OBJECTIVES: Currently no measure can identify, with a high degree of positive predictive power, suicidal behavior. Because suicide occurs at a low base-rate, studies of instruments designed to predict this outcome often lack an adequate sample size to prove the tool's predictive ability. Our aim is to identify an assessment with the most promise of predicting suicidal behavior in veteran or military patients and present options to overcome previous research hurdles. METHODS: Two systematic reviews, one performed for the US Department of Veterans [1], and the other as part of NICE guidance development [2] provided the background for our analysis. These summaries were reviewed to identify the most predictive assessments yet developed. Sensitivity, specificity, positive and negative predictive power were tabulated for all reported instruments. Study limitations were recorded along with these results. **RESULTS:** One instrument showed promise of meeting the objective. The Affective States Questionnaire (ASQ) was able to predict suicide within 3 months with a sensitivity of 60%, specificity of 74% and positive predictive power of 32% [3]. The study that produced those results was performed on an inpatient and outpatient veteran population. However, the sample was small with only 283 patients and the risk of bias was unclear. A larger study may provide the needed evidence to make the Affective States Questionnaire a useful screening tool. We propose the Affective States Questionnaire be transferred to electronic administration and provided as part of routine admissions at VA facilities. Deploying the tool electronically could provide the large sample sizes required to detect effects on this low base-rate outcome. CONCLUSIONS: The Affective States Questionnaire shows promise of becoming an appropriate screening tool for suicide in a military population. Electronic capture may allow for large scale deployment, therefore gaining sufficient sample to determine applicability as a screening tool.

#### PRM151

RE-VALIDATION OF THE SELF-INJECTION ASSESSMENT QUESTIONNAIRE© (SIAQV2.0©) IN RHEUMATOID ARTHRITIS PATIENTS ON CERTOLIZUMAB PEGOL TREATMENT

<u>Coteur G</u>

UCB Pharma, Brussels, Belgium

**OBJECTIVES:** To evaluate psychometric properties of the revised Self-Injection Assessment Questionnaire in rheumatoid arthritis patients (pts) receiving certoli-zumab pegol. **METHODS:** In the study (NCT00674362), pts with low to moderate rheumatoid arthritis (RA) received certolizumab peopl (CZP; 400mg at Weeks [Wks] 0, 2, 4, then 200mg every other wk). In the open-label extension (OLE; NCT00843778), pts could self-administer CZP using a pre-filled syringe. Pts in OLE completed the revised Self-Injection Assessment Questionnaire (SIAQ<sub>v2.0</sub><sup>©</sup>) at Wks 0, 2, 4, 6, 8, 10, 12. Domain scores were calculated per authors' recommendations, and internal consistency was assessed using the Cronbach's alpha statistics. Floor and ceiling effects were reported as % pts with the worst/best domain score. Construct validity was assessed by confirmatory factor analysis fitting the current conceptual framework of the questionnaire and by calculating the Bentler's Comparative Fit Index (CFI) and the root mean square error of approximation (RMSEA). RESULTS: 86 pts (mean age: 50.8 years; disease duration: 4.6 years) entered the OLE and completed the SIAQ at least once. At first self-injection visit, DAS28 (ESR) was 4.0 and HAQ-DI 0.9. The internal consistency of all domains was >0.8 at any visit. Floor effect was <5% at any visit; ceiling effect was ≤13% for Self-Confidence, Ease of Use (EU) and Satisfaction domains, but reached 40% for Feeling and Injection-Site Reactions domains. The ceiling effect of the EU domain was lower (10%) than the original validation (22%). The conceptual framework structure was supported by the confirmatory factor analysis with CFI values of 0.75–0.86 and RMSEA values of 0.10–0.13, which, given the limited sample size, would indicate reasonable goodness of fit. CONCLUSIONS: Modifications brought to the  $SIAQ_{\nu_2,0}^{\circ}$  appeared to remediate the acquiescence bias issue that was noted during the validation of  $SIAQ_{\nu_1}$ . The appropriateness of the internal consistency reliability and construct validity of the  $SIAQ_{v2.0}$ <sup>©</sup> were confirmed

#### PRM152

PHYSICIANS' PREFERENCES FOR BONE METASTASES TREATMENTS IN TURKEY <u>González JM</u><sup>1</sup>, Gatta F<sup>2</sup>, Arellano J<sup>3</sup>, Qian Y<sup>3</sup>, Ertugrul G<sup>4</sup>, Hauber AB<sup>1</sup>, Posner J<sup>1</sup>, Oksuzoglu B<sup>5</sup>

<sup>1</sup>RTI Health Solutions, Research Triangle Park, NC, USA, <sup>2</sup>Amgen (Europe) GmbH, Zug, Switzerland, <sup>3</sup>Amgen Inc., Thousand Oaks, CA, USA, <sup>4</sup>Amgen Turkey, Istanbul, Turkey, <sup>5</sup>Ankara Oncology Training and Research Hospital, Ankara, Turkey

**OBJECTIVES:** To evaluate Turkish physicians' preferences when selecting between the different bone-targeted agents (BTAs) available for preventing skeletal-related events (SREs) in patients with bone metastases from advanced solid tumors. METHODS: Physicians from several centres, currently treating patients with bone metastases from solid tumours were recruited by phone or personal invitation and then engaged in a face-to-face interview where they completed a web-enabled discrete-choice experiment survey. Each survey included 10 choices between pairs of hypothetical treatment profiles for the two putative patient profiles. The hypothetical treatment profiles included five attributes within a pre-defined range (based on prescribing information): time until first SRE (10, 18 and 28 months); time until worsening of pain (3, 6 and 10 months); annual risk of osteonecrosis of the jaw (ONJ; 0, 1 and 5%); annual risk of renal impairment (0,4 and 10%); and mode of administration (oral tablet, subcutaneous injection, 15-minute or 120-minute intravenous infusion). Choice questions were based on an experimental design with known statistical properties. A main-effects random parameters logit model was estimated. **RESULTS:** A total of 105 physicians agreed to participate in the face-to-face interview and accessed the online survey. Of these, 104 physicians were eligible and consented to participate and 99 were included in the analysis. Estimated preference weights for all applicable attributes were consistent with the natural ordering of the categories. Risk of renal impairment and months until first SRE were the most important attributes influencing physicians' decisions, with better clinical outcomes preferred to worse outcomes. Preventing pain progression was the third most important attribute followed by mode of administration.

Annual risk of ONJ was the least important attribute. **CONCLUSIONS:** When making treatment decisions regarding choice of BTA for patients with bone metastases, the main treatment goals for Turkish physicians are reducing risk of renal impairment and delaying first SRE.

# PRM153

## VALIDITY OF THE EQ-5D-5L IN STROKE PATIENTS

<u>Golicki D</u><sup>1</sup>, Niewada M<sup>1</sup>, Buczek J<sup>2</sup>, Karlinska A<sup>2</sup>, Kobayashi A<sup>2</sup>, Janssen MF<sup>3</sup>, Pickard AS<sup>4</sup> <sup>1</sup>Department of Experimental and Clinical Pharmacology, Medical University of Warsaw, Warsaw, Poland, <sup>2</sup>2nd Department of Neurology, Institute of Psychiatry and Neurology, Warsaw, Poland, <sup>3</sup>Department of Medical Psychology and Psychotherapy, Erasmus MC, Erasmus University, Rotterdam, The Netherlands, <sup>4</sup>Department of Pharmacy Systems, Outcomes, and Policy, College of Pharmacy, University of Illinois at Chicago, Chicago, LL, USA

OBJECTIVES: To assess EQ-5D-5L validity in patients with acute stroke, in comparison to EQ-5D-3L, EQ VAS, modified Rankin Scale (mRS) and Barthel Index (BI). METHODS: Cross-sectional study of 408 patients (51.5% males; mean age 69 years), after median 8 days from stroke onset. We assessed: construct validity in terms of known-groups validity, convergent validity of EQ-5D-5L dimensions with other stroke outcome measures, and criterion-related validity in terms of concurrent validity, with mRS as a gold standard. RESULTS: A total of 2.9% EQ-5D-5L and 3.7% EQ-5D-3L questionnaires had at least one missing answer, indicating good feasibility of both instruments in patients with stroke. The proportion of patients reporting 'no problems' was 38.2% for BI, 6.1% for EQ-5D-3L, 5.6% for EQ-5D-5L, 5.0% for mRS and 2.5% for EQ VAS. Results of the known-groups validity tests confirmed prior hypotheses: health state utilities were lower in females, patients with high mRS score, low BI or VAS score, patients with subarachnoid hemorrhage or intracerebral hemorrhage, and when proxy respondent was used. Convergence of EQ-5D-5L dimensions with mRS, BI and EQ VAS was improved or at least the same as EQ-5D-3L dimensions. For predicting outcome in patients with stroke, the sum of mRS related EQ-5D-5L dimensions (Mobility, Self-care, Usual activities), gave 1% of false positive and 0% of false negative results. CONCLUSIONS: Results support the validity of the EQ-5D-5L descriptive system as a generic measure assessed by self-report and proxy in patients with acute stroke, demonstrating some psychometric advantages in comparison to EQ-5D-3L and substantially lower ceiling effect in comparison to Barthel Index.

### PRM154

AN EVALUATION OF THE PERFORMANCE OF EQ-5D: A REVIEW OF REVIEWS OF PSYCHOMETRIC PROPERTIES

Longworth L<sup>1</sup>, <u>Singh J</u><sup>1</sup>, Brazier J<sup>2</sup>

<sup>1</sup>Brunel University, Uxbridge, UK, <sup>2</sup>University of Sheffield, Sheffield, UK

OBJECTIVES: EQ-5D has been widely used to measure health status in a variety of conditions and the amount of evidence of its performance has increased over recent years. The aim of this study was to consolidate this evidence by reviewing papers reporting systematic reviews of the psychometric properties (validity and reliability) and/or responsiveness of EQ-5D. METHODS: Medline and Embase were searched for systematic reviews of the performance of EQ-5D. Supplementary searches were carried out in Cochrane Library, Web of Science, reference lists of included studies, the EuroQol database and hand searching of EuroQol Scientific Plenary Proceedings. In addition the website of the Oxford Patient Reported Outcome Measures (PROMs) Group was searched for reports. Data were extracted using a template designed specifically for the study. RESULTS: 25 reviews were identified in this study and a further 18 were identified from the Oxford PROMs group website. The majority of studies focussed on adults. Overall there was evidence of good to fair performance of EQ-5D in depression, diabetes (type 2), rheumatoid arthritis, skin conditions, cancer, cardiovascular disease, asthma, personality disorder and urinary incontinence. Evidence was mixed in COPD, dementia, schizophrenia and vision disorders, and poor for hearing disorders. The was little evidence for liver transplantation, venous leg ulcers, haemophilia, bipolar disorder and low back pain; although limited, the evidence showed positive results for liver transplantation, haemophilia and leg ulcers. No evidence was identified for, among others, skin cancer and systemic lupus erythematous. CONCLUSIONS: This study has provided a comprehensive overview of the evidence of the performance of EQ-5D. Most evidence suggests good psychometric properties of EQ-5D; however there are particular concerns about its ability to capture the impact of dementia, schizophrenia, visual impairment and hearing disorders. Further research is encouraged in conditions where data or reviews of psychometric properties of EQ-5D are lacking.

### PRM155

HEALTH-RELATED QUALITY OF LIFE IN ITALIAN PATIENTS WITH MODERATE AND SEVERE CROHN'S DISEASE: INTERIM RESULTS FROM THE SOLE STUDY Lazzaro C<sup>1</sup>, Cappello M<sup>2</sup>, Cortelezzi C<sup>3</sup>, Costantino G<sup>4</sup>, Fiorino G<sup>5</sup>, Mastronardi M<sup>6</sup>, Giannotta M<sup>7</sup>, Galletti B<sup>8</sup>, Cicala M<sup>9</sup>, Vadalà di Prampero S<sup>10</sup>, Gualberti G<sup>11</sup>, Caprioli F<sup>12</sup>, Gasbarrini A<sup>13</sup>, Meregaglia M<sup>14</sup>

Gasoammin', Janeteggila M.
Gasoammin', Janeteggila M.
Studio di Economia Sanitaria, Milan, Italy, <sup>2</sup>Università di Palermo, Palermo, Italy, <sup>3</sup>AOU di
Circolo - Fondazione Macchi, Varese, Italy, <sup>4</sup>Università di Messina, Messina, Italy, <sup>5</sup>Istituto Clinico
Humanitas, Rozzano (MI), Italy, <sup>6</sup>IRCCS S. De Bellis, Castellana Grotte, Italy, <sup>7</sup>Azienda Ospedaliero
Universitaria di Careggi, Firenze, Italy, <sup>8</sup>Ospedale S. Salvatore, L'Aquila, Italy, <sup>9</sup>Università Campus
Bio Medico, Roma, Italy, <sup>10</sup>Azienda Ospedaliero-Universitaria S. Maria della Misericordia di
Udine, Italy, <sup>11</sup>AbVie, Campoverde di Aprilia (LT), Italy, <sup>12</sup>Università degli Studi di Milano,
Milano, Italy, <sup>13</sup>Università Cattolica del Sacro Cuore, Rome, Italy, <sup>44</sup>Bocconi University, Milan, Italy **OBJECTIVES:** To investigate health-related quality of life (HRQQL) in Italian
patients with moderate and severe Crohn's disease (CD) (Harvey Bradshaw
Index: 8). **METHODS:** EuroQoL 5-dimension 3-level (EQ-SD-3L) questionnaire
and visual analogue scale (VAS) were administered to 540 consecutive patients
with moderate and severe CD who referred to a convenience sample of 38 Italian
inflammatory bowel disease centres (21 teaching-hospitals; 2 private hospitals;
3 self-governing hospitals; 3 Local Health Authority hospitals; 2 private hospitals;
a self-governing in the ongoing Survey on Quality Of Life in Crohn's Patients (SOLE)