

rubles (\$209) per extra patient without moderate and severe disability after 3 months of treatment. **CONCLUSION:** Betahistine is an appropriate alternative to cinnarizine for patients with vertigo.

PNL9

COST-EFFECTIVENESS OF ALTERNATIVE POLIO IMMUNIZATION POLICIES IN SOUTH AFRICA

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OBJECTIVE: To assess the cost-effectiveness of switching from oral polio vaccine (OPV) to inactivated poliovirus vaccine (IPV), or to cease polio vaccination in routine immunization services in South Africa. **METHODS:** The incremental cost-effectiveness of three different polio vaccination alternatives was compared to the current schedule of six doses of OPV: (1) IPV at 2, 4, and 6 months; (2) IPV at 6, 10, 14 weeks and 18 months and (3) cessation of polio vaccination. The costs of introducing IPV in a separate vial as well as in different combination vaccines were estimated. Assumptions about IPV vaccine prices were based on indications from vaccine manufacturers. Treatment costs of polio and the costs of lost productivity were included. The health impact of OPV cessation was measured in terms of Vaccine Associated Paralytic Paralysis [VAPP] cases and Disability Adjusted Life Years [DALYs] averted. One-way sensitivity analysis was performed on the most uncertain variables. **RESULTS:** The use of OPV in routine immunization services is projected to result in 2.96 VAPP cases in the 2005 cohort. A switch to IPV will increase the total vaccine budget by at least 20%. The cost-effectiveness of the different IPV alternatives varies between US\$ 118,000 and US\$594,000 per discounted DALY averted. 3 doses of IPV in a 10-dose vial is the most cost-effective option. **CONCLUSION:** Due to the risk of VAPP, it has been recognized that when global polio eradication has been achieved, all countries must cease the use of OPV if the world is to remain polio-free. However, at the assumed vaccine prices, IPV does not appear to be cost-effective in the South African situation. The alternative of ceasing polio vaccination altogether is more economically acceptable, but the perceived risks of this alternative could be a hindrance for its implementation.

PNL10

THE COSTS OF INFORMAL CARE IN NEUROLOGICAL DISORDERS IN SPAIN

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OBJECTIVE: In addition to the costs of treatment and prevention, diseases generate other types of costs that are not always addressed. The purpose of the present work is to identify measure and evaluate the costs of informal care for neurological diseases in Spain. **METHODS:** The data collected in the Survey on Disabilities, Impairments, and State of Health (EDDES, for its initials in Spanish) of the National Institute of Statistics (INE) was used to estimate these costs. The EDDES is a national survey that covers all individuals residing in primary family housing. A total of 79,000 households were selected and information regarding 290,000 people was collected. We estimate that 423,188 people (1.03% of Spanish population in 2001) suffer an incapacity caused by a neurological disease: stroke, sclerosis, dementia (including Alzheimer) and Parkinson. Our estimation includes only those costs that have to do with informal care; that

is, those caregivers that are not paid for their work. We estimated the opportunity cost of the time of caregivers, distinguishing if the caregiver has given up his job or has reduced the total supply of hours of work. **RESULTS:** The informal costs estimated range between 2402 and 2926 millions of euros (at year 2002 prices), depending on how comorbidity is handled. The estimated costs of informal care of each neurological disease were: stroke (823 to 1007); dementia (1021 to 1246); Parkinson disease (329 to 401); and multiple sclerosis (229 to 272). The estimated informal costs represent a %6.3 to %7.7 per cent of the total health care costs of the Spanish National Health System. We also estimated the informal costs per patient and disease. **CONCLUSIONS:** The cost of informal care in main neurological disorders is substantial, and if financed it could devote a considerable budget from the overall Spanish Health Care System expenditure.

PNL11

A REVIEW OF THE ECONOMIC EVIDENCE FOR BOTULINUM TOXINS IN SPASTICITY ASSOCIATED WITH STROKE AND CEREBRAL PALSY

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OBJECTIVES: To identify and summarise the economic evidence for botulinum toxins in post-stroke spasticity and spasticity associated with cerebral palsy. **METHODS:** Cost-effectiveness and cost-analysis studies of interventions for treatment of postictal and cerebral-palsy-related spasticity, in which at least one arm consists of a botulinum toxin, were considered for inclusion in the review. Medline, Embase, NHSEED and the proprietary Allergan Botulinum Database were searched up until February 16, 2004 for relevant studies. Additionally, conference proceedings of seven clinical and pharmacoeconomic organisations were hand searched for the period of 2001 to 2004. **RESULTS:** One cost-effectiveness (Wallesch 1997), two cost-consequence (Houltram 2001, Loaiza 2000) and two cost studies (Balkrishnan 2002, Radensky 2001) met the criteria for inclusion in the review. Wallesch presented the incremental cost per unit improvement in Ashworth scale, Loaiza presented quality adjusted life years and Houltram presented Modified Ashworth Scale together with several other functional measures. The cost analyses found that overall treatment costs were lower in treatment plans that included botulinum toxin A (Btx-a). Although Btx-a increased drug costs by between \$750 and \$1000 annually, overall treatment costs were lower due to the reduced hospitalisation and nursing facility admissions associated with Btx-a treatment. Btx-a treatment was also associated with fewer co-administered treatments, and resulted in lower treatment costs than treatment plans that did not include Btx-a. **CONCLUSION:** The addition of botulinum toxin to a treatment regimen appears to be cost neutral. There is a need for cost-effectiveness analyses using outcome measures with greater external validity than those identified in the studies included in the review. A cost-utility analysis based on clearly derived utilities is required.

PNL12

A RETROSPECTIVE STUDY OF DRUG TREATMENT PATTERNS AMONGST UK PRIMARY CARE PATIENTS WITH RESTLESS LEGS SYNDROME (RLS) BETWEEN 1ST APRIL 2004 AND 31ST MARCH 2005

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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 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. **CON-**

CLUSIONS: 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 tetraplegia 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