ability to determine cost-effectiveness in specific settings. While site-specific research will likely be necessary, so is the need to critically evaluate such literature before blindly using it for decision-making.

**THE BPE-PIT—AN ADAPTATION OF THE BPE-P FOR USE IN A MULTINATIONAL CLINICAL TRIAL**

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**OBJECTIVE:** The Benign Prostate Enlargement-Partner questionnaire (BPE-P) was initially developed to assess the impact of patient’s Benign Prostatic Hyperplasia (BPH) on his partner’s quality of life (QOL). The objective of this study was to adapt the BPE-P for use in the clinical trial setting, and to linguistically validate the resulting questionnaire in US, Spanish, Canadian English and Canadian French subjects.

**METHODS:** The BPE-P was reworded to facilitate use in a clinical trial, and reviewed by a multidisciplinary team including clinicians, QOL experts, and linguists. This US English version was translated according to standard methodology: 2 forward translations, 1 reconciliation, 1 back-translation by a native English-speaker, 3-4 reviews by independent bilingual experts, and final reconciliation by a native-speaking language coordinator. Pilot testing and cognitive debriefing interviews were performed with a minimum of 10 subjects per language/country who were partners of men with BPH.

**RESULTS:** The following changes were made to the questionnaire prior to translation: a) recall period of 30 days was incorporated; b) questions were changed to past tense to reflect the recall period; c) wording on problems with sex life was changed to sexual satisfaction to better suit the trial setting and to prevent a response floor effect; d) responses to the sexual satisfaction and overall QOL question were revised; e) sexual satisfaction question was moved to the penultimate item on the scale to better suit the flow of questions. No significant problems were detected during translation. Subjects found the translations and their content suitable and relevant to their situation. The resulting instrument is now called the Benign Prostate Enlargement-Partner Impact of Treatment scale (BPE-PIT) to better reflect its adaptation to the clinical trial setting.

**CONCLUSION:** The BPE-PIT was successfully translated for use in an international clinical trial. Psychometric validation of this new instrument remains necessary.

**BENIGN PROSTATIC HYPERPLASIA—CONSEQUENCES OF THE PATHOLOGY FOR THE SPOUSE: RISK OF SOMNOLENCE**

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Urinary problems secondary to benign prostatic hyperplasia (BPH) are found in 20 to 25% of the male population over 50 years of age. This is thus a public health problem with a number of diagnostic, therapeutic and economic facets. The severity of the condition is assessed by the IPSS score, a well-known and recognized questionnaire.

**OBJECTIVE:** To evaluate the impact of this male pathology on the spouse as part of the growing importance attached to the caregiver.

**METHODS:** As part of a cohort study conducted between October 2000 and March 2001, the GP gave the patient two PFM (Patient Family Measurement) self-questionnaires for himself and for his spouse. During the consultation, 36.1% of the patients spontaneously complained of sleep problems.

**RESULTS:** We are most interested in the impact of daytime somnolence. The Epworth Scale was used to evaluate this. The score observed in a control population with normal sleeping habits is 5.9. For the analysis, we used 482 patient questionnaires and 382 spouse questionnaires. The rate of return of the spouse questionnaires (80%) was very satisfactory. The risk of daytime somnolence for the patient increased with the severity of the urinary problems with scores of 5.9, 6.4, and 8.9 on the PFM for slight, moderate, and severe urinary problems respectively. Similarly, for the spouses, the PFM score increased with increasing severity: slight = 4.7; moderate = 5; severe = 7.4. There is therefore a significant risk of daytime somnolence among spouses of patients with severe BPH.

**CONCLUSION:** As it is known that somnolence is responsible for a third of all road accidents, it is essential for these patients to limit the severity of their pathology by undergoing appropriate treatment.

**BENIGN PROSTATIC HYPERPLASIA: RECOGNITION OF THE CONSEQUENCES OF THE PATHOLOGY FOR THE SPOUSE**

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Urinary problems secondary to benign prostatic hyperplasia (BPH) are found in 20 to 25% of the population of men over 50 years of age. This is therefore a public health problem with a number of diagnostic, therapeutic and economic facets. The severity of the problem is assessed by the score obtained on the IPSS, a well-known and recognized questionnaire.

**OBJECTIVE:** As part of the growing importance attached to the caregiver, it is interesting to evaluate the consequences of this masculine pathology for the spouse.
METHOD: As part of a cohort study conducted between 10/2000 and 03/2001, GPs gave their patients two Patient Family Measurement (PFM) self-questionnaires for himself and his spouse.

RESULTS: For the analysis, 357 patient questionnaires and 316 spouse questionnaires were used. The rate of return of the spouse questionnaires (88%) was very satisfactory. The quality of life (QOL) of the patient was measured by SF12. The results consisted of two scores: mental (MCS-12), and physical (PCS-12). The norm observed in the American population, and from which the scores were standardized, was 50. In patients where the QOL had deteriorated, all the scores were lower than this norm, (PCS-12 = 46, MCS-12 = 47.2). This deterioration in the quality of life also applied to the spouse. (PCS-12 = 44.4, MCS-12 = 45.9). For the PCS-12, the difference was significant.

CONCLUSION: The rate of return of the spouse questionnaires showed the interest and involvement of spouses in their husband’s pathology. The deterioration in the quality of life of the spouse highlighted the impact of the disease on those around him. For both the patient and the spouse, the quality of life deteriorated with the severity of the BPH.

A RISK-ASSESSMENT MODEL FOR ERECTILE DYSFUNCTION: THE SEXUAL-HEALTH INVENTORY FOR MEN AND RELATED MEDICAL CONDITIONS

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OBJECTIVES: To help physicians identify patients most likely to have erectile dysfunction (ED), we studied the relationship between ED and health-related correlates among adult male patients using the Sexual Health Inventory for Men (SHIM), a validated five-item questionnaire assessing the presence and severity of ED. The correlates included age, smoker/nonsmoker status, and medical conditions: diabetes, depression, hypertension, any prostate disease, and high cholesterol.

METHODS: A convenience sample of patients (N = 31,054) from more than 600 primary care and specialty physician offices in the US completed the SHIM. ED corresponds to a SHIM score <21. Physicians or staff recorded medical variables. The risk assessment model for ED was created using multiple logistic regression analysis in a 50% random sample (n = 15,491) and validated in the remaining sample (n = 15,563).

RESULTS: 61.2% of patients (mean age = 53, range 18 to 101 years) had a SHIM score compatible with ED (mean score 18.5 ± 5.68, range from 5 to 25). Probability of a SHIM score <21 increased with age (odds ratio (OR) = 1.07/year). Diabetes was the variable most strongly correlated with a SHIM score compatible with ED (OR = 3.50), followed by depression (OR = 2.43), prostate disease (OR = 2.08), hypertension (OR = 1.64), smoking (OR = 1.57), and high cholesterol level (OR = 1.52). All ORs were significant (P < .05). The risk assessment model (cutoff P > .5) had good sensitivity (82.2%) and moderate specificity (59.2%). These statistics were repeatable and verified in the remaining half sample during model validation. Age thresholds were calculated to determine the patient age beyond which medical conditions increased the likelihood of ED: diabetes = 34 years old; depression = 40; prostate disease = 42; hypertension = 45; smoking = 46; high cholesterol = 46; no medical condition = 52.

CONCLUSIONS: Our risk-assessment model was strongly correlated with a SHIM score compatible with ED. It provides a simple means of identifying patients likely to have ED. This information can assist clinicians in questioning patients and in making appropriate treatment decisions based on risk factors.

COST-EFFECTIVENESS ANALYSIS OF THE SPECTRON VERSUS CHARNLEY HIP PROSTHESSES

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OBJECTIVE: To assess the cost-effectiveness of the SPECTRON® hip prosthesis in comparison with the Charnley for all diagnoses.

METHODS: A Markov model was employed to examine the cost-effectiveness of the Spectron prosthesis relative to the commonly used Charnley prosthesis. Revision rates were estimated from patient-level data in the Swedish National Hip Arthroplasty Register (1992–2000) assuming a constant hazard function in the first instance. Other assumptions included: a 1% risk of death during a THR procedure; a 4% annual risk of re-revision following an initial revision; costs of a primary and revision THR (excluding prosthesis), respectively, of £3,685 and £4,493 based on data from the Nuffield Orthopaedic Centre (NOC). Quality-adjustment weights were taken from a patient level database at the NOC that mapped patients into the EQ-5D health index both immediately before and at one year following hip replacement surgery.

RESULTS: From the Swedish Register, the risk of revision with the Spectron was 0.38 (95% CI 0.22–0.66) relative to the Charnley (employing a constant hazard assumption). This lower revision risk resulted in the Spectron generating more QALYs than the Charnley, with most of the Spectron’s higher acquisition cost being offset by reduced long-term costs. The incremental cost per QALY gained with the Spectron ranged from £300 (95% CI −£1000 to £3400) in younger patients to £1300 (95% CI −£600 to £6000) in older patients. Fitting a more flexible form to the hazard function that allows for both increasing and decreasing risks of revision suggests that the Spectron could be both cost saving and more effective than the Charnley.

CONCLUSION: The costs and QALY results from this analysis indicate that the Spectron is a cost-effective use of health-service resources. **SPECTRON** is a trademark of Smith & Nephew.