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 gynecomastia (n = 20). From the OLS regression EQ-5D and SFQ-3D disturbances were estimated for ED (−0.042; −0.075); reduced libido (−0.053; −0.047); ejaculatory disorder (−0.046; −0.028), and gynecomastia (−0.045; −0.037) respectively. EQ-5D and SFQ-3D were weakly correlated (r = 0.296).

CONCLUSIONS: The condition-specific and generic measures indicate the impact of the respective-prevented treatment outcomes on HRQL. While the magnitude of disorders 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.

PHH33 PSYCHOMETRIC VALIDATION OF AN ABBREVIATED VERSION OF THE SEXUAL FUNCTION QUESTIONNAIRE (ASQF)
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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 (ASQF). 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 ASQF, 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). Psychometric validity (comparing the ASQF with high versus low levels of disorder, or the WSDQ at end of treatment) and responsiveness of the areas of FSD was also assessed. RESULTS: The ASQF domains demonstrated excellent internal consistency with Cronbach’s alpha ranging from 0.73 to 0.88. All ASQF 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 ASQF. 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 ASQF is recommended for use in studies where patient burden needs to be minimalized.

PHH34 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. CI were semi-structured asking subjects to describe 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 specific 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.

PHH35 DEMONSTRATING CONCEPTUAL EQUVALENCE 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 respective translated questionnaire and participated in a cognitive interview. Interviews 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 by the translated IPAQ, which was across language versions. RESULTS: 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.

PHH36 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 gonadotropins, in women undergoing ovarian stimulation. METHODS: VENUSF questionnaire with 14 items was constructed after a four-stage process (concept identification and item generation; item review by an expert in female infertility and written content validation; elicitation of questionnaire according to interviews results) in which both experts on health outcomes research and fertility professionals and patients were involved, a posteriori observational study (non-randomised patients, national setting) using 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 respective translated questionnaire and participated in a cognitive interview. Interviews 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 by the translated IPAQ, which was across language versions. RESULTS: 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.

PIH37 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 wherever 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 not vaguely claimed to improve quality of life (34.2%). Majority of respondents agreed that incorrect dosage instructions on the drug label would mislead the patient (39.2%) and gynecologist (36.7%). Most of them 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