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 interviewed by telephone to determine work status prior to and after MI. Work-related outcomes included self-reported work performance using the Work Performance Scale (WP, 1 = lowest, 4 = highest performance) and number of days absent. The SF-12 was administered to determine physical (PCS-12) and mental (MCS-12) functional status. **RESULTS:** Of 202 patients interviewed, 30.2% worked prior to the reference MI. Of these, 80.3% were male, mean age was 56.1 years, and 26.2% did not return to work. Those not returning had lower median PCS-12 scores (28.5 versus 42.8 for returnees, $p < 0.001$), prior MI (62.5% versus 17.8% for returnees, $p = 0.003$), and history of congestive heart failure (25.0% versus 4.4% for returnees, $p = 0.03$). Returnees had a median WP of 3.6, and 82.2% indicated no absences. Median WP scores were lower for patients with lower ejection fractions (EF) (3.2 for EF $< 40\%$ versus 3.8 for EF$^3 > 40\%$, $p = 0.01$), hypertension (3.5 versus 3.8 without hypertension, $p = 0.02$), or prior MI (3.3 versus 3.8 without previous MI, $p = 0.01$). Workers reporting absences had lower EF (40% EF $< 40\%$ versus 11.4% EF $< 40\%$ for no absences, $p = 0.05$), lower median PCS-12 score (31.1 versus 44.5 for no absences, $p = 0.02$), and prior MI (50.0% versus 10.8% if no absences, $p = 0.02$). **CONCLUSIONS:** Preexisting cardiac disease, lower EF at discharge, and poorer physical functioning were negatively related to work-related outcomes. This small study demonstrates the need for a larger, broader study that includes, health beliefs, psychosocial assessment, treatment, and other job/patient factors that may influence work-related outcomes.

DIABETES/GASTROINTESTINAL DISORDERS

DG1

THE RELATIONSHIP OF DIABETES SYMPTOMS AND HEALTH-RELATED QUALITY OF LIFE

Pfalzgraf AR, Nau DP
West Virginia University, Morgantown, WV, USA

OBJECTIVES: To determine the relationship between diabetes symptom burden and patients' perceptions of health-related quality of life (HRQL). **METHODS:** A questionnaire was sent to 3,716 adults with diabetes enrolled in a managed care organization in West Virginia and southeastern Ohio. Diabetes symptom burden was measured using a 17-item scale (Diabetes TyPE, Form 2.1). The Health Status Questionaire (HSQ-12), Version 3.0 was utilized to measure patients' perception of their HRQL. Analyses focused on six domains from the HSQ-12: General Health Perception (GHP), Physical Functioning (PF), Bodily Pain (BP), Energy/Fatigue (EF), Social Functioning (SF), and Mental Health (MH). Linear regression was used to examine the impact of diabetes symptoms on each of the HRQL domains. **RESULTS:** Usable responses were obtained from 1,027 persons with diabetes (27.6% response rate). The summated scale of diabetes symptom burden had acceptable internal consistency (alpha = 0.90). Analyses revealed a significant inverse relationship between diabetes symptom burden and each of the six domains from the HSQ-12, when controlling for gender, age, and education. Overall symptom burden was found to be most highly associated with Social Functioning ($r = -.57$), while somewhat less strongly associated with the other five domains: GHP ($r = -.52$); PF ($r = -.49$); BP ($r = -.51$); EF ($r = -.54$); MH ($r = -.50$). As overall symptom burden increases, the patients' perception of health across all six HRQL domains decreases. **CONCLUSIONS:** Diabetes symptom burden is inversely related to health-related quality of life. Thus, interventions targeted towards the alleviation of diabetes symptoms should also lead to improvements in patients' perceptions of their health and well-being.

DG2

THE INCREMENTAL COST OF DIABETES IN CHRONIC ILLNESS CO-OCCURRENCES

Garis RI[1], Farmer KC[2], Arora M[1]
[1]Creighton University, Omaha, NE, USA; [2]University of Oklahoma, Oklahoma City, OK, USA

OBJECTIVES: The cost and management of patients with multiple chronic conditions present unique challenges to the health care system. Major chronic conditions such as diabetes often co-occur with other chronic illnesses. The objective of this study is to report the incremental cost of diabetes mellitus when it co-occurs with cardiovascular conditions, depression, hypertension, psychosis, respiratory/asthma, or acid peptic disease. **METHODS:** A one-year retrospective database analysis using an integrated Medicaid dataset from the State of Oklahoma. Disease states were identified by ICD-9-CM codes and a validated drug-based classification. Patients included in the study had the chronic condition identified by both drug and diagnosis information. The incremental costs of diabetes when co-occurring with other chronic conditions was determined by subtracting the cost of the non-diabetes single condition from the co-occurring disease group. **RESULTS:** Seven groups of patients consisted of; diabetes only (n = 1038), diabetes co-occurring with hypertension (n = 313), respiratory illness/asthma (n = 62), depression (n = 48), cardiovascular illness (n = 35), psychosis (n = 35), and acid peptic disease (n = 30). Diabetes as a single chronic illness had an annual cost of $818 over patients with no evidence of chronic illness. The incremental cost of diabetes when co-occurring with psychosis was $7,211, respiratory illness/asthma $3,161, hypertension $1,595, depression $1,319, acid peptic disease

$977, and cardiovascular illness $−35. The incremental cost of diabetes co-occurring with psychosis was significantly higher than all other disease co-occurrences. Differences in the incremental cost of diabetes were not statistically significant between the other disease combinations. ANCOVA was performed with longevity in the program as a covariate to adjust for differential enrollment time. **CONCLUSION:** The cost and management of chronic conditions such as diabetes may be highly influenced by other chronic conditions the patient may have. Disease management programs may incorporate co-morbidity research and models when evaluating the cost and treatment of chronic conditions.

DG3

A RETROSPECTIVE EVALUATION OF NONSTEROIDAL ANTI-INFLAMMATORY DRUG-INDUCED GASTROINTESTINAL COMPLICATIONS AMONG ADULTS IN A MANAGED CARE HEALTH PLAN

Dodd MA[1], D'Angio R[2], Gupchup GV[1], Nelson C[3]
[1]The University of New Mexico, Albuquerque, NM, USA; [2]Pfizer Inc, Cedar Crest, NM, USA; [3]Presbyterian Healthcare Services, Albuquerque, NM, USA

OBJECTIVE: To obtain a profile of adult patients at risk for nonsteroidal anti-inflammatory drug (NSAID) induced gastrointestinal (GI) complications in a large managed care health plan in the Southwest United States. **METHODS:** Patients with NSAID prescription claims between July 1996 and June 1997 were identified from a health plan claims database. Patients with claims associated with ICD-9 and CPT codes indicating serious GI complications were then identified. The ICD-9 codes used were those associated with GI ulcers (531.x, 532.x, 533.x, and 534). A total of 19 CPT codes for GI procedures indicative of a GI complication were used. A forward stepwise logistic regression analysis, using the likelihood-ratio (LR) test, was performed to identify predictors of GI complications. Predictors included in the model were individual NSAIDs and the following potential risk factors: age, gender, previous GI drug usage, previous steroid usage, and total days supply of NSAIDs during the study period. **RESULTS:** A sample of 15,772 patients with prescription claims for NSAIDs was identified. Of these patients, 213 (1.4%) had an ICD-9 or CPT code suggestive of serious GI complications secondary to a NSAID. The logistic regression results indicated that women (OR = 0.65, 95% CI = 0.48–0.87) were less likely to develop GI complications. However, patients with previous GI drug usage (OR = 5.97, 95% CI = 4.51–7.90), those who used ketorolac (OR = 2.01, 95% CI = 1.10–3.67) and those who used oxaprozin (OR = 1.82, 95% CI = 1.10–3.00) were more likely to develop GI complications. **CONCLUSION:** Users of ketorolac and oxaprozin, as well as those with previous GI drug usage were at a higher risk, while women were at a lower risk of GI complications in this managed care population.

DG4

DISEASE SEVERITY DETERMINES COST OF GASTROESOPHAGEAL REFLUX DISEASE IN A MIDWEST USA HEALTH CARE PLAN

Brelje T[1], Heaton A[1], Martin S[1], Bhattacharjya A[2], Dodd S[2], Thornhill J[2]
[1]Prime Therapeutics, Inc, Eagan, MN, USA; [2]Janssen Pharmaceutica Products, Titusville, NJ, USA

OBJECTIVES: The primary objective was to describe the cost of illness of gastroesophageal reflux disease (GERD) in a managed care population. Secondary objectives were to characterize GERD costs and to quantify the dependence of costs on disease severity. **METHODS:** This retrospective study utilized claims data from a large (1.4 million lives) Midwest USA health care plan. Study population had complete medical and pharmacy coverage continuously from 1996 to 1998 and possessed at least one medical claim for GERD. Claim costs were compiled for all GERD-attributable medical and drug claims. Costs were also categorized by health care sector, such as hospital inpatient or pharmacy. ICD-9 codes were used to categorize subjects' GERD into four progressively worse states plus a non-symptomatic state: GERD0 {no GERD claims}, GERD1 {mild esophagitis}, GERD2 {reflux esophagitis}, GERD3 {esophageal ulceration}, and GERD4 {strictures and complications}. **RESULTS:** A total of 7575 subjects meeting the inclusion and exclusion criteria were identified. The median age was 50 and there were 50% females. Over the three year study period, more than $23 million was spent on GERD-related claims, or $86 per subject per month. Pharmacotherapy contributed 31% of GERD health care costs, inpatient hospital charges 37%, outpatient facility charges 26%, and doctor office charges 6%. Mean cost per month was highly dependent on GERD disease state: GERD0 cost $38 per month, GERD1 was $189, GERD2 was $232, GERD3 was $536, and GERD4 was $412. At higher GERD states, pharmacotherapy was a lower contributor to cost. **CONCLUSIONS:** For payers of health care, GERD is an expensive disorder to manage. Overall costs associated with GERD increase with the severity of the disease, although the relative contribution of each health care cost sector changes with disease severity.

INFECTIOUS DISEASE

ID1

DEVELOPMENT OF A STOCHASTIC DECISION ANALYSIS MODEL OF TREATMENT OF PYELONEPHRITIS FROM THE RESULTS OF AN RCT

Davey P[1], Wang J[1], Claxton K[2], Fenwick E[2], Sculpher M[2], Talan D[3]
[1]University of Dundee, Dundee, Scotland; [2]University of York, York, UK; [3]Olive View-UCLA Medical Centre, Sylar, CA, USA

OBJECTIVE: To model the relationship between resistance to trimethoprim sulphamethoxazole (TMP-SXT)

and outcome of pyelonephritis from an RCT comparing TMP-SXT with ciprofloxacin (Talan, JAMA, 283:1583–1590,2000). **METHODS:** In the trial cost analysis was limited to a comparison between the two treatment groups, which did not permit analysis of effect modifiers, such as TMP-SXT resistance. A probabilistic model was developed and distributions were assigned to expected costs and probabilities of cure, failure (persistent or recurrent infection) and superinfection (reinfection with a new organism) from the trial data. These distributions, which characterise the second order uncertainty surrounding these outcomes following the trial, were propagated through the model using Monte Carlo simulation in order to generate cost-effectiveness acceptability curves. **RESULTS:** There were 255 patients in the per protocol analysis. The mean cost for patients with treatment failure ($476, n = 34) was significantly higher than the cost for patients who were either cured ($307, n = 174) or had superinfection ($325, n = 11). However, treatment with ciprofloxacin reduced both the probability and cost of treatment failure (the mean difference in treatment cost between success and failure was only $4 in the ciprofloxacin arm compared with $267 in the TMP-SXT arm). The probability that ciprofloxacin was dominant (greater efficacy at lower cost) was >95% at 18% TMP-SXT resistance and remained >95% down to a resistance rate of 10%. These results were sensitive to a small number of hospitalisations (1 ciprofloxacin, 5 TMP-SXT). Taking outpatient costs alone, the threshold value of treatment failure at which ciprofloxacin was 90% likely to be cost-effective ranged from $700 for 18% resistance to $350 for 30% resistance. **CONCLUSIONS:** The stochastic model produces results that are importantly different from a simple analysis based on point estimates of probability and cost, particularly if the latter assumes that the cost of treatment failure is the same for both treatments.

ID2

HEALTH VALUES FOR THE LIPODYSTROPHY SYNDROME

Lenert LA[1], Fedderson M[2], Sturley A[2], Lee D[1]
[1]University of California at San Diego, San Diego, CA, USA; [2]San Diego VA Research Foundation, San Diego, CA, USA

BACKGROUND: There is increasing concern about the potential effects of the lipodystrophy syndrome on the health and quality of life of HIV-infected patients. **OBJECTIVE:** Understand patients' perception of the significance of the lipodystrophy syndrome's quality-of-life effects. **DESIGN:** Cross-sectional study of volunteer HIV-infected patients. **SETTING:** An urban, university-affiliated HIV clinic in San Diego, California. Patients: 75 well-educated, predominantly male, HIV-infected patients. **MEASUREMENTS:** Patients' beliefs about the importance of appearance upon quality of life and preferences for hypothetical states performed using the standard gamble and time trade-off methods. **RESULTS:** Almost all patients (95%) indicated that appearance was important to their quality of life, and 89% agreed that they would be "really bothered" if their HIV diagnosis were revealed by their appearance. Patients were willing, on average, to give up 2 years (s.d. 2.8), out of a 10-year life-expectancy, to live in good health rather than live with the syndrome, over and above what they would give up to be free of symptoms from HIV infection. Patients would take an additional 13% (s.d. 20%) risk of death to be cured of HIV infection when complicated by the syndrome (median increase in risk, 9%), above the risk they would accept to be cured of uncomplicated HIV infection. The amount that the patients would trade off was associated with beliefs about the importance of their appearance to quality of life ($p = 0.0045$) and worry that their appearance would expose their diagnosis by ($p = 0.032$). **CONCLUSIONS:** The physical effects of the lipodystrophy syndrome are important enough to cause many patients to consider accepting considerable risks of death or trading off substantial life-expectancy to avoid the syndrome. Physicians may need to tailor HIV care to this aspect of patients' preferences.

ID3

COST-EFFECTIVENESS ANALYSIS OF AN INTRANASAL INFLUENZA VACCINE FOR HEALTHY CHILDREN

Luce B[1], Zangwill K[2], Palmer C[1], Mendelman P[3], Yan L[4], Wolff M[4], Cho I[3], Iacuzio D[5], Belshe B[6]
[1]MEDTAP International Inc, Bethesda, MD, USA; [2]Harbor-UCLA Medical Center, Torrance, CA, USA; [3]Aviron, Mountain View, CA, USA; [4]The EMMES Corporation, Potomac, MD, USA; [5]Roche Pharmaceuticals, Nutley, NJ, USA; [6]St. Louis University, St. Louis, MO, USA

OBJECTIVE: Intranasal influenza vaccine has proven clinical efficacy and may be better tolerated by young children and their families than an injectable vaccine. This study determined the potential cost-effectiveness (CE) of intranasal influenza vaccine among healthy children. **METHODS:** The CE analysis included clinical and medical utilization data collected in 1996–8 during a prospective 2-year efficacy trial of intranasal influenza vaccine. These data were supplemented with data from the literature where necessary. The analysis included both direct and indirect costs. The trial enrolled 1,602 healthy children 15–71 months of age in year 1, 1,358 of whom were enrolled in year 2. Children received 1 or 2 doses of either intranasal influenza vaccine or placebo. The main outcome measure was cost per febrile influenza-like illness (ILI) day avoided. The base case assumed that the vaccine was given twice in the first year and once each year thereafter at a total cost of $20 for the vaccine and its administration (i.e. per dose). **RESULTS:** Vaccinated children had an average of 1.2 fewer ILI fever days over 2 years than unvaccinated children. In an individual-based vaccine delivery scenario, CE was approximately $30/febrile ILI day avoided with the vaccine, and ranged from $10–$59/febrile ILI day avoided at a cost per dose of

$10–$35, respectively. In a group-based delivery scenario, vaccination was cost-saving compared to no vaccine and remained so if the vaccine cost was <$28/dose (the break-even price). In the individual-based scenario, vaccination was cost-saving if the cost was <$5/dose. In this scenario, nearly half of lost productivity in the vaccine group was attributable to visits to administer the vaccine, which overshadowed the relatively modest savings in ILI-associated costs averted. **CONCLUSIONS:** Routine use of intranasal influenza vaccine among healthy children may be cost-effective and may be maximized by using group-based vaccination approaches.

ID4

THE CONFUSION BETWEEN SEPTICEMIA AND SEVERE SEPSIS

Linde-Zwirble WT[1], Ball DE[2], Cooper LM[2], Lidicker J[1], Angus DC[3]
[1]Health Process Management, Owings Mills, MD, USA; [2]Eli Lilly and Company, Indianapolis, IN, USA; [3]University of Pittsburgh School of Medicine, Pittsburgh, PA, USA

INTRODUCTION: The American College of Chest Physicians/Society of Critical Care Medicine Consensus Conference defined severe sepsis as a systemic inflammatory syndrome in response to infection associated with acute organ dysfunction. Often, septicemia codes have been used in administrative datasets as a proxy for severe sepsis. However, these entities are not necessarily the same and one study found large differences in mortality between septicemia patients with and without severe sepsis (54% vs. 15%). We explored the accuracy of septicemia codes as identifiers of severe sepsis. **METHODS:** We selected all patients with septicemia or severe sepsis (bacterial or fungal infection plus acute organ failure) in the 1996 Florida hospital discharge database (n = 1,936,479) and compared differences between the groups. Septicemia was defined using the ICD-9-CM code 038.xxx. We defined severe sepsis using a more sophisticated strategy previously validated against prospective clinical and physiologic criteria. **RESULTS:** We found 58,598 patients with severe sepsis, 53.4% of whom were in the intensive care unit (ICU). We found 57,875 patients with septicemia, 30.9% of whom were in the ICU. Patients with severe sepsis had a higher mortality (24.1% vs. 18.0%, $p < 0.001$) and higher hospital costs ($20.4k vs. $14.4k, $p < 0.001$). For patients with an ICU stay, hospital mortality was 14.4% among the 7,927 septicemia cases without severe sepsis, 23.5% among the 21,655 cases of severe sepsis without septicemia and 42.1% among the 9,970 cases of severe sepsis with septicemia. The mean hospital cost in these three groups was $18,381, $24,396, and $33,470 respectively. Of all selected patients (n = 99,126), 17.5% met criteria for both septicemia and severe sepsis. The sensitivity and positive predictive values of septicemia codes as predictors of severe sepsis are 29.6% and 30.0% respectively. **CONCLUSIONS:** Septicemia codes are not accurate for identifying patients with severe sepsis.

MENTAL HEALTH

MH1

THE IMPACT OF SECOND-GENERATION ANTIPSYCHOTIC MEDICATIONS ON AMBULATORY PATIENTS WITH SCHIZOPHRENIA

Mulani PM, McCombs J
University of Southern California, Los Angeles, CA, USA

BACKGROUND: The Medi-Cal program in California added second-generation antipsychotic medications to its formulary in October 1997. **OBJECTIVE:** Investigate the impact of the formulary expansion on patient outcomes for olanzapine and risperidone patients before and after the formulary expansion. **STUDY POPULATION:** The study population consisted of 13,106 olanzapine and 15,718 risperidone ambulatory patients from the 100% Medi-Cal dataset, who were classified into 3 groups. New: no previous antipsychotic drug therapy history. Restarters: re-started antipsychotic drug therapy while not on active therapy. Switcher: who switched to one of these products while on active drug therapy. **METHODS:** Models of one-year treatment costs were estimated using both OLS regression and propensity score methods. Models included over 85 covariates for patient demographics, prior use of services, prior antipsychotic drug profile and diagnostic profile. Separate models were estimated for the 3 patient populations. Outcomes include total costs over one year broken down into component costs and days of uninterrupted drug therapy achieved after re-starting therapy. **RESULTS:** The formulary expansion immediately increased the number of new, switcher, restarter patients starting therapy with risperidone and olanzapine. Olanzapine patients were more likely to be male, between the ages of 30 and 60, urban residents and AFDC recipients. For restarters and switchers, Olanzapine patients also appear to be more compliant with their prior antipsychotic drug regimen. Once these differences were accounted for, Risperidone and olanzapine patients exhibited similar treatment cost profiles in the post-expansion period. **CONCLUSIONS:** More research is needed to determine if the formulary expansion reduced the cost of treating patients with schizophrenia. Furthermore, future comparison across drugs must take into account potential treatment selection bias and formulary expansion effects on the decision to start drug therapy.

MH2

FUTURE EMPLOYABILITY: A NEW APPROACH TO COST-EFFECTIVENESS ANALYSIS OF ANTIPSYCHOTIC THERAPY

Ganguly R, Miller LS, Martin BC
University of Georgia, Athens, GA, USA

OBJECTIVE: Antipsychotic therapies are often evaluated on the basis of clinical endpoints (BPRS, PANSS) and measures of direct cost. However, schizophrenia patients

pose a substantial burden in terms of indirect costs, much of which is attributable to loss of employment. We present a new approach to assess the cost-effectiveness of Risperidone Vs Haloperidol, using employability as an outcome measure. **METHODS:** A decision analytic cost-effectiveness model was developed to compare the two treatments over a one-year period including all direct medical costs and the number of employable persons as a measure of effectiveness. A measure of executive functioning, the Wisconsin Card Sort Test (WCST), was used as an intermediate endpoint from which employability was modeled. A Monte-Carlo procedure, using WCST sampling distributions from clinical trials, simulated the WCST score distribution for a cohort of 10,000 patients. A clinically stable patient, with a Positive and Negative Syndrome Scale (PANSS) score increase of at least 20% and a WCST-Category score of ≥ 3.5 was assumed to be employable. Sensitivity analysis was performed for key values. **RESULTS:** The base case per-patient cost of Risperidone and Haloperidol was $5,967 and $4,622 respectively and the number of employable persons was 3,258 (32.58%) and 2,517 (25.17%) respectively. Risperidone remained cost increasing and had higher number of employable persons over all the ranges used in the sensitivity analysis. The base case incremental cost-effectiveness ratio for Risperidone was $14,507 for each additional employable person. The incremental CE ratio ranged from a high of $100,000 to a low of $3,000 per employable persons when the rates of clinical stability for Risperidone and Haloperidol therapy were varied. **CONCLUSION:** Gains from earning rates for employed schizophrenics, savings in informal caregiver costs and other intangible positive effects could justify an incremental cost of $14,507 for each additional employable person prescribed Risperidone.

MH3

CLINICAL ASSESSMENT OF QUALITY OF LIFE AMONG SCHIZOPHRENIA PATIENTS WITH DEFICIT SYNDROME

Russo P[1], Kirkpatrick B[2]
[1]The MEDSTAT Group Inc, Washington, DC, USA; [2]University of Maryland Psychiatric Research Center, Baltimore, MD, USA

OBJECTIVE: To determine whether persons with deficit syndrome exhibit lower quality of life than do their counterparts. **METHODS:** Participants were drawn from the U.S. Schizophrenia Care and Assessment Program (SCAP). Trained assessors collected baseline data. Baseline QLS was used ($n = 781$; mean = 56) and was modeled as a linear function of covariates, including demographic, clinical, medication adherence, and site variables. Presence of deficit syndrome was assigned based on proxy methods using clinical data collected at the baseline assessment (Kirkpatrick B., et al., 1993). **RESULTS:** Modeling revealed that deficit syndrome had a negative impact of 4.7 points ($p < .001$) on quality of life score (range 0–120), suggesting that persons with deficit syndrome may experience a significantly lower quality of life than their non-deficit counterparts, all else equal. Those having higher hallucinations/delusions scores ($p < .001$) exhibited lower QLS scores and those with higher functioning scores (GAF; $p < .001$) exhibited higher QLS scores. The presence of insurance other than Medicare or Medicaid (as compared to no insurance) revealed a positive relationship to QLS score. Significance was achieved on one site variable and indicated a negative relationship. Weak evidence was obtained ($p = .0587$) indicating a positive association between higher education level and QLS score. **CONCLUSIONS:** Findings suggest that persons with deficit syndrome experience lower quality of life than those who are non-deficit. The result is expected given the use of clinical assessment of quality of life and is contrary to the expectation of higher self-reported quality of life for persons with deficit. Although the clinical and functional scores are significant, the impact of deficit syndrome is at least five times greater than that of hallucinations/delusions. The interpretation of significance on the insurance and site variables is less clear and may suggest that the observed variation is a result of an unobserved mediating process, such as selection or differential access.

MH4

APPLICATION OF THE RASCH MODEL TO THE SF36 MENTAL HEALTH 5 ITEM SCALE (MH5)

Perneger TV, Bovier PA
Geneva University Hospital, Geneva, Switzerland

OBJECTIVES: To verify whether the SF36 Mental Health 5 item scale (MH5), an instrument commonly used in mental health research, fulfills criteria of unidimensionality and invariant measurement specified by item response theory (IRT). **METHODS:** As part of a survey of health care needs among university students in Geneva, Switzerland, 1257 respondents (64% of eligible persons) filled the MH5 (version 2). Each item was scored on a 5-level frequency scale ("never" to "all of the time"). We analyzed these data using both the traditional method (summative scoring), and the polytomous one-parameter IRT (or Rasch) model. **RESULTS:** In traditional analysis, the MH5 scale performed as expected (single factor, Cronbach alpha 0.85, mean 67.1, standard deviation 17.6, range 0–100). Rasch analysis revealed the good fit of all item characteristic curves. Threshold locations for feeling "nervous" (mental health logits: −3.2, −0.7, 2.0, 3.3), "down in the dumps" (−4.0, −1.7, 0.4, 1.5), "calm and peaceful" (−3.0, −0.6, 0.9, 6.0), "downhearted and blue" (−4.2, −1.6, 1.0, 3.0), and "happy" (−3.1, −0.9, 0.7, 4.2) were all ordinal, consistently with theory, and spread widely over a span of 10.2 logits. While classic MH5 scores and Rasch-based scores were closely correlated ($r = 0.98$), their relationship was S-shaped: the intervals, in mental health logits, between MH5 scores 0–10, 10–20, etc, up to 90–100 were: 2.23,

1.22, 1.00, 0.90, 0.85, 0.83, 0.90, 1.09, 1.54, and 3.21. **CONCLUSIONS:** The five MH5 items fit the Rasch model very well. Classic summative scoring tends to compress the measurement scale at its extremities, by assigning scores that are too low at the high end, and too high at the low end. Rasch scoring may render MH5 more sensitive to changes among well populations and among the very sick.

MUSCULOSKELETAL DISORDERS

MS1

COST-EFFECTIVENESS OF INTERVENTIONS FOR LATERAL EPICONDYLITIS: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL IN PRIMARY CARE

Korthals-de Bos IBC, Smidt N, Tulder M, Bouter L
Vrije Universiteit Amsterdam, Amsterdam, Netherlands

OBJECTIVES: In 1997, the Dutch College of General Practitioners in the Netherlands issued guidelines which recommend a wait-and-see policy for patients with lateral epicondylitis. However, these guidelines are not evidence-based. This paper presents the results of an economic evaluation in conjunction with a randomized controlled trial to evaluate the effects of three interventions for patients with lateral epicondylitis. **METHODS:** 185 Patients with pain at the lateral side of the elbow were randomized to one of three interventions: a wait-and-see policy (n = 59), corticosteroid injections (n = 62) or physiotherapy (n = 64). Clinical outcomes included general improvement, pain during the day, elbow disability and quality of life (EuroQol). Direct and indirect costs were measured by means of cost diaries over a period of 12 months. Differences in mean costs between groups were evaluated by applying non-parametric bootstrap techniques. **RESULTS:** After 12 months, the success rate in the physiotherapy group (91%) was significantly higher than in the injection group (69%), but only slightly higher than in the wait-and-see group (83%). With regard to pain during the day and elbow disability, physiotherapy differed significantly over time, comparing to injection group, for these clinical outcomes. The mean total costs per patient for corticosteroid injections were Euro 430, compared to Euro 631 for the wait-and-see policy and Euro 921 for physiotherapy. These differences were statistically significant for corticosteroid injections compared to physiotherapy. The cost-effectiveness ratios showed no statistically significant differences between the three groups. The cost-utility ratio comparing physiotherapy and wait-and-see policy was 34,461 (1,982; 9,535,522); the other cost-utility ratios were not statistically significant. **CONCLUSIONS:** The results of this economic evaluation provide no reason to update or amend the Dutch guidelines for general practitioners, which recommend a wait-and-see policy for patients with lateral epicondylitis.

MS2

RESPONSIVENESS TO CHANGE OF THE SF-36 IN RAPOLO, A LONGITUDINAL STUDY OF RHEUMATOID ARTHRITIS PATIENTS TREATED WITH ETANERCEPT

Lubeck DP[1], Yelin E[1], Katz P[1], Roepke L[1], Wanke LA[2], Buatti M[3]
[1]University of California at San Francisco, San Francisco, CA, USA; [2]Immunex Corporation, Seattle, WA, USA; [3]Wyeth-Ayerst Research, Philadelphia, PA, USA

OBJECTIVES: To evaluate the responsiveness of the SF-36 subscales, the generic physical (PCS) and mental (MCS) components of the SF-36, and the SF-36 Arthritis-Specific Health Index (ASHI) to changes in disability measured by the Health Assessment Questionnaire (HAQ) in RAPOLO. **METHODS:** We identified 388 participants from RAPOLO, a longitudinal, observational study of RA, who had repeated measures of arthritis specific function (HAQ and ASHI) and general function (SF-36). We categorized patients into three groups according to HAQ score—(1) stable, (2) declined (increase in HAQ score >of 0.25) and (3) improved (a decline in HAQ score of >0.25). For each group we calculated Guyatt's statistic—a measure of responsiveness to change. The larger the absolute value of Guyatt's statistic, the greater the responsiveness to change. **RESULTS:** Cohort is 79% female; mean disease duration is 13.2 yrs; mean age is 55 yrs. There were 286 participants who had no change in HAQ score. Guyatt's statistic ranged between 0.04 to 0.17 (Social Functioning). There were 52 participants who declined. The Guyatt's statistics for the SF-36 ranged from 0.11 (Role Emotional) to 1.88 (Role-Physical). There were 46 participants who improved in HAQ score. The Guyatt's statistic ranged from 0.14 (Mental Component Summary Score) to 1.58 (Role-Physical). **CONCLUSIONS:** Statistics less than 0.3 indicate no responsiveness to change, statistics >0.5 reflect responsiveness to change. The physical subscales of the SF-36, the PCS, and the ASHI were moderately to highly responsive to change in HAQ score. The emotional subscales were not responsive to change in disability.

MS3

CORRELATION OF A GENERIC HEALTH-RELATED QUALITY OF LIFE QUESTIONNAIRE AND SELF-ADMINISTERED RHEUMATOID ARTHRITIS DISEASE ACTIVITY INSTRUMENT

Kim SS, Drabinski AM, Williams GR, Formica CA
Knoll Pharmaceutical Company, Mount Olive, NJ, USA

BACKGROUND: Health-related quality of life (HR-QOL) measures have been used to study the impact of disease activity in patients with rheumatoid arthritis (RA). The objective of this study was to evaluate the correlation between SF-36 scales, physical function (PF), role physical (RP) and bodily pain (BP) and Rapid Assessment of Disease Activity in Rheumatology (RADAR). **METH-**

ODS: Baseline data was analyzed from the Study of New Onset Rheumatoid Arthritis (S.O.N.O.R.A.SM), a 5-year prospective, longitudinal, inception cohort study to document long-term functional, clinical, and humanistic outcomes and patterns of treatment in patients with new onset rheumatoid arthritis. Baseline data collection consisted of RADAR and SF-36 via telephone interviews by trained interviewers. To assess the correlation, Pearson product moment correlation coefficients were calculated. **RESULTS:** One hundred thirty-one patients completed the baseline survey. Mean age of the sample was 56 years; 78% were female; 82% were Caucasian. SF-36's PF, RP, and BP scales had means of 54 (SE = 0.02), 31 (SE = 0.03), and 47 (SE = 0.02), respectively. Mean scores for RADAR items were 7.2 (SE = 0.22) for "arthritis activity over the past 6 months (AA6M)", 4.9 (SE = 0.23) for "arthritis activity today (AAT)", 4.2 (SE = 0.22) for "arthritis pain today (APT)", and 2.6 (SE = 0.15) for "morning stiffness today (MST)". SF-36's PF scale correlated with AA6M ($r = 0.39$, $p < 0.001$), AAT ($r = 0.49$, $p < 0.001$), APT ($r = 0.51$, $p < 0.001$), and MST ($r = 0.40$, $p < 0.001$). SF-36's RP scale correlated with AA6M ($r = 0.37$, $p < 0.001$), AAT ($r = 0.38$, $p < 0.001$), APT ($r = 0.44$, $p < 0.001$), and MST ($r = 0.33$, $p < 0.001$). SF-36's BP scale correlated with AA6M ($r = 0.50$, $p < 0.001$), AAT ($r = 0.48$, $p < 0.001$), APT ($r = 0.59$, $p < 0.001$), and MST ($r = 0.42$, $p < 0.001$). **CONCLUSION:** The SF-36's BP domain resulted in the highest correlation with RADAR items. The APT item of RADAR had the highest correlation with all three domains of SF-36. These results suggest that the level of bodily pain is indicative of functioning and well-being of patients.

MS4

A SYSTEMATIC REVIEW OF HEALTH STATE VALUES FOR OSTEOPOROSIS RELATED CONDITIONS

Brazier JE[1], Green C[2], Kanis J[1]
[1]University of Sheffield, Sheffield, UK; [2]MEDTAP UK, London, UK

An important weakness of economic models in the field of osteoporosis has been the dependence on assumptions or expert judgments rather than empirical estimates for the utility values of key health events associated with osteoporosis. **OBJECTIVES:** This paper seeks to identify the best available utility estimates for health states associated with osteoporosis and make recommendations about their use. **METHODS:** This review has been based on a systematic search of the main literature databases. Studies meeting the inclusion criteria have been reviewed in terms of the appropriateness of the valuation technique, the validity of the descriptive system (where one was used), the number and type of respondents and overall study quality. **RESULTS:** Twenty-three estimates of health state values (HSVs) were found across four conditions from five studies. These empirical estimates were found to differ significantly from the commonly used assumptions in published economic models of interventions or osteoporosis, but with a wide variation between estimates for the same state (0.32 to 0.80) for vertebral fracture states). This variation can be partly explained by differences in the valuation technique, health state descriptions and the background and perspective of the respondent, and leaves considerable scope for discretion that could be abused. There are also problems in applying values obtained from these studies to the populations being examined in economic models and a particular difficulty in predicting the HSV in those who avoid a fracture as a result of an intervention. **CONCLUSION:** The review recommends a set of HSVs as part of a reference case for use in economic models. Due to the paucity of good quality estimates in this area, further recommendations are made regarding the design of future studies to collect HSVs relevant to economic models.

RESPIRATORY DISORDERS/DISEASES

RS1

OUTCOME ASSESSMENT IN PEDIATRIC ASTHMA: A COMPARISON OF SYMPTOM-FREE TIME AND MULTI-ATTRIBUTE SCALE

Chiou CF[1], Weaver MR[2], Bell MA[2]
[1]Zynx Health Inc.—a subsidiary of Cedars-Sinai Health System, Beverly Hills, CA, USA; [2]University of Washington, Seattle, WA, USA

INTRODUCTION: Most current asthma outcome measures are either not sensitive enough to detect changes caused by interventions or not broad enough to cover all health domains affected by the disease. **OBJECTIVE:** To develop a comprehensive measure of health outcomes for children with asthma that is in compliance with the recommendations of the U.S. Panel on Cost-Effectiveness in Health and Medicine, and compare health outcomes estimated with that measure to those estimated with the symptom-free day, the most commonly used measure. **METHODS:** 1) Develop a multi-attribute Pediatric Asthma Health Outcome Measure, PAHOM, that assesses the impact of asthma on children's symptoms, emotions, and physical activity; 2) Collect data on preference weights (Ui) for asthma health states from 101 adults using the standard gamble technique; 3) Collect data on the incidence of health states (Pi) from 72 children with asthma using PAHOM calendar; and 4) Calculate the expected utility by summing all of (Ui*Pi). The expected utility can be used as a proxy of health outcome if it is assumed that health outcomes of these children are constant for the remaining life years. **RESULTS:** On a scale ranging from zero to one, where perfect health had a score of one, the average utility of pediatric asthma patients in the study was 0.900 when measured with the PAHOM, compared to 0.955 when measured with a symptom-free day. **CONCLUSION:** PAHOM, a more comprehensive measure of health outcomes than symp-

tom-free day measure, provides lower estimates of average utility of asthma pediatric asthma patients.

RS2

USING SELF-ADMINISTERED DIRECT TTO QUESTIONS TO ELICIT UTILITY VALUES FOR ASTHMATIC PATIENTS WITH DIFFERENT SEVERITY OF DISEASE

Szende A[1], Meszaros A[2], Berta GY[3], Stahl E[4], Svensson K[4]
[1]AstraZeneca, Torokbalint, Hungary; [2]Semmelweis Medical University, Budapest, Hungary; [3]Hospital for Chest Diseases, Mosdos, Hungary; [4]AstraZeneca R&D Lund, Lund, Sweden

OBJECTIVES: To gain utility values for asthmatic patients, self-administered direct TTO questions may seem to be a simple option. This study examined reported TTO values by disease severity groups, and the relationship between other health status measures, and with age. **METHODS:** 228 consecutive adult outpatients and inpatients at four sites in Hungary participated in the study. Doctors had to report GINA severity group and lung function values. Patients had to fill in three QoL questionnaires and a direct TTO question that offered a choice between 20 years in current health or shorter length of life in perfect health. Statistical analysis applied F-statistics. **RESULTS:** Mean TTO values were 0.99, 0.96, 0.82, 0.73 in the four severity groups, respectively. These were higher than corresponding EQ-5Dindex results of 0.93, 0.76, 0.65, 0.52. Correlation coefficients between TTO values and EQ-5Dindex, EQ-5Dvas, SF-36(PCS), SF-36(MCS), SGRQ, and FEV1% were 0.40, 0.40, 0.34, 0.25, −0.36, and 0.36, respectively. Age explained 23% of differences in TTO values after controlling for asthma severity. Within severity groups 4 and 3, patients over 50 reported TTO values lower by 0.21 and 0.20 than those below this age. These differences were larger than corresponding differences in EQ-5D index values suggesting that direct TTO responses may incorporate different concepts of remaining life years of the older. Results were statistically significant ($p < 0.0001$). **CONCLUSIONS:** Utility values gained from direct TTO questions can lead to higher scores than generic utility-based questionnaires, low correlation values with other measures, and to biases in patient groups of heterogeneous age.

RS3

PSYCHOMETRIC EVALUATION OF THE CAP-SYM QUESTIONNAIRE: A NEW, PATIENT-BASED MEASURE OF SYMPTOMS IN COMMUNITY ACQUIRED PNEUMONIA

Lamping D[1], Schroter S[1], Sagnier PP[2], Duprat-Lomon I[2]
[1]London School of Hygiene & Tropical Medicine, London, UK; [2]Bayer Plc, Slough, UK

OBJECTIVES: To develop a practical and scientifically rigorous, patient-based outcome questionnaire to evaluate symptoms in community-acquired pneumonia (CAP). **METHODS:** The CAP-Symptom questionnaire (CAP-Sym) is an 18-item, interviewer-administered questionnaire that measures the bothersomeness of 18 symptoms during the past 24 hours using a 6-point Likert scale. We used gold-standard psychometric methods to comprehensively evaluate the acceptability, reliability, validity and responsiveness of the CAP-Sym in field testing involving 556 patients in 13 countries. The development and validation of the CAP-Sym were carried out as part of the CAP 2000 study, a multicentre, multinational, prospective, randomised, double-blind study to compare the effectiveness of moxifloxacin oral tablets to standard oral treatment regimes in patients with CAP. **RESULTS:** Field testing in all countries confirmed the acceptability (item non-response, item endorsement frequencies, item/scale floor and ceiling effects), reliability (internal consistency, item-total and inter-item correlations, test-retest reliability), validity (content, construct, convergent, discriminant, known groups) and responsiveness of the CAP-Sym. **CONCLUSIONS:** The CAP-Sym is a practical and scientifically sound patient-based outcome measure that can be used to evaluate CAP-related symptoms in clinical trials or clinical audit. The disease-specific CAP-Sym shows preliminary evidence of being more responsive than the generic SF-36 as a measure of outcome in CAP.

RS4

A MODEL-BASED EVALUATION OF INHALED STEROIDS IN MILD-TO-MODERATE ASTHMA

Paltiel A[1], Fuhlbrigge A[2], Kitch B[2], Weiss S[2], Neumann P[3], Kuntz K[3]
[1]Yale School of Medicine, New Haven, CT, USA; [2]Harvard School of Medicine, Boston, MA, USA; [3]Harvard School of Public Health, Boston, MA, USA

OBJECTIVE: To forecast the discounted costs and clinical consequences of inhaled corticosteroids (ICS) in a population of adults with mild-to-moderate asthma. **METHODS:** We developed a Markov, state-transition simulation of asthma patient care and its pharmacoeconomic impact. We employed this framework to compare quick relievers (e.g., b-agonists) on an as-needed basis to quick relievers plus ICS therapy targeted to one of three severity sub-populations. State-space dimensions included patient age, clinical history, and lung dysfunction (measured via forced expiratory volume in one second, FEV1). Risk functions were estimated from symptom, exacerbation, and hospitalization rates obtained from literature reviews and analyses of primary, cross-sectional data. Systematic review of published trials yielded 16 eligible studies and produced the following outcome ranges for sensitivity analysis: 1%–21% improvement in FEV1; monthly costs of $14–$76; and 0%–4% probability of major toxicity. Societal costs were derived from published economic studies of inpatient and outpatient asthma. We collected preference weights (using standard gambles, time tradeoffs, and the Health Utilities Index) in a cross-sectional

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

PAM1

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

Kim SS, Drabinski AM, Williams GR, Formica CA
Knoll Pharmaceutical Company, Mount Olive, NJ, USA

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 ± 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

Chen KS[1], White TJ[2], Chang E[2]
[1]University of Southern California, Los Angeles, CA, USA;
[2]Prescription Solutions, Costa Mesa, CA, USA

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