(salvage therapy), 2nd-remission, 2nd-relapse, 2nd-progression, 3rd-line treatment (salvage therapy) and dead. **RESULTS:** The direct medical cost included diagnostic and stratification USD$2,152.01 ($2,016.77–$2,287.26); 1st-line CHOP [7.19 cycles (6.97–7.42)] USD$841.17 ($813.03–$869.31); R-CHOP [7.20 cycles (6.32–8.08)] USD$17,823.19 ($12,670.83–$22,975.55); 1st-salvage treatment (Bone Marrow Transplant, BEAM scheme) USD$56,174.10; 2nd-salvage treatment ICE-Scheme USD$18,162.34, DHAP-Scheme USD$4,138.10; ESHAP-Scheme USD$3,730.22; and monthly cost of support therapy and follow-up USD$382.15 ($301.74–$462.57). The estimated management cost at the fifth year was USD$59,785.68 for R-CHOP and USD$52,966.70 for CHOP. The CE rate for the use of R-CHOP vs CHOP was USD$6,526.54 for each free-progression year, a clear trend toward the use of monoclonal antibody inclusion. **CONCLUSIONS:** Long term results are fundamental for any evaluation of NHL treatment scheme. Under this scenario, the increase in the free-progression survival and global survival, with R-CHOP a CE ratio under one GDP per-capita in Mexico (USD$7,785.89—A WHO accepted threshold) for every free-progression year gained and it is evident that this treatment is cost-effective.

PSY15

ECONOMIC IMPLICATIONS OF IRON CHELATION IN PATIENTS WITH REFRACTORY ANEMIA RELATED TO MYELODYSPLASTIC SYNDROME

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OBJECTIVES: To determine whether use of chelation therapy in patients with refractory anemia (RA) related to myelodysplastic syndrome (MDS) is cost-effective relative to no chelation in transfusion-dependent patients. **METHODS:** A 10-year cohort model with monthly cycles was built to predict the health and economic implications for patients receiving chelation therapy with 20 mg/kg deferasirox compared with no chelation. The model included increased risk of death with no chelation; major adverse events (e.g., cardiac disease) were assumed non-differential, thus excluded, in the base analysis. Risk of death was determined based on published prognostic data from chelated (overall median survival = 115 months from diagnosis) and non-chelated (median = 51 months) patients. Costs and utilities were applied in each cycle by WHO Risk Classification. Unit costs, obtained from US cost data sources, were used to calculate the costs of medication, management and transfusions. Risks of death and complications, life expectancy, resource use, initial utility value and decrease in utility due to complications were taken from published literature. Costs were discounted at 3% per year; benefits were not discounted. **RESULTS:** In the base case analysis, when initial utility value was taken as 0.6 and cost of deferasirox was assumed to be $70/day, costs per patient were estimated at $97,619 with deferasirox vs. $28,712 with no chelation. Deferasirox was predicted to increase QALYs by 1.43 years per patient, resulting in ICER = $48,172/QALY gained. Increasing the initial utility value to 1 resulted in an ICER of $28,903. **CONCLUSIONS:** Chelation therapy with deferasirox is predicted to result in higher QALYs and substantially fewer adverse events due to excess iron accumulation at a reasonable cost. Resulting cost-effectiveness ratios are estimated to be within acceptable limits.

PSY16

THE ECONOMIC IMPACT OF DIFFERENT STRATEGIES OF MANAGING RARE DISEASES WITH HIGH TREATMENT COSTS: THE CASE OF USING ACTIVATED RECOMBINANT FACTOR VII IN SEVERE BLEEDS IN ACQUIRED HAEMOPHILIA PATIENTS

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OBJECTIVES: The decision to use a drug first-line instead of second-line (salvage therapy) could have a significant clinical outcome and economic impact especially in rare diseases with high treatment costs such as acquired haemophilia. The aim of this study is to compare the cost-effectiveness of first-line versus second-line use of recombinant activated factor VII (rFVIIa) in the management of severe bleeds in patients with acquired haemophilia. The perspective of the study is that of the United States hospital authorities. **METHODS:** We modelled the economic impact of different treatment strategies reported from the only existing compassionate-use database containing data from 38 patients with acquired haemophilia for whom rFVIIa was used in the management of 78 severe bleeding episodes from 1990–1995. **RESULTS:** In 14 bleeds, rFVIIa was used as the first-line therapy with 100% success in controlling the bleeds, while a success rate of 75% was reported for 64 bleeding episodes in which rFVIIa was used as a salvage therapy. The mean treatment cost of rFVIIa as the first-line therapy was $362,906 compared to $416,793 when rFVIIa was used as a salvage therapy. Furthermore, the cost per effectively treated bleed for the second-line strategy was $545,113 compared to $362,468 for first-line use. **CONCLUSIONS:** Based on these results, rFVIIa, as a first-line therapy, is the cost-effective treatment option in the management of severe bleeding episodes in acquired haemophilia patients as compared to second-line treatment strategies.

PSY17

PRECISE STUDY: BASELINE ANALYSIS OF A COST EFFECTIVENESS STUDY ON FAILED BACK SURGERY SYNDROME

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OBJECTIVES: Failed Back Surgery Syndrome (FBSS) is a chronic neuropathic pain disorder characterized by persistent lower back and/or leg pain after lumbar spine surgery. We are developing a cost-effectiveness study evaluating Spinal Cord Stimulation (SCS) treatment compared to conventional medical management (CMM) in FBSS patients. Here we report the baseline cost and health-related quality of life (HR-QoL) data from a societal perspective. **METHODS:** A prospective, pre-post, observational study is ongoing in nine Italian centers. Enrolled patients will be followed for two years. A questionnaire was developed to collect clinical (NRS—pain Numerical Rating Scale), economic (visits, drugs, diagnostic-tests, hospitalizations, productivity losses, medical aids), and quality of life (EQ-5D, SF-36 and Oswestry) patient outcomes and productivity losses for caregivers. **RESULTS:** Eighty patients were enrolled (mean age 58; 58% female). The mean NRS valued in the year before enrolment was 7.6 ± 1.5. The average total cost per patient per month was

€287.96: 55% private expenses and 45% charged to NHS. Hospitalizations created the highest burden (22%, NHS) followed by home-care and transport (both private). In the last year 26 patients (33%) varied their occupational status due to pain. Fifty-eight (73%) patients required a caregiver; caregivers were absent from work in 80% of cases. A strong impairment in baseline HR-QoL was documented. Patients reported an average value of 37 in the EQ-VAS ('pain/discomfort' and 'usual activities' are the most impaired domains), using the UK conversion values the mean utility score was 0.07, using the Catalonian it was 0.10. According to the Oswestry questionnaire, 44% of patients were considered crippled and 39% severely disabled. The physical role was the most impaired dimension as measured with the SF-36. **CONCLUSIONS:** Our baseline analysis demonstrates FBSS is a very expensive disease that severely impairs HR-QoL. Future analyses will evaluate the cost-effectiveness of SCS and CMM in the treatment of FBSS.

PSY18

COST-EFFECTIVENESS OF FENTANYL ITS (IONSYS™) IN POST-OPERATIVE PAIN MANAGEMENT: A FINNISH HOSPITAL PERSPECTIVE ANALYSIS

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OBJECTIVES: To evaluate the cost-effectiveness of fentanyl ITS (iontophoretic transdermal system—IONSYS™) versus epidural analgesia (EA) or intravenous patient-controlled analgesia (IV-PCA) for acute post-operative pain management (POPM) from a Finnish hospital perspective. **METHODS:** The cost-effectiveness of IONSYS™ was assessed using a decision analytic model estimating costs (2008€) and POPM patient outcomes (pain relief, minor and major POPM-related complications) from surgery to discharge. Groups receiving 1, 2 or 3 day(s) of IV-PCA or EA were compared to groups receiving respectively 1, 2 or 3 day(s) of IONSYS™. Pain relief data were derived from clinical trials and published literature. Complication rates were predicted from a longitudinal hospital database. Resource use included drugs, consumables, equipment, POPM-related complications and staff time, the latter derived from expert panels and a literature review. Costs were based on official tariffs and price lists. **RESULTS:** The costs of IONSYS™ for 1, 2 or 3-day groups were €1,825, €2,240 and €2,655. For 1 day of IV-PCA and 1, 2, 3 day(s) of EA respectively, savings were €70, and €164, €167, €174. For 2 or 3 days of IV-PCA respectively additional costs were €19 and €105. The percentage of complication-free patients was consistently higher with IONSYS™ as regards minor and major complications with increment ranges of [1.44%, 3.95%] and [0.04%, 2.29%], respectively. The percentage of patients reporting no or mild pain with IONSYS™ was the same as with IV-PCA and lower than with epidural with respective increments for 1, 2 and 3-day groups of −4.02%, −4.33% and −5.26%. **CONCLUSIONS:** Compared to EA, IONSYS™ offers lower costs and fewer complications. EA however offers improved pain relief. Compared to IV-PCA, IONSYS™ dominates the 1-day group and for the 2 and 3-day groups offers fewer complications at a higher cost.

PSY19

MEDICAL AND COST EFFECTIVENESS OF BARIATRIC SURGERY IN OBESITY. RESULTS OF AN HTA COMMISIONED BY THE GERMAN AGENY FOR HEALTH TECHNOLOGY ASSESSMENT

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OBJECTIVES: Health Technology Assessment to evaluate the medical effectiveness and cost-effectiveness of bariatric surgical procedures in the therapy of morbid obesity in adults compared to standard interventions. **METHODS:** Systematic literature review (published since 2001), targeting adult subjects with morbid obesity (BMI >= 40 kg/m^2 or BMI >= 35 kg/m^2 with severe comorbidities). Relevant publications are identified by means of a structured search of 28 databases (e.g. Medline, Embase, Cochrane Central) on November 12th, 2007. In addition a manual search of identified reference lists was conducted. Titles and abstracts of the identified publications have been independently screened by two experts on evidence based medicine and health economics. The methodological quality of included studies have been assessed using the criteria recommended by the Scottish Intercollegiate Guideline Network (SIGN) Grading Review Group. Randomised as well as non-randomised studies are included, case reports and series are not considered. The methodological quality of the economic publications has been assesed using checklists of the German Scientific Working Group of Technology Assessment for Health Care and the methodological guide of the EURONHEED project. **RESULTS:** Among 5910 retrieved publications, 25 medical articles and seven health economic studies met the inclusion criteria. Among the included medical publications are nine RCTs, 13 papers on non-randomised clinical trials, and three systematic reviews with meta-analysis. Within the economic assessment, three CEA and four systematic reviews have been identified. Three of the non-randomised studies assess bariatric vs. conventional procedures. All other studies compare different surgical procedures among each other. Follow-up time varies between one and five years in the RCT and goes up to eleven years in one clinical trial. Both medical studies assessing effectiveness of bariatric vs. conventional procedures show a significant greater weight loss after surgery and decline in comorbidities. Diabetes incidence after ten years is lower in the surgery group, but no significant differences can be seen for hypertension, dislipoproteinemia. Among the economics publications, three studies evaluated the cost-effectiveness of certain bariatric surgeries. One study examined two bariatric operations, adjustable gastric banding and gastric bypass, for the treatment of obesity in patients with Type 2 diabetes mellitusOne of the studies included deals with a comparison of GBP vs. no treatment, whereas the other compares the two surgical procedures VBG and AGB among each other. Furthermore, four systematic literature reviews are among the included economic publications, estimating the cost-effectiveness of bariatric treatments based on published data. The focus of the reviews lies both, on the comparison of the cost-effectiveness among the bariatric procedures, as well as on the comparison to no treatment at all. **CONCLUSIONS:** The short and medium term effectiveness of bariatric procedures on weight loss can be assumed and is cost-effective. The weight loss is generally accompanied by a reduction of comorbidities, in particular diabetes, and a decreased overall mortality. There is a lack of studies that focus long term effects and costs. Therefore, based on the available literature no recommendation can be given with respect to the choice of a certain bariatric procedure in usual care or to the