with COPD, a total of 33.3% patients showed moderate to severe depressive symptoms and nearly 50% of cases had a marked impairment in HRQoL. Educational and occupational status, body mass index (BMI), depressive symptoms, physical impairment and dyspnoea were associated with the diagnosis of depression in patients with COPD, whereas, body mass-index, forced expiratory volume in 1 second (FEV1) dyspnoea and medication were associated with patients with COPD.

CONCLUSIONS: More than one third of patients with COPD had either depression or poor HQoL in India. The study suggest need for regular screening for depression in COPD patients with COPD especially among obese and patients with compromised or severe respiratory functions.

PRM92 MEASURING THE SYMPTOMS AND IMPACTS OF ENDOMETRIOSIS: PSYCHOMETRIC VALIDATION OF THE ENDOMETRIOSIS SYMPTOM DIARY AND ENDOMETRIOSIS IMPACT SCALE

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OBJECTIVES: As a disease caused by pain, Patient-Reported Outcomes (PROs) are important for determining disease severity and evaluating the efficacy of endo- metriosis treatments. In the absence of existing PROs that comply with the FDA PRO Guidance, two new PROs have been developed: The Endometriosis Symptom Diary (ESD) and Endometriosis Impact Scale (EIS). The content validity of these instruments has been demonstrated by extensive qualitative and quantitative research with women suffering from endometriosis. The aim of this study was to report the initial validation of the ESD and EIS scores derived from the ESD and EIS are presented herein.

METHODS: Three methods were involved: (i) 12 focus groups as a non-interventional study, (ii) a study where women with endometriosis completed ESD and EIS diary and came to our centre for an endoscopic procedure, and (iii) a cohort of patients participating together throughout the study using an electronic handheld device, including ESD, EIS, Riberouga & Behrman Scale, Endometriosis Health Profile-30, Patient Global Improvement, Change measures, multi-item pain severity andvisual analogue scales. Pre-specified analyses were conducted to evaluate the test-retest reliability, convergent validity, known-groups validity and responsiveness of scores derived from the ESD and EIS.

RESULTS: Intra-class correlation coefficients along with component measures were calculated and established the test-retest reliability of ESD/EIS scores. Correlations between scores for the ESD/EIS and concurrent measures were consistent with a priori hypotheses, demonstrating convergent validity. Furthermore, Analysis of Covariance models revealed statistically significant (p<0.05) differences in ESD/EIS scores among participants of varying levels of symptom severity (as determined by scores on concurrent measures). Finally, observed ESD/EIS score changes in participants whose clinical status had improved (according to scores on concurrent measures) were statistically greater than unchanged, providing evidence of responsiveness.

CONCLUSIONS: Findings support the reliability and validity of scores derived from the ESD and EIS. Future research will seek to explore definitions of meaningful change in ESD/EIS scores using data from clinical studies.

PRM93 WHAT TYPE OF RESPONSE SCALE IS THE MOST RESPONSIVE? A COMPREHENSIVE REVIEW OF RESPONSE SCALE OPTIONS FOR PATIENT-REPORTED OUTCOME MEASURES

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OBJECTIVES: Selection of response scales for patient-reported outcome (PRO) measures is often driven by therapeutic area convention or preferences of measure developers. To help guide response scale selection, an objective of this project was to identify the optimal scale type for the responsiveness of common response scale types. METHODS: A comprehensive literature review was conducted for studies published from January 2004 through October 2014 that provided direct comparisons of the responsiveness of different response scale types. Additional searches were conducted for abstracts and presentations on this topic from relevant scientific conferences.

RESULTS: The most common types of response scales evaluated were the 100mm visual analog scale (VAS), the 11-point numeric rating scale (NRS), and the verbal rating scale (VRS) (with varying number of levels). Three studies directly compared responsiveness of all three types. Of these, one found no difference in responsiveness of the three types, one found superior responsiveness for the NRS compared to the VAS, and one found the VAS to be most responsive for one domain while the NRS was most responsive for another. Three studies compared VAS to VRS, with one finding no difference and one study each finding greater responsiveness for the VAS and a 7-point VRS, respectively. Four studies compared NRS vs. VRS, with three demonstrating no difference and one demonstrating superior responsiveness for the NRS compared to a 6-point VRS.

CONCLUSIONS: There are a number of considerations in response scale selection, including target population, study design, concept of interest, recall period, data collection mode, and scale responsiveness. Several reviewed studies demonstrated equivalent responsiveness for the most common response scale types, however, evidence suggests the 11-point NRS may be slightly more responsive than the other response scales in some settings. Limitations of this review include its 10-year timeframe and the paucity of empirical studies comparing common response scales.

PRM94 PSYCHOMETRIC VALIDATION OF THE FATIGUE SYMPTOMS AND IMPACTS QUESTIONNAIRE—a RELAXING MULTIPLE SCLEROSIS (FSIQ-RMS), 4

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OBJECTIVES: Fatigue is an important symptom for multiple sclerosis (MS) patients. Current research supported initial context validity of the FSIQ-RMS™, the first patient-reported outcome (PRO) measure of fatigue in relapsing-remitting MS (RRMS) developed according to the 2009 FDA PRO guidance. To confirm appropriate- ness, validity, and reliability of the FSIQ-RMS, further psychometric analyses were conducted. METHODS: A total of 154 patients with RRMS (mean age 45 years; range 19-65 years; 76% female) and 14 impact items (weekly recall period, 1 subdomain) was administered over 3 months (three 7-day intervals) in a multicenter, non- intervention study. The approved study design was different for RRMS (relapse and remission subtypes (relapsing remitting, secondary progressive, progressive relapsing) and a subset of matched healthy controls (week 1 only). Data analyses included: item response and dimensionality, content and construct validity, internal consistency and reliability, as well as attribution of fatigue to RMS. Evaluations were supported by those from a cross-sectional, multicenter study, in which RMS patients completed the FSIQ-RMS™ Symptoms domain. RESULTS: The psychometric validation study included 164 RMS patients (mean age 45 years [range 19-65 years; 76% female] and 74 controls [40 [18-65 years]; 73% female]. Two redundant symptom items were deleted, leaving 7; impact items were unchanged. A 0-100 scoring algorithm was developed for the FSIQ-RMS™ (sub)domains. Internal consistency and validity of the FSIQ-RMS™ are presented herein.

CONCLUSIONS: Content and validity measurement of the 11-point NRS may be slightly more responsive than the 11-point VRS (sub)domains.

PRM95 FEASIBILITY OF USING THE SF-36 HEALTH SURVEY TO SCREEN FOR RISK OF MAJOR DEPRESSIVE DISORDER

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OBJECTIVES: To assess the feasibility of the SF-36v2 Mental Health (MH) domain and SF-36v2 Physical Health (PH) domain cutoff scores for the classification of risk for major depressive disorder (MDD), and determine the cutoff scores in a US sample and chronic pain subpopulation. METHODS: Data were analyzed from the 2013 National Health and Wellness Survey (adults ≥18 years old, N=75,000). Respondents were also classified into subpopulations based on self-report: chronic pain (n=6,679) and chronic pain receiving medication for depression (i.e., depression vs. n=5,814). The primary definition for classifying respondents at risk of MDD was a score >10 on the Patient Health Questionnaire (PHQ-9). Logistic regression modeling was used to predict risk at MDD, or not, and receiver operating characteristic curves were produced. RESULTS: The total sample had MH scores of 48.8 and MCS scores of 48.9, similar to the normative mean for the US adult population. The percent of respondents with a PHQ-9 ≥10 were 15.0%, 29.1% and 25.9% for the total sample, chronic pain alone, and chronic pain with depression, respectively. Cutoff scores (PHQ-9 ≥10) in the total sample for the MH domain and MCS were 43.0 and 46.0, respectively. Specificities of recommended cutoff scores for the MH domain and MCS were 77.8% and 76.1%, sensitivities were 84.8% and 84.1%. Among the subpopulation with chronic pain alone, cutoff scores for the MH domain and MCS were 40.4 and 43.1. Similar cutoff scores for the MH domain and MCS were 77.9% and 73.9%; sensitivities were 78.3% and 83.4%. Trends were similar among the chronic pain with depression subgroup. CONCLUSIONS: SF-36v2 can be used to screen for risk of MDD and sensitivity and specificity to categorize participants at risk for MDD. It is feasible to use the SF-36v2, a widely used measure to assess health status, to better characterize the mental health of populations.