Child-Friendly version of EQ-5D will be discussed to realize the final version of the questionnaire.

PIH15

DEVELOPMENT OF AN ICIQ NOCTURNAL ENURESIS QOL QUESTIONNAIRE

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OBJECTIVES: There is a lack of a validated QoL questionnaire assessing the psychological burden and treatment benefits of bedwetting as evaluated by the child. This abstract reports the results of the initial validation tests for such a questionnaire. It is being developed in accordance with the validation standards of the ICIQ. **METHODS:** A literature review was conducted and led to quantitative interviews with 28 children suffering from Nocturnal Enuresis and 28 pairs of parents. Consequently a questionnaire including 20 questions was developed and tested in a multinational Randomised Clinical Trial completed by 196 children and 196 parents in antidiuretic treatment before and during the trial. **RESULTS:** Based on review and interviews, a list of issues was identified: Social isolation, emotional distress, low self-esteem, problems in parent-child relation, delayed independence and fear of being teased at school and home. Two or more questions were developed for each of the six issues to add room for elimination of poorly performing questions. The RCT data indicated promising cluster effect, i.e. the well treated children showed a high QoL, and the questions seemed test-retest consistent. Some questions yield a high level of missing answers. **CONCLUSION:** The tests led to reformulation of the questions yielding missing answers and the questionnaire is now ready for the coming validation, including sensitivity analysis and item reduction. We are convinced that future research in Nocturnal Enuresis will profit from the final questionnaire.

PIH16

TREATMENT DURATION FOR ATROPHIC VAGINITIS: CLINICAL TRIALS VERSUS "THE REAL WORLD"

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OBJECTIVE: Duration of vaginal estrogen therapy (VET) may vary. This study sought to compare and contrast treatment duration of women prescribed vaginal tablets (VT) or vaginal creams (VC) in clinical trials with that in clinical practice. **METHODS:** Adults initiating VET between January and June, 2004 in 57 managed care plans (PharMetrics database) in the United States were identified and followed for up to 10 months to examine their treatment duration. A Kaplan-Meier analysis was performed to obtain average and median time to discontinuation for individuals treated with VT or VC. A weighted average of treatment duration was calculated for a total of seven clinical trials identified in the literature. These results were stratified by study inclusion criteria. Differences in average treatment duaration were statistically tested using t-tests. **RESULTS:** Of 5599 patients undergoing VET (mean age = 54 ± 9.1 years), 4355 (77.8%) received VC and 1244 (22.2%) received VT. Patients prescribed VT had a significantly longer average (median) treatment compared to patients prescribed VC [(198.5 ± 82.4 days (221 days) vs. 177.1 ± 86.7 days (190 days)); $p < 0.01$)]. This duration in clinical practice was significantly longer than that in seven clinical trials [165 days (240 days for three trials of both VC and VT; 90 days for two VT-only studies; and 69 days for two VC-only studies)]. **CONCLUSIONS:** Duration of VET was longer in a real-world clinical practice setting than in clinical trials. Moreover, subjects treated with VT exhibited significantly longer treatment duration than subjects treated with VC. Possible factors explaining longer duration with VT include ease of use, reduced messiness, accurate dosing resulting in improved effectiveness and fewer adverse events, and consequently improved quality of life. Future studies should prospectively examine factors associated with these differences.

PIH17

ASSESSING PSYCHOLOGICAL BURDEN AND TREATMENT BENEFITS IN PEDIATRIC PATIENTS WITH BEDWETTING

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OBJECTIVES: Nocturnal enuresis (NE) can pose significant psychological burden on children's self-esteem and quality of life (QoL). Therefore, patient-reported outcome (PRO) measurement is essential to fully understand the burden posed by NE and the benefits of treating this condition. To our knowledge, it has not been investigated which instruments should be used to assess the psychological burden of NE. The aim of this study was to identify and evaluate PRO instruments used in children with NE. **METHODS:** A literature search of Medline and other databases was conducted to identify publications from 1995–2006 which contained PRO instruments used in children with NE. **RESULTS:** 40 studies and 32 PRO instruments were identified. Instruments were evaluated based on psychometric properties and responsiveness to change. Some studies used several PRO instruments. The Child Behavior Checklist was the most commonly used instrument (8/40 studies, 20%). Measures of self-esteem were used in 11/40 studies (28%). No generic QoL measures were used in these trials. No disease-specific PRO instruments were found to be fully validated in the NE. population. Currently, a new disease-specific QoL questionnaire is in development for NE. **CONCLUSIONS:** The results of this study highlight the lack of patient-reported disease-specific PRO measures to assess the burden and treatment benefits of NE. A new disease-specific instrument may be able to fill this gap.

PIH18

DIMENSIONS OF HRQOL AND SATISFACTION WITH LIFE IMPROVE IN ED PATIENTS SWITCHING FROM OTHER ORAL ED MEDICATION TO TADALAFIL

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OBJECTIVES: To compare Finnish patients with erectile dysfunction (ED) and men from the Finnish general population in measures of self-reported Health-Related QOL (HRQoL) and satisfaction with life, and to investigate whether switching patients from current oral ED medication to tadalafil impacts these measures. **METHODS:** A total of 202 Finnish men over 18 years successfully treated with oral ED prescription medication (tadalafil excluded) voluntarily entered this multicenter, open-label, one-arm, 3-month study. Upon enrollment, patients discontinued their previous therapy and were started on tadalafil 10 or 20 mg (dose determined by investigator) on demand. Outcome was measured using the 15D and Life Satisfaction-11 (LiSat-11) checklists. 15D is a generic, comprehensive, 15-dimensional, standardized, self-administered measure of HRQoL

used as both a profile and single score measure. LiSat-11 is a generic validated checklist for self-perceived satisfaction with life. A Finnish, age-matched male population cohort was used for comparison. **RESULTS:** A total of 194 patients provided data for analysis at baseline and outcome at 3 months. The changes observed (baseline to endpoint) were as follows: average usage of ED tablets per four weeks increased from 4.7 to 9.7, intercourse attempts from 6.4 to 10.6, and the success rate of intercourses from 79% to 92%. At baseline, the 15D score was higher for the study patients than for the comparator population (0.924 vs. 0.902). Nevertheless, significant improvement (baseline to endpoint) was reported on the 15D dimensions of mobility, depression, distress (all $p < 0.01$), and sexual activity ($p < 0.001$); and life in general ($p < 0.05$), leisure ($p < 0.01$), sexual life, family life, and partnership relation (all $p < 0.001$) domains of LiSat-11. **CONCLUSIONS:** When patients switched from other oral ED medication to tadalafil, improvement was seen in 3 of 15 dimensions of 15D and in 5 out of 11 domains of LiSat-11, including the closeness items: sexual life, partnership relation, and family life.

PIH19

ESTIMATING UTILITY IN ROTAVIRUS GASTROENTERITIS IN CHILDREN UNDER FIVE IN THE UK

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OBJECTIVE: To estimate the health state utility of differing severities of gastro-enteritis associated with rotavirus infection in children under five. **METHODS:** Health state descriptions were developed based on the major symptoms of gastro-enteritis infection. Health states for children who could be treated at home and those requiring hospitalisation were presented to GPs (N = 25), and for hospitalised cases, health states for children with two levels of dehydration were presented to paediatricians (N = 25). Both GPs and paediatricians were asked to score these health states using the EQ-5D questionnaire for children in two age bands (< 18 months, 1.5–5 years). Scores were modified to take into account the limited capacity for mobility and self-care among children in this age range. Utility estimates were calculated from these scores using standard methodology. **RESULTS:** From GP scores subjects requiring or not hospitalisation have a mean utility value (95% CI) of 0.425 (95 CI: 0.330; 0.520) and 0.781 (95 CI: 0.678; 0.884) in children <18 months, and 0.200 (95 CI: 0.049; 0.352) and 0.688 (95 CI: 0.553; 0.824) in children 1.5 yrs–5 yrs respectively. From paediatrician scores, mean utility values for hospitalised cases with 3–8% and ≥9% dehydration were 0.595 (95 CI: 0.528; 0.662) and 0.256 (95 CI: 0.157; 0.354) in children <18 months, and 0.634 (95 CI: 0.549; 0.718) and 0.077 (95 CI: –0.057; 0.210) in children 1.5 yrs–5 yrs respectively. In each case, confidence intervals between severe and less severe health states did not overlap. **CONCLUSION:** Gastroenteritis associated with rotavirus has a significant impact on the health related quality of life in children under five. This study provides useful estimates of health state utilities for economic evaluation of interventions to prevent rotavirus infection.

PIH20

CONJOINT-ANALYSIS QALYS FOR ACUTE CONDITIONS

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OBJECTIVE: Demonstrate using conjoint analysis to obtain generalized, nonlinear, time-tradeoff estimates of quality-adjusted life-years (QALYs) for clinically relevant durations and severities of acute, non-fatal conditions such as vasomotor symptoms. **METHODS:** A self-administered, web-enabled, graded-pairs conjoint-analysis survey elicited women's preferences for the treatment of vasomotor symptoms. The included treatment attributes are frequency and severity of vasomotor symptoms (daytime hot flashes and nighttime sweats) and duration of these symptoms. Participants also considered vasomotor-symptom, treatment-related side effects. Observed tradeoffs between symptom duration and symptom relief were used to calculate generalized conjoint time equivalents for specified health states without first calculating utilities anchored at 0 and 1. **RESULTS:** A total of 523 women with a mean age of 52 years completed the survey. For these women, improvement from severe (severe >6 hot flushes a day and >3 sweats a night) to moderate (moderate 3–6 hot flushes a day and 1–3 sweats a night) vasomotor symptoms over a 7-year treatment period is equivalent to 3.7 years of normal health, while improvement from moderate to mild (mild 1–2 hot flushes a day and no night sweats) symptoms is equivalent to 4.4 years of normal health. QALY benefits of symptom relief are larger for younger women (<= 2) than for older women (>52). For example, an improvement from moderate to mild is equivalent to 3.3 years of normal health for younger women, where it is to 6.8 years of normal health for older women. **CONCLUSIONS:** Conjoint analysis is a feasible method for estimating QALYs directly for acute health states. This approach avoids ad hoc approaches such as the chaining method. Its advantages over standard-gamble and time-tradeoff methods include avoiding clinically irrelevant tradeoffs involving death or life expectancy, avoiding restrictive assumptions such as linear time preferences, and eliciting preferences in the realistic context of both efficacy and side-effect risks.

PIH21

INFLUENCE OF CONCOMITANT DISEASES ON THE CLINICAL RESPONSE TO TREATMENT FOR ERECTILE DYSFUNCTION

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Erectile dysfunction (ED) is defined as the persistent or recurring incapacity to achieve or maintain sufficient rigidity of the penis to be able to have satisfactory sexual intercourse. **OBJECTIVE:** To determine the clinical response to treatment (patient satisfaction, onset of action and reproducibility of the effect) in patients with ED, with or without other concomitant diseases. **METHODS:** A retrospective, epidemiological study was conducted in which we collected demographic data, medical and sexual history, concomitant medication, diagnostic and therapeutic procedures applied to ED and the clinical response to the prescribed treatment in male patients over 18 years of age who had visited their doctor in the 3 months prior to the start of the study. **RESULTS:** data was collected from 5281 patients. The most prevalent associated disorders were cardiovascular (28.6%), endocrine (23.7%) and genitourinary (15.4%). A total of 77.1% of the patients with concomitant disorders indicated they were satisfied with the erection obtained (sufficient for intercourse) (90.9% of the patients without other associated disorders; $p < 0.0001$). A totalof he patients with concomitant diseases referred they were satisfied with the onset of action of the treatment (91.1% without other associated disorders; $p < 0.0001$). 75.8% of the patients with concomitant diseases were confident to obtain and maintain a sufficient erection at each new attempt (90.0% without other associated disorders; $p < 0.0001$). Clinical response was better in patients with cardiovascular or endocrine conditions vs. genitourinary disorders ($p < 0.03$; $p < 0.04$). The mean prescribed dose was 15.9 mg (SD 5.2) of vardenafil, 18.6 mg (SD 6.9) of tadalafil and 60.6 mg (SD 23.7) of