

gested by these clinical experts. The resulting health states ( $n = 17$ ) were piloted and used in a societal-based valuation study ( $n = 100$ ). Participants rated half of the total health states in a standard gamble interview to derive health state utility scores. Data were analysed using a mixed model analysis. This study was conducted in line with standard NICE appraisal methodology. **RESULTS:** All tumour response statuses and toxicities were independent significant predictors of utility ( $p < 0.001$ ). Stable disease with no toxicity (our base state) had a utility value of 0.65. Utility scores ranged from 0.67 (responding disease with no toxicity) to 0.47 for progressive disease. **CONCLUSION:** This study reflects the value that society places on the avoidance of disease progression and severe toxicities associated with the treatment of second-line advanced NSCLC.

## PCN70

**RELIABILITY AND VALIDITY OF HEALTH UTILITIES INDEX (HUI) SCORES FOR SURVIVORS OF BRAIN TUMORS IN CHILDHOOD: AGREEMENT BETWEEN PATIENTS AND PARENTS**

Horsman JR<sup>1</sup>, Spitzer R<sup>2</sup>, Hsu T<sup>1</sup>, Duckworth J<sup>3</sup>, Barr RD<sup>1</sup>, Furlong W<sup>1</sup>

<sup>1</sup>McMaster University, Hamilton, ON, Canada, <sup>2</sup>University of Toronto, Toronto, ON, Canada, <sup>3</sup>McMaster Children's Hospital, Hamilton, ON, Canada

**OBJECTIVES:** Assess inter-rater agreement (patient and parent) of HUI utility scores for survivors of brain tumors in childhood. **METHODS:** Patients and their parents were interviewed twice using an interviewer-administered HUI questionnaire. Agreement was assessed using intra-class correlation coefficients (ICC). T-tests assessed the statistical significance of differences in mean overall and pain utility scores between patients reporting no pain and those reporting pain. **RESULTS:** HUI data for 40 brain tumor survivors (57.5% female) were collected during late 2000 and early 2001 (interview 1). To date, 26 re-assessment interviews have been completed during 2005–2006 (interview 2). One patient has died. Patient mean age was 6.8 years at diagnosis and 16.2 years at the first survey. For overall health-related quality of life scores (HRQL), there was substantial inter-rater agreement (HUI3 ICC = 0.723,  $p < 0.001$ ) at interview 1 and moderate agreement (HUI3 ICC = 0.561,  $p = 0.03$ ) at interview 2. There was substantial to almost perfect agreement at both interviews for attributes considered readily observable (vision, speech, ambulation and dexterity) (ICC 0.783 to 0.988,  $p < 0.001$ ). For less observable attributes (emotion, cognition, pain), agreement was moderate or less (ICC from 0.101 to 0.611,  $p = 0.372$  to 0.002). Statistically significant differences were detected for both mean HRQL (difference = 0.36,  $p = 0.003$ ) and pain (difference = 0.24,  $p = 0.003$ ) scores between patients reporting pain ( $n = 14$ ) and those pain free at interview 1. At interview 2, the mean scores were not statistically significantly different between patients reporting pain ( $n = 7$ ) and those with no pain ( $n = 19$ , HRQL  $p = 0.317$ ; pain attribute  $p = 0.067$ ). **CONCLUSIONS:** There was moderate or better inter-rater agreement for HRQL and all readily observable single-attribute HUI3 scores both at interview 1 and interview 2. Levels of ICC are consistent with previous studies of childhood cancer survivors in Brazil and Uruguay. Differences in mean HRQL and pain scores between patients with and without pain is evidence of discriminative validity.

## PCN71

**PSYCHOMETRIC EVALUATION OF A PATIENT REPORTED OUTCOME QUESTIONNAIRE FOR METASTATIC COLORECTAL CANCER**

Mathias SD<sup>1</sup>, Pritchard ML<sup>1</sup>, Mathias SD<sup>1</sup>, Lu ZJ<sup>2</sup>, Wright N<sup>3</sup>

<sup>1</sup>Ovation Research Group, San Francisco, CA, USA, <sup>2</sup>Amgen, Inc, Thousand Oaks, CA, USA, <sup>3</sup>Amgen, Inc, Cambridge, England

**OBJECTIVES:** Assess the reliability and validity of a newly developed patient-reported outcome (PRO) questionnaire for metastatic colorectal cancer (mCRC) patients. **METHODS:** The questionnaire, which includes five scales [NCCN/FACT Colorectal Cancer Scale (CS), De Novo Bother Life Quality Index (DNB), EORTC QLQ-C30 Global Quality of Life Subscale (EORTC), EQ-5D Index Scale (EQ-5D) and the EQ-5D visual analog scale (VAS)], was administered every four weeks to mCRC patients in a Phase III clinical trial. Its psychometric properties were evaluated, including internal consistency reliability, test-retest reliability, construct validity, known groups validity, and responsiveness. **RESULTS:** A total of 391 mCRC patients completed the questionnaire at baseline and at least one follow-up assessment. Internal consistency was demonstrated with Cronbach's alphas for all scales  $>0.70$  (range: 0.81–0.92). The 4-week test-retest reliability, as measured by the intra-class correlation, among patients who had stable EQ-5D scores and also among patients whose ECOG performance status was unchanged, ranged from 0.58–0.76 and 0.61–0.76, respectively. Construct validity was demonstrated based on proposed inter-scale correlations being borne out [e.g., CS was highly correlated with EORTC (0.72)]. Known groups validity was evaluated by examining the scale scores of patients categorized by their ECOG performance status. Other than DNB, patients with better performance status reported better scores than those with a lower performance status (ECOG = 0 or 1 vs. 2). Significant differences were reported on all scales ( $p < 0.001$ ) at baseline and week 8 with the exception of DNB. Responsiveness, as measured by Guyatt's statistic, was  $>0.20$  for all scales from baseline to week 8 (range 0.56–1.13) and from weeks 4 to 12 (range 0.29–1.11). EORTC and EQ-5D Index scales were the most responsive. **CONCLUSIONS:** Results provide preliminary evidence of the reliability, validity, and responsiveness of the questionnaire. Additional work is needed to estimate the minimal clinical important difference and more fully investigate test-retest reliability.

## PCN72

**A COMPARISON OF PATIENT REPORTED OUTCOMES ACROSS CURATIVE TREATMENTS OF ELDERLY PROSTATE CANCER PATIENTS**

Jayadevappa R, Chhatre S, Wein AJ, Malkowicz SB

University of Pennsylvania, Philadelphia, PA, USA

**OBJECTIVE:** We examined demographics, clinical characteristics, Health Related Quality of Life (HRQoL) and satisfaction with care across two treatments (radical prostatectomy or RP and external beam radiation or EBRT) for older prostate cancer (PCa) patients. **METHODS:** In this prospective cohort study we recruited 215 newly diagnosed PCa patients, 65 years or older, from the urology clinics of an urban academic hospital and a VA hospital. Patients completed generic (SF-36), prostate specific (UCLA-PCI) HRQoL, and satisfaction with care (CSQ-8) surveys prior to treatment and at 3, 6, and 12 months post-treatment. Clinical and demographic data were obtained using hospital based databases. Repeated measures ANOVA was used to examine changes in generic and PCa specific HRQoL across treatments. Log-linear regression was used to determine factors associated with 12 month HRQoL. Survival curves were used to

compare return to baseline (RTB) for HRQoL. A seven point difference (considered to be clinically significant) between baseline and follow-up score was considered as RTB. **RESULTS:** ANOVA indicated that RP group had higher scores for generic HRQoL subscales of physical function ( $p = 0.019$ ), role emotional ( $p = 0.037$ ), vitality ( $p = 0.033$ ) and general health ( $p = 0.05$ ). Step-wise log-linear regression models showed that RP was associated with higher 12 month scores for most of the generic HRQoL scales, bowel function (OR = 1.12), urinary bother (OR = 1.6) and bowel bother (OR = 1.5). For generic HRQoL (SF-36) at 12 month follow-up, higher proportion of the RP group returned to baseline on eight sub-scales. RP group had lower proportion returning to baseline for urinary ( $p = 0.0012$ ) and sexual ( $p < 0.0001$ ) functions, and higher proportion returning to baseline for bowel function, urinary bother and bowel bother ( $p < 0.005$ ). Satisfaction with care was comparable between treatment groups. **CONCLUSIONS:** Older patients appear to have better tolerance for RP as indicated by patient reported outcomes. Thus age alone need not be a criterion in treatment decision.

## PCN73

#### VARIATIONS IN SATISFACTION WITH CARE AND EMOTIONAL WELL-BEING OF EARLY-STAGE PROSTATE CANCER PATIENTS

Jayadevappa R<sup>1</sup>, Chhatre S<sup>1</sup>, Wein AJ<sup>2</sup>, Malkowicz SB<sup>1</sup>

<sup>1</sup>University of Pennsylvania, Philadelphia, PA, USA, <sup>2</sup>University of Pennsylvania, Philadelphia, PA, USA

**OBJECTIVE:** To compare self-reported satisfaction with care and emotional well-being of newly diagnosed prostate cancer (PCa) patients receiving either Radical Prostatectomy (RP) or External Beam Radiation Therapy (EBRT). **METHODS:** The study was part of a larger prospective cohort study. We recruited 231 newly diagnosed African-American and Caucasian PCa patients from urology clinics of an urban academic hospital and a VA hospital. Patients completed the Client Satisfaction Questionnaire (CSQ-8), SF-36, FACT-p and UCLA-PCI prior to their treatment and at 3, 6, and 12 month follow-up. Demographic and clinical data were obtained from hospital based databases. Parametric and nonparametric tests were used to compare demographics, clinical characteristics and FACT-p subscales between treatment groups. Log linear regression models were used to assess factors associated with satisfaction. **RESULTS:** The RP group was younger ( $p < 0.0001$ ), had a higher proportion of Caucasians ( $p < 0.0001$ ), and were more like to be married ( $p < 0.0001$ ), have incomes greater than \$40,000 ( $p < 0.0001$ ) and be employed full-time ( $p < 0.0001$ ). Gleason score, TNM stage and Charlson comorbidity score were comparable by groups. Higher number of EBRT group reported poorer outcome measures on emotional well being subscale of FACT-p, compared to RP group. A higher proportion of RP patients indicated that they were likely to recommend the treatment to a friend ( $p = 0.0244$ ) and that they would seek the same treatment if needed again ( $p = 0.0328$ ). ANOVA of total CSQ8 score indicated significant differences between the groups and over time ( $p = 0.0059$  and  $0.0228$ , respectively). Log linear regression showed that RP treatment (OR = 1.13,  $p = 0.045$ ), baseline PSA (OR = 0.98,  $p = 0.0062$ ) and VA hospital (OR = 0.84,  $p = 0.0299$ ) were associated with total satisfaction with care. **CONCLUSION:** EBRT, higher baseline PSA and non-VA hospital type are associated with lower satisfaction with care of PCa patients at 12 months post-treatment.

## PCN74

#### UTILITIES ASSOCIATED WITH NON-SMALL CELL LUNG CANCER (NSCLC): A COMMUNITY STUDY

Tabberer M<sup>1</sup>, Stamuli E<sup>1</sup>, Walker M<sup>2</sup>, Summerhayes M<sup>2</sup>, Lees M<sup>1</sup>

<sup>1</sup>Oxford Outcomes Ltd, Oxford, Oxon, UK, <sup>2</sup>Roche Products Ltd, Welwyn Garden City, Herts, UK

**OBJECTIVE:** Exploring impact of NSCLC on quality of life (QOL) by eliciting utilities from a community sample. Non-small cell lung cancer (NSCLC) and its treatment both have a substantial negative effect on QOL. Little published research quantifies these effects in advanced disease. **METHODS:** Health state descriptions were developed from the literature and refined through clinician interviews ( $n = 6$ ). Treatment response, stable disease, progressed disease, near-death and adverse events (AEs): neutropenia, febrile neutropenia, nausea, diarrhoea, stomatitis, neuropathy and rash were described. The impact of oral versus intravenous (IV) medication was also explored. A total of 154 lay people across the UK (Glasgow, Oxford, London, Cardiff) were presented with information on NSCLC. Health states, presented randomly, were valued using the EQ-5D. These values were converted to utilities for each health state. **RESULTS:** All health states were associated with low utility values. The utility value for near-death was the lowest (0.15) and that for treatment response the highest (0.49). There was no statistical difference between treatment response and stable disease (0.46). Stable disease receiving IV therapy had a significantly lower utility (0.43) than stable disease with no treatment; stable disease receiving oral therapy (0.45) did not. The utility value associated with progressed disease (0.22) was closer to that for near-death. Utilities for AEs were valued relative to the stable disease state. The greatest disutility was associated with febrile neutropenia (-0.27) and the lowest with rash (-0.06). Disutilities associated with other AEs were neuropathy (-0.15), neutropenia (-0.14), nausea (-0.14), stomatitis (-0.14) and diarrhoea (-0.13). **CONCLUSIONS:** Societal valuation showed that all disease states and AEs associated with NSCLC have a substantial impact on QOL, with disease progression, febrile neutropenia and near-death having the greatest impact. Treatment related rash is the least serious adverse event. Stable disease is associated with a better QOL than progressed disease.

## INFECTION

## PINI

#### CLINICAL AND ECONOMIC IMPACT OF INTRODUCING A QUADRIVALENT (6, 11, 16, 18) HUMAN PAPILLOMAVIRUS VACCINE IN SWITZERLAND

Gerber S<sup>1</sup>, Heinzl S<sup>2</sup>, Largeron N<sup>3</sup>, Bénard S<sup>4</sup>

<sup>1</sup>CHUV, Lausanne, Switzerland, <sup>2</sup>Kantonsspital, Bruderholz, Switzerland, <sup>3</sup>sanofi pasteur MSD, Lyon, France, <sup>4</sup>st[e]ve consultants, Lyon, France

**OBJECTIVES:** Human Papillomavirus (HPV) is a necessary cause of cervical cancer (CC). To date, CC screening programmes have been the only tool to help to prevent CC by detecting and removing precancerous lesions. With the expected licensure of a quadrivalent HPV vaccination, a decision analysis model was developed to quantify the health and economic benefits of a quadrivalent (6, 11, 16, 18) HPV vaccine alongside CC screening in Switzerland. **METHODS:** The vaccine was considered to prevent 100% of HPV 6, 11, 16 and 18-associated diseases, with lifetime duration of protection and 40% coverage rate, when given to girls at age 12. Resource consumption included physician visits, medical examinations, treatments and hospitalisations. Data for management of abnormal pap smears, cervical dysplasia and genital warts were estimated by Swiss experts.