WHY DO PATIENTS NOT ADHERE TO PRESCRIBED MEDICATION REGIMES? RESULTS OF TWO GERMAN SURVEYS
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OBJECTIVES: The aim of this study is to answer the following questions: 1) How high is the self-reported non-adherence (NA) of German patients with the need to regularly take medication? and 2) Which factors capable of explaining this self-reported NA can be identified by multivariate analysis? METHODS: Two cross-sectional surveys (phone survey with 1177 patients; face-to-face in-depth survey with 340 patients in 17 German pharmacies) were conducted. Self-reported NA was measured by the generic Morisky scale (either as 4 items or 8 item MMAS). Identifying explanatory factors was conducted on the basis of multivariate logistic regression analysis (including the calculation of additive risks by dichotomization of significant explanatory factors). RESULTS: 1) Approximately 35–40 % of the patients can be described as non-adherent (NA probability rate of 10.4 %, for patients displaying all identified risk factors this rate increases to 93.9 %). CONCLUSIONS: Our surveys are the largest and most detailed to have been conducted in Germany concerned with the theme of medication-based NA. Our results show that approximately one-third of patients can be classified as non-adherent. Intentional NA explanations can explain the NA considerably better than do socio-economic factors.

RETROSPECTIVE EVALUATION OF THE IMPACT OF COST-SHARE INCREASES FOR SPECIALTY MEDICATIONS ON ADHERENCE AND PERSISTENCE
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OBJECTIVES: Women with PMO are most often treated with bisphosphonates (BPs), as well as a 3 %, P < 0.01, and related (SR) and ranolazine (RLX). However, the percentage of patients is not persistent after 1 year of therapy, which can compromise treatment effectiveness (Imaz I, Osteoporo Int 2010) and thus increase the risk of fractures. The objective was to estimate the persistence to PMO treatments in a region of Spain (Catalonia) representative of the Spanish population. METHODS: A database analysis included women with PMO from 6 primary care centers, aged ≥20 years who initiated BPs (alendronate, ibandronate, risedronate), SR or RLX between January 1, 2004 and June 30, 2008. Patients with cancer, other bone diseases, hospitalisation >30 days or <1 year follow-up data were excluded. Persistence was measured at 1, 2 or 3 years according to prescriptions dispensed at office-based pharmacies. Three patients’ cohorts were analyzed: patients with ≥1 year (cohort 1), ≥2 years (cohort 2) and ≥3 years (cohort 3) follow-up. Patients with no access to medication for >1 month were considered non-persistent and a switch to another PMO treatment was considered a discontinuation. In a secondary analysis, switch was not considered a discontinuation. Statistics were performed using Kaplan-Meier methodology. RESULTS: A total of 3,049 patients (mean age ± SD; 68.3 ± 9.7 years) were included in cohort 1; 30% were persistent after 1 year (95% CI:27.5–32.5). In cohort 2 (n = 2698; 68.9 ± 9.3 years) persistence was 35% (CI:32.6–38.6) and 16% (CI:13.6–19.2) after 1 and 2 years, respectively. In cohort 3 (n = 2163; 68.4 ± 9.5 years) persistence was 36% (CI:33.9–39.7), 20% (CI:18.3–21.7) and 9% (CI:5.9–12.1) after 1, 2 and 3 years, respectively. The results were similar by drug and frequency of administration, and when switch was not considered a discontinuation. CONCLUSIONS: In this Spanish population of postmenopausal women with osteoporosis, persistence to treatment was poor, even when a switch was not considered a discontinuation.
utility estimates. Regression models (tobit, OLS; Censored least absolute deviation) were used to estimate specific changes in HRQL associated with the side effects.

RESULTS: Many participants reported more than one symptom, with ED most common (n = 139); reduced libido (n = 99); ejaculatory disorder (n = 98), and gynaecomastia (n = 20). From the OLS regression EQ-5D and SQoL-3D utilities were estimated for ED (-0.042; -0.075); reduced libido (-0.053; -0.047); ejaculatory disorder (-0.046; -0.028), and gynaecomastia (-0.045; -0.037) respectively. EQ-5D and SQoL-3D were weakly correlated (r = 0.296). CONCLUSIONS: The condition-specific and impact domains indicate the impact of prostate-related problems on HRQL. While the magnitude of disutilities is similar the poor correlation between the two measures suggests they are measuring different aspects of HRQL. The value of condition-specific versus generic methods for estimating utilities will be discussed.

PSYCHOMETRIC VALIDATION OF AN ABBREVIATED VERSION OF THE SEXUAL FUNCTION QUESTIONNAIRE (ASFAQ)

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OBJECTIVES: The Sexual Function Questionnaire (SFQ-28) is a well established and validated self-reported screening and outcomes measure of female sexual dysfunction (FSD). In order to reduce patient burden and focus on symptoms of FSD, two domains (partner and enjoyment) have been removed to create an abbreviated version (ASFAQ). The objective of this study was to ensure that the removal of these domains had not changed the psychometric properties of the measure. METHODS: Forty seven pre-menopausal women with diagnosed female sexual arousal disorder (FSAD); primarily cognitive arousal difficulties, completed the ASFAQ, the Women's Sexual Distress Questionnaire (WSDQ), an FSAD daily diary and a meaningful benefit question (MBQ) as part of a double-blind, placebo-controlled, 3-way crossover trial. Baseline data were used to assess internal consistency and convergent validity (with the FSAD diary). Internal consistency (comparing the high versus low levels of distress on the WSDQ at end of treatment) and responsiveness of the domains of ASFAQ were also assessed. RESULTS: The ASFAQ domains demonstrated excellent internal consistency with Cronbach's alpha ranging from 0.73 to 0.88. All ASFAQ domains showed excellent convergent validity with the respective items on the FSAD diary. Excellent known groups validity was demonstrated for the desire and arousal cognitive domains with those with higher distress scores showing poorer scores on these dimensions of the ASFAQ. Moderate effect sizes were observed in the arousal domains for those who indicated they had a meaningful improvement in their arousal disorder during the trial. CONCLUSIONS: The results confirm that the removal of two domains from the SFQ-28 has not impacted on its psychometric properties or responsiveness. The ASFAQ is recommended for use in studies where patient burden needs to be minimized.

CONTENT VALIDITY OF THE BENIGN PROSTATIC HYPERPLASIA IMPACT INDEX (BII): RESULTS FROM CONCEPT ELICITATION AND COGNITIVE INTERVIEWS

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OBJECTIVES: The objective of this qualitative interview study was to assess the content validity of the BII in a sample of men with signs and symptoms of BPH using concept elicitation (CE) and cognitive interviewing (CI) methods. METHODS: Fifty men with BPH participated in the study; 27 completed the CE and 23 completed the CI. CEs were semi-structured asking subjects to describe the BPH symptoms they experience and how symptoms impact their life. CIs were semi-structured, asking subjects to describe their 1) difficulties completing the BII; 2) understanding of item meaning and terminology; 3) understanding of response options; and 4) ability to respond appropriately to the specified recall period. All interviews were audio recorded and transcribed. Data was analyzed using Atlas.ti. a saturation table was used to identify when no new concepts were forthcoming. Inter-rater agreement (IRA) was evaluated by having three coders independently dual-code 3 (11%) transcripts. Consistency of coding was characterized by agreement in the identification of concepts, and agreement in assignment of codes. RESULTS: Saturation of concepts was reached by the completion of 21 CE interviews. High agreement on coding consistency was achieved at 69.4 to 89.4% for identification of concepts, and 87.8 to 96% for assignment of codes. The BII was shown to be readily understandable and easily completed in a short period of time, and supported by the qualitative results as measuring the relevant impacts related to BPH. CONCLUSIONS: The BII shows strong evidence of content validity and provides an assessment of disease-related, clinically meaningful impacts of BPH symptoms and treatment outcomes in BPH studies.

DEMONSTRATING CONCEPTUAL EQUIVALENCE ACROSS MULTIPLE CULTURES: TRANSLATION AND LINGUISTIC VALIDATION OF THE IPAQ

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OBJECTIVES: Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multinational clinical trials. The Injection Pen Assessment Questionnaire (IPaq) is a dyadic (parent and child together) or self-report of ease of use and preference tool that allows objective and normative comparisons across and between injection pens used to administer human growth hormone (hGH). The purpose of this work was to translate and linguistically validate the IPaq, which was developed in English in the United States, for use in 7 countries: Czech Republic, Germany, The Netherlands, Slovakia, Sweden, Turkey and United Kingdom. METHODS: The IPaq was translated according to industry standard methodology. Five parent-child dyads (children 5 to 18) rated the impact of the completed translated questionnaire and then participated in a cognitive interview. Interviws were conducted using a standardized guide to assess the relevance, understandability, and appropriateness of the wording of the translations. Qualitative analyses were performed to ensure equivalence and that the content validity was maintained. RESULTS: The study sample consisted of 35 parent-child dyads who use injection devices to administer hGH (42.8% male). Mean age of the children was 12 years. The sample consisted of patients who speak 7 languages collectively. All IPaq items were well understood and proved relevant to the patients in this sample. Of interest, terms such as “cartridge”, “needle guard” and “injecting the medicine” were understood similarly by participants across countries. CONCLUSIONS: The results indicate the IPaq translations were conceptually equivalent to the English source version and easily understood by the target population in all countries. We consider these translations acceptable for PRO assessment in international research, clinical practice and clinical trials.

PATIENT SATISFACTION WITH FOLLITROPIN ALFA PREFILLED PEN IN WOMEN UNDERGOING OVARIAN STIMULATION: ELABORATION AND VALIDATION OF VENUSF QUESTIONNAIRE

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OBJECTIVES: To elaborate and validate a questionnaire on patient satisfaction with the follitropin alfa prefilled pen, compared with previously used injectable gonadotro- pins, in women undergoing ovarian stimulation. METHODS: VENUSF questionnaire with 14 items was constructed after a four-stage process (concept identification and item review; item review by an expert on female infertility; patients interview; and replying to the wording of questionnaire according to interviews results) in which both experts on health outcomes research and fertility professionals and patients were involved, a post-authorization observational study (non-randomised patients, national setting) was undergone in order to validate the questionnaire. After assessing sample adequacy (Kaiser-Meyer-Olkin index and Bartlett’s test of sphericity), Rasch analysis (infit and outfit statistics) provided a reduced version of the questionnaire. Its psychometric properties were assessed: feasibility (omitted response and time to fulfil it), variability (differential scaling effects), validity (factor analysis and nonparametric tests) and reliability (Cronbach’s alpha). RESULTS: Initial questionnaire (14 items and 6 additional questions) was answered by 91.1% of sample (n = 107) in an average of 5.04 minutes (SD = 3.3). Statistical correlation was observed between scores from two dimensions of questionnaire and overall treatment satisfaction, as well as variables Numbering of previous treatments, Time since last treatment and Minutes required to prepare pen. Rasch analyses yielded 9 items in the final version of the questionnaire. This process was confirmed by sample adequacy (KMO = 0.72, statistically significant value of Bartlett’s test of sphericity) and reliability parameters (Cronbach’s alpha = 0.78). CONCLUSIONS: The reduced version of the questionnaire VENUsf a feasible, valid and reliable tool for assessing patient satisfaction with follitropin alfa prefilled pen in women undergoing ovarian stimulation.

DISPENSED MEDICATIONS LABELING IN MALAYSIA: VIEWS FROM GENERAL PRACTICE

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OBJECTIVES: To assess the perceptions of the general public in Malaysia about the importance of drug labeling. METHODS: A cross sectional study using pre-validated questionnaire was undertaken with a convenient sample of general public in the State of Penang, Malaysia. All data was analyzed using SPSS for Windows version 12.0. Inferential statistics were used whenever appropriate at alpha value of 0.05 or less considered significant. RESULTS: A total of 365 respondents had participated in the survey. Majority of them agreed that drug labeling is important to any person dispensing medicines (74.8%), caretakers (76.2%), health care professionals (77.8%) and patients (80.6%). Besides, they believed that it is important to ensure all drug labels are easily understood by the target population (65.8%). Patients (80.6%) and health care professionals (77.8%) agreed that incorrect dosage instructions on the drug label would worsen the quality of life (73.2%). Majority of respondents (58.4%) believed that drug labeling is highly important to ensure safe and effective drug use. Majority also expected that all drug products and controlled medicines should be labeled with product name (97.5%), active ingredients (78%), date of manufacture and expiry (87%), and dosage...