PMR152
TRANSLATION AND CULTURAL ADAPTATION OF THE POLISH VERSION OF “DISABILITIES OF THE ARM, SHOULDER AND HAND” (DASH) AND QUICKDASH QUESTIONNAIRES
Galicka D1, Kryziuk M2, Strzelczyk P3
1Department of Social and Experimental Clinical Pharmacology, Medical University of Warsaw, Warsaw, Poland, 2Oddzial Rehabilitacji Dzieciej, MCR Stower, Konstancin-Jeziorna, Poland, 3The Kosciuszko Foundation scholar, New York, NY, USA
OBJECTIVES: To translate into Polish and adapt culturally DASH and QuickDASH outcomes. METHODS: We followed recommendations issued by Institute for Work and Health (IWH, 2007). Two forward translations were made – by an informed (T1) and uninformed translator (T2). Discrepancies were discussed and resolved with participation of the third unbiased investigator and a synthesis of translations was produced (T12). Two native speakers, totally blind to the original version, translated back T12 version into English (BT1 and BT2). Eight experts: 2 orthopedic surgeons, physical therapists, 2 English-English, 2 English-Polish and 1 Polish language specialist formed an Expert Committee (EC). Committee consolidated all the versions, review all the translations and reached a consensus on any discrepancy found. Decisions were made to achieve semantic, idiomatic, experiential and conceptual equivalence with the original version. RESULTS: We report 65 discrepancies raised by Expert Committee members and their solutions. The Polish pre-final versions of DASH and QuickDASH questionnaires, ready for pilot testing, were produced. Written reports from all stages of the process were submitted to the IWH Cross-Cultural Adaptation Review Committee for approval. CONCLUSIONS: Numerous translation discrepancies were resolved by discussion between Expert Committee. The Polish pre-final versions of DASH and QuickDASH questionnaires were produced and used in pilot testing.

PMR153
LINGUISTIC TRANSLATION AND CULTURAL ADAPTATION OF FUNCTIONAL ASSESSMENT OF CHRONIC ILLNESS THERAPY-TUBERCULOSIS INSTRUMENT INTO ARABIC LANGUAGE
Dajani A1, Syed Sulaiman SA1, Hassali MA2, Awaseri A1, Bilal1, Dajani MA1, Bredle1
1Universiti Sains Malaysia, Minden, Malaysia, 2Universiti Sains Malaysia, Penang, Malaysia
OBJECTIVE: To examine the factorial invariance of the WHOQOL-OLD across different gender, age, and resident area groups. To examine the factorial invariance of the WHOQOL-OLD across different gender, age, and resident area groups respectively. Besides, a redefinition of the target construct and the importance of values (i.e., reprioritization) and a redefinition of the target construct and the importance of values (i.e., reprioritization) and a redefinition of the target construct. RESULTS: All three aspects of response shift were observed. Recalibration and reprioritization were occurred in three items of PWB (‘nurses’, ‘problem with family’, ‘side effects’). Reconceptualization was observed from FWB to EWB in two items (‘nauses’ and ‘pain’) and from EWB to FWB in two items, ‘times and’ and ‘nervousness’ observed. The adjustment of response shift was observed in FWB (the across occasion difference of common factor mean [alpha] = 0.238, P < 0.001) during first 6 months, and in PWB (alpha = 0.605, P < 0.001) and EWB (alpha = 0.234, P < 0.05) during first 12 months, while observed data analyses indicated statistically significant change in FWB and PWB during first 12 months. CONCLUSIONS: Captured response shifts in this study may not be explained by various potential confounders such as non-participation of cancer and/or received treatments. These results will help improve reliability of HRQOL measurements in a longitudinal study.

PMR154
ESTIMATING THE SOCIAL DISTRIBUTION OF HEALTH IN ENGLAND
Asaria M1, Griffith R1, Cummins R1, Koch1
1University of York, York, UK
OBJECTIVE: To develop a model of quality adjusted life expectancy (QALE) in England and estimate the social distribution of both mortality and morbidity by socio-economic characteristics such as gender, ethnicity and deprivation. METHODS: The 2011 wave of the Health Survey for England (HSE) is used to model EQ-5D as a function of gender, ethnicity, Index of Multiple Deprivation and other relevant characteristics using appropriate regression techniques to account for the skewness of the EQ-5D distribution. Previous waves of the HSE are used to validate the model. RESULTS: A function of gender, ethnicity, Index of Multiple Deprivation and other relevant characteristics was produced. The 2011 wave of the HSE is used to model EQ-5D as a function of gender, ethnicity, Index of Multiple Deprivation and other relevant characteristics. Previous waves of the HSE are used to validate the model. OBJECTIVES: This study aimed to capture response shift and true change in health related quality of life (HRQOL) scores of breast cancer patients after surgery. METHODS: A data set from a prospective study to identify predictive factors of HRQOL (Taiar N, Shizumoya K, et al: Breast Cancer Res Treat, 2011) was analyzed, which included clinical, pathological, well-being, and EQ-5D data. RESULTS: Of the 191 female breast cancer patients during a two-year postoperative period (at baseline [1 month after surgery]), 6, 12, and 24 months postoperatively. (8) results of the relative modeling equation approach was used to investigate three aspects of response shift: (a) change in the respondent’s social standard of measurement (i.e., recalculation); (b) a change in the respondent’s importance of values (i.e., reprioritization) and (c) a redefinition of the target construct (i.e., reconceptualization). RESULTS: All three aspects of response shift were observed. Recalibration and reprioritization were occurred in three items of FWB (‘nurses’, ‘problem with family’, ‘side effects’). Reconceptualization was observed from FWB to EWB in two items (‘nauses’ and ‘pain’) and from EWB to FWB in two items, ‘times and’ and ‘nervousness’ observed. The adjustment of response shift was observed in FWB (the across occasion difference of common factor mean [alpha] = 0.238, P < 0.001) during first 6 months, and in PWB (alpha = 0.605, P < 0.001) and EWB (alpha = 0.234, P < 0.05) during first 12 months, while observed data analyses indicated statistically significant change in FWB and PWB during first 12 months. CONCLUSIONS: Captured response shifts in this study may not be explained by various potential confounders such as non-participation of cancer and/or received treatments. These results will help improve reliability of HRQOL measurements in a longitudinal study.

PMR155
FACTORIAL INVARIANCE OF THE WHOQOL-OLD ACROSS GENDER, AGE, AND RESIDENT AREA IN TAIWAN
Suzuki AK1, Shimizu K2, Suzuki YO1, Taiia N1, Shirowa T1, Shibahara H1, Saito S5
1Nihon University, Kusatsu, Japan, 2Tokoh University, Saitama, Japan, 3Okayama University Hospital, Okayama, Okayama, Japan, 4National Institute of Public Health, Saitama, Japan, 5Okayama University, Okayama, Japan
OBJECTIVES: To examine the factorial invariance of the WHOQOL-OLD across gender, age, and resident area for the old people in Taiwan. METHODS: Data were collected from FWB to EWB in two items, ‘times and’ and ‘nervousness’ observed. The adjustment of response shift was observed in FWB (the across occasion difference of common factor mean [alpha] = 0.238, P < 0.001) during first 6 months, and in PWB (alpha = 0.605, P < 0.001) and EWB (alpha = 0.234, P < 0.05) during first 12 months, while observed data analyses indicated statistically significant change in FWB and PWB during first 12 months. CONCLUSIONS: Captured response shifts in this study may not be explained by various potential confounders such as non-participation of cancer and/or received treatments. These results will help improve reliability of HRQOL measurements in a longitudinal study.

PMR156
A REVIEW OF COGNITIVE INTERVIEWING METHODOLOGIES DURING LINGUISTIC VALIDATION OF CLINICAL OUTCOME ASSESSMENTS (COAS)
Simon M1, Sweeney E2, Moravec H3
1TheranPerf, San Francisco, CA, USA, 2TheranPerf, New York, NY, USA
OBJECTIVES: Per ISPOR and FDA guidelines, conducting cognitive interviews during the linguistic validation of COAS is recommended to increase comprehension and conceptual equivalence between language versions. However, multiple methods are available to conduct cognitive interviews, partially enabled by the increased availability and ease of technology to facilitate the interviews. This poster will review the various methodologies that can be used to conduct cognitive interviews. METHODS: A review of cognitive interview methodologies from past projects as well as potential alternative methodologies was conducted, including: 1) in-person interviews, 2) telephone interviews, 3) interviews via video conferencing. Consideration was given to ease of implementation, cost, and patient responder burden. Every methodology presented pros and cons, including: 1) in-person interviews enable the interviewer to gauge the respondent’s body language, signaling where he/she may be struggling, 2) telephone interviews enable easier scheduling of interviews and reduce cost, but do not allow the interviewer to gauge the body language of the respondent and comfort him/her. 3) video conferencing may enable easier scheduling of interviews, allow an interviewer to gauge the body language of the respondent, and signaling where he/she may be struggling. RESULTS: Different interview methodologies presented pros and cons, including: 1) in-person interviews enable the interviewer to gauge the respondent’s body language, signaling where he/she may be struggling, 2) telephone interviews enable easier scheduling of interviews and reduce cost, but do not allow the interviewer to gauge the body language of the respondent and comfort him/her. 3) video conferencing may enable easier scheduling of interviews, allow an interviewer to gauge the body language of the respondent, and signaling where he/she may be struggling. CONCLUSIONS: There are various ways of conduct-
considering interviews during the linguistic validation process of COAs. Further research is required to develop industry guidelines to ensure that the interviews are able to achieve their purpose: garnering accurate and meaningful feedback from respondents in order to increase comprehension and cross-cultural equivalence of multiple language versions.

**PRM158 DEFINING STANDARDS OF CLINICIAN QUALIFICATIONS FOR THE LINGUISTIC VALIDATION OF CLINICAL OUTCOME ASSESSMENTS (COA)**

Swiebocki S, Nkofochewa Y
TransPerfect, New York, NY, USA

**OBJECTIVES:** As the linguistic validation of COA instruments often involves a review of medical terminology, it is important to confirm that the in-country clinician reviewer has sufficient qualifications to ensure quality as well as to elicit the highest level of conceptual equivalence in a linguistic validation project. This poster will discuss a comprehensive clinician assessment instrument and recommend guidelines for the qualifications of medical reviewers.

**METHODS:** An examination was conducted of past linguistic validation projects involving an in-country review step with a medical professional. A review was conducted of COAs (Clinician-Reported, Caregiver-Reported, as well as Patient-Reported questionnaires and diaries) within various therapeutic areas. This review also included an analysis of the specific background of each in-country clinician reviewer. **RESULTS:** In the examination of linguistic validation projects that included a medical review step, it was determined that the experience level of clinician reviewers varied between projects. In an effort to standardize this step, a minimum requirement was defined on study needs and project type is proposed. **CONCLUSIONS:** After a thorough review of past linguistic validation projects, it was decided that the in-country clinician reviewer should, at a minimum, encompass the following qualifications: 1) 2+ years experience diagnosing and/or treating the patient population; 2) M.D. or relevant equivalent in target country; 3) Native language and/or advanced medical terminology training in the target language/country. Implementing minimum qualifications standards will help to ensure that an in-country medical reviewer will conduct a high-quality review for linguistically validated COAs.

**PRM159 EVALUATION OF THE PSORIASIS AREA AND SEVERITY INDEX (PASI) AS PATIENT RELEVANCE OUTCOME IN THE BENEFIT ASSESSMENT OF PSORIASIS THERAPIES**

Gutknecht M, Augustin M, Rustenbach S.J., Schäfer I
University Medical Center Hamburg-Eppendorf, Hamburg, Germany

**OBJECTIVES:** Psoriasis vulgaris is one of the most frequent chronic diseases in dermatology and can cause a high disease burden and reduction of quality of life. The severity of psoriasis is determined by the clinical parameter PASI (Psoriasis Area and Severity Index). It is the most often cited measurement to determine the efficacy of therapies in the treatment of patient relevant treatment benefit. In the absence of gold standard measures, the objective of the study was to test to what extent PASI improvements agree with patient relevant benefit parameter. **METHODS:** A multicenter longitudinal observational study was conducted in n = 238 patients with psoriasis vulgaris. Data collection took place at the beginning of psoriasis treatment and between three and eight weeks after treatment. In addition to PASI, physician and patient data were collected, e.g. socio-demographics, clinical features, dermatology-specific QoL, and assessment of treatment. **RESULTS:** Each level of PASI (50, 75, 90) showed relevant improvements in patient reported outcomes. The satisfaction with the treatment and the patient benefit was greater, the higher PASI was reduced. This result has been seen for improvements of all scales, but only significant for FBl for all levels of PASI. Furthermore, results showed that not only changes in PASI but also its absolute value at the end of treatment has an impact for the patient’s satisfaction. **CONCLUSIONS:** The PASI as a measure of treatment of the disease severity is a valid and reliable tool for describing the benefit in better values of FBl and higher treatment satisfaction. **CONCLUSIONS:** The clinical reduction of the severity of psoriasis vulgaris correlates with the improvement of the quality of life and with the patient defined treatment benefit. However, the PASI does not completely reflect the patient relevant outcome in the benefit assessment. Therefore, it is recommended to make additional elicitation of patient defined objectives and benefits in the evaluation of psoriasis therapies.

**PRM160 THE INFLUENCE OF CHOICE TASK LAYOUT ON THE OUTCOMES OF A DISCRETE CHOICE EXPERIMENT**

Velikovsky J, Lambrou M, van Til JA, Smit HA, de Wit G

**OBJECTIVES:** To test to what extent the presentation of choice tasks contrasting display in words or graphics, influences the attribute estimates, relative importance and participation probability and the conclusions drawn from a Discrete Choice Experiment (DCE). **METHODS:** A DCE questionnaire was sent to the parents of 2,500 newborn babies aged 6 weeks at maximum. Each questionnaire contained two versions of the same 9 choice tasks, one in which the levels were presented in words, and one with graphic attribute levels. The DCE consisted of five attributes: vaccine effectiveness, severity of side effects, protection duration, vaccine administration, out-of-pocket costs. Choice consistency was estimated, panel-mixed logit models were conducted to estimate the relative importance of the attributes and internal sample validation was calculated. **RESULTS:** In total 13% answered all choice tasks, 19% answered all choice tasks, but only 9% answered all choice tasks and 51% answered inconsistently in more than two choice tasks. Respondents who were presented with word choice tasks at first were significantly more consistent compared to respondents that were presented with graphic choice tasks at first. Although out-of-pocket costs was the most important and frequency of severe side effect was the least important attribute in both datasets, the relative importance of the other attributes differed. All results differed by educational level. Estimated and observed choices showed higher correlation in the word dataset. **CONCLUSIONS:** The presentation of the choice tasks by either using words or graphics influences study outcomes. The use of graphics to present attribute levels in choice tasks seems less favored by respondents in a random order of tasks and 51% answered inconsistently in more than two choice tasks, discussions about the presentation of the choice tasks should be included in the focus group stage of the designing process. Extensive research on respondents’ participation of choice tasks should be conducted to enable the formation of task presentation guidelines.

**PRM161 SIMILARITIES AND DIFFERENCES ACROSS SAME LANGUAGE QUESTIONNAIRES FOR DIFFERENT COUNTRIES: LINGUISTIC VALIDATION OF THE ASTHMA SYMPTOM DIARY (ASD) AND KIDNEY DISEASE AND QUALITY OF LIFE (KD-QOL) INSTRUMENTS**

Sweeney E, Scharf I
ICN PCL, Oxford, UK

**OBJECTIVES:** Prior to use in an international study, the Asthma Symptom Diary and Kidney Disease and Quality of Life underwent linguistic validation into over 30 languages. This involved linguistic validation work on common languages targeted for different countries via the forward / backward translations or adaptation steps and cognitive debriefing step. This study aims to investigate similarities and differences in the translation of key terms and wording and determine potential patterns across groups of languages. **METHODS:** This investigation was carried out as follows: 1) Identification of key terms and words, 2) Collation and comparison of the translations across the same language versions, 3) Identification of similarities and differences; and 4) Review of discussions and issues from the translation process. **RESULTS:** The linguistic validation process was shown to be able to identify and resolve recurring issues. Key findings included the identification of potential recurring translation issues between same language groups. Within the German, French and Spanish languages, technical terminology was translated alike; however there were differences in the way technical and disease-specific terms were translated. **CONCLUSIONS:** With the insight of the linguistic validation process, important differences were identified and resolved between technical terms and general words across same language groups. Cognitive debriefing is highly recommended and this will ensure appropriate comprehension across cultures and facilitate international comparison and pooling of data.

**PRM264 DETERMINING THE MAGNITUDE OF A DETECTABLE AND A RELEVANT TREATMENT BENEFIT IN AESTHETIC MEDICINE USING A PHOTOGUIDE AND THE INTERNET**

Hurl A, Bushmakin AC, Shields A, Jensen J, Cappelleri JC

**OBJECTIVES:** Photoguides are used as measures of treatment effect. To interpret the results, an understanding of what change is “enough” is required. The purpose of this study was to determine the magnitude of a detectable and a relevant treatment benefit. **METHODS:** Data for 18 patients with psoriasis vulgaris. Data collection took place at the beginning of psoriasis treatment and between three and eight weeks after treatment. The satisfaction with the treatment and the patient benefit was greater, the higher PASI was reduced. This result has been seen for improvements of all scales, but only significant for FBl for all levels of PASI. Furthermore, results showed that not only changes in PASI but also its absolute value at the end of treatment has an impact for the patient’s satisfaction. **CONCLUSIONS:** The PASI as a measure of treatment of the disease severity is a valid and reliable tool for describing the benefit in better values of FBl and higher treatment satisfaction. **CONCLUSIONS:** The clinical reduction of the severity of psoriasis vulgaris correlates with the improvement of the quality of life and with the patient defined treatment benefit. However, the PASI does not completely reflect the patient relevant outcome in the benefit assessment. Therefore, it is recommended to make additional elicitation of patient defined objectives and benefits in the evaluation of psoriasis therapies.

**PRM162 PARENT RATINGS OF ABILITY TO CONSENT FOR CLINICAL TRIALS IN FRAGILE X SYNDROME**

Bairier D, Rapsa M, Wheeler A

**OBJECTIVES:** Advances in understanding the neural underpinnings of intellectual disabilities (ID) such as fragile X syndrome (FXS) have led to clinical trials testing medications addressing disease-specific targets. Individuals with ID ought to have a voice in the research process, but the extent to which they can meaningfully participate is unclear. We conducted a survey to assess whether or not children with FXS and their parents are capable of doing is unknown. We discuss the importance of involving individuals with ID in the consent process and report results from a study of parents’ perceptions of their child’s ability to consent. **METHODS:** A survey was conducted with 432 families who had a child with FXS. Parents rated items assessing their child’s abil-