clinical rational for lumbar fusion surgery. Patients who underwent a ALIF, PLF or T/PLIF with "stand-alone" DDD had significantly lower total payments and significantly shorter LOS, while patients with DDD and additional back diagnoses had significantly higher total payments and longer LOS compared to patients who underwent an ALIF, PLF, or T/PLIF without a comorbid diagnosis of DDD.

PSU32

A COMPARISON OF RESOURCE UTILIZATION AND MEDICAL CHARGES AMONG LUMBAR INTERBODY FUSION SURGICAL PATIENTS WITH AND WITHOUT REVISION

Kemner JE[1], Lage MJ[2], Treglia M[2]
[1]Medtronic Spinal & Biologics, Memphis, TN, USA, [2]HealthMetrics Outcomes Research, Delray Beach, FL, USA

OBJECTIVES: Compare resource utilization and medical charges among patients who had an anterior lumbar interbody fusion (ALIF), posterior lumbar interbody fusion (PLF), or transforaminal posterior lumbar interbody fusion (T-PLIF) and a subsequent revision surgery to those without such a revision surgery. **METHODS:** The MedStat MarketScan databases from 2006 - 2009 were utilized for this retrospective analysis. Patients were included if had a ALIF, PLF, or T-PLIF and had continuous insurance coverage for 2 years post procedure. Revision patients were then matched to non-revision patients at a 2:1 ratio based upon type of initial procedure, year of birth, sex, and region of residence Medical payments and resource utilization were compared between the two cohorts using t-statistics for continuous variable and chi-square statistics for categorical variables. **RESULTS:** In the 2 years post procedure, patients with a subsequent revision were significantly more likely to visit a physical therapist (92% v 62%; P<0.0001), receive an epidural steroid injection (58% v 47%; P=0.0074), or visit the emergency room with a diagnosis of back pain (20% v 9%; P<0.0001). The average cost the initial surgery was similar among the two cohorts ($39,925 v $38,341; P=0.6422) while the mean cost associated with a revision surgery was $35,296 (std dev=$32,814). Total payments for the two cohorts, ignoring the cost of the initial procedure was $33,180 for patients who did not have a subsequent revision, and $89,770 for patients with a subsequent revision (P<0.0001). These differences translate into a $56,590 cost premium associated with a revision surgery – 62% of which can be accounted by the revision surgery itself. **CONCLUSIONS:** Revision surgery was associated with significantly more resource utilization post initial surgery. Comparing costs among the two groups reveal a significant cost premium associated with revision surgery and that such costs extended beyond the cost of the revision surgery itself.

PSU33

CHARACTERISTICS AND BURDEN OF TUBEROUS SCLEROSIS COMPLEX: RESULTS OF A PATIENT AND CAREGIVER SURVEY IN THE UNITED STATES

Pashos CL[1], Rentz A[2], Liu J[3], Pelletier C[4], Prestifilippo J[5], Nakagawa J[6], Frost MD[7], Dunn DW[8], Wheless JW[9]
[1]United BioSource Corporation, Lexington, MA, USA, [2]United BioSource Corporation, Bethesda, MD, USA, [3]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA, [4]Novartis, Florham Park, NJ, USA, [5]Novartis, East Hanover, NJ, USA, [6]Tuberous Sclerosis Alliance, Silver Spring, MD, USA, [7]Minnesota Epilepsy Group, PA, St. paul, MN, USA, [8]Riley hospital for Children, Indianapolis, IN, USA, [9]Le Bonheur Children's Hospital, Memphis, TN, USA

OBJECTIVES: Tuberous sclerosis complex (TSC) is a rare genetic disorder characterized by benign tumor growth in multiple organs. TSC's subsequent and varied impacts on patients are typically treated by many different types of procedures. This study aimed to assess the principal clinical manifestations imposed by the disease and consequent major types of health care resource utilization experienced among TSC patients in the United States (US). **METHODS:** An Institutional Review Board-approved Internet-based survey of US TSC patients and caregivers solicited information on prevalence of manifestations, disease management, and impact on patients. Descriptive statistics were calculated. **RESULTS:** Of the 380 initial respondents, 53% were patients and 47% were caregivers. Surveys provided data on 380 patients, of whom 59% were female and the mean age was 30.4 years (SD: 17.3; median: 32.5). The majority of patients reported experiencing skin lesions (53%) while seizures, cognitive concerns, cerebral tumors, angiomyolipomas (AML), and subependymal giant cell astrocytomas (SEGA) were reported by 46%, 36%, 26%, 23%, and 21%, respectively. Ninety patients (24%) reported only one manifestation of TSC, while 18%, 14%, and 38% reported 2, 3, or 4 or more. Over half of patients (52%) had some type of TSC-related surgery including but not limited to brain surgery (33%), embolization (12%), nephrectomy (7%), kidney transplant (6%), and laser surgery (12%). Patients with SEGAs reported the highest level of brain surgery (55%). Among patients with AMLs, embolization for kidney lesions (28%), nephrectomy (12%) and kidney transplant (8%) were reported. **CONCLUSIONS:** In this analysis of initial respondents, TSC presents significant, and varied, epidemiological and clinical burden in the US. Patients with SEGA and AMLs seemed to experience the highest rates of invasive procedures among all patients with TSC.

PSU34

EPIDEMIOLOGICAL MODELING OF PATIENT SURVIVAL AFTER LIVER TRANSPLANTATION IN GERMANY

Jugl S, Langsdorf V, Schüle S
Novartis Pharma GmbH, Nuremberg, Bavaria, Germany

OBJECTIVES: The number of performed heart transplantations per year are well published and can easily be accessed. Nevertheless, there are no exact figures on the prevalence and incidence of patient survival after heart transplantation in Germany, although these patients have high health care needs. Purpose of this study was to generate these missing figures for the past and present as well as taking an outlook into the future development until 2030. **METHODS:** Primarily based on statistics from the Federal Statistical Office and liver transplant quality reports of the German AQUA-Institute, relevant parameters and data were identified and used to develop an epidemiological model. Key drivers of the model are yearly patient survival rates as well as growth rates of performed liver transplantations. The model starts in 1987 and is able to predict the future development of the cumulative liver transplant patient population until the year 2030. To account for uncertainty, a 1.000 replication Monte-Carlo-Simulation with random samples within published ranges of the input parameters was run. **RESULTS:** According to our model currently (2012) about 7.773 (95% Confidence interval: 7.701 – 7.844) patients with prior liver transplantation live in Germany. Until 2030 the model estimates an increase of the population size to 17.490 (95% CI: 17.105 – 17.875) people. The number of performed liver transplantations is estimated at 3.068 (95% CI: 2.988 – 3.148) in 2030. **CONCLUSIONS:** With current assumptions the liver transplant patient population size will continuously grow. The growth of this population will primarily be limited by available organs for transplantation.

PSU35

EPIDEMIOLOGICAL MODELING OF PATIENT SURVIVAL AFTER HEART TRANSPLANTATION IN GERMANY

Jugl S, Langsdorf V, Schüle S
Novartis Pharma GmbH, Nuremberg, Bavaria, Germany

OBJECTIVES: The number of performed heart transplantations per year are well published and can easily be accessed. Nevertheless, there are no exact figures on the prevalence and incidence of patient survival after heart transplantation in Germany, although these patients have high health care needs. Purpose of this study was to generate these missing figures for the past and present as well as taking an outlook into the future development until 2030. **METHODS:** Primarily based on statistics from the Federal Statistical Office and heart transplant quality reports of the German AQUA-Institute relevant parameters and data were identified and used to develop an epidemiological model. Key drivers of the model are yearly patient survival rates as well as growth rates of performed heart transplantations. The model starts in 1980 and is able to predict the future development of the cumulative heart transplant patient population until the year 2030. To account for uncertainty, a 1.000 replication Monte-Carlo-Simulation with random samples within published ranges of the input parameters was run. **RESULTS:** According to our model currently (2012) about 4.072 (95% Confidence interval: 4.028 – 4.116) patients with prior heart transplantation live in Germany. Until 2030 the model estimates a decrease of the population to 3.028 (95% CI: 2.980 – 3.077) people. Peak number of patients after heart transplantation was estimated at 2007: 4.225 (95% CI: 4.192 – 4.257). The number of performed heart transplantations is estimated at 266 (95% CI: 261-271) in 2030. **CONCLUSIONS:** Even though the peak number of patients with heart transplants according to our model has occurred in the past, still a considerable heart transplant patient population is living at Germany and seeking health care services for their needs.

PSU36

EVIDENCE BASED MEDICINE: A CASE STUDY OF ITS APPLICATION TO INNOVATIVE SURGICAL PROCEDURES IN THE UK

Mauskopf J[1], Beach W[2], Mcintyre L[3], Bhattacharyya SK[4], Higgins L[5], Mordin M[6], Copley-merriman K[6]
[1]RTI Health Solutions, Research Triangle Park, NC, USA, [2]Tuckahoe Orthopaedic Associates, Henrico, VA, USA, [3]Westchester Orthopaedic Associates, White Plains, NY, USA, [4]DePuy Mitek, Inc., Raynham, MA, USA, [5]Brigham and Women's Hospital; Harvard Medical School, Boston, MA, USA, [6]RTI Health Solutions, Ann Arbor, MI, USA

INTRODUCTION: Evidence based medicine (EBM) is frequently used as the basis for clinical guidelines and reimbursement recommendations. The hierarchy of evidence is: Level I - randomized controlled trials (RCTs); Level II - nonrandomized cohort studies; Level III - case control studies, Level IV - case series, and Level V - expert opinion. RCTs are generally required when developing clinical guidelines or reimbursement recommendations for drugs. **OBJECTIVES:** The purpose of this case review is to illustrate an application of EBM to an innovative surgical procedure and highlight how the recommendations for use changed with new evidence. **METHODS:** NICE guidelines for arthroscopic surgery for femoro-acetabular impingement were reviewed. This case study was selected because the treatment modality represents a new surgical technology in which guidelines for coverage recommendations, first promulgated in 2007, were later changed in 2011, illustrating the impact of additional evidence generation. **RESULTS:** In 2007, efficacy evidence considered by NICE were two case series, with 158 and 10 patients respectively. In 2011, efficacy evidence considered by NICE covered 1126 patients from 3 non-randomized controlled studies (none compared with natural history or non-arthroscopic surgical techniques), 5 case series (with 100 to 200 hips), and 1 case report. Twenty-two smaller case series were also identified. In 2011, four out of five specialist advisors viewed the procedure as established while one advisor considered the efficacy and safety still to be uncertain. In 2007, NICE concluded "current evidence . . . does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research" while in 2011 NICE concluded "current evidence. . ... is adequate in terms of symptom relief in the short and medium term." **CONCLUSIONS:** For innovative surgical procedures in the UK, non-randomized controlled studies and case series, supported by specialist recommendation, may be sufficient for a positive recommendation by NICE.

DISEASE-SPECIFIC STUDIES

CANCER - Clinical Outcomes Studies

PCN1

USE OF THE 5-HT3-RA ANTIEMETICS IN THE PREVENTION AND TREATMENT OF RADIATION INDUCED NAUSEA AND VOMITING

Knoth RL[1], Faria C[1], Chang E[2], Broder M[2]
[1]Eisai, Inc., Woodcliff Lake, NJ, USA, [2]Partnership for Health Analytic Research, Beverly Hills, CA, USA

OBJECTIVES: Radiation-induced nausea and vomiting (RINV) is commonly experienced by cancer patients undergoing radiation treatment. Current NCCN guidelines recommend the use of the 5-hydroxytryptamine-3 serotonin receptor antagonists (5-HT3-RAs) for the prevention and treatment of RINV. The purpose of this study was to examine the incidence of 5-HT3-RA utilization and subsequent RINV, in patients diagnosed with colon cancer and undergoing radiation treatment. **METHODS:** This was a retrospective analysis using HIPAA-compliant medical and pharmacy claims in a commercially-insured U.S. patient population. The study identified continuously enrolled adult patients diagnosed with colon cancer who received radiation treatment during the period from 4/1/2007 to 8/31/2009. Patients receiving combination chemotherapy were excluded. The index date was the date of initiation of radiation treatment and patients were followed for 30 days. Prophylactic administration of a 5-HT3-RA was defined by medication on the day of or the day prior to radiation therapy. The incidence of RINV was calculated from medical claims for an outpatient appointment, inpatient admission, or ER visit with a primary diagnosis of RINV. **RESULTS:** A total of 2,400 patients were identified as meeting the inclusion and exclusion criteria for the study. Average age of patients was 57.6 years old and 43.8% were female. Radiation therapy included localized treatment (48.6%), total body irradiation (30.9%), or both (20.5%). Of the patients identified, 73.9% received no 5-HT3-RA, 5.0% were treated prophylactically, and 21.1% received a 5-HT3-RA in the days after radiation therapy. Of the patients who received the 5-HT3-RA prophylactically, 58.2% were treated with an oral formulation. Incidence of subsequent RINV for all patients, independent of rescue medication use, was 15.2%. **CONCLUSIONS:** The results showed use of the 5-HT3-RA antiemetics in patients undergoing radiation treatment for colon cancer was uncommon and prophylactic administration was relatively rare.

PCN2

DATA ANALYSES ON PREVALENCE AND TREATMENT OF ACUTE MYELOID LEUKAEMIA IN GERMANY

Tomeczkowski J[1], Theidel U[2], Mittendorf T[2], Fleischmann J[1], Tapprich C[1]
[1]*Janssen-Cilag GmbH, Neuss, Germany,* [2]*Herescon GmbH, Hannover, Germany*

OBJECTIVES: To determine the number of patients with diagnosed acute myeloid leukaemia (AML) including chemotherapy rates, types and care settings using sickfund data. **METHODS:** Data provided by 4 statutory sick funds (SHI) and 2 data providers were analyzed for 2010. AML diagnosis was identified by ICD-10 C92.0 and other types of cancer by ICD-10 C00-79; D00-09; D37-48. Prevalence was extrapolated to the German population by correcting for a representative age- and gender distribution. **RESULTS:** The median proportion of AML patients > 60 years was 61.1% or 6,590 patients (SHI A: 63.0% = 4,938; B: 50.9% = 5,858; C: 68.9% = 8,975). The proportion of AML patients > 65 years (sick fund D) was 47.6% or 4,400 patients. Gender ratio was 57% male and 43% female. On average, 2 additional oncological disorders were found in 77% of AML patients. 50% had an unspecified leukaemia (C95.90), 25% had CML (C92.1*) and 20% MDS (D46.9). Among patients >65 years the rate of treatment was 60.9% (Anatomical Therapeutic Chemical (ATC) Code L01* (40%), pharmacy number (PZN) 9999092 (19%), operating and procedure code (OPS) 854* (26%)). 16.4% received both out- and inpatient treatment, 34.5% received outpatient treatment and 10.0% inpatient treatment. Identification of comppunds was possible when ATC codes were reported. 63.6% received imatinib and/or hydroxycarbamide, 11.4% tioguanine, 9.1% mercaptopurine, 9.1% cytarabine and 6.8% received dasatinib. The outpatient treatment rate in patients > 60 years diagnosed with AML only was 34.3% (6,2% mercaptopurine and idarubicine, 28.1% PZN 9999092). **CONCLUSIONS:** Prevalence was higher than previously reported incidence numbers of 3,100 AML patients (SHI, all age groups). The yearly outpatient treatment rate was relatively low with 34.3% in patients diagnosed with AML alone. Other oncological disorders are likely to be diagnosed before AML diagnosis could be confirmed. Treatment rates increased with additional oncological disorders with the use of substances not approved for AML.

PCN3

QUALITY-ADJUSTED SURVIVAL IN PATIENTS WITH WILD-TYPE (WT) KRAS METASTATIC COLORECTAL CANCER (MCRC) RECEIVING FIRST-LINE THERAPY WITH PANITUMUMAB PLUS FOLFOX VERSUS FOLFOX ALONE

Wang J[1], Zhao Z[2], Barber B[2], Zhang J[1], Sherrill B[1], Braun S[3], Sidhu R[2], Gallagher M[2], Douillard JY[4]
[1]*RTI Health Solutions, Research Triangle Park, NC, USA,* [2]*Amgen Inc., Thousand Oaks, CA, USA,* [3]*Amgen (Europe) GmbH, Zug, Switzerland,* [4]*ICO R. Gauducheau, ST HERBLAIN, France*

OBJECTIVES: Panitumumab plus FOLFOX significantly improved progression-free survival (PFS) in patients with WT KRAS mCRC. The objective of this analysis was to use the quality-adjusted time without symptoms of disease or toxicity of treatment (Q-TWiST) method to compare quality-adjusted survival between the treatment arms. **METHODS:** Patients with mCRC were randomized to panitumumab plus FOLFOX or FOLFOX alone in a phase III clinical trial. For each treatment arm, the area under the survival curve, which was estimated using the Weibull distribution, was partitioned into health states: toxicity (TOX), time without symptoms of disease progression or toxicity (TWiST, i.e., PFS minus TOX), and relapse period (REL, i.e., overall survival (OS) minus PFS); and adjusted using utility weights derived from patient-reported EuroQoL 5-dimensions measures. The null hypothesis of no difference between treatment groups was tested based on the normal approximation with standard errors calculated by the bootstrap method. Sensitivity analyses were performed using the standard Q-TWiST approach with means restricted to median OS. **RESULTS:** Of 1,183 patients who were randomly assigned, 1,096 patients (93%) had available tumor *KRAS* status, of which 656 patients (60%) had WT *KRAS* tumors (panitumumab plus FOLFOX, n=325; FOLFOX alone, n=331) and were included in this analysis. Compared to patients treated with FOLFOX alone, the panitumumab plus FOLFOX group had significantly longer quality-adjusted PFS (8.5 versus 7.2 months, respectively; 1.3 additional quality-adjusted months; p = 0.02) and quality-adjusted OS (22.4 versus 18.6 months; 3.8 additional quality-adjusted months; p = 0.04). When analysis was restricted to 24 months follow-up, the Q-TWiST advantage was smaller but still significant (14.0 versus 13.0 months; 1.0 additional quality-adjusted month; p = 0.04). **CONCLUSIONS:** This Q-TWiST analysis showed that in patients with previously untreated WT KRAS mCRC, panitumumab plus FOLFOX significantly improved the duration of the quality-adjusted survival compared with FOLFOX alone.

PCN4

DECISION-ANALYTIC MODEL FOR THE FIRST-LINE THERAPY OF CHRONIC MYELOID LEUKEMIA

Rochau U[1], Sroczynski G[2], Wolf D[3], Schmidt S[4], Conrads-Frank A[2], Jahn B[2], Saverno KR[5], Brixner D[6], Gastl G[7], Radich J[8], Siebert U[9]
[1]*UMIT; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T.;Innsbruck, Tyrol, Austria,* [2]*UMIT - University for Health Sciences, Medical Informatics and Technology; Oncotyrol - Center for Personalized Cancer Medicine, Hall i.T.;Innsbruck, Tyrol, Austria,* [3]*University of Bonn, Medical University Innsbruck, Bonn/Innsbruck, Austria,* [4]*Internal Medicine V, Hematology and Oncology, Medical University, Innsbruck, Austria,* [5]*UMIT- Univ. for Health Sciences, Medical Informatics and Technology, Hall i.T., Austria; Univ. of Utah, Salt Lake City, USA, Hall i.T.;Innsbruck, Tyrol, Austria,* [6]*University of Utah, College of Pharmacy, Salt Lake City, UT, USA,* [7]*Medical University Innsbruck, Innsbruck, Austria,* [8]*Fred Hutchinson Cancer Center, Seattle, WA, USA,* [9]*UMIT/ Oncotyrol/ Harvard University, Hall i.T.;Innsbruck, Tyrol, Austria*

OBJECTIVES: About a decade ago, the introduction of the tyrosine kinase inhibitor (TKI) imatinib dramatically extended the life span of chronic myeloid leukemia (CML) patients. Currently, there are several different TKIs approved for CML treatment. The goal of this study is to develop a clinical decision-analytic model for the evaluation of the comparative long-term effectiveness of first-line therapy for CML within the Austrian health care context. **METHODS:** We developed a Markov state-transition model for patients in the chronic-phase of CML treated with first-line TKI imatinib, dasatinib or nilotinib. Seven different strategies including different combinations of first and second-generation TKIs as well as chemotherapy or stem cell transplantation were evaluated. The model was parameterized using published trial data, data from the Austrian CML registry and from an Austrian CML expert panel. The model was analyzed as a cohort simulation over a lifelong time horizon. Health outcomes evaluated were life-years (LYs) gained and quality-adjusted life years (QALYs) gained. Deterministic and structural sensitivity analyses were performed. **RESULTS:** Nilotinib followed by dasatinib after failure is the most effective treatment in terms of both LYs gained (19.71 LY) and QALYs gained (17.08 QALYs). All strategies including a second-line TKI were superior compared to strategies without second-line TKI. Deterministic sensitivity analyses showed that the ranking of the strategies was mostly influenced by the duration of first- and second-line therapies. In a structural sensitivity analysis, where patients move directly from second-line TKI therapy to advanced stage of disease, strategies without second-line therapy are most effective. **CONCLUSIONS:** Based on our analyses results, the most clinically effective strategy is nilotinib followed by dasatinib as second-line therapy. All three TKIs are approved as first-line therapy in Austria. Our results may support clinicians and patients in their decision making.

PCN5

CABAZITAXEL PLUS CORTICOSTEROIDS IN COMPARISON TO CORTICOSTEROIDS ALONE FOR THE TREATMENT OF METASTATIC HORMONE REFRACTORY / CASTRATION-RESISTANT PROSTATE CANCER (MHRPC)

Schinzel S[1], Herbold M[1], Bramlage P[2]
[1]*Sanofi-Aventis Deutschland GmbH, Frankfurt, Germany,* [2]*Institut für Pharmakologie und präventive Medizin, Mahlow, Germany*

OBJECTIVES: A combination Cabazitaxel plus Corticosteroids (CC) has been shown to prolong survival in patients with mHRPC versus Mitoxantrone plus Corticosteroids (MC) in the TROPIC study of patients with mHRPC. As there is no direct comparison CC vs. Corticosteroids (C) as requested by the German regulatory bodies we aimed to provide an indirect comparison. **METHODS:** A systematic search of the DIMDI database was conducted in 12/2011. Data were combined using meta-analyses and indirect comparisons ("Bucher et al. J Clin Oncol 2008"). The endpoints analysed were all cause mortality overall and in patients with or without pain and pain response (Hazard/Response Ratios with 95%-confidence intervals). **RESULTS:** A total of 168 potential publications resulted in three relevant studies (Berry, 2002; Kantoff, 1999; Tannock, 1996) for MC vs. C. A meta-analysis of mortality in the three studies resulted in HR=0.92 (95%-CI 0.74-1.13) for MC vs. C. Combined with TROPIC (CC vs. MC 0.70; 0.59-0.83) the indirect comparison (CC vs. C) resulted in HR=0.64 (0.49-0.84). For mortality in patients without pain at baseline, the HR for MC vs. C was 0.89 (0.59-1.34) (Berry). The indirect comparison CC vs. C resulted in HR=0.51 (0.30-0.84) using TROPIC patients without pain (HR=0.57; 0.42-0.77). For mortality in patients with pain at baseline, the HR for MC vs. C was 0.83 (0.60-1.16) (Tannock). The indirect comparison CC vs. C resulted in HR=0.65 (0.43-0.98) using TROPIC patients with pain (HR=0.78; 0.60-1.00). In patients with pain at baseline, pain response was higher with MC vs. C (RR=2.33; 1.19-4.57) (Tannock). The indirect comparison CC vs. C resulted in RR=2.77 (1.05-7.32) using TROPIC patients with pain (RR=1.19; 0.59-2.39). **CONCLUSIONS:** The analyses indicate a statistically significant reduction of mortality in patients with mHRPC receiving CC vs. C with or without pain and an increased pain response.

PCN6

THE EVALUATION OF THE USE AND EFFECTIVENESS OF BEVACIZUMAB FOR PATIENTS WITH METASTATIC RENAL CELL CARCINOMA IN DAILY PRACTICE

de Groot S[1], Redekop W[1], Oosting S[2], Oosterwijk E[3], Kiemeney L[3], Uyl-de Groot C[1]
[1]*Erasmus University Rotterdam, Rotterdam, The Netherlands,* [2]*University Medical Centre*