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 domain scores were estimated for ED (r = 0.042, p = 0.075); reduced libido (r = 0.053, p = 0.047); ejaculatory disorder (r = 0.046, p = 0.228), and gynecomastia (r = 0.045, p = 0.037) respectively. EQ-5D and SFQ-3D domain scores were weakly correlated (r = 0.296). **CONCLUSIONS:** The condition-specific and generic domains should be compared to the respective domains of HRQL. While the magnitude of correlations 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.

**PH33**

**PSYCHOMETRIC VALIDATION OF AN ABBREVIATED VERSION OF THE SEXUAL FUNCTION QUESTIONNAIRE (ASFQ) Williams K, Abraham L, Symonds T Pfizer Ltd, Sandwich, Kent, UK

**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 (ASFQ).

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-affective difficulties, completed the ASFQ, 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). The criterion validity (comparing those with high versus low levels of distress on the WSDQ at end of treatment) and responsiveness of the arousal domains of ASFQ were also assessed. **RESULTS:** The ASFQ domains demonstrated excellent internal consistency with Cronbach's alpha ranging from 0.73 to 0.88. All ASFQ 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 ASFQ. 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 ASFQ is recommended for use in studies where patient burden needs to be minimized.

**PH34**

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

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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 CEs and 23 completed the CI. CE As were semi-structured asking subjects to describe the BPH symptoms they experience and how symptoms impact their life. CI As 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 specified recall period. All interviews were audio recorded and transcribed. Data was analyzed using Atlas.ti. A saturation table was used to identify when 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:** Sanatization 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 BII. **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.

**PH35**

**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 completed the respective translated questionnaire and later 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 of the IPAQ was across language populations.

**RESULTS:** The study sample consisted of 33 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.

**PH36**

**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 on female infertility; item generation; editing 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) taking place in 14 hospital centres with 48 departments, were assessed on a 5-point Likert scale and the results were compared with the EQ-5D-5L. **RESULTS:** Patient satisfaction with the follitropin alfa prefilled pen was 8.98/10 (SD 0.3). Psychometric properties were assessed: feasibility (adherence to response and time to fulfill it), variability (response and ceiling effects), validity (factor analysis and nonparametric tests) and reliability (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.

**PH37**

**DISPENCED 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 not vaguously claimed to improve quality of life (54.2%). Majority of respondents agreed that incorrect dosage instructions on the drug label would influence 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 labelled with product name (97.5%), active ingredients (78%), date of manufacture and expiry (87%), and dosage...