

school 4 years after implantation. This prospective economic analysis adopted the health care payer's perspective and took into account direct medical, direct non-medical and indirect costs **RESULTS:** Two hundred and three implanted children were included in the study and followed during four years. The rate of school children implanted later (i.e. after 2 years) goes from 71,4% to 95,3% four year after implantation and goes from 28,6% to 87,5% for children implanted earlier (i.e. before 2 years). If children are implanted earlier (i.e. < 2 years), they are more likely to integrate ordinary classroom four years after implantation (69.0%) than if children were implanted later (46,9%). The mean total costs over one year period were €34,703 (+/- 5,231). The preoperative, implantation and one year follow-up mean costs were €1,304 (+/- 1,014), €24,285 (+/- 1,150) and €9,115 (+/-4,694) respectively. Ambulatory care was the costs driver in preoperative and one year follow up costs (42,0% and 66,6% respectively), while in implantation costs the driver was implant cost (90,0%). The cost of the next three year follow-up is being processed **CONCLUSIONS:** CI is an expensive medical treatment but they have a positive impact on children education.

PSS8

USE OF BIOLOGIC AGENTS IN THE TREATMENT OF PSORIASIS: AN ANALYSIS OF THE QUEBEC PROVINCIAL DRUG REIMBURSEMENT PROGRAM DATABASE

Lachaine J¹, Beauchemin C¹, Desjardins O²

¹University of Montreal, Montreal, QC, Canada, ²Abbvie, St-Laurent, QC, Canada

OBJECTIVES: The purpose of this study was to describe the use of biologics in the treatment of psoriasis, in a real life Canadian setting. **METHODS:** A retrospective study of the Quebec provincial drug reimbursement program (RAMQ) was conducted using a random sample of patients who had received at least one diagnosis of psoriasis (ICD-9: 6961/6968/6969) and had used at least one biologic in the period from January 1, 2001 to August 31, 2011. Agents included in the study were adalimumab, etanercept, infliximab, abatacept, anakinra, efalizumab, golimumab, rituximab, tocilizumab and ustekinumab. The use of biologics was analyzed in terms of patient characteristics, treatment patterns and health care resource utilization. **RESULTS:** A total of 1382 patients who used at least one biologic were included in the study. The average age was 45,8 years (SD=15,0) and the proportion of men was slightly higher (53,5%). Most patients had other concomitant inflammatory diseases (80,8%), such as rheumatoid arthritis (48,6%), psoriatic arthritis (44,9%), and Crohn's disease (15,0%). During the course of the study period, most patients used only one biologic (80,3%). Out of the 34,320 scripts for a biologic, 16,421 were for etanercept (47,9%), 8,868 for adalimumab (25,8%) and 7174 for infliximab (20,9%). Average annual cost for biologics in psoriasis was \$19,026 and was slightly higher in the first year of treatment. Costs per patient of health care resource utilization in the year following the initiation of a biologic were \$CAD486 lower than during the one year period preceding the biologic initiation; 45% of this reduction was associated with outpatient visits and 23% with hospitalizations. **CONCLUSIONS:** Psoriasis is associated with many other inflammatory conditions. Biologics use for the treatment of psoriasis has significantly increased over time. Although this is associated with higher medication costs, the initiation of a biologic is associated with a reduction of other medical costs.

PSS9

DIALYSIS FACILITY-LEVEL ANALYSIS OF THE ECONOMIC IMPACT OF PRURITUS AMONG END-STAGE RENAL DISEASE PATIENTS RECEIVING HEMODIALYSIS THERAPY

Ramakrishnan K¹, Graybill CA¹, Massey K², Sood V², Sibbel SP¹

¹DaVita Clinical Research, Minneapolis, MN, USA, ²Mitsubishi Tanabe Pharma America, Inc., Warren, NJ, USA

OBJECTIVES: Itchy and dry skin, symptoms of pruritus, are commonly reported by patients with end-stage renal disease (ESRD) and may impact health outcomes. However, the economic burden to dialysis facilities is poorly understood. This retrospective cohort study measured dialysis-related costs in patients reporting itchiness/dryness at a large dialysis organization (LDO). **METHODS:** Adult patients (≥ 18 years old) were identified in the LDO database if they responded to the Kidney Disease Quality of Life (KDQOL) survey administered between December 1, 2008 and June 30, 2012, which included questions about itchy/dry skin. Medicare patients were included if they answered a survey ≥ 3 months after dialysis initiation. Costs of medications, laboratories, and missed sessions were measured over a 6-month follow-up period. Patients were censored for death, transplant, change in treatment modality, discontinued treatment, or loss of observation. Mean utilization for medication and laboratory costs was determined by unit prices published in RED BOOK and physician fee and coding guide. Costs of missed sessions were derived by the standard 2012 Medicare composite reimbursement rate for in-center dialysis. Cost differences were determined by covariate adjusted generalized linear mixed models. **RESULTS:** Over the 6-month period, in unadjusted models (n = 38,815) increasing trends in total costs were observed with increasing severity of itchiness (\$507, \$803, \$1,520, and \$2,238) and dryness (\$542, \$840, \$1,610, and \$2,729) compared to no itchiness/dryness. The adjusted model demonstrated similar trends, yet attenuated differences. A subgroup analysis comparing combined severe itchiness and dryness versus neither itchiness nor dryness showed a mean estimate of \$2348 increased costs. All results were statistically significant (p < 0.0001). Drivers of overall dialysis costs were increased utilization of erythropoiesis-stimulating agents and missed sessions. **CONCLUSIONS:** ESRD patients with pruritus symptoms impose higher costs to dialysis facilities. Pruritus symptom relief may be an important target for therapeutic intervention.

PSS10

COST-EFFECTIVENESS OF INTRAVITREAL AFLIBERCEPT INJECTION (IAI) IN TREATING NEOVASCULAR AGE-RELATED MACULAR DEGENERATION IN THE US

Vitti R¹, Clements KM², Panchmatia H³, Hulbert E⁴, Wittrup-Jensen K⁵, Lewis BE¹

¹Regeneron Pharmaceuticals, Inc., Tarrytown, NY, USA, ²OptumInsight, Medford, MA, USA, ³OptumInsight, Cambridge, MA, USA, ⁴OptumInsight, Eden Prairie, MN, USA, ⁵Bayer Schering Pharma, Berlin, Germany

OBJECTIVES: Anti-VEGF therapy with ranibizumab (RBZ) dosed monthly improves visual acuity over time in patients with neovascular ("wet") age-related macular degeneration (wAMD). In two identical phase 3 trials, IAI dosed every 2 months, following 3 initial monthly doses demonstrated clinically equivalent efficacy and a similar safety profile to RBZ0.5mg dosed monthly (RBZQ4). We assessed U.S. cost effectiveness of IAI 2Q8 compared with RBZ Q4 in treating wAMD. **METHODS:** A Markov model was developed to characterize treatment with IAI 2Q8 and RBZ Q4 over two years. Patients move among health states based on visual acuity in the better-seeing eye. The model assumed patients discontinue treatment when vision drops below 20/400; ten percent were assumed to be treated in both eyes. The model calculated direct medical costs (drug, administration, monitoring, vision impairment and adverse events) and quality adjusted life-years (QALYs). Model parameters were estimated from clinical trial data, published literature, or expert opinion. Cost-effectiveness was reported through incremental cost-effectiveness ratios (ICERs) for a 2-year horizon. Costs and outcomes were discounted 3% per year. Deterministic and probabilistic sensitivity analyses were performed. **RESULTS:** Treatment with IAI 2Q8 cost \$30,700 over two years, compared with \$54,300 for RBZ Q4. Treatment cost was the largest cost component, comprising 78% and 85% of total costs of the IAI and RBZ regimens, respectively. Both regimens resulted in similar QALY gains (1.124 for IAI, 1.125 for RBZ). Compared with IAI, RBZ cost nearly \$26 million per QALY gained. The model was most sensitive to unit drug cost and utility weights. IAI was dominant in 41% of PSA iterations. **CONCLUSIONS:** In treating wAMD, IAI 2mg dosed every 2 months, following 3 initial monthly doses is less expensive than monthly RBZ. Both demonstrate similar efficacy. Of the two, IAI is the cost-effective alternative at conventional willingness to pay thresholds.

PSS11

THE COST-EFFECTIVENESS OF THREE COMMERCIALY AVAILABLE CELLULAR ENGINEERED SKIN SUBSTITUTES USED TO TREAT VENOUS LEG ULCERS

Carter M¹, Waycaster C², Schaum K³

¹Strategic Solutions Inc, Cody, WY, USA, ²Healthpoint Ltd., Fort Worth, TX, USA, ³Healthpoint Biotherapeutics, Fort Worth, TX, USA

OBJECTIVES: To determine the comparative cost-effectiveness of three commercially available cellular engineered skin substitutes used in the treatment of venous leg ulcers (VLU). **METHODS:** A Markov simulation model was developed to compare the one year direct costs and outcomes of a porcine small intestinal submucosa (SIS) wound matrix to fibroblast-derived (FSS) and fibroblast/keratinocyte-derived (FKSS) cellular and/or tissue-derived products (CTDP) used in the treatment of chronic VLUs. The model used three health states: a chronic ulcer, a healed ulcer and death. To predict clinical and economic outcomes a systematic literature search was conducted to identify 1) comparative chronic VLU clinical trials that reported healing/recurrence outcomes for the three skin substitutes, and 2) economic studies reporting VLU treatments and resource utilization. The effectiveness of the products was assumed equal to that reported in four clinical trials identified in the literature. Ulcer-free weeks were used as the measure of clinical effectiveness. Direct costs of treatment were derived from Medicare-allowable costs and economic studies identified in the literature which included costs associated with hospitalization, home health care, ambulatory clinic visits, CTDP products, drugs, compression stockings and other resources associated with VLU care. The payer perspective was taken in the analysis and sensitivity analyses were performed to assess model uncertainty. **RESULTS:** SIS was the economically dominant therapy compared to FKSS and FSS with a comparative effectiveness ratio of \$215 per ulcer-free week versus \$367 and \$409, respectively. Relative to SIS, the incremental cost-effectiveness ratio (ICER) for FKSS was \$1609 while the ICER for FSS was \$1132. SIS remained the least costly alternative per ulcer-free week across all sensitivity analyses. **CONCLUSIONS:** When cellular and/or tissue-derived products are needed for chronic VLU therapy our results indicate that SIS is the most cost-effective choice between the three commercially available alternatives analyzed.

PSS12

COST-EFFECTIVENESS OF DEXAMETHASONE INTRAVITREAL IMPLANT IN THE TREATMENT OF MACULAR EDEMA (ME) FOLLOWING CENTRAL RETINAL VEIN OCCLUSION (CRVO)

Vicente C¹, Koster B², Zilbershtein R¹, Piwko C¹

¹PIVINA Consulting Inc., Mississauga, ON, Canada, ²Allergan Inc., Markham, ON, Canada

OBJECTIVES: This pharmacoeconomic study evaluates the cost-effectiveness of OZURDEX™ (dexamethasone intravitreal implant) compared to observation (primary intervention at the time of model development) in management of patients with ME following CRVO, from a Canadian public payer and societal perspective. **METHODS:** A Markov model was developed to estimate lifetime outcomes and costs for patients with ME and vision loss following CRVO, receiving either OZURDEX™ implant or observation. The model consists of six health states based on Best Corrected Visual Acuity (BCVA) and one absorbing (Death) state. The model was developed using GENEVA trial results with a systematic review for extrapolation of clinical data beyond the trial period. The model incorporated direct medical costs of managing patients with CRVO, treatment, drug related adverse events and vision loss; a societal perspective was examined as well. Utilities were derived from the published literature based

on the Visual Function Questionnaire – Utility Index and subsequent mapping to BCVA. Both costs (2012 Canadian dollars) and outcomes were discounted (5%). A Canadian panel of clinical experts in the treatment of CRVO validated the model structure and resource utilization. One-way and probabilistic sensitivity analyses (PSAs), were performed to test the robustness of the model to variations in key inputs. **RESULTS:** The resulting incremental cost-utility analysis (ICUR) was \$21,568 and \$14,103 from the public payer and societal perspective, respectively, for OZURDEX™ versus observation. Results of the one-way and multivariate analysis suggest that the results were robust. Throughout the 1,000 iterations of the PSA the ICUR consistently fell below a willingness-to-pay threshold of \$50,000/QALY gained. Although robust, the model was most sensitive to age of entry and the utilities used for both the best-seeing eye and worst-seeing eye. **CONCLUSIONS:** Based on a willingness-to-pay threshold of \$50,000/QALY gained, OZURDEX™ is a cost-effective treatment for CRVO compared with observation.

SENSORY SYSTEMS DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

PSS13

VALIDATION AND COMPARISON OF THE SF-6D AND EQ-5D IN CHINESE PATIENTS WITH MODERATE TO SEVERE PSORIASIS

Zhao M¹, Wu J¹, Zheng M², Zheng ZZ², Yue N⁴

¹Tianjin University, Tianjin, China, ²Second Affiliated Hospital Zhejiang University College of Medicine, Hangzhou, China, ³Huashan Hospital, Fudan University, Shanghai, China, ⁴Johnson & Johnson, Beijing, China

OBJECTIVES: To validate and compare the psychometric properties of two generic preference-based HRQoL instruments, EuroQol (EQ-5D) and Short-Form 6D (SF-6D) among psoriasis patients in China. **METHODS:** Validity of the EQ-5D and SF-6D was examined with the patients in conjunction with Dermatology Life Quality Index (DLQI). Responsiveness was tested using the effect size (ES), relative efficiency (RE) and receiver operating characteristic (ROC) curves. Agreement between EQ-5D and SF-6D was tested using intra-class correlation coefficient (ICC) and Bland-Altman plot. **RESULTS:** A total of 150 moderate to severe patients were included with 50% female, mean age of 43.87 and mean disease duration of 5.19 years. The mean utility scores (SD) were 0.64 (0.32) for EQ-5D and 0.72(0.12) for SF-6D. There were no serious floor effects for EQ-5D and SF-6D but large ceiling effects for EQ-5D existed. Validity was demonstrated by the moderate to strong correlation coefficients (range: 0.50-0.71, P<0.001) for six of the ten hypotheses in both instruments. Both of EQ-5D and SF-6D showed a well discriminative capacity similarly (ES=0.98-1.27, ES=0.99-1.26) between groups with different psoriasis specific health status. RE showed that SF-6D (6.00-39.00%) was more efficient than EQ-5D in three domains of DLQI (recreation, relationships and treatment). Conversely, SF-6D (-1.00 - -13.00%) was less efficient than EQ-5D in three domains of DLQI (symptoms and feelings, daily activities and work and studies). The areas under ROC of them all exceeded 0.5 (0.71- 0.84, P<0.001). Poor agreement between them was observed with ICC (0.38, P<0.001) and Bland-Altman plot analysis. **CONCLUSIONS:** This study provides evidence that EQ-5D and SF-6D are valid and sensitive preference-based HRQoL instruments in Chinese patients with moderate to severe psoriasis. SF-6D may be a more effective tool with lower ceiling effect. Further study is needed to compare other properties, such as reliability and longitudinal response.

PSS14

HEALTH UTILITY AND ITS AFFECTING FACTORS FOR PATIENTS WITH PSORIASIS IN CHINA

Wu J¹, Zhao M¹, Zheng ZZ², Zheng M², Yue N⁴

¹Tianjin University, Tianjin, China, ²Huashan Hospital, Fudan University, Shanghai, China, ³Second Affiliated Hospital Zhejiang University College of Medicine, Hangzhou, China, ⁴Johnson & Johnson, Beijing, China

OBJECTIVES: To assess health utilities and examine factors affecting health utilities among patients with moderate to severe psoriasis in China. **METHODS:** Data were obtained from a cross-sectional HRQoL survey of psoriasis patients in 29 tertiary hospitals of 7 cities in China from June to July, 2012. Eligible patients were assessed with moderate to severe psoriasis by physicians and treated with prescriptions during the visit/hospitalization. Degree of moderate and severe was estimated by physicians based on definition of BSA score 3-10% and >10%. Participants completed HRQoL measures of EuroQol 5 domains (EQ-5D), Short Form 6 domains (SF-6D) and Dermatology Life Quality Index (DLQI). Socio-demographic and treatment satisfaction information were also collected from the participants. Mean scores were compared and stepwise multivariate linear regression was conducted to assess factors associated with health utilities. **RESULTS:** A total of 150 patients were included with 50% female, mean age of 43.87 years and mean disease duration of 5.19 years. About 22.67% patients reported having at least one comorbidity with anxiety/depression (14.00%) and related infection (10.00%) listed on the top. 36.67% patients expressed dissatisfaction with their current treatment. Mean EQ-5D, EQ-VAS, SF-6D and DLQI scores were 0.64, 63.23, 0.72 and 11.09, respectively, with significant difference between the severe and moderate group in all measures (0.50 vs. 0.77, 58.12 vs. 67.48, 0.67 vs. 0.75, 14.43 vs. 8.33, all p<0.001). Regression analysis indicated that health severity indicated by DLQI score was significantly associated with value scores of EQ-5D, EQ-VAS, SF-6D. Sleeplessness and living in Tier 1st city decreased EQ-5D and SF-6D scores and treatment dissatisfaction had the negative impact on EQ-VAS and SF-6D scores with statistic significant. **CONCLUSIONS:** Compared with moderate patients, patients with severe psoriasis have poorer health utilities. Increasing the patients' satisfaction with their treatment and controlling insomnia may raise their health utilities effectively.

PSS15

UNDERSTANDING THE PSORIASIS PATIENT PERSPECTIVE: USING A COMBINATION OF QUALITATIVE AND QUANTITATIVE ANALYSES TO EXPLORE AND DESCRIBE SYMPTOMS, IMPACTS, AND TREATMENT-RELATED EXPERIENCES ACROSS THE COURSE OF DISEASE

Brown TM¹, Carter C², Farahi K³, Rose A³, Fehmel S¹, Pariser D⁴, Ellis C⁵, Schenkel B²

¹RTI Health Solutions, Research Triangle Park, NC, USA, ²Janssen Scientific Affairs, LLC, Horsham, PA, USA, ³Janssen Medical Affairs, Horsham, PA, USA, ⁴David Pariser Derm Specialists, Norfolk, VA, USA, ⁵University of Michigan Medical Center, Ann Arbor, MI, USA

OBJECTIVES: Psoriasis (PsO) is a systemic, inflammatory disease manifesting in the skin and associated with psoriatic arthritis. The objective of this study was to describe and quantify patients' disease experiences, including symptoms and impact on daily lives and function. **METHODS:** This observational study was conducted in patients with moderate-to-severe PsO across 8 US sites. Qualitative data were obtained through semi-structured face-to-face interviews, including open-ended questions and patients' ranking of bothersome symptoms. Quantitative data were captured using a case report form addressing demographic and clinical characteristics and standard measures of disease severity. Each interview was transcribed and thematically coded; all mentions of symptoms and areas of life-impact were quantified. Qualitative (ATLAS.ti) and quantitative (SAS) software analysis tools were used. **RESULTS:** A total of 101 patients participated. Mean age was 49 years (SD = 14), mean duration of disease was 19 years, and 54% were male. Patients averaged 15% of body surface area involved with PsO. Mean Psoriasis Area and Severity Index score was 8.7 (SD = 8.0) and 46% of patients were receiving biologic therapy. The most frequent patient-reported symptoms were flaking/scaling (non-scalp areas) (90%), itching/scratching (88%), rash (75%), flaking/scaling (scalp area) (63%), skin pain (63%), skin bleeding (59%), and redness (58%). Most bothersome symptoms were itching/scratching, flaking/scaling (non-scalp areas), and skin pain. Nearly all patients reported an emotional (98%) and social (95%) life-impact. Other impacts included family (74% of patients), professional (69%), physical (52%), educational (23%), and sexual (21%). Positive and negative treatment-related experiences were reported. **CONCLUSIONS:** Results provide a detailed description of PsO symptoms and identify important targets for treatment based on the patient perspective. PsO has a significant multidimensional impact on patients' lives. Recording patient interviews and coding the themes, symptoms, and impacts of PsO provide rich material for analysis of patients' health-related quality of life.

PSS16

PATIENT REPORTED OUTCOMES IN GLAUCOMA A SYSTEMATIC REVIEW

Aggarwal S, Segal J, Messenger M

Novel Health Strategies, Bethesda, MD, USA

OBJECTIVES: Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improvements in health-related quality of life (HRQoL). Glaucoma is a chronic disease with high importance for patient HRQoL. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with Glaucoma. **METHODS:** A systematic literature search for Glaucoma trials with PROs endpoints was undertaken for the databases Pubmed, Embase, Biosis, Google Scholar and Cochrane. Data was collected for the study size, interventions, year, PRO instrument and results for PROs. Analysis for conducted to identify trends in commonly used PRO instruments and categorize results as positive, neutral or negative. **RESULTS:** Thirty-one studies with a total of 9819 patients were identified. In these studies there were eleven different PROs instruments were identified that were Glaucoma health perception index, Glaucoma quality of life questionnaire (Glau-QoL), Glaucoma utility index, Impact of vision impairment, Low vision quality of life questionnaire, National eye institute visual function index-19 items, National eye institute visual function index-51 items, Nursing home vision quality of life questionnaire, Quality of life and visual function questionnaire, Vision core module 1, and Vision quality of life index. The most commonly used instruments were Impact of vision impairment (used in 7 studies) and Low vision quality of life questionnaire (used in 4 studies). **CONCLUSIONS:** Patients with glaucoma have significant impairment in their QoL, hence collection of such data is important for new medical products. PRO instruments such as Impact of vision impairment and Low vision quality of life questionnaire have been commonly used to generate evidence to show which therapies improve patient QoL.

PSS17

A CONCEPTUAL FRAMEWORK OF FUNCTIONAL READING INDEPENDENCE IN GEOGRAPHIC ATROPHY

Tschosik EA¹, Bressler NM², Colman S³, Dolan C⁴, Leidy NK⁵, Oestreicher N⁶, Sunness JS⁷, Varma R⁸, Kimmel M⁹

¹Genentech, Hindsdale, IL, USA, ²John Hopkins University School of Medicine, Baltimore, MD, USA, ³Genentech, South San Francisco, CA, USA, ⁴Genentech, Sandy, UT, USA, ⁵United BioSource Corporation, Bethesda, MD, USA, ⁶Affymax, Inc, Palo Alto, CA, USA, ⁷Greater Baltimore Medical Center, Baltimore, MD, USA, ⁸Illinois Eye and Ear Infirmary, University of Illinois at Chicago, Chicago, IL, USA

OBJECTIVES: To develop a conceptual framework of functional reading independence to support development of a patient-reported outcome (PRO) measure for patients with geographic atrophy (GA) from age-related macular degeneration. **METHODS:** The conceptual framework was developed based on a literature review, expert opinion and patient input. Patient input was gathered in a qualitative concept elicitation study with 23 GA patients, where functional reading independence emerged as the most relevant concept. A draft conceptual framework and PRO questionnaire (interviewer-administered) were developed. Cognitive interviews were then conducted with 17 additional GA patients to assess understanding, completeness and relevance of the concept