OBJECTIVES: To explore how participants evaluate and complete the choice tasks in Discrete Choice Experiments (DCEs), with special attention to the impact of educational level and health literacy. METHODS: Two existing DCE questionnaires on rotavirus vaccination and prostate cancer screening served as a case for the current study. In total, 70 participants were sampled based on educational level [5 per case study during structured interviews, participants completed five choice tasks aloud. Interviewers monitored how participants read the choice tasks, how they interpreted the included risk attributes and what decision strategy they used to make their decision and whether they had to complete the DCEs with any assistance holds. RESULTS: The majority of the participants read all the attributes within each choice task. Nearly all participants chose the scenario with the optimal attribute values (monotonicity axiom). In accordance with the continuity axiom, most participants mentioned three or more attributes when justifying their decisions. Overall, higher educated participants more often included three or more attributes when motivating their decision and used trading between attributes more often as a decision strategy. CONCLUSIONS: The majority of participants were able to complete a DCE with assistance, which is important in future studies. However, the assumptions did not hold for a subset of lower educated and less literate participants. Based on participants’ age, educational level and health literacy additional measures should be undertaken to enhance participants’ understanding of the attributes, the attribute levels and the choice tasks in a DCE.

PM140
THE MEASUREMENT OF UTILITIES IN ASTHMA PATIENTS: A PRELIMINARY STUDY
Yen TV, Shafie AA
Department of Business Management, Penang, Malaysia
OBJECTIVES: To assess the feasibility of a computer-based Standard Gamble (SG) visual prop whilst measuring utilities of different asthma health states at the same time. METHODS: Twenty adult asthma patients literate in either Malay or English language were conveniently sampled from a public hospital in Penang, Malaysia. They were interviewed by two trained interviewers using a bilingual script. Each patient was requested to value the given health states using Visual Analogue Scale (VAS) prior to SG exercise. There were three chronic health states (C1, C2, C3) for 3 months, and three anchor states (healthy and death). During the SG exercise, the visual prop was fully operated by the interviewers. The probability of being in a worse state was changed in a ‘ping-pong’ fashion until the indifference point was reached. RESULTS: All patients understood the SG exercise and rated SG easier than VAS. Around 85% (n=17) completed SG within 30 minutes. There was 90% (n=18) who ranked T3 as the worst temporary health state during VAS. 85% of patients provided logical inconsistency data in SG. The preferences by SG were higher than VAS. Preferences were also higher in temporary states measured by chained SG than other states by conventional SG. The mean utilities for C1=0.56 (SD 0.38), C2=0.47 (SD 0.53), C3=0.53 (SD 0.38), T1=0.65 (SD 0.51), T2=0.53 (SD 0.35), and T3=0.63 (SD 0.33). CONCLUSIONS: The drops are feasible for utilities measurement in asthma, based on the agreements achieved with other studies on the pattern of utilities measured in this preliminary study.

PM141
DISCRETE-CHOICE EXPERIMENT VERSUS RATING SCALE EXERCISE TO EVALUATE THE RELATIVE IMPORTANCE OF ATTRIBUTES: A STUDY OF THE MAXIMUM PROBABILITY QUESTIONNAIRE
Wijnen BF1, van der Putten IM2, Grootenhuis S1, de Kinderen BJA1, Noben CYC3, Paulus ATU1, Ramaekers BLT1, Vogt GCVWM, Hillemann M1
1Maastricht University The Netherlands, Maasstricht, The Netherlands, 2Maastricht University Medical Center, Maastricht, The Netherlands
OBJECTIVES: Eliciting preferences has become increasingly important in health care decision making. Our study aimed to compare the relative importance of aspects of health and health care. In this study, we aim to examine the difference between a discrete-choice experiment (DCE) and a rating scale exercise (RSE) to determine the most important attributes of undergraduate students when selecting a study programme. METHODS: First-year health sciences students were asked to complete a questionnaire that included a DCE and a RSE. Six attributes were identified in focus groups: “possible acquainted masters”, “job opportunity”, “scope of specialization”, “quality of education”, “hours self-study” and “personal interest” of the continuation. However, the assumptions did not hold for a subset of lower educated and less literate participants. Based on participants’ age, educational level and health literacy additional measures should be undertaken to enhance participants’ understanding of the attributes, the attribute levels and the choice tasks in a DCE.

PM142
THE DEVELOPMENT AND PRELIMINARY VALIDATION OF THE MANCHESTER SLEEP SYMPTOMS INDEX (MSSI) FOR PEOPLE WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)
Garwood AP1, Yorke J1, Khan NO2, Tyson S1, Singh D1, Vestbo J4
1University of Manchester, Manchester, UK, 2The Medicines Evaluation Unit, Manchester, UK
OBJECTIVES: In COPD, disturbed sleep is related to exacerbation frequency, poor quality of life and early mortality. We developed the Manchester Sleep Symptoms Index (MSSI) to assess night-time symptoms and disturbed sleep in COPD. METHODS: Identification of potential items was guided by interviews and focus groups involving COPD patients and age-matched controls. Hierarchical methods and Rasch analysis informed the development of a unidimensional construct. Internal consistency and test-retest reliability were assessed. Concurrent validity was examined using Pearson’s correlation with the St George’s Respiratory Questionnaire (SGRQ), modified Mini-Mental Dysfunction Scale (MM-DSF), FACIT-fatigue scale, MOS Sleep Scale, HADS Anxiety and Depression scores. RESULTS: Qualitative data from 36 patients with COPD and 10 age-matched controls informed an initial list of 22 items. The cross-sectional study included 203 COPD patients (COLD: I: 14% II: 41% III: 25% IV 7%, male: 63%, mean age: 68±12.5 y. 5 years) and 60 non-COPD controls. 12 items were removed during subsequent hierarchical methods and a further two following Rasch analysis. The final MSSI contains 8 sleep-related items that are specific to COPD patients: breathlessness, chest pains, fatigue, depression, anxiety, snoring, nightmares, restless legs syndrome. The construct validity was measured using Cronbach’s alpha 0.87, test-retest reliability (intraclass correlation coefficient 0.77) and validity. Total MSSI scores significantly correlated with the SGRQ (r=0.64), MRC Dysfunction scale (r=0.46), FACIT-F (r=0.61), MOS Depression (r=0.62), MOS Sleep disturbances (r=0.69), MOS HADS anxiety (r=0.56) and depression (r=0.48). There was good overall fit to the Rasch model (Chi-squared: 29.2 df 16 p=0.01) and distribution of item scores. CONCLUSIONS: The MSSI is a reliable, valid, uni-dimensional self-reported outcome measure of sleep and night-time symptoms for people with COPD. It is simple and quick to use making it suitable for research and practice. Further work is needed to determine the minimal clinical important difference and cross cultural validity.

PM143
PSYCHOMETRIC EVALUATION OF THE PATIENT’S KNEE IMPLANT PERFORMANCE (PKP) QUESTIONNAIRE FOR THE ASSESSMENT OF PRIMARY TOTAL KNEE ARTHROPLASTY
Coles T1, Dwyer KA1, Morris M1, Williams V1, Claworthony M1, Yates P1, Hamilton W1
1RTI Health Solutions, Research Triangle Park, NC, USA, 2The Medicines Evaluation Unit, Manchester, UK
OBJECTIVES: The objective of this study was to evaluate the psychometric properties of a new patient-reported measure of knee implant functional performance associated with physical activities prior to and following primary total knee arthroplasty (TKA). METHODS: The Patient’s Knee Implant Performance questionnaire (PKP) was developed to assess factors that lead to patient dissatisfaction and describe unmet needs in knee functional performance. METHODS: The psychometric analysis sample (n=764) was based on a multicenter, prospective, noncomparative longitudinal study of patients within six UK hospitals undertaking TKA at 22 international sites. The PKP and additional patient-reported outcomes and clinical measures were collected preoperatively, postoperatively at 1 year, at a minimum of 1 year, and at 2 years. The PKP structure and its reliability, construct validity, discriminant ability, and responsiveness were assessed. RESULTS: Based on inter-item correlations, factor analyses, and results of previous qualitative research, the PKP was scored as four subscales (Stability, Satisfaction, Function, and Activity Modification) and on an overall patient satisfaction score. The Overall PKP score correlated 0.63 with internal consistency: alpha = 0.78 at minimum 1 year; test-retest: intra-class correlation coefficient = 0.77). Correlations between the PKP and other available measures provided evidence of construct validity. For example, the PKP correlated 0.19 and 0.50 with the American Knee Society Score preoperatively and at less than 1 year, respectively, and correlated 0.69 and 0.77, with the Knee Injury and Osteoarthritis Outcome Score (KOOS) and KOOS subscale. The PKP was able to evaluate functional differences between patients with better or worse knee functioning as defined by clinician-rated problems; hypothesis tests were in the predicted direction and mostly statistically significant. The effect size for the Overall PKP score was 2.38, indicating that the PKP was highly responsive. CONCLUSIONS: The reliability, validity and responsiveness of the PKP support its use in patients undergoing primary TKA.

PM144
VALIDITY AND RESPONSIVENESS OF THE BRISTOL RAMHEMATOID ARTHRITIS FATIGUE MULTIDIMENSIONAL QUESTIONNAIRE (BRAF-MDQ) IN A RANDOMIZED CONTROLLED CLINICAL TRIAL
Kawalka J1, Coteur G1, Davies F1, Nicklin J1, Byron D1, Hewlett S1
1Bristol Royal Infirmary, Bristol, UK, 2UCB Pharma, Brussels, Belgium, 3UCB Pharma, Raleigh, NC, USA
OBJECTIVES: To evaluate the validity of the BRAF-MDQ in a new group of patients in a clinical trial setting, to confirm its internal factor (domain) structure and to document its sensitivity to change. METHODS: Poole data from a randomized controlled trial (NCT01242488) in patients with moderate to severe RA were collected at baseline (BL) and week 12 (W12). Spearman’s correlation coefficients, Bland-Altman limits of agreement, as well as internal consistency (Cronbach’s α > 0.7) were calculated for each measure. BRAF-MDQ scores were compared with fatigue measures; hypothesis tests were in the predicted direction and mostly statistically significant. The effect size for the Overall BRAF-MDQ score was 2.38, indicating that the BRAF-MDQ was highly responsive. CONCLUSIONS: The reliability, validity and responsiveness of the BRAF-MDQ support its use in patients undergoing primary TKA.
CONCLUSIONS: The BRAF-MDQ was completed well by participants, related to appropriate measures of disease severity, retained its factor structure, gave reproducible results and was responsive to clinical change, confirming its validity as a measure of RA fatigue.

PMR145

CDAD-DAYSYM™: A NEW PATIENT-REPORTED OUTCOME TOOL FOR CLOSTRIDIUM DIFFICILE-ASSOCIATED DIARRhoea (CDAD)

CONCLUSIONS: The draft I-TAQ was then cognitively debriefed using “think-aloud” methods. Verbatim transcripts were analyzed using thematic analysis and Atlas.ti.

OBJECTIVES: Patient-reported outcome (PRO) measures provide relevant information on longer-term impact and more increase in RTI primary data and are especially relevant for clinical practice and registration trials. Despite the importance of symptom assessment in CDAD, there is no validated PRO for Clostridium difficile-associated diarrhoea (CDAD).

A qualitative research study was conducted to develop a CDAD PRO according to US FDA guidance and the ICH E11 requirements. A total of 47 participants were included, forming the conceptually comprehensive 22-item I-TAQ.

The utility observations available for each patient were used to examine the relationships between HRQoL and a number of disease- and time-based variables, including treatment effect, progression status and time to death, via a mixed effects regression model.

RESULTS: Progression status was found not to be significantly predictive of utility (p = 0.29). Of the variables considered, the strongest relationship was with time to death, the mixed effects model for which was significantly predictive of utility (p = 0.03). HRQoL dropped as patients approached death. The ipilimumab had a utility of 0.86 if time to death was more than 1 year, which reduced to 0.61 during the final month of life. The ipilimumab treatment variable was associated with a small negative coefficient (-0.02), accounting for the adverse event profile of the drug when added to dacarbazine (p = 0.06). CONCLUSIONS: Analysis of the CA184-024 HRQoL data showed that time to death rather than progression status was significantly predictive of utility. Hence, modellers should carefully examine primary data to determine if a time to event approach based on the assumption of a unimodal expression of HRQoL would be appropriate to model utility best reflecting the pathology of the disease.

PMR149

RASCH FIRST? FACTOR FIRST?

CONCLUSIONS: Successive rounds of interviews resulted in a treatment acceptance measure with strong content validity. Next steps are to psychometrically validate the I-TAQ in a population with experience of taking alirocumab.

PMR147

THE INFLUENCE OF GENE EXPRESSION PROFILING (GEP) ON DECISIONAL CONFLICT IN CHEMOTHERAPY TREATMENT DECISION-MAKING FOR EARLY-STAGE BREAST CANCER (BRCA)

Reassuring is the finding that the I-TAQ can be used in a variety of contexts, in different countries and in different languages. This is an important finding as it supports the potential for the I-TAQ to be used in a variety of settings, which is essential for the development of a PRO for CDAD.

PMR148

PATIENT REPORTED UTILITIES IN FIRST-LINE ADVANCED OR METASTATIC NON-SMALL CELL LUNG CANCER: ANALYSIS OF TRIAL CA184-024

METHODS: We embedded the validated GEP into our discrete choice experiment survey examining preferences for chemotherapy treatment in early BrCa. Of the 1004 general population participants, 200 completed the DCS before (DCS-1; no GEP test score in scenario) and after (DCS-2; GEP test score added to scenario) the discrete choice experiment.

CONCLUSIONS: As anticipated, total score and all subscores (uncertainty, informed, values clarity, support, and effective decision) decreased significantly (p < 0.05) in the group of respondents (n = 33) who indicated uncertainty about taking chemotherapy in DCS-1 but changed to no chemotherapy after receiving a GEP test score in DCS-2. In the group of respondents (n = 25) who indicated they would undergo chemotherapy in DCS-1 but changed to unsure in DCS-2, their effective decision decreased significantly (p < 0.05). In the overall sample (n = 200), total decisional conflict decreased from DCS-1 to DCS-2 by 0.5 (p = 0.3) and all subscores had non-significant decreases with the exception of effective decision, which had a non-significant increase. CONCLUSIONS: GEP influences chemotherapy treatment decision-making. However, we do not observe this effect in all patients who do not change their chemotherapy treatment decision.