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11th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR)

Athens, Greece, 8-11 November 2008

The 11th Annual European Congress of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) was held recently in Athens, Greece, at the Hilton Athens and attracted around 1200 submissions, a 28% increase. The following is a selection of some of the research highlights from this meeting.

1. Rivaroxaban for Venous Thromboembolism Prevention in Various Settings

The recently completed RECORD trials have shown that rivaroxaban has better efficacy and safety than enoxaparin when used prophylactically for venous thromboembolism (VTE) after major orthopaedic surgeries such as total hip replacement (THR) and total knee replacement (TKR). Using data from the RECORD trials, five studies presented at ISPOR suggest that rivaroxaban appears to be a cost-effective alternative to enoxaparin for the prevention of VTE after such surgeries. These studies were supported by Bayer HealthCare.

Prophylactic anticoagulation therapy after major orthopaedic surgeries is a standard practice to reduce the incidence of VTE. Enoxaparin, a factor Xa inhibitor, has been the prophylactic agent of choice after THR and TKR; however, its use is limited by the requirement for subcutaneous administration. In this regard, new agents such as rivaroxaban, an oral direct factor

Xa inhibitor, appear to be promising candidates not affected by the limitations associated with parenteral administration of anticoagulants.

In RECORD 1 and 2, 35 days of oral rivaroxaban was compared with 35 days of subcutaneous (SC) enoxaparin (RECORD 1) or with 12 days of enoxaparin (RECORD 2) for THR, whereas, in RECORD 3, 12 days of oral rivaroxaban was compared with 12 days of SC enoxaparin for TKR. Compared with enoxaparin, rivaroxaban was associated with a 70% reduction in total VTE (composite: any deep-vein thrombosis, non-fatal pulmonary embolism or all-cause mortality) in RECORD 1, a 79% and 80% reduction in total and symptomatic VTE, respectively, in RECORD 2, and a 49% and 66% reduction in total and symptomatic VTE, respectively, in RECORD 3.

The five studies presented at the congress used data from the RECORD trials to evaluate the cost effectiveness of rivaroxaban in various healthcare settings.¹⁻⁵

1.1 After Hip Surgery in Spain, Canada and the UK

The first study, conducted from a Spanish healthcare perspective, used a cost-utility model populated by RECORD 1 and 2 data to compare rivaroxaban with enoxaparin over 5 years.¹ Treatment for 35 days with rivaroxaban was dominant over treatment for 35 days with enoxaparin with a cost saving of €48.10 per patient and a small

QALY gain, and was cost effective against the 12-day enoxaparin treatment with an incremental cost per QALY of €3156. When both RECORD 1 and 2 data were combined, rivaroxaban remained dominant over enoxaparin with a QALY gain of 0.011 and a cost saving of €12.24 per patient. Following sensitivity analyses, rivaroxaban was cost effective in 100% of cases and dominant in 60% of cases, compared with enoxaparin.

The second study was similar to the first, but it was conducted from a Canadian Ministry of Health perspective;^[2] costs were expressed in \$Can, year 2008 values, and included potential savings following oral administration. In this study too, rivaroxaban dominated the 35-day enoxaparin treatment with a cost saving of \$Can282.58 per patient and a small QALY gain, and was cost effective against the 12-day enoxaparin treatment with an incremental cost per QALY of \$Can33 323; reduced outpatient administration costs were a major contributing factor to the observed cost savings. In sensitivity analyses, rivaroxaban dominated enoxaparin in 98% of cases.

In the third study, conducted from a UK healthcare perspective, cost effectiveness of rivaroxaban versus enoxaparin was assessed over 5 years using RECORD 1 and 2 data.^[3] Costs were expressed in £, year 2008 values, included potential savings associated with administration and monitoring. Rivaroxaban dominated both the 35-day enoxaparin treatment (cost saving £67.82 per patient) and the 12-day enoxaparin treatment (cost saving £22.38 per patient; QALY gain 0.022); cost savings were mainly driven by reduced outpatient administration costs. In sensitivity analyses, rivaroxaban dominated in 98% and 55% of cases, compared with the 35-day and 12-day enoxaparin treatment, respectively.

1.2 After Knee Surgery in Spain and the UK

The fourth study was conducted from a healthcare perspective and used data from RECORD 3 to assess the cost effectiveness of oral rivaroxaban versus SC enoxaparin in the UK and Spain in preventing VTE after TKR;^[4] a 5-year cost-utility model was constructed. The UK analysis included potential savings from oral

administration, whereas in the Spanish analysis, drug administration costs were included in hospitalization charges. In both the UK and Spain, rivaroxaban was dominant over enoxaparin. Rivaroxaban-associated improved health outcomes were similar for both countries. However, cost savings associated with rivaroxaban were £89.15 per patient in the UK and €144.93 per patient in Spain; in the UK, the savings were mainly driven by reduced costs of treating symptomatic VTE and related long-term complications, and oral outpatient administration. Following sensitivity analyses, rivaroxaban dominated enoxaparin in >99% of cases in both countries.

1.3 Cost Saving in Italy

The fifth study was a cost-consequence study conducted from an Italian healthcare perspective and used a 5-year economic model to assess economic and clinical consequences of rivaroxaban versus enoxaparin;^[5] data from RECORD 1, 2 and 3 were combined. Costs (2008 values) excluded the costs of rivaroxaban and enoxaparin. Results suggested that rivaroxaban was associated with an overall improvement of 0.021 symptomatic VTE events per patient undergoing surgery, and with a reduction in nondrug costs of €81.32, compared with enoxaparin. The researchers estimated that rivaroxaban could be associated with an overall total annual nondrug cost saving of about €7.6 million in Italy.

2. Other Cardiovascular Disease Interventions

2.1 Statin plus Niacin Combination and Costs in the US

Researchers from the US presented data suggesting that a comprehensive treatment approach involving a combination of a statin and extended-release (ER) niacin can improve lipid values and lead to lower total medical costs.^[6]

Clinical and economic data for the 12 months prior to and after initiation of combination therapy were evaluated for a retrospective cohort of 845 patients (mean age 52.6 years) at primary or secondary risk for cardiovascular disease (CVD).

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2.2 Simvastatin

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The mean changes in lipid values for low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol and triglycerides were -10.81 mg/dL, +2.73 mg/dL and -22.67 mg/dL, respectively.

Multivariate analysis revealed an increased likelihood of goal attainment for LDL cholesterol (odds ratio 1.56), HDL cholesterol (1.58) and triglycerides (1.39) after initiation of statin and niacin therapy. Moreover, generalized estimating equation (GEE) results suggested significant improvements from pre-index in both annual CVD-attributable inpatient visits (17 vs 9 per 100 patients; $p < 0.0001$) and total medical costs (\$US3214 vs \$US2039; $p < 0.0001$).

2.2 Simvastatin plus Niacin in US Health Plan Formulary

Another US study found that the addition of ER niacin and simvastatin therapy to a health plan formulary improved individual and combined optimal lipid values, thereby having the potential to reduce the incidence of cardiovascular (CV) events and CV-related medical costs.^[7]

Using data for primary and secondary risk patients abstracted from the Health-Core Integrated Research Database, the researchers modelled the effect of two hypothetical formularies (one with fixed-dose, ER niacin and simvastatin, and one without) on costs and outcomes over a 3-year period. The results showed that a revised formulary (containing ER niacin and simvastatin) would increase optimal lipid value attainment by 0.57% over 3 years, compared with the current formulary.

The cost for a 1% improvement in optimal LDL cholesterol, HDL cholesterol and triglyceride attainment was estimated at \$US3103, \$US952 and \$US2047, respectively. There would be an estimated cost of \$US1147 for every 1% increase in combined optimal lipid value attainment with the revised versus current formulary.

2.3 Evaluation of Irbesartan for Hypertension in Greece

An analysis reported by researchers from Greece concluded that, for different patient po-

pulations, irbesartan represents good value for money in the Greek National Health Service (NHS) setting, compared with commonly used alternatives.^[8]

A Markov model was constructed to evaluate irbesartan in relation to losartan and valsartan in the treatment of hypertension in Greece. For the baseline cohort with mild-to-moderate disease (age 57 years, systolic blood pressure 147 mmHg, cholesterol 6.00 mmol/L, body mass index 29 kg/m²), irbesartan generated 12.67 QALYs, and a total cost of €15146, compared with 12.63 QALYs and €15486 for losartan, and 12.64 QALYs and €15613 for valsartan. In patients with severe hypertension, irbesartan was likely to be more effective and less costly than the other two medications, suggesting economic dominance.

2.4 Amlodipine/Atorvastatin for Cardiovascular Disease-Primary Prevention in Korea

Another presentation at the meeting suggested that single pill amlodipine/atorvastatin represents a cost-effective strategy for the primary prevention of CVD in Korea.^[9]

A Markov model was designed to assess the cost effectiveness of a single pill combination of amlodipine/atorvastatin for the primary prevention of CVD among a cohort of 171 adults aged ≥55 years who were CVD-free but who met current Korean criteria for treatment with the combination therapy. Follow-up was simulated for 40 years. The model showed that, compared with no treatment, single pill amlodipine/atorvastatin would have an incremental cost-effectiveness ratio (ICER) of about 1.4 million Korean Won per QALY gained, and about 1.9 million Korean Won per year of life saved (1000 Korean Won is approximately equal to \$US1). Sensitivity analysis indicated these results to be robust, the researchers noted.

2.5 High-Dose Atorvastatin versus Standard Simvastatin in Spain ...

Even in a low-cost generics market, high-dose atorvastatin is a good option compared with standard therapy with simvastatin, according to a

presentation by researchers from Spain and the UK.^[10] The IDEAL (Incremental Decrease in Events through Aggressive Lipid Lowering) trial involved 8888 patients with a history of acute myocardial infarction (MI) who were randomized to receive atorvastatin 80 mg or simvastatin 20–40 mg; median follow-up was 4.8 years. A within-trial pharmacoeconomic analysis was developed to estimate the cost per event avoided. Direct and indirect costs were included in the model.

After 4.8 years, treatment with intensive atorvastatin could avoid one in six CV events, compared with moderate simvastatin therapy among patients with congestive heart disease. Although atorvastatin has a higher acquisition cost than simvastatin, this cost was offset by reduced hospitalizations and work days lost for atorvastatin recipients. Using Spanish costs, the incremental cost for atorvastatin to avoid one event (vs simvastatin) would be €15 168.

2.6 ... and Medium-Dose Atorvastatin in the UK

Furthermore, according to another presentation, high-dose atorvastatin (80 mg) is likely to be more cost effective than medium-dose atorvastatin (40 mg) in patients with acute coronary syndrome in the UK.^[11]

The investigators built a Markov model using efficacy results based on a preliminary Bayesian meta-analysis linking a decrease in LDL cholesterol levels to decreases in secondary cardiac events (MI, stroke, cardiovascular death), drawing data from the A to Z and PROVE-IT (Pravastatin or Atorvastatin Evaluation and Infection Therapy) trials and using priors from other statin trials. UK cost data embedded in the model showed that, at a 12% event risk during the first 6 months and a 4% risk during later months, and an estimated 10% additional efficacy for high-dose versus medium-dose atorvastatin, the estimated number needed to treat (NNT) to avoid one event would be about 50. Costs per life-year gained and per QALY gained were estimated at below £10 000 for high-dose versus medium-dose atorvastatin.

The investigators reiterated that their analysis is preliminary, and that the results may alter following reconsideration of the priors. In addition, they commented that subsequent probabilistic analysis would be used to explore uncertainties around the estimates.

3. Value of Human Papillomavirus Vaccine in European Countries

Human papillomavirus (HPV) has been implicated as a causal factor in cervical cancer, which ranks as the number two cancer-related death in women globally. HPV DNA is detected in 99.7% of all such cancers, and safe, effective vaccines against HPV are now being developed with a view to administering these preventive vaccines to adolescent girls in many countries. As with any new therapies, the costs and benefits associated with the use of HPV vaccine are of utmost concern to payers and patients alike. These issues were considered in several studies presented at the meeting.

3.1 The Netherlands

A multinational group of researchers reported that immunization of 12-year-old Dutch girls against HPV infection is a cost-effective strategy in protection against cervical cancer.^[12] The researchers adapted an existing Markov model to the Netherlands; in the base-case analysis, 100% HPV vaccine coverage was assumed among girls aged 12 years at a price of €100 per dose. According to the model, the addition of an HPV vaccine to the Dutch cervical cancer screening programme would cost about €31.5 million annually. However, cervical intraepithelial neoplasia (CIN) and cervical cancer costs would be reduced by €11.5 million with the vaccine, and 2907 life-years would be saved, for an ICER of €22 700 per life-year gained (LYG) [€18 500 per QALY] versus no HPV vaccination (discounted at 4% for costs and 1.5% for outcomes).

The researchers commented that, although they made several assumptions, their estimated ICER corresponds with previous analyses relating to cervical cancer vaccination.

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3.2 Spain

Vaccination against HPV has been recommended for girls aged 11–14 years in Spain. Researchers from that country reported results of an analysis to determine the cost effectiveness of the bivalent HPV-16/18 vaccine CervarixTM in the current Spanish setting with cervical cancer screening.^[13]

Their Markov model (calibrated to Spanish epidemiological endpoints) showed that, assuming screening practices remain unchanged, vaccinating all 12-year-old girls would result in decreases of 79.1% and 79.5% in the number of cervical cancer cases and deaths, respectively. They concluded that, at a discount rate of 3% for costs and outcomes, the introduction of CervarixTM would be expected to cost an additional €31 749 per QALY gained, and at discount rates of 4% for costs and 1.5% for outcomes, would cost €14 707 per QALY gained.

3.3 Finland

HPV is currently responsible for significant healthcare costs in Finland, and vaccination of 12-year-old girls against HPV would be an effective and economically profitable method to reduce the burden of the HPV-related diseases, according to investigators from Finland and France.^[14] The results of a analysis were presented in which they used Finnish national healthcare, social insurance and cancer registries to evaluate the costs associated with cervical cancers, cervical lesions and genital warts diagnosed between 2001 and 2005. An incidence-based model was developed to evaluate the effects of HPV-6, -11, -16 and -18 vaccination among 12-year-old girls, from the perspectives of the healthcare payer and society.

They estimated that HPV vaccination would cost an additional €11 122 per QALY gained (costs discounted at 3.5% and health benefits at 1.5%) compared with the current screening strategy. This figure would render such vaccination cost effective, based on the €50 000/QALY threshold generally adopted by developed countries.

4. Other Cancer Interventions

4.1 Trastuzumab for Early Breast Cancer in Portugal and the Netherlands

Two Markov model-based studies indicated the use of 1 year of trastuzumab therapy to treat early breast cancer was cost effective compared with standard care.

In the first study, researchers estimated the cost effectiveness of 1 year's trastuzumab versus standard care (observation following standard adjuvant chemotherapy) in early-stage breast cancer in Portugal.^[15] The model assumed a hypothetical cohort of patients similar to those included in the HERA (HERceptin Adjuvant) study, and considered both the healthcare payer and the societal perspectives. Trastuzumab therapy increased discounted life expectancy by 2.11 years (14.95 vs 12.84 years) and by 2.01 QALYs, compared with standard care. Direct and indirect costs were €61 839 and €19 759 with trastuzumab, and €40 559 and €25 391 with standard care, corresponding to ICERs of €10 067 and €10 595 (direct costs only) and €7789 and €7400 including indirect costs, per LYG and per QALY, respectively.

The second study was a cost-effectiveness analysis from the Netherlands that again estimated the use of trastuzumab for 1 year compared with observation.^[16] From a healthcare perspective, the ICER for trastuzumab for a 55-year-old patient was estimated to be €19 463 per QALY. From a societal perspective, the ICER was €14 867. As expected, the ICERs improved with younger age. Overall, the Dutch cost-effectiveness estimate was well below the Dutch informal threshold of €80 000 per QALY.

4.2 Adjunctive Rituximab for Follicular Lymphoma in Spain

Rituximab has recently received European approval for use in combination with any chemotherapy. The^o addition of rituximab to CVP (cyclophosphamide, vincristine, prednisolone), MCP (melphalan, chlorambucil, prednisone) or CHOP (cyclophosphamide, doxorubicin, vincristine, prednisolone) regimens increases quality-

adjusted life expectancy and is cost effective, according to results presented by researchers from Spain.^[17] Their study used a Markov model based on three randomized controlled clinical trials comparing the addition of rituximab to the above chemotherapy regimens, compared with chemotherapy alone, in patients with advanced follicular lymphoma. The trial endpoints were progression-free survival and overall survival. Medication and supportive care costs and QALYs were estimated over a time period of 10 years. From a Spanish NHS perspective, adding rituximab to chemotherapy increased QALYs by 0.795, 1.129 and 0.971 years for CVP, MCP and CHOP, respectively, compared with chemotherapy alone. The incremental cost per QALY gained was €10 190, €6092 and €7855 for CVP, MCP and CHOP, respectively. The incremental cost per LYG was €10 168, €6348 and €8190, for CVP, MCP and CHOP, respectively.

4.3 Dasatinib Dominates Imatinib for Chronic Myeloid Leukaemia in Europe

Treatment of chronic myeloid leukaemia (CML) with dasatinib appears to provide better efficacy at a lower cost than imatinib in Central and Eastern Europe, according to the results of a cost analysis presented at the conference.^[18] Researchers assessed the cost needed to achieve one complete cytogenetic response with dasatinib 140 mg compared with imatinib 600 and 800 mg in patients with imatinib-resistant CML. The analysis was conducted using the NNT to achieve one complete cytogenetic response; the incremental cost of achieving this in 15 months was evaluated. To achieve one cytogenetic response, the NNT was 6.25 patients for imatinib and 2.5 for dasatinib. The costs to achieve one response during 15 months of treatment were €363 172 (Czech Republic), €218 492 (Hungary) and €334 146 (Romania) lower for dasatinib compared with imatinib 800 mg. Dasatinib retained its economic advantage when compared with imatinib 600 mg. The incremental costs to achieve one complete cytogenetic response between imatinib 600 mg and dasatinib were €228 664 (Czech Republic), €218 492 (Hungary) and €205 316 (Romania).

4.4 Erlotinib Switch in Non-Small-Cell Lung Cancer May Provide Savings in Portugal

It was reported in another presentation that switching from docetaxel or pemetrexed to erlotinib as second- or third-line treatment for non-small-cell lung cancer (NSCLC) could provide annual savings for the Portuguese NHS that would range between €135 046 and €1 755 602 (docetaxel replacement) and €291 801 and €3 793 409 (pemetrexed replacement), with a gain in terms of QALYs.^[19] The cost-minimization and cost-utility analysis employed a Markov model to evaluate the costs and benefits of second- and third-line treatment with erlotinib in advanced or metastatic NSCLC compared with docetaxel, pemetrexed or best supportive care. A time horizon of 2 years was used. Costs were updated to 2008, and an annual discount of 5% was applied to costs and utilities. Erlotinib treatment was associated with a lower per-patient cost (€26 478) compared with docetaxel (€29 262) or pemetrexed (€32 762) and a higher per-patient cost compared with best supportive care (€16 112). QALYs per patient were higher with erlotinib (0.250) than with docetaxel (0.225), pemetrexed (0.241) or best supportive care (0.186). In the cost-utility analysis, erlotinib was dominant, being less expensive and more effective than docetaxel and pemetrexed. The base-case analysis results were confirmed by a sensitivity analysis.

5. Overactive Bladder Treatments

5.1 Solifenacin versus Tolterodine in Italy

Italian researchers used a Markov model to compare the cost effectiveness of solifenacin 5 mg/day, ER tolterodine 4 mg/day and no treatment over a 52-week time horizon.^[20] Only direct healthcare costs were included, and the base-case scenario was from the patient perspective. Both solifenacin and tolterodine were associated with significant gains in symptoms and quality of life at costs of €540–640/patient/year and €680–780/patient/year, respectively. Solifenacin dominated tolterodine and had an incremental cost-utility ratio (ICUR) of €7600–18 600/QALY gained.

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compared with no treatment. Should a decision for reimbursement be made by the Italian NHS, the ICUR decreased to €600–2400/QALY, which the researchers described as favourable.

5.2 Solifenacin versus Tolterodine, Fesoterodine in the UK

Two UK-based studies presented at the congress suggested that solifenacin was more cost effective than tolterodine and fesoterodine, respectively, whereas a third study found fesoterodine to be the most cost-effective treatment of the three.

The first study was based on a 1-year decision-tree model, from the UK NHS perspective. Solifenacin 5–10 mg was compared with tolterodine ER 4 mg in this cost-utility analysis.^[21] Costs included were those associated with direct treatment and were reported in 2007–8 values. The ICERs for urgency, frequency and incontinence outcomes were £6406, £9065 and £14374 per QALY gained, respectively. In sensitivity analyses, ICERs remained below the threshold of £30 000/QALY. The researchers concluded that solifenacin is likely to be a cost-effective strategy, compared with tolterodine, in the UK NHS.

In the second cost-utility analysis, also conducted from the UK NHS perspective, solifenacin 5–10 mg was compared with fesoterodine 48 mg in a 1-year decision-tree model (2007–8 values).^[22] In the base-case scenario, solifenacin was more effective and less costly than fesoterodine for frequency and urgency outcomes. Fesoterodine was more effective for incontinence outcomes, but at an ICER of £84 686/QALY gained. Based on a threshold of £30 000/QALY gained, fesoterodine does not provide a cost-effective treatment option relative to solifenacin, according to the researchers.

In contrast, the third study, undertaken by researchers from the UK, the US and France, found that fesoterodine was a cost-effective treatment for overactive bladder, compared with tolterodine and solifenacin.^[23] This 52-week cost-utility analysis, involving medical, out-of-pocket and productivity costs and based on data from a randomized controlled trial, compared fesotero-

Table 1. Costs and benefits of overactive bladder treatments

Strategy	QALYs gained	Overall costs (£)
Tolterodine	0.0111	1424
Solifenacin	0.0115	1344
Fesoterodine 4 mg	0.0124	1352
Fesoterodine 8 mg	0.0143	1294

dine 4 mg/day, fesoterodine 8 mg/day, tolterodine ER 4 mg/day and solifenacin (dosage not stated). Fesoterodine 8 mg/day was associated with the greatest gains in QALYs and the lowest overall costs (table 1).

6. Cost Effectiveness of Ranibizumab for Age-Related Macular Degeneration in Austria

Another presentation indicated that the use of ranibizumab to treat age-related macular degeneration (AMD) is cost effective in Austria.^[24] The Markov model-based study evaluated the cost effectiveness of ranibizumab versus verteporfin in the treatment of AMD and was adapted to the Austrian situation. The clinical data included were based on three clinical trials (MARINA [Minimally Classic/Occult Trial of the Anti-VEGF Antibody Ranibizumab in the Treatment of Neovascular AMD], ANCHOR [Anti-VEGF Antibody for the Treatment of Predominantly Classic Choroidal Neovascularization in AMD] and PIER [Phase 3b, Multi-Center, Randomized, Double-Masked, Sham Injection-Controlled Study of the Efficacy and Safety of Ranibizumab in Subjects with Subfoveal Choroidal Neovascularization with or without Classic CNV Secondary to AMD]). The effectiveness of the two drugs was assessed using vision-years (VYs) and QALYs. Costs were reported in €, year 2007 values.

Over the 10-year time period considered, ranibizumab therapy was associated with a gain of 4.2 QALYs versus 3.91 for verteporfin therapy. The ICER for ranibizumab compared with verteporfin was €15 647. With regard to VYs gained, the ICER was €3642. The results were unchanged after a sensitivity analysis.

7. Rufinamide Option for Lennox-Gastaut Syndrome

According to the results of a cost-effectiveness analysis, rufinamide should be considered as a treatment option for Lennox-Gastaut syndrome (LGS), particularly because treatment choice is important for this devastating and rare condition.^[25]

The analysis used a Markov model to determine the cost effectiveness of rufinamide relative to topiramate and lamotrigine as adjunctive therapy for LGS. Safety and efficacy data were obtained from the literature. QALY benefits accumulated over 3 years were calculated using LGS-related health-state utilities obtained from a utility study carried out using the time trade-off (TTO) method and EQ-5D questionnaires. Costs were estimated from the perspective of the UK NHS and personal social services.

The base-case analysis using TTO utilities suggested that, over 3 years, rufinamide was associated with an incremental cost per QALY of £20 538 compared with topiramate and £154 831 compared with lamotrigine. Using EQ-5D utilities, a secondary analysis found that rufinamide was associated with an incremental cost per QALY of £12 034 compared with topiramate and £56 466 compared with lamotrigine.

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