

CANCER—Patient Reported Outcomes

PCN39

A SYSTEMATIC REVIEW OF THE UCLA PROSTATE CANCER INDEX'S MEASUREMENT PROPERTIESEpstein JD¹, Gwadrý-Sridhar F²¹University of Southern California, Los Angeles, CA, USA, ²University of Western Ontario, and London Health Sciences Centre, London, ON, Canada

OBJECTIVES: The UCLA Prostate Cancer Index (UCLA-PCI) is a disease specific Health-related Quality of Life (HRQOL) measure used in early stage prostate cancer patients. We examined the UCLA-PCI's measurement properties in this study. **METHODS:** We systematically identified all published papers citing the original publication using the Science Citation Index. For completeness, we also searched the PubMed and Ovid databases from 1995 to the present. We analyzed all English articles reporting measurement properties of the UCLA-PCI. **RESULTS:** We identified 224 papers. Seventy-seven of these papers reported results using the UCLA-PCI in either cross-sectional designs (43) or in longitudinal analyses (34). The UCLA-PCI exhibited high reliability (intraclass correlation coefficients ranged from 0.66 to 0.97). The UCLA-PCI also had good face and content validity, as demonstrated by the number of studies that incorporated the instrument and by its translation into five other languages. The construct validity of the UCLA-PCI's functioning domains has been demonstrated with correlations of 0.42 to 0.88 when compared with other relevant disease-specific HRQOL measures; however further study comparing the UCLA-PCI to other disease-specific HRQOL measures (FACT-P, EORTC-P, IPSS) may be warranted. Although this instrument has been used in many longitudinal research designs, its evaluative validity only was assessed in one study (effect sizes ranged from 0.77 to 1.51). The responsiveness of the UCLA-PCI to HRQOL changes has been shown in many studies usually by comparing changes in the study population with the UCLA-PCI values of older men without prostate cancer (reported in 1999). To maximize interpretability of each domain, both anchor and distributional techniques should be utilized to determine what changes the patient may perceive as minimally important differences. **CONCLUSIONS:** Although the UCLA-PCI has been shown to be reliable and valid, we encourage further research establishing its interpretability and expanding its validity through its assessment in clinical trials.

PCN40

THE IMPACT OF HUMAN PAPILLOMAVIRUS INFECTION AND CERVICAL CANCER ON HEALTH-RELATED QUALITY OF LIFE: A REVIEW OF VALIDATED INSTRUMENTS CURRENTLY AVAILABLERofail D¹, Abetz L², Jenkins D³, Lindsay L³, De Vuyst H³¹Mapi Values Limited, Macclesfield, Cheshire, UK, ²Mapi Values Limited, Bollington, Cheshire, UK, ³GSK Biologicals, Rixensart, Belgium

OBJECTIVES: To identify the most appropriate instruments which could be used to assess health-related quality of life (HRQoL) on the full-spectrum of human papillomavirus (HPV) related cervical disease, namely HPV infection, cervical screening, pre-cancer and cancer. **METHODS:** Electronic databases (PsycINFO, EMBASE, and PUBMED), the internet, and conference proceeding abstracts were searched. The impact of the health states on HRQoL domains was documented and each instrument was reviewed according to its domain coverage, assessment features, and psychometric properties. **RESULTS:** The search strategy produced 1011 articles. Of these 94 reported HRQoL data, of which 53 used multidimensional HRQoL

instruments. Results indicated that HPV infection, screening, cervical precancer and cancer have a direct and sizeable effect on HRQoL, although not all domains were impacted per health state. Overall, 24 different instruments were identified and categorised as follows: generic (8), illness-specific (2), cancer specific (5), psychosocial (5), or screening instruments (4). A review of the instruments suggest that the Medical Outcomes Study Short Form Health Survey (SF-36) would be most appropriate generic HRQoL instrument which could be used in any health state, and the European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC-QLQ-C30) would be the most suitable HRQoL cancer-specific instrument in cervical cancer. Either the Psychosocial Effects of Abnormal Pap Smears Questionnaire (PEAPS-Q) or the Cervical Dysplasia Distress Questionnaire (CDDQ) could be used to assess psychosocial impact in cervical dysplasia, and either the Quality of Life for Population Screening (SCREENQOL) or the Self-Evaluation Quality of Life Questionnaire (SEQOL) could be used as a screening instrument. **CONCLUSIONS:** There was no single instrument that covered all the domains that would be directly relevant to each health state. Thus, our recommendation is that when possible a battery of instruments including one from each category identified should be administered in any study.

PCN41

EQ-5D IN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC): ASSESSMENT OF VALIDITY AND RESPONSIVENESSSundaram M¹, Kutikova L², Enas NH², Lu H², Liepa AM²¹West Virginia University School of Pharmacy, Morgantown, WV, USA,²Eli Lilly and Company, Indianapolis, IN, USA

OBJECTIVE: Given a paucity of validity data for the EQ-5D in cancer patients, we investigated its psychometric properties and its ability to differentiate clinically different groups in patients with advanced NSCLC. **METHODS:** The EQ-5D index and Visual Analog Scale (VAS) were administered within a phase II trial of combination chemotherapy over 6 months (at baseline, start of each 3-week cycle, and end of patient's last cycle). Clinical assessments included radiological tumor response and Eastern Cooperative Oncology Group performance status (PS). Reliability was assessed using Cronbach's α (internal consistency) and Pearson correlation (test-retest). Analysis of variance assessed construct validity. Effect size (ES) and standardized response mean (SRM) were calculated to evaluate responsiveness to change in clinical indicators. **RESULTS:** Data from 195 patients were analyzed. Cronbach's α for EQ-5D index was 0.68 at baseline. Correlations for test-retest (mean = 7 days between assessments) were 0.70 and 0.80 for the index and VAS, respectively. Index and VAS scores differentiated patients by PS at all assessments ($p < 0.05$), demonstrating construct validity. Mean index scores were 0.73 (complete or partial response [CR/PR], $n = 42$), 0.68 (stable disease [SD], $n = 90$), and 0.58 (progressive disease [PD], $n = 32$). Index scores were significantly lower in patients with PD, compared to those with CR/PR ($p = 0.047$), while VAS scores showed no significant differences. ES and SRM for index change scores were: 1) -0.73 and -0.38 , respectively, in patients whose PS worsened; -0.08 each in patients with stable PS at the beginning of cycle 6; and 2) -0.27 and -0.38 , respectively, in patients with CR/PR; -0.36 and -0.34 , respectively, in patients with SD; -0.44 and -0.28 , respectively, in patients with PD. **CONCLUSIONS:** The EQ-5D was reliable and valid in NSCLC. EQ-5D scores differentiated patients by performance status and best tumor response, which is important for generating utilities associated with health states defined by these clinical indicators.