OBJECTIVE: Restless legs syndrome (RLS) is a neurological disorder characterised by unpleasant sensations in the legs and an irresistible urge to move the legs to relieve the discomfort. This study aims to describe the drug treatment patterns amongst UK RLS patients during a 12-month period; in this period pharmacological therapy was based on "off-label" use of medication. **METHODS:** A data base capturing nationally representative prescribing for patients presenting in general practice (DIN-LINK) was used to describe treatments received by patients with a diagnosis of RLS presenting to a GP in the 12 months up to 31st March 2005 (n = 556). This data base covers a population of about 800,000 patients and about 400 GPs. **RESULTS:** Annually, the number of patients with RLS for which they were receiving drug treatment was estimated to be up to 46 per 100,000 catchment population (up to 66% of the 70 per 100,000 patients with RLS who annually make contact with a GP). Drug treatments included the following (the percentages of patients receiving the different types of drug treatments are shown in brackets): antidepressants (20% of whom 71% received amitriptyline), anticonvulsants (18% of whom 76% received clonazepam), quinine (13%), non-narcotic analgesia (13%), dopamine agonists (5%), hypnotics (6%), tranquilisers (4%) NSAIDs (3%) and L-dopa (4%). **CONCLUSIONS:** The substantial percentage of patients receiving some form of analgesia or treatment for insomnia may be a reflection of the limited success of existing patterns of treatment in controlling symptoms (presumably, clonazepam in line with UK guidelines, was used mostly for insomnia). A large proportion of RLS patients were given amitriptyline which can worsen RLS and quinine, a treatment effective only when cramps co-exist.

PNL13

IMPLANTABLE SYSTEMS PERFORMANCE REGISTRY (ISPR) A MEDICAL DEVICE AND PATIENT REGISTRY

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OBJECTIVES: ISPR is a prospective, post-market, surveillance registry designed to monitor implantable neurological devices. For each patient enrolled demographics, implant and practice techniques, and patient reported outcomes are collected and analyzed to elucidate the etiology of device complications. The goal is to expand registry centers, based on pre-defined criteria, and generate data representative of the medical community and its patients. This registry is a foundation and electronic platform for outcome registry projects. **METHODS:** Single and multi-physician centers follow standard clinical practice and a common registry protocol. Center activation includes software and protocol training and IRB approval at each center. Information registered with the U.S Food and Drug and Administration (FDA) mandated Device Registration System (DRS) pre-populates the registry avoiding redundant data submission, while centers provide additional information through electronic data capture. Active surveillance occurs at 6-month intervals with data reporting required for device or patient events. These event data are electronically communicated to fulfill FDA-mandated event reporting regulations, thus creating efficiencies for the sponsor and physician. The potential of selection bias in ISPR is minimized through 100% eligibility of all implanted devices at each center. The approach for ISPR center expansion is based on geographic, specialty, and practice distribution to achieve a representative sampling of real world experience, effectiveness and safety. A multidisciplinary advisory board oversees reporting with the goal of peer reviewed scientific presentation and publication. **RESULTS:** Annual aggregate and center specific reports are generated including descriptive statistics and survival curves. **CONCLSUIONS:** The data collected in this registry are representative of the medical community with generalizability to a broader patient population. ISPR results may illuminate methods to improve therapy and guide development, provide insight into the etiology of events through evaluation beyond what is possible with passive surveillance, and generate best practices associated with reduced events and improved outcomes.

PNL14

USE OF THE SELF-ADMINISTERED NEUROPATHY TOTAL SYMPTOM SCORE—6 (NTSS-6 SA) IN AN INTERNATIONAL STUDY

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OBJECTIVES: To measure frequency and intensity of diabetic peripheral neuropathy (DPN) symptoms a 6 item scale was developed in US English for health care professionals (HCP): the Neuropathy Total Symptom Score-6 (NTSS-6). Prior to use in an international study a self-administered (SA) version was developed and translated into 9 languages. **METHODS:** The development of the SA version involved the establishment of patient instructions and the comprehension test on 5 US patients with DPN and 2 diabetologists. The following translation process was conducted by a specialist in each target country: (1) two forward translations; (2) back translation; (3) review by a clinician; (4) comprehension test on 5 subjects with DPN and (5) international harmonisation. Where translations of the HCP version existed, an SA version was developed and the accuracy of the translations checked. **RESULTS:** The first challenge was maintaining conceptual equivalence between the HCP and SA versions. The development of the SA version required patients' understanding the meaning of the explored symptoms and their level of severity without clarification by HCPs. The second challenge was finding conceptually equivalent and culturally relevant expressions of the different types of pain. In some instances literal equivalents for the original symptom existed, but according to patients did not correspond to the original concept. In other cases the original did not have a literal equivalent and had to be paraphrased. **CONCLUSIONS:** The 9 languages of the NTSS-6 SA were established according to a rigorous development and translation process to ensure conceptual equivalence and cultural relevance across languages and ultimately the international comparison and pooling of data. Issues encountered during this process support the advantage of integrating international feedback on concepts and wording before finalizing a scale.

PNL15

PREFERENCE FOR RECONSTRUCTIVE INTERVENTIONS OF THE UPPER EXTREMITIES IN TETRAPLEGIA: THE IMPACT OF TREATMENT CHARACTERISTICS

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Different surgical procedures are described to improve hand-function in tetraplegie either with or without implantation of an 8-channel electrical stimulator. Clinical experience shows that patients are not always willing to accept these devices despite their severe functional limitations. This can be explained because the offered treatment is too demanding. For future clinical applications and for further technical developments it is necessary to obtain more insight into the factors that determine willingness to accept assistive technology. **OBJECTIVES:** To determine the

effect of treatment characteristics of upper extremity interventions on the decision of tetraplegic subjects to accept treatment. **METHOD:** A discrete choice experiment (DCE) was performed, where treatment characteristics were obtained to establish different treatment scenarios. Seven different treatment characteristics were obtained from a panel of international experts. Tetraplegics were offered 20 sets of two different treatment scenarios and asked to select the best scenario. **RESULTS:** A total of 47 tetraplegic subjects with C5–6 lesions, motor group M1–4 were selected. Relative importance of treatment characteristics were: intervention type (surgery or surgery with FES implant) 13%, number of operations 15%, in patient rehabilitation period 22%, ambulant rehabilitation period 9%, complication rate 15%, improvement of elbow function 10%, improvement of hand function 15%. Effects of various changes of treatment protocols were determined. An inpatient rehabilitation period of maximum 4 weeks increases preference for treatment with 32%. One instead of two operative procedures increases the preference with 25%. **CONCLUSION:** In-patient rehabilitation period appears to have the greatest impact on the decision by patients to have surgery or not. Implantation of a neural implant is not the main reason for not accepting this type of treatment.

PNL16

THE ECONOMIC BURDEN OF PARKINSONISM IN ITALY

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OBJECTIVES: The primary objective is to evaluate health, non-health cost and utilities differences between Parkinson patients with diagnosis performed through SPECT (Single Proton Emission Computerized Tomography) and patients diagnosed traditionally. **METHODS:** This economic analysis is part of the prospective, multicentre, observational study DIAPASON (Diagnosis of Parkinson's Disease: Economics and Outcomes Impact), which involved 17 neurology centers. The present poster presents the preliminary economic results. Inclusion criteria: all subjects with suspect parkinsonism, "de novo" patients or in dopaminergic therapy for 3 months at the most. Exclusion criteria: subject with dementia senile, subjects treated with antidopaminergic drugs, subjects with iatrogenic forms of disease already known or clear vascular lesions of substantia nigra or caudato or putamen. The prospectives used in the study were: national health system (NHS) and society. Data were collected using an electronic case report form. Utilities were calculated using the EuroQol (EQ-5D) questionnaire. **RESULTS:** In November 2004, 147 patients (50 NO SPECT, 97 SPECT) had already performed the second visit. For both first and second visit the total cost for patients with diagnosis performed through SPECT was higher than that obtained for patients diagnosed traditionally: the mean health cost supported by NHS per patient was €2,577.79 (€1,562.63 for NO SPECT patients and €3,024.00 for SPECT ones), and mean non health cost obtained per patient was €3,553.56 (€3923.44 for SPECT patients, €2712.08 for NO SPECT patients). For subjects diagnosed traditionally the cost per QALYs gained was €36,225.2 compared to €15,291.6 for SPECT patients group. **CONCLUSION:** The introduction of new technologies, as SPECT, and the use of new radiolabelled drugs concur to improve early diagnosis of Parkinson's disease and related diseases. Diagnosis using SPECT has health and non health cost higher than traditional diagnosis, but a cost-utility analysis demonstrate its cost saving role in comparison with traditional diagnosis.

PNL17

A COST-UTILITY MODEL COMPARING AZILECT® (RASAGILINE) WITH STANDARD CARE AND ENTACAPONE IN THE TREATMENT OF PARKINSONIAN PATIENTS WITH MOTOR FLUCTUATIONS UNDER LEVODOPA IN FINLAND

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OBJECTIVE: Assess the cost-utility of rasagiline, entacapone and standard care (levodopa) in Parkinson's disease (PD) patients with motor fluctuations in Finland. **METHODS:** A 2-year probabilistic Markov model with 3 health states: ≤25% off-time/day', '>25% off-time/day' and 'dead' was used. Model inputs included transition probabilities from randomised clinical trials, utilities from a preference measurement study and costs and resources from a Finnish cost-of-illness study. Effectiveness measures were Quality Adjusted Life Years (QALYs) and number of months spent with ≤25% off-time/day. The primary analysis was performed from the societal perspective. Extensive sensitivity and subgroup analyses on severe patients were performed. A parity price was assumed for rasagiline and entacapone based on WHO-DDD. **RESULTS:** Over 2 years, rasagiline appeared to show both greater effectiveness and cost reductions compared with standard care (0.38 additional QALYs, over 55% additional time spent with ≤25% off-time/day and €900 savings (95% CI: [–€3400; €1090]) per treated patient. Rasagiline and entacapone yielded similar effectiveness and costs. A trend in favour of rasagiline was observed in the severe patient subgroup (approximately €660 total cost savings/patient). Sensitivity analyses confirmed robustness of the results vs. standard care. Results vs. entacapone were sensitive to changes in transition probabilities and drug prices. **CONCLUSION:** This economic model supports the use of rasagiline as a cost-effective treatment compared with levodopa alone and combined with entacapone in PD patients with motor fluctuations in Finland. Further improvements of the model should be applied to different settings to confirm these results.

PNL18

COST-EFFECTIVENESS OF CONTINUOUS DUODENAL DELIVERY OF LEVODOPA (DUODOPA®) IN PATIENTS WITH SEVERE PARKINSON'S DISEASE

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OBJECTIVE: To explore costs and health benefits of replacing conventional oral therapy with intraduodenal infusion of carbidopa/levodopa (Duodopa®) for severe Parkinson's disease (PD). **METHODS:** In the DIREQT trial 24 patients aged 50–79 years with Hoehn & Yahr stage 2.5–4.0 (at best) were randomised to receive either three weeks of conventional oral therapy followed by three weeks of Duodopa, or vice versa. Later, patients could choose to switch permanently to Duodopa. Health Related Quality of Life (HRQOL) was recorded with the 15D instrument at entry into the trial, during the trial, and then at 8 follow-ups during the subsequent 6 months. Use of health care was registered before, during and after the trial. Two-year costs and health consequences of Duodopa and conventional therapy were estimated in a decision analytic model. Costs were based on market prices and customary charges in Sweden. **RESULTS:** The mean quality-of-life scores were 0.77 for Duodopa and 0.72 for conventional therapy with considerable variation in scores for individual patients over time. The expected two year cost was $93,600 for Duodopa and $28,700 for conventional oral therapy. The expected number of Quality