

discontinued medication. The most commonly cited reason for discontinuation was the medication(s) did not work well (35%); side effects was the second most common reason (20%). Additional reasons included lack of need for frequent use (17%), cost of treatments (11%), and dislike of taking pills all the time (12%). When asked about medication-taking behaviors, 155 (21%) out of 752 patients taking oral medications reported skipping doses. Reasons for skipping doses included forgetting to take medication (68%), dislike of taking pills all the time (14%), and cost of medication (10%). Of those reporting skipping doses of medications, 41% reported this occurs every couple of weeks; 30% and 25% reported it occurs weekly and monthly respectively. Only 4% reported daily skipping of doses. **CONCLUSIONS:** A significant portion of BPH patients using oral treatments reported discontinuing therapy due to lack of efficacy and a variety of other reasons. Skipping doses was also a problem for over 20% of patients taking oral medications.

PIH13

COMPLIANCE WITH PRESCRIBED ONCE A DAY PLACEBO IN ADOLESCENT HEALTHY VOLUNTEERSVander Stichele R¹, Grinnan TR², Vrijens B³¹Gent University, Gent, Belgium, ²MeadWestvaco Corporation, London, UK, ³Pharmionic Systems, Visé, Belgium

OBJECTIVES: The objective of the present study is to describe the compliance observed with a prescribed once a day placebo over a 28 days period in adolescent healthy volunteers, in school-dwelling youngsters in Belgium. **METHODS:** Eighty students were asked to take a placebo once a day during 28 days. Tablets supply was dispensed by sequences of 14 days either in an electronic pill box (MEMS®) or in an electronic blister pack (Cerepak®) according to a crossover design. Both devices allowed real time electronic compilation of dosing histories. At the end of the study, students were asked to assess their own compliance with a structured questionnaire. **RESULTS:** Compliance data were available for 78 students. We observed no difference in compliance between the two monitoring devices ($p = 0.682$), nor between periods ($p = 0.462$), and no carry-over effects ($p = 0.599$). 46% of the students took most of their doses in the morning (before 10:00AM) and 49% in the evening (after 04:00PM). Compliance was higher ($p = 0.016$) among the students who took their pills in the morning (92% vs 85%). Only 9 (11%) students took all of the 28 prescribed doses and 36 (46%) missed more than 5 doses. There was a strong weekend effect. The probability to take a tablet on a Friday or a Saturday was reduced by 30% ($p < 0.0001$). Only 58% of the subjects were able to estimate reasonably well their compliance with the prescribed regimen. **CONCLUSIONS:** To be compliant with drug therapy is a burden for the majority of adolescents, most of whom are in good health and have little experience with taking medicines. Evening and weekend discipline seems to be problematic. No differences in compliance by measuring device were observed. When precise assessment of compliance is crucial for the interpretation of study results, electronic monitoring should be used, especially in adolescent populations.

PIH14

RECALL PERIODS FOR SATISFACTION WITH SEXUAL INTERCOURSE: TWO APPROACHES FOR ASSESSING OUTCOMES

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OBJECTIVES: The recall period associated with any patient-reported outcome (PRO) measure is critical to the interpretation of the measure. However, the most appropriate recall period is

often unclear. The objective of this analysis was to compare responses to two satisfaction with sexual intercourse (SSI) measures with different recall periods. **METHODS:** Sexual health data and intravaginal ejaculatory latency time (IELT) were collected from 1115 men and their female partners as a part of a two-month observational study of men with and without premature ejaculation (PE) from five European countries. Data from men diagnosed with PE are included in this analysis ($n = 196$). IELT was measured by a female-operated stopwatch and recorded by the male subject on an event log. Two single-item measures of SSI were collected: 1) "Over the past month, was your satisfaction with sexual intercourse: 0 = very poor, 1 = poor, 2 = fair, 3 = good, or 4 = very good?" and 2) "Were you satisfied overall with this sexual experience?" (yes/no). Responses to the first item were recorded by the male subjects at the study site. The second measure was assessed following each sexual intercourse and recorded on the event log along with the IELT. For this per-event item, a mean percentage SSI was computed for each subject over a one-month period so that the recall periods for the two measures were comparable. **RESULTS:** There was a strong association between SSI measures based on one-month recall and the percentage of satisfactory sexual experiences based on the event log data: Very poor (Mean = 12.6%, SD = 29.4%, $n = 11$), Poor (Mean = 24.0%, SD = 19.0%, $n = 49$), Fair (Mean = 63.7%, SD = 25.0%, $n = 66$), Good (Mean = 85.6%, SD = 16.8%, $n = 52$) and Very good (Mean = 95.6%, SD = 7.3%, $n = 18$). **CONCLUSIONS:** Measures of SSI assessed on a per-event basis and using a one-month recall period are highly associated suggesting that either measure could be used to assess outcomes related to SSI among men with PE.

PIH15

BARRIERS TO COMMUNICATION ABOUT ERECTILE DYSFUNCTION IN PATIENTS TAKING ANTIHYPERTENSIVE MEDICATIONSHarnett J¹, Sklar G², Bolge SC³, Anastasio G⁴¹Pfizer Inc, New York, NY, USA, ²University of Maryland School of Medicine, Baltimore, MD, USA, ³Consumer Health Sciences, Princeton, NJ, USA, ⁴Pfizer Inc, Charlotte, NC, USA

OBJECTIVES: To evaluate barriers to communication about erectile dysfunction (ED) and their impact on patient-reported outcomes. **METHODS:** Male participants in the May 2004 internet-based National Health and Wellness Survey (NHWS) who reported being married/living with a partner, difficulty achieving/maintaining an erection but had not spoken with a physician about ED, and taking medication for blood pressure were recontacted in December 2004. Patients were asked whether they had spoken with a physician about ED since the May 2004 survey and barriers to communication about ED. ED status and severity were confirmed with the Erectile Function (EF) domain of the International Index of Erectile Function. Data were also collected from the SF-8, Erectile Distress Scale (EDS), and the 2004 NHWS. **RESULTS:** Of the 233 ED patients who were recontacted and completed the questionnaire, 31% reported speaking with their physician about ED. Patients who spoke (vs did not speak) with their physician were younger (63 vs 67 y, $P = 0.008$), had less severe ED (EF domain score, 12.1 vs 7.7, $P < 0.001$), and were more distressed about ED (EDS scores, 4.1 vs 4.7, $P = 0.002$). Among those who spoke with their physician, 83% initiated the discussion, and the most common motivator was their spouse; 32% reported currently taking a phosphodiesterase type 5 inhibitor. Fifty-seven percent of these patients waited ≥ 1 year before discussing ED with their physician, most commonly because of a belief that ED was a natural part of aging (42%). Of those who did not speak with their

physician, 45% reported interest in an ED treatment, and 72% believed that physicians should routinely inquire about ED. **CONCLUSIONS:** Although most ED patients reported not speaking with their physician, almost half were interested in treatment. Patients reported initiating ED discussions more often than physicians; however, the majority felt that physicians should routinely ask about sexual function.

PIH16

WHAT EXPECTATIONS DO MEN WITH BENIGN PROSTATIC HYPERPLASIA (BPH) HAVE FOR TREATMENT?

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OBJECTIVE: To interview men with BPH to determine their expectations regarding treatment. Collection of demographic data, International Prostate Symptom Score (IPSS), bother score, and patient satisfaction information are standard outcome measures that provide contextual information for reviewing patient expectations. **METHODS:** Multiple individual subject interviews were conducted at 4 geographically dispersed sites in the US. Subjects with diagnosed BPH who met entry were included. Research subjects completed the IPSS, BPH “bother score”, general health questionnaires, and provided up to two top expectations from treatment of BPH. Patients were thoroughly debriefed on their answers to clarify unclear responses. **RESULTS:** Thirty-seven subjects who met the criteria were interviewed as part of the qualitative research. The mean age was 66 years [range, 45–82 years] and the mean IPSS score was 20 [range, 7–31]. Subjects reported a mean Bother Score of 3.1. Thirty-five subjects (95%) reported a primary expectation for treatment, and 26 subjects (70%) expressed primary and secondary expectations from treatment. Thirty-one subjects (89%) expressed symptom relief as their primary expectation, followed by reduced, or no side-effects from treatment (9%). Detailed primary expectations included reduction in abnormal urination (31%), reduction in frequency (20%), and reduction in nocturia (17%). Similarly, 88% patients reported symptom relief as their top secondary expectation. Urine control (35%), reduction in frequency (15%), lack of sexual side-effects (8%) and reduction in nocturia (8%) were among the top secondary expectations from BPH treatment. **CONCLUSIONS:** This research indicates that men with BPH primarily expect treatments to relieve symptoms. Most symptoms were identical to over-active bladder in females. The results from this small qualitative research study will help inform future selection of optimal measurement instruments for subjects in clinical trials and in routine clinical practice.

PIH17

DEVELOPMENT OF A PATIENT SATISFACTION WITH TREATMENT QUESTIONNAIRE FOR BENIGN PROSTATIC HYPERPLASIA (BPH-PSTQ)

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OBJECTIVE: To develop a questionnaire that focuses on patient satisfaction with treatment for BPH symptoms. There are no current questionnaires that focus on this important patient-reported outcome. **METHODS:** Multiple individual subject interviews (ISIs) with patients currently or recently receiving treatment for BPH was conducted to finalize content for a patient satisfaction with treatment questionnaire. Patients selected were required to have a diagnosis of BPH, and an IPSS total score of greater than or equal to seven. Interviews were conducted using an initial pool of items developed from previous patient research. The literature was also utilized to complement item selection.

Open-ended questions about their disease and its impact were conducted to assess missing content in the questionnaire. Subjects were debriefed thoroughly on satisfaction with content, vocabulary, and item. **RESULTS:** Twelve patients were interviewed and a total of 13 questions were developed from this research. The mean age was 62.3 yrs (range 54–72 yrs) with majority being Caucasian males (92%) with various levels of education. Mean IPSS score was 20.58 (range 14–30). The final questionnaire developed utilized a 5-point Likert scale with some questions including a 6th option for “does not apply”. The content of the final questionnaire ranged from medication impact on various symptoms of BPH, including over-active bladder type symptoms of frequency, urgency, and nocturia. Activity impact was also significant and included impact of medication on ability to interact more freely in social situations, impact on travel, activities, and relationships (family and sexual). Cost and side effects were also issues that concerned many of the subjects and were included in the final questionnaire. **CONCLUSIONS:** The 13-item final questionnaire (BPH-PSTQ) generated after ISIs with 12 subjects was easily understood by subjects in this qualitative development research. The content was also found to be comprehensive of subjects concerns and major issues.

PIH18

EXPLORATORY FACTOR ANALYSIS OF A 13 ITEM BPH PATIENT SATISFACTION WITH TREATMENT QUESTIONNAIRE (BPH-PSTQ)

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OBJECTIVES: The factor structure of the BPH-PSTQ was evaluated. **METHODS:** A cross sectional survey was conducted with BPH subjects that included the BPH-PSTQ. Exploratory factor analysis was conducted using maximum likelihood estimation and MINRES. Many criteria were evaluated to assess the number of factors including scree plots, the number of factors with eigenvalues greater than one, proportion of variance explained by factors, and various oblique and orthogonal rotations of the initial unrotated solution. **RESULTS:** A total of 768 subjects had complete data for analysis. The initial unrotated solution using maximum likelihood estimation left two factors with eigenvalues greater than one (25.2, 1.7). The variance explained by the dominant factor in the unrotated solution was 93%. Significance tests suggested that more than two factors were needed based upon chi-square results. Analysis of scree plot results demonstrated that there was one dominant factor and possibly a second factor that could be considered before there was a significant plateau on the plot. Quartimax rotation demonstrated a one factor solution with questions 11 and 13 not loading very highly on the dominant factor (0.54, 0.53). Final communality estimate were also not as good for these two items. Other rotations confirmed the misfit of item 13. **CONCLUSIONS:** The unidimensionality of the BPH-PSTQ needs to be further explored to determine if there are multiple underlying factors with sub-scales or multiple distinct factors via confirmatory factor analysis modeling. Item 13 was the only item that did not seem to fit with any of the other items in the scale, and did not load well on any latent factors.