Pooled Relative Risk for at least one relapse in four trials including all doses was 0.7, a non-significant RR (95% CI: 0.42–1.17, P = 0. 17). Summary RR for at least one relapse in two trials in which doses of 3 mg/kg or 6 mg/kg or 300 mg every 4 weeks were administered gave a values of 0.5 as a significant RR (95% CI: 0.42–0.61, P < 0.0001). The summary RR for at least one new Gd-enhancing lesion was 0.22, a non-significant RR (95% CI: 0.05–1.01, P = 0.051). Three deaths were reported in natalizumab group. Comparing adverse events between natalizumab and placebo yielded a non significant RR of 0.99 (95% CI: 0.96–1.01, P = 0.34) for any adverse events (n = 3), and a significant RR of 0.39 (95% CI: 0.29–0.52, P < 0.0001) for serious adverse events (n = 2). A summary RR for withdrawal due to adverse events by natalizumab vs. placebo therapy between two trials was 1.43, a non-significant RR (95% CI: 0.68–3.02, P = 0.35). **CONCLUSIONS**: It seems that using 3 mg/kg or 6 mg/kg every four weeks is the best experienced method of administration of natalizumab for preventing relapse and occurrence of new Gd-enhancing. Further clinical trials are still needed.

PND4

THE FEATURES OF MULTIPLE SCLEROSIS IN IRAN

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OBJECTIVES: Multiple Sclerosis (MS) is a chronic, recurrent, inflammatory disease with unrelenting attacks from the immune system. It is the major cause of non-traumatic disability in young adults. Iran, contrary to the other countries in Middle-east, is considered to have a high prevalence of MS that mentioned as the National disaster in Iran. While much is known about the MS in the world, there is a paucity of the feature of MS in Iran. **METHODS**: In a 6-month cross-sectional study 248 MS patients were studied in Iran. Data was collected by employing a 32- item self-administered questionnaire. Parametric, nonparametric tests and descriptive statistics analysis were applied (p value <0.05). **RESULTS**: The prevalence and incidence was estimated to be 25/100000 and 2.5/100,000, respectively. The patients were diagnosed in 2001 onward were more frequently than the patients in1981–1990(40:1). The mean age 31.9 ± 8.7, the mean onset age 26.3(26.3 ± 8:1) and the mean duration of illness were 5.6 ± 5.3 years. A family history of ms was reported in 11%. The sex ratio was 3:1(female:male). **CONCLUSIONS**: In contrast to reports from Caucasians , MS Iranian population significantly differ with respect to the age, onset age, disease duration, family history and sex ratio. This might reflect the different in some environmental-genetic factors and life style as well, in this population. Some of our finding were comparable to the so-called "western type" of MS such as : BMI, birth season and education stand.

NEUROLOGICAL DISORDERS – Cost Studies

PND5

BUDGET IMPACT ANALYSIS IN THE TREATMENT OF MAJOR DEPRESSIVE DISORDER IN VARIOUS ITALIAN REGIONS: THE ROLE OF VENLAFAXINE

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OBJECTIVES: Venlafaxine is a serotonin-norepinephrine reuptake inhibitor (SNRI) approved for the treatment of major depressive disorder (MDD). Following patent expiration, venlafaxine is available as generic at a reduced price. We evaluated the overall savings to the National Health System (NHS) following venlafaxine's price reduction. **METHODS**: A simulation model was constructed in Microsoft Excel to carry out a Budget Impact Analysis. Three scenarios were hypothesized: the first simulation evaluated the potential savings to the NHS following venlafaxine's price reduction. The second and third simulations assessed additional potential savings to the NHS supposing an increase in the market share of venlafaxine by substitution of different proportions of other branded products namely duloxetine and escitalopram. Costs were obtained from IMS Health, efficacy data were derived from the available literature. **RESULTS**: Mean annual treatment cost with venlafaxine decreased from €567 to €284 resulting in overall savings to the NHS of more than €44 million per year. Treatment switching from escitalopram and/or duloxetine to venlafaxine was always a dominant strategy and resulted in a higher number of patients treated more efficaciously since venlafaxine performs better in terms of remission and is less expensive. Sensitivity analyses on effectiveness (response) and cost variables confirmed our results. **CONCLUSIONS**: This analysis suggests that extended use of generic venlafaxine is likely to lead to overall cost savings to the NHS due to its cost-effectiveness profile compared with other antidepressants such as duloxetine and escitalopram.

PND6

ESTIMATION OF PER-MEMBER-PER-YEAR COSTS FOR MANAGING FALLS OR FRACTURES AMONG HYPNOTIC USERS IN A MANAGED CARE PLAN

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OBJECTIVES: Previous research identified hypnotic-users to have a greater risk of falls and fractures vs. controls. The objective of this study was to determine the economic burden of falls and fractures to managed care among hypnotic users. **METHODS**: A retrospective study was designed using data from a national managed care commercial claims database. First time hypnotic-users were identified using pharmacy claims and matched to two controls on gender, region, payer, and age. Subjects were followed for 12-months post index-date to capture events and costs of falls and fractures identified using specific ICD-9-CM and E-codes. Multivariate regression models were used to estimate the incremental burden of falls or fractures at a per-hypnotic user per year (PHUPY) for a hypothetical managed care plan of 1 million membership with hypnotic-use rate of 4.5% and stratified by age-categories: young-adults (18–44 yrs), middle-age (45–64 yrs) and elderly (>65 yrs). **RESULTS**: A total of 40,549 hypnotic-users and 81,098 controls met the inclusion criteria. Both groups were demographically similar (p > 0.05) at baseline. Hypnotic-users had higher Charlson comorbid index scores (1.07 vs. 0.60, p < 0.001) and proportion of balance disorders (3.33% vs. 2.18%, p < 0.001) compared to controls. For those who had an event, the total annual mean direct costs of managing falls and fractures was $2,559 (95%CI: 2117–3001), and $3294 (95%CI: 2916–3673), respectively, with costs linearly increasing with age. Based on hypnotic-use rate of 4.5% and age distribution, total hypnotic-users in the hypothetical plan were estimated to be 33,750. Falls/fracture related PHUPY translated into $50 (Range: 24–82), $63 (Range: 39–92), and $245 (Range: 28–615) for young, middle-age and elderly hypnotic users. Overall burden due to falls/fractures as a consequence of hypnotic use to managed care was estimated to be $2,092,500 (Range: 1,451,250–2,801,250) **CONCLUSIONS**: The unintended consequence (i.e. managing falls/fractures) of current hypnotic use may be burdensome to a managed care plan.

PND7

BUDGET IMPACT AND COST—EFFECTIVENESS OF SUGAMMADEX IN THE REVERSAL OF PATIENTS WITH NEUROMUSCULAR BLOCK

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OBJECTIVES: Sugammadex (SGX) is a modified gamma-cyclodextrin that bonds with rocuronium and vecuronium, leading to reversal of the neuromuscular blockade. The objective of this study was to evaluate the budget impact and the cost-effectiveness of SGX in the routine reversal of patients with neuromuscular block (NMB) from the Spanish National Health System perspective. **METHODS**: A decision-analytic (DAM) and a budget impact model (BIM) was developed to assess the mean treatment costs per patient (€2009), life-years gained (LYG), and incremental cost per LYG of SGX, the spontaneous reversal and neostigmine/atropine in the reversal of patients with NMB. The DAM simulates the probability of experiencing an adverse effect and the direct costs produced by each treatment alternative. The BIM accounts for the time that SGX could save in the operating room (OR), shortening the time to extubation, thereby accelerating the movement of patients in and out of the OR. Clinical data was obtained from the clinical trial performed with SGX, the SmPC of each drug and form secondary sources. Costs were obtained for Soikos database. **RESULTS**: In the routine reversal of patients, ROC+SGX is associated with higher costs than the spontaneous reversal or neostigmine/atropine but also with higher LYG. The cost-effectiveness range of SGX vs. neostigmine/atropine varies between €13,26 and 4,976 per LYG, and vs. spontaneous reversal between €6,880 and 17,657 per LYG. In the BIM, SGX could save between 108 and 171 minutes of OR, that would mean that 1 or 2 more surgeries could be performed, and a total budget saved between €1400 and 2000 per OR per day. **CONCLUSIONS**: Under the established assumptions, SGX would be a cost-effective alternative for the routine reversal of patients with NMB and could be a cost-saving strategy due to the increase of the turn over of the OR.

PND8

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF SUBCUTANEOUS INTERFERON BETA-1A FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS IN SPAIN

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OBJECTIVES: Relapsing-remitting multiple sclerosis (RRMS) is the most common form of multiple sclerosis. Beta interferons have been shown to reduce relapse rates by a third. The aim of this study is assessing the value of subcutaneous interferon beta-1a when compared to other available disease modifying drugs for RRMS patients in Spain. **METHODS**: Pharmacoeconomic model based on subcutaneous interferon beta-1a clinical trials efficacy data (relapses and progression of disability both on the medium and long run) and local expert panel. This analysis was undergone from the Spanish National Health System (SNHS) perspective, included only direct medical costs and employed an annual discount rate of 3% on both costs and health outcomes. The model provided estimations of cost per avoided relapse and cost per avoided progression, as well as probabilistic sensitivity analysis with 1000 Monte Carlo simulations. Budget impact analysis was also undergone to forecast the implications of subcutaneous interferon beta-1a increased market share in a 4-year horizon. **RESULTS**: Subcutaneous interferon beta-1a and natalizumab result in the lowest MS relapse rates with an estimated cost per avoided relapse of €28,847, €29,918, €36,299, €42,027 and €55,379 when subcutaneous interferon beta-1a, interferon beta-1b, glatiramer acetate, natalizumab and intramuscular interferon-1a are employed. Cost per avoided

progression is €150,000–350,000 for each therapy but glatiramer acetate (€651,796). Probabilistic sensitivity analysis confirmed subcutaneous interferon beta-1a and interferon beta-1b as the most cost-effective therapies (confidence intervals remained below €45,000 per avoided relapse). Estimated budget impact of assuming 5–9% annual increase of subcutaneous interferon beta-1a market share equals 0.17–0.52% of actual RRMS cost in Spain. **CONCLUSIONS**: Subcutaneous interferon beta-1a is an efficient strategy for RRMS in Spain as it allows an appropriate management and treatment of RRMS relapses and progression with a minor budgetary impact for SNHS.

PND9

COST-EFFECTIVENESS AND BUDGET IMPACT MODELLING OF LACOSAMIDE IN THE TREATMENT OF PARTIAL-ONSET SEIZURES IN FINLAND

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OBJECTIVES: Economic evaluation of Lacosamide (LCM) and standard treatment with commonly used antiepileptic drugs (ST) vs. ST alone in the Finnish setting. LCM is a new antiepileptic drug, indicated for adjunctive treatment of partial-onset seizures (POS) with or without secondary generalisation in patients aged 16 years and older. **METHODS**: A probabilistic decision tree based cost-effectiveness analysis (CEA) with second-order Monte Carlo simulation and a 2-year time-frame was performed in Excel from the Finnish societal perspective (productivity losses and VAT excluded). The efficacy data were obtained from the LCM-trials, and the Finnish costs (inpatient, outpatient, GP, laboratory, drug) and utilities from published studies. Budget impact modelling (BIM) with a five year time-frame was done to assess the net monetary impact of LCM launch to the refractory epilepsy budget. Only drug costs were included in BIM. Conservatively, generic prices were used in all analyses. **RESULTS**: According to CEA, LCM+ST was associated with an incremental cost of €945 (mainly related to seizure management and drug acquisition), a gain of 0.040 QALYs and 8.92 seizures avoided compared to ST alone. LCM+ST was associated with a cost of €23,396 per QALY gained and €106 per seizure avoided compared to ST alone. According to the cost-effectiveness acceptability frontier, the probability of LCM's cost-effectiveness was 67.9% and 85.6% with €30,000 and €50,000 per QALY gained, respectively. The results were robust in sensitivity analyses. According to BIM, the expected annual budget increase due to launch of LCM is €0 in 2008, €7,653 in 2009, €47,350 in 2010, €134,949 in 2011, and €232,609 in 2012. The relative increase in the annual epilepsy budget due to LCM is 0.08% in 2009, 0.46% in 2010, 1.31% in 2011, and 2.23% in 2012. **CONCLUSIONS**: LCM is a valuable option for POS treatment because of its potential cost-effectiveness and low budget impact.

PND10

COST ANALYSIS OF ACTIVA RC®: RECHARGABLE NEUROESTIMULATOR FOR DEEP BRAIN ESTIMULATION THERAPY (DBS)

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OBJECTIVES: Neurostimulators (NS) for DBS are replaced when the battery goes to an end-of-life (EOL). Activa® RC, Medtronic's new rechargeable NS, offers guaranteed 9 years longevity. The objective was to perform a cost analysis of Activa® RC, vs. Kinetra® (previous non-rechargeable NS), based on the number of EOL replacements needed. **METHODS**: The following costs were included (hospital perspective, €, 2009): 1) DBS acquisition costs; 2) surgical procedure cost: Spanish tariff for Parkinson disease surgery; 3) EOL NS's replacement procedure cost: includes surgical procedure cost (excluding the acquisition costs of therapy components) and the NS cost. The EOL depends on patient energy requirements (disease-related) and on the NS: Kinetra®: dystonia patients replacements every 2 years; Parkinson disease, every 3–4 years; essential tremor, every 4–5 years(expert opinion). Activa® RC: every 9 years for all indications. Cumulative costs/year was obtained for a 9-years timeframe to compare the costs and number of surgical replacements avoided with Activa® RC. The main cost driver, surgical procedure cost, was changed as a sensitivity analysis (SA). **RESULTS**: Thanks to higher battery longevity, the following savings could be obtained: 1) Dystonia patients, as higher energy requirement are needed, higher economic benefits are observed: at year €9, 57.585 saved/patient or 4 EOL-replacement avoided; 2) Parkinson disease, at year 9, 2 replacements are avoided, that represents €21.867 saved/patient; 3) Essential tremor, savings oscillates between €4.008-€21.867, avoiding 1–2 EOL-replacement in 9 years. **CONCLUSIONS**: Although initial acquisition costs of Activa® RC are higher, compared to Kinetra®, those are compensated after the first Kinetra®'s EOL surgical replacement, obtaining important cost savings at year 9 (4.008€-57.585€/patient), avoiding 1–4 surgical replacements. The more energy requirements, the higher economic benefits are observed with Activa® RC. An adequate patient selection is needed to maximize clinical and economic benefits of Activa® RC-DBS.

PND11

NEW ACTIVA PC® FAMILY: COST ANALYSIS OF THE NEW FEATURES FOR DEEP BRAIN STIMULATION THERAPY (DBS)

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OBJECTIVES: Activa®, Medtronic's DBS, is an effective,safe and reversible therapy for Parkinson disease, essential tremor and dystonia. A cost analysis was perform to estimate the economic benefits related to 2 features of Activa PC® family, new DBS generation devices, and the net Budget impact (BI) for Spanish hospitals, compared to Kinetra®. **METHODS**: The 2 features: neurostimulator's (NE) lower size and new stretchable extensions; both can avoid some adverse events (AEs) associated with Kinetra (no other benefits were considered). A literature search was done to retrieve safety studies. Selection criteria: AEs related with NE &/or the extension, their incidence and detailed treatment description. Health resource use was assigned to AEs treatment (Spanish hospital costs, Euros 2009): regional tariffs; acquisition costs. A net cost for each AEs was obtained, multiplying each AEs treatment incidence by its total cost. Total cost obtained with Activa PC®, compared to Kinetra®, corresponds to savings/patient. The net BI for Spanish hospitals was calculated: total incremental cost/Activa PC® treated patient instead of Kinetra® (considering AEs avoided and its savings). An AE incidence comparison was made as a sensitivity analysis (SA). **RESULTS**: 2 safety studies were selected. The 2 features could avoid 6 AEs, 2 related to NEs (hematoma in the NE implant site; infection/erosion); 4 with the extension (lead broke after a fall; extension fracture; skin ulceration in the connector; local discomfort). In total, avoiding these AEs involved 591€ saved/patient treated with Activa PC® family (SA obtained similar data). Including Activa PC® instead of Kinetra family in Spanish Hospitals involved a net BI per patient of €1.781. **CONCLUSIONS**: The new Activa PC family may avoid AEs related to the previous generation, Kinetra, with a decrease in the total cost per patient. The substitution of Kinetra® for Activa PC® family involves a small net budget impact per patient.

PND12

COST AND RESOURCE USE RELATED TO NEWLY DIAGNOSED MULTIPLE SCLEROSIS: REAL-WORLD DATA FROM A LARGE US CLAIMS DATABASE

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OBJECTIVES: To examine the economic burden of newly diagnosed multiple sclerosis (MS) on the US health care system using a large, managed care database. **METHODS**: This was a retrospective cohort analysis of a large, US claims database. Cases were defined as having either an MS diagnosis (ICD-9-CM 340) on at least 2 claims or 1 prescription for MS treatment (glatiramer acetate, interferon betas, or natalizumab) between 2004 and 2006. The index date was the first qualifying diagnosis or prescription. We excluded patients with an MS diagnosis or treatment over the 12 month pre-index period, or without continuous enrollment from 12 months pre- to 12 months post-index date. Each case had 5 controls without MS diagnoses or treatment matched on geographic region, insurance type, gender, relation to employee, age and lack of comorbid conditions with a similar period of continuous enrollment. Use of services was compared using chi-square tests, and 2008 adjusted costs were compared using the Wilcoxon rank-sum nonparametric tests. **RESULTS**: There were 1412 cases and 7,060 matched controls in the study. Sixty-six percent of the study population was female. MS patients were twice as likely to have emergency department (ED) visits (25.5% vs. 12.2%), 1.3 times as likely to have physician office visits (95.8% vs. 75.1%), and 2.4 times as likely to have used physical therapy (all p-values <0.001) services over the follow-up period. MS patients also had higher costs related to these services ($380 vs. $166, $614 vs. $228, and $268 vs. $74, respectively; all p-values <0.001). Total costs for MS patients were significantly higher than for controls ($16,984 vs. $3,639 $p < 0.001$). **CONCLUSIONS**: Newly diagnosed MS patients present a large burden on the health care system with additional 1st-year cost of over $13,000. While MS treatment drugs are expensive, this represents only one-third of the additional cost of care within the 1st year.

PND13

IMPACT OF CHRONIC (CM) AND EPISODIC MIGRAINE (EM) ON WORK PRESENTEEISM IN 9 COUNTRIES

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OBJECTIVES: Migraine is prevalent, and headache-related disability can impact the ability of migraineurs to work and perform daily activities. This study examined the impact of CM compared to EM on work patterns and productivity across countries. **METHODS**: Web-based survey data were collected from migraineurs in the US, Canada, Germany, UK, France, Italy, Spain, Australia, and Taiwan. According to ICHD-2 criteria, presence of migraine (past 3-months headaches with pain, nausea, and photophobia/phonophobia) and ≥15 headache days/month indicated CM, and <14 headache days/month indicated EM. Questions on absenteeism and presenteeism (reduced efficiency) in the preceding 4 weeks assessed headache impact on work or school. Linear and logistic regressions, as appropriate, compared migraine group and adjusted for age, gender, race, education, comorbidities, and country. **RESULTS**: Of 63,001 invitees, 20,987 responded. A total of 9,118 completers (14.5%) comprised the final cohort [n = 516 (Australia) to 1597 (US)]; 83.6% female; 5.5% CM, 90.2% EM. CM respondents were 1.4 times more likely than EM to report that they had missed any work/school due to headache (95% CI = 1.1, 1.8). CM reported missing a higher number of work/school days due to headache symptoms than EM (adjusted mean ± SE = 8.83 ± 0.59 vs. 4.05 ± 0.44, $p < 0.0001$), as well as working more days