

0.431(HAMD-17), -0.224(PCS), -0.650(MCS) -all $p < 0.001$ -. Differences in CUDOS scores between severity levels were found ($p < 0.03$ -Bonferroni correction-). The ability of CUDOS for predicting remission was adequate (AUC = 0.837; CI = 0.740-0.934; $p < 0.001$). A cut-off point (CUDOS = 24) was estimated (sensitivity = 0.81, specificity = 0.77). **CONCLUSIONS:** The Spanish version of the CUDOS is a reliable and valid measure of depression which can detect MDD patients with a suboptimal response and be easily used during clinical practice in Primary Care.

PMH39

IDENTIFYING DISEASE-DEFINING CONCEPTS USING SPONTANEOUS AND PROBED RESPONSES FROM SEMI-STRUCTURED QUALITATIVE INTERVIEWS IN PATIENTS WITH MAJOR DEPRESSIVE DISORDER

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OBJECTIVES: To identify symptoms and functional impacts associated with major depressive disorder (MDD) using concept elicitation interviews with patients to determine relevant concepts for assessment in patient-reported outcome (PRO) measures. **METHODS:** Qualitative interviews were conducted at 6 U.S. clinical sites for cross-sectional assessment in a sample of adults (18-65 years) meeting DSM-IV-TR criteria for MDD with a depressive episode within the last 6 months and HAM-D score >18 at screening. Semi-structured individual interviews conducted by trained research staff used open-ended questions and day-reconstruction exercises to elicit spontaneous reports of symptom/impact concepts. Subsequent probing was used to assess concepts not spontaneously reported by subjects. Interviews were audio-recorded and transcribed. Transcripts were coded and analyzed using Atlas.ti and summarized by like-content. Interview guide notations were used to tag concepts offered by either spontaneous or probed report. **RESULTS:** A total of 40 interviews were conducted with subjects (mean age: 46.2±11.8; 67.5% female) representing a broad range of demographic characteristics. Saturation of concepts was achieved within the first 32 interviews. Symptoms identified by the majority of subjects included: Sadness (80.0% of subjects overall [and 52.5% spontaneously]), Tiredness (75.0[65.0]), Anger (72.5[57.5]), Loneliness (70.0[45.0]), Difficulty Falling Asleep (67.5[55.0]), Low Self-Esteem (65.0[32.5]), Anxiety (62.5[55.0]), Guilt (62.5[42.5]), Trouble Focusing (60.0[42.5]), Difficulty Waking (60.0[35.0]), Fatigue (57.5[50.0]) and Irritability (57.5[42.5]). The most frequently reported impacts were: Having Fewer Friends (92.5[65.0]), Feeling Isolated (82.5[57.5]), Dropping Daily Activities (82.5[55.0]), Difficulty with Chores (77.5[30.0]), Interpersonal Difficulties (72.5[37.5]), Workplace Difficulties (65.0[52.5]) and Neglecting Self-Hygiene (65.0[17.5]). **CONCLUSIONS:** Symptoms and functional impacts associated with MDD were identified through qualitative interviews. Relevant patient-identified concepts should be considered in the development of patient-reported outcomes. Concepts reported spontaneously provide good support for relevance, whereas other concepts identified primarily through probing may not offer the best candidates for assessment. Strength of these findings is suggested by achievement of concept saturation.

PMH40

HOW DO PATIENTS DESCRIBE THEIR DEPRESSION? - INCORPORATING THE PATIENT'S VOICE INTO INSTRUMENT DEVELOPMENT

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OBJECTIVES: To identify ways patients describe Major Depressive Disorder (MDD) symptoms and impacts so new patient-reported outcome (PRO) measures can effectively incorporate the patient's voice and perspective. **METHODS:** Qualitative interviews were conducted with adult MDD patients (18-65 years) recruited from 6 US clinical sites. Patients were required at screening to have a Hamilton Depression Rating Scale (HAM-D) score of >18 and suffer depression within the past 6 months. Individual interviews conducted by trained researchers used a semi-structured interview guide designed to elicit responses about MDD symptoms and related impacts. Interviews were audio-recorded, transcribed, cataloged and organized into a coding framework using Atlas.ti software for content analysis. **RESULTS:** Forty interviews were conducted. Mean age of participants was 46.2 (SD=11.8); 67.5% were female, and 45.0% described their race as white. Saturation of concepts was achieved within the first 32 interviews. A total of 3022 symptom and 830 impact code stems were derived from the transcripts. Eleven different domains were developed in the coding framework for symptoms. Domains with the greatest number of symptom expressions included Emotions/Mood (624/3022 [20.6%] of expressions), Anxiety (398/3022 [13.2%]), and Cognition (358/3022 [11.8%]). Four different impact domains were identified, with Difficulty with Daily Activities (340/830 [41.0%]) and Social/Relationship Changes (319/830 [38.4%]) receiving the greatest number of expressions. A variety of different descriptions were used to communicate these domains and sub-domains; representative quotations will be presented. **CONCLUSIONS:** A broad range of concepts and terminology is used by patients to describe the symptoms and impacts associated with their depression. Participants identified symptoms that included both expected (based on diagnostic criteria) and those not commonly described as core symptoms of MDD. Organization of quotations into a coding framework and dictionary allows for the selection of concepts and incorporation of the most meaningful patient language into early stages of PRO instrument development.

PMH41

A CHANGE OF DYSURIA, XEROSTOMIA, ANXIETY AND DEPRESSION AFTER INITIATION OF INHALED DRUGS

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OBJECTIVES: Dysuria, xerostomia, anxiety and depression after initiation of treatment with inhaled medicine have not been fully evaluated. The aim of this study was to investigate the impact of treatment with inhaled drugs on these symptoms. **METHODS:** This was a multicenter, prospective study conducted in 3 respiratory clinics in Korea. The symptoms of dysuria, xerostomia, anxiety and depression were observed via the International Prostate Symptoms Score (IPSS), Xerostomia questionnaire (XQ), Hospital Anxiety & Depression Scale (HADS) at the baseline, 4 weeks, 12 weeks after initiation of inhalation therapy. The patients were divided into two subgroups according to inhaled medication (\pm : combination of inhaled corticosteroids (ICS) and long-acting β_2 -agonist (LABA) II: Long-acting muscarinic antagonist (LAMA)). **RESULTS:** Among 90 patients enrolled, 84 patients were analyzed. After initiation of treatment with inhaled drugs, IPSS and XQ were not changed significantly (IPSS, 11.96 ± 9.85, 12.98 ± 9.88, 13.85 ± 0.08; XQ, 8.92 ± 10.96, 10.31 ± 11.33, 11.42 ± 12.82 in the baseline, 4 weeks, 12 weeks respectively). HADS at 12 weeks were significantly higher than that in the baseline. ($p = 0.037$) (9.61 ± 5.18, 10.36 ± 6.07, 10.85 ± 6.27 in the baseline, 4 weeks, 12 weeks respectively). **CONCLUSIONS:** This study results indicate that inhaler adversely affected dysuria, xerostomia, anxiety and depression in new inhaler users. But those differences were not statistically significant except HADS. And further large sample size study is needed.

PMH42

ASSESSING IMPACTS OF MAJOR DEPRESSIVE DISORDER (MDD) ON COGNITIVE FUNCTION

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OBJECTIVES: 1) to identify concepts relevant to patients when measuring cognitive symptoms of depression and their impacts, and 2) to adapt an existing patient-reported measure of cognitive function for MDD. **METHODS:** Four age-stratified focus groups (total N = 33) were conducted with adults under treatment for MDD. Following open concept elicitation, participants provided feedback on two self-report measures of cognitive symptoms: the Applied Cognition General Concerns Scale (Gerson et al., 2006) and the Perceived Deficits Questionnaire (PDQ) (Sullivan et al., 1990). Focus group results led to a modified PDQ for MDD. Two sets of cognitive interviews with additional MDD patients (N = 17) refined the instrument, resulting in the PDQ for Depression (PDQ-D). **RESULTS:** Focus group participants reported seven different categories of cognitive symptoms. Across the age strata, the most bothersome were difficulties with concentration, attention and memory. Patients described many ways their cognitive symptoms affected them; productivity limitations were among the most salient. While most focus group participants deemed the PDQ content appropriate, a shorter reference period and more explicit response options were suggested. Cognitive interview results suggested that the initial version of the 20-item PDQ-D was an appropriate and comprehensive assessment of cognitive symptoms of MDD. Interview participants found the items easy to understand and answer. Minor modifications made in early interviews facilitated completion of the measure in later interviews. **CONCLUSIONS:** The PDQ-D is a patient-reported assessment of cognitive function with potential to provide unique information important for comprehensive evaluation of individual patients with MDD and new treatments for this disorder.

PMH43

MODELLING THE LONGITUDINAL LATENT EFFECT OF PREGABALIN ON SELF-REPORTED CHANGES IN SLEEP DISTURBANCES AND DISABILITY IN OUTPATIENTS WITH GENERALIZED ANXIETY DISORDER (GAD) TREATED IN ROUTINE CLINICAL PRACTICE IN SPAIN

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OBJECTIVES: To model the longitudinal latent effect on self-reported changes in sleep disturbances and disability of adding pregabalin (PGB) to the usual care (UC) therapy of outpatients with GAD treated in routine (Real World) clinical practice. **METHODS:** A post-hoc analysis was performed using refractory outpatients with GAD enrolled in a 6-month, prospective study carried-out in psychiatric clinics. Anxiety symptoms, self-reported sleep disturbances and disability changes at end-of-trial visit were assessed with the Hamilton-Anxiety (HAM-A), MOS-sleep and WHO-DAS-II scales, respectively. Adding PGB to the UC was compared to UC alone and its direct and indirect effects (expressed in percentages as the total effect explained by the model) were estimated by means of a conditional latent curve model applying structural equation modeling, with treatment as exogenous variable, and anxiety as covariates. **RESULTS:** A total of 1546 (68% women, mean age; 45.5 years) PGB naïve patients were included in the analysis. Either symptoms of anxiety, sleep disturbances or disability scores were significantly improved at end-of-trial, with higher scores reduction in the cohort adding PGB: -15.92 vs. -14.48 in HAM-A ($F = 4.9$, $p = 0.027$), -29.67 vs. -23.98 in MOS-sleep ($F = 16.3$, $p < 0.001$), and