OBJECTIVES: Measurement of the risk-benefit tradeoffs in healthcare decision-making relies on capturing preferences for treatment attributes that are most important to individuals. The goal of this study is to develop and validate a methodological framework for identifying, validating, and prioritizing attributes for inclusion in discrete choice experiments (DCE). METHODS: The study enrolled 48 caregivers of a child aged 4-11 years or younger diagnosed with asthma or allergic rhinitis to complete an online questionnaire assessing a patient’s physical and mental health. Data collected were processed through IDIs (n=6) and six focus groups (n=42). Following qualitative methods for grounded theory and content analysis, attributes were identified in four distinct patient groups. First, in individual interviews (IDIs) were analyzed to identify concepts reflecting distinct situations influencing treatment decisions. Second, the concepts were validated by researcher-caregiver agreement in defining the concept. Third, caregivers prioritized the concepts by severity of the condition and importance in making treatment decisions for their child. Fourth, a final list of attributes was chosen based on the subset of attributes that had high researcher-caregiver agreement and that were a high priority. Triangulation, member checking, and participants’ and stakeholder partners’ feedback was used throughout the process. RESULTS: Sixteen concepts were identified from the IDIs. Researcher-caregiver agreement in concept definition ranged between 21-76%. The concepts rated as high priorities in decision-making were managing asthma behavior, advocating for the child needs, and communicating with providers. The financial impact and getting a label were low priorities in treatment decisions. Seven concepts rated as low priorities and with low decision influence were discarded in a final list of nine attributes. CONCLUSIONS: Systematic methods for attribute identification, as well as stakeholder involvement, will inform the development of DCE instruments that closely reflect the tradeoffs in health. Methodological standards for attribute identification would enhance the application and interpretation of DCE in preference elicitation.

PM908
PHARMACISTS-LED INTERVENTIONS TO IMPROVE HEALTH-RELATED QUALITY OF LIFE OF PULMONARY TUBERCULOSIS PATIENTS IN PAKISTAN: AN INSIGHT FROM A RANDOMIZED CONTROLLED NON-ClinICAL Trial
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OBJECTIVES: To evaluate the importance of a health-educational intervention program to improve Health-Related Quality of Life (HRQoL) among Pulmonary Tuberculosis (PTB) patients in Pakistan, under the supervision of registered hospital pharmacists. METHODS: A health-educational intervention to improve HRQoL was offered to the PTB patients through registered hospital pharmacists. In this non-clinical randomized controlled trial, PTB patients were briefed regarding treatment and management of PTB and their HRQoL was measured by WHOQOL-BREF. Both descriptive and inferential statistics were used to determine patients’ demographic characteristics and inter-group comparison. Data was analyzed by SPSS 21.0. RESULTS: Two hundred and eighty PTB patients were recruited for the study i.e. one hundred and forty patients in each group. No significant differences were observed in either group for mean age, gender, education level, occupation and income whereas a significant increase (p<0.001) in the WHOQOL-BREF score was observed in the intervention group. CONCLUSIONS: HRQoL was significantly improved in the intervention group after the pharmacist-led intervention program which advocates the vital role of ‘pharmacists in patients’ education and a better health care system of Pakistan.

PM909
DEVELOPING SF-6D-V2: EXAMINING THE DIMENSIONALITY OF THE SF-36 USING LARGE MULTINATIONAL DATASETS
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OBJECTIVES: The SF-36 is a measure of health related quality of life that is widely used internationally. SF-36 produces scores for eight dimensions (physical functioning (PF), role physical (RP), bodily pain (BP), general health (GH); vitality (VT); social functioning (SF); role emotional (RE); mental health (MH)). However there is debate about whether these dimensions are applicable cross culturally, and also to what extent they are dependent on the MH and VT dimensions. The aim is to explore the dimensionality using multinational datasets as part of the development of SF-6D-V2. METHODS: Exploratory and confirmatory factor analysis was used to examine dimensionality, and was assessed for a range of patient and general population datasets from the UK, Australia, Canada, USA and Japan (n = 55,923). Analysis was carried out separately for each country, and on the combined data. The general health items were not included as the focus was the specific health areas measured. RESULTS: For both the RE and VT dimensions, exploratory factor analysis from data for each country and speaking countries suggests that the SF, BP, SF and RE dimensions are relatively consistent but there are inconsistencies regarding the MH and VT, where the items split into factors based on whether the item is positively or negatively worded. The data from Japan suggests that the role dimensions do not split into physical and emotional constructs. Confirmatory analysis suggests that both the original seven factor model, and a model splitting MH and VT based on the direction of the items, fit the data acceptably. CONCLUSIONS: There is evidence for cross cultural differences in the role functioning dimensions of the SF-36, most likely due to differences in the perception of emotional health. The inconsistency of the MH and VT dimensions may be due to the combination of positive and negative items, order effects, or content overlap.

PM100
DEVELOPMENT AND VALIDATION OF THE PROMIS NETWORK TO EVALUATE PATIENT-REPORTED HEALTH STATUS ASSOCIATED WITH CLOSTRODIUM DIFFICILE INFECTION
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OBJECTIVES: The Patient-Reported Outcome Measurement Information System (PROMIS), funded by the National Institute of Health (NIH) is a large database of measures of patient-reported health status for physical, mental, and social well-being. Use of the PROMIS tools to evaluate humanistic outcomes in hospitalized patients with Clostridium difficile infection (CDI) has not been studied. The objective of this study was to identify and validate the use of specific PROMIS network questions to evaluate patient-reported health status associated with CDI. METHODS: This was a prospective, observational, two-center, mixed-methods study. Hospitalized adult patients with CDI were interviewed within seven days of a positive toxin test for C. difficile and again within one week of hospital discharge (N = 40). Patients were asked open-ended questions regarding their top three concerns related to CDI. Results were analyzed using ATLAS.ti 7 and classified by PROMIS item. Responses to the network items were analyzed with the PROMIS network identified. An additional 15 patients with CDI were interviewed using the PROMIS questions to validate relevant questions. RESULTS: Patient-reported humanistic outcomes within seven days of CDI diagnosis were primarily associated with mental concerns (75%) related to anxiety and worry about future complications. Physical concerns (8%) were related to ongoing diarrhea, bowel incontinence and other abdominal complaints. Social concerns (3%) included living in family and finances. Patient reported outcome responses did not change significantly during the follow-up interview. Using these responses from direct interviews of CDI patients, 18 PROMIS network questions were identified and demonstrated evidence of reliability. CONCLUSIONS: Using the NIH PROMIS network, we identified 18 patient-reported health status questions that can be used to evaluate humanistic outcomes in patients with CDI. Future studies should use these questions to assess changes in health status of CDI patients over time.

PM101
VALIDATION AND EVALUATION OF THE PREFERENCE-BASED HEALTHINDEX
USING EQ-5D-5L IN THE HONG KONG POPULATION
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OBJECTIVES: The EQ-5D is a preference-based measure of health for economic evaluation. This study is to develop a Hong Kong (HK) Chinese version of EQ-5D-5L and to assess validity in local people. This study consists of three parts including (I) Translation and Cultural Adaptation of the HK Chinese version of EQ-5D-5L by forward/backward translation and lay panel assessment, (II) Valuation Study using HK Chinese version of the EQ-5D-5L, (III) Creation of norms values in HK by secondary analysis of data from part II study. METHODS: A preference-based health index was performed based on the translation protocol of the EuroQol group, cognitive interview with 20 laymen which are conducted for cultural adaption of the HK Chinese version of EQ-5D-5L. The English version of EQ-5D-5L (EQ-5D-5L HK) is to be collected from the general population in HK. RESULTS: In part I: Forward/backward translation of the English version of EQ-5D-5L was performed based on the translation protocol of the EuroQol group, cognitive interview with 20 laymen which are conducted for cultural adaption of the HK Chinese version of EQ-5D-5L. In part II: A total of 475 out of 1000 subjects were recruited for face-to-face interviews with computer-assisted using EQ-5D-5L HK. The sample (88.9% in 18-44 yrs; 36.6% in 45-64 yrs; 24.4% in 65 yrs and above) was predominantly female and with a secondary education level. CONCLUSIONS: A preference-based values using EQ-5D-5L HK are to be collected from the general population in HK. This value set data will then be used to derive an algorithm model to estimate the preference-based health index in the Hong Kong population. The norms of health-related quality of life in Hong Kong population using EQ-5D-5L will be presented by different demographic groups including age, gender and education level.

PM102
USABILITY TESTING OF THE WEB-BASED VERSIONS OF THE STANDARDISED ASThma QUALITY OF LIFE QUESTIONNAIRE FOR 12 YEARS AND OLDER (AQ-QLQ12) AND THE ASThma Control QUESTIONNAIRE (ACQ-5) USING US USERS
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OBJECTIVES: The main objective of this study was to assess the usability of the newly developed web-based UK versions of the Standardised Asthma Quality of Life Questionnaire for individuals 12 years and older (AQ-QLQ12) and the Asthma Control Questionnaire (ACQ-5). METHODS: Individual interviews were conducted with eight patients with asthma. During the session, each patient was requested...
1) to fill in the questionnaire online, focusing on the instructions developed for online use; 2) to comment on the understanding of the instructions and items/response choices. After the test session, the interviewers asked about ease of completion, navigation, instructions, screen and font size, and also reported on any hesitations or questions asked by the patient during the process. The severity of the issues encountered during the test was divided into three levels with level 1 indicating inability of use and/or incomprehensibility of instructions. RESULTS: All respondents were able to answer the questions on their own without help. The respondents found the instructions very clear, and completing the online versions of the instruments proved to be easy and quick. For those who wished to correct their answers, going back to the previous screens was also easy. Minor changes were suggested to the screen resolution, font size of the response choices of the AQLQ(S)-12, and to the wording of a few items to improve clarity and functional posturing. No concerns were raised about the appropriateness of the concept. No concerns were raised about the use of the scale and all physicians concurred with the recommended discharge criteria. The clinician ratings provided evidence of strong inter-rater reliability of the scale using the intra-class correlation coefficient (ICC) using IBM SPSS Statistics 22. Measurement equivalence between the paper and electronic versions of the SF-36v2 held version was developed in 2012. The objectives of this study were to evaluate the measurement equivalence between the paper and electronic versions of the SF-36v2 administered using a handheld device or a smartphone app, and to determine patient preference for mode of administration. METHODS: This was a randomized crossover study with type II diabetes and completed the SF-36v2 on two modalities: paper and either the electronic handheld (PHT LogPad® LW) or the smartphone App (PHT LogPad App). Subjects completed the assessment in a single session with distraction activities between completion of the first and second modality and an exit survey which assessed patient preference for mode of administration. RESULTS: Study data will be analyzed to test score level equivalence and to calculate the intraclass correlation coefficient (ICC) and other measures of reliability. The study is ongoing, and findings will be ready to present for this meeting. 82% of subjects found the electronic method easy to use and 80% found it easy to navigate. Of those subjects who expressed a preference, 57% found it more physically comfortable and 69% found it faster to complete than paper. 65% would prefer the electronic method over paper when responding to questions in a clinical trial. CONCLUSIONS: This study will evaluate the measurement equivalence between standard paper versions of the SF-36v2 and the handheld versions as deployed on an electronic handheld device or a smartphone App. Patients with diabetes generally prefer to complete the SF-36v2 electronically rather than on paper.

PRM105
DEVELOPMENT EQUIMENT AND PATIENT PREFERENCES FOR THE SF-36V2 ON A HANDHELD DEVICE AND SMARTPHONE APP
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OBJECTIVES: The Short-Form 36 Health Survey version 2 (SF-36v2) is a validated patient-reported outcome instrument. A validated single-item format version exists for deployment on computer screens/tablet-sized devices, and an electronic handheld version was developed in 2012. The objectives of this study were to evaluate measurement equivalence between the paper and electronic versions of the SF-36v2 administered using a handheld device or a smartphone app, and to determine patient preference for mode of administration. METHODS: This was a randomized crossover study with type II diabetes and completed the SF-36v2 on two modalities: paper and either the electronic handheld (PHT LogPad® LW) or the smartphone App (PHT LogPad App). Subjects completed the assessment in a single session with distraction activities between completion of the first and second modality and an exit survey which assessed patient preference for mode of administration. RESULTS: Study data will be analyzed to test score level equivalence and to calculate the intraclass correlation coefficient (ICC) and other measures of reliability. The study is ongoing, and findings will be ready to present for this meeting. 82% of subjects found the electronic method easy to use and 80% found it easy to navigate. Of those subjects who expressed a preference, 57% found it more physically comfortable and 69% found it faster to complete than paper. 65% would prefer the electronic method over paper when responding to questions in a clinical trial. CONCLUSIONS: This study will evaluate the measurement equivalence between standard paper versions of the SF-36v2 and the handheld versions as deployed on an electronic handheld device or a smartphone App. Patients with diabetes generally prefer to complete the SF-36v2 electronically rather than on paper.

PRM106
DEVELOPMENT AND VALIDATION OF THE ANGIOTENSIN-CONVERTING ENZYME INHIBITORS (ACEI) INDUCED ANGIOEDEMA INVESTIGATOR RATING SCALE AND PROPOSED DISCHARGE CRITERIA
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OBJECTIVES: Angiotensin-converting enzyme inhibitors (ACEI) have been implicated in bradykinin-mediated angioedema. With ever-widening indications for ACEI including hypertension, congestive heart failure, diabetic nephropathy, etc., a concomitant increase in ACEI-Angioedema (ACEI-A) has been reported. At present there is no validated severity scoring or discharge criteria for ACEI-A. We sought to develop an investigator rating scale with corresponding discharge criteria to determine clinical readiness for discharge and ultimate discharge of patients with ACEI-A. METHODS: In-depth, 60-minute qualitative telephone interviews were conducted with 12 US-based emergency physicians. Beforehand, clinicians were sent four case studies describing patients experiencing different severities of angioedema attacks. Clinicians were initially asked open-ended questions about their experience about patients’ symptoms, treatment and discharge decisions. Clinicians then rated each patient case study and discussed patient diagnoses, ratings of symptoms, severity and discharge evaluation. The ratings were used to assess inter-rater reliability of the scale using the intra-class correlation coefficient (ICC) using IBM SPSS Statistics 22. RESULTS: The findings provide support for scoring the four key symptoms of airway compromise scored on a 0-4 scale: 1) Difficulty Breathing, 2) Difficulty Swallowing, 3) Voice Changes and 4) Tongue Swelling and the corresponding discharge criteria of a score of 0 or ‘No symptoms’ for Difficulty Breathing and a score of 0 or ‘No symptoms’ for Difficulty Swallowing indicating mild or absent symptoms of Voice Change and Tongue Swelling. Eleven clinicians agreed the absence of standardized discharge criteria supported the use of the scale and all physicians concurred with the recommended discharge criteria. The clinician ratings provided evidence of strong inter-rater reliability for the rating scale (ICC>0.80). CONCLUSIONS: The investigator rating scale and discharge criteria are clinically valid, relevant and reliable. Moreover, both address the current unmet need for standardized discharge criteria.

PRM107
DEVELOPMENT OF A DISEASE MODEL FOR SPORADIC INCLUSION BODY MYOSITIS (sIBM)
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OBJECTIVES: sIBM is a progressive idiopathic inflammatory myopathy characterized by the asymmetric atrophy and weakness of proximal and distal muscle groups. Atrophy of the quadriceps, wrist, and finger flexor muscles and dysphagic processes are clinical hallmarks and result in significant functional disabilities with progression. To understand impact on patients, a qualitative study was conducted to support the development of a disease model. The study aimed to determine patient concepts relevant to disease progression that may be impacted by the treatment of sIBM. No such disease model is currently available. METHODS: A literature review was conducted to identify relevant studies and to determine key symptoms and their severity, and diagnosis between 0 and 100%. RESULTS: This was followed by therapeutic area expert input and interviews of patients diagnosed with sIBM (n = 20). Based on all results, a model was constructed. RESULTS: Results from literature and expert input allowed for the development of an initial disease model from a diagnostic to a progression phase with various factors (e.g. age, gender, duration, severity, falls), proximal concepts of signs and symptoms of disease (weakness, atrophy), function (upper extremity, lower extremity, general, swallowing) and through more distal psychological concepts (emotions, mood, relationships). Patient feedback was used to further refine the model. Some physical