

## PGI23

**STAPLED HAEMORRHOIDOPEXY IN THE TREATMENT OF HAEMORRHOIDAL PROLAPSE—COMPARISON OF HTA REPORTS, FOR TWO ITALIAN REGIONS**Berto P<sup>1</sup>, Lopatriello S<sup>1</sup>, Schivazappa C<sup>1</sup>, Benvenuti F<sup>2</sup>, Boccasanta P<sup>3</sup>, Bordoni L<sup>4</sup>, Lenisa L<sup>5</sup>, Naldini G<sup>6</sup>, Nepi S<sup>2</sup>, Todaro A<sup>7</sup>, Valeri A<sup>7</sup><sup>1</sup>PBE Consulting, Verona, Italy, <sup>2</sup>Ospedale Valdelsa, Poggibonsi, Italy, <sup>3</sup>Fondazione IRCCS Ospedale Policlinico Mangiagalli e Regina Elena, Milano, Italy, <sup>4</sup>Ospedale di Circolo e Fondazione Macchi, Varese, Italy, <sup>5</sup>Casa di Cura S. Pio X, Milano, Italy, <sup>6</sup>Ospedale Policlinico Santa Chiara, Pisa, Italy, <sup>7</sup>Azienda Ospedaliera Careggi, Firenze, Italy

**OBJECTIVES:** Surgical management of Haemorrhoidal Disease includes Milligan-Morgan (MM) haemorrhoidectomy and Stapled Haemorrhoidopexy (PPH). Scope of work was to compare HTA Reports for PPH vs. MM (especially cost and budget impact analyses) for two Italian Regions: Lombardia and Toscana. **METHODS:** Literature search; identification of the surgical course (intervention, hospital admission) and global course (clinical evaluation, surgical phase, follow-up) at the local hospital level; micro-costing for PPH vs. MM at 3 hospitals per Region; comparison of direct medical costs, reimbursement tariffs and budgetary impact in 2008 Euro values. **RESULTS:** PPH surgical pattern generates costs to Hospitals of €2,306 and €2,177/case, respectively in Lombardia and Toscana; MM surgery costs are €1558 and €1277/case, respectively. Higher unitary costs of personnel and operating theatre in Lombardia drive higher surgical intervention costs, irrespective of procedure type. Whereas hospital admission costs were similar for PPH (€698 vs €638), the gap between Lombardia and Toscana widens for MM hospitalization costs (€812 vs €638), because of longer length of stay in full admission setting. The Lombardia DRG158 tariff (€1209) is not sufficient to recap costs of both alternatives, whilst the Toscana tariff (€1400) is remunerative only for MM, but not when applying higher levels of operating theatre unit cost. The global course generates costs of €2532 (PPH-Lombardia) and €2400 (PPH-Toscana) vs €1781 (MM-Toscana) and €1527 (MM-Toscana). Sensitivity analyses on literature data confirmed the robustness of basecase results. Budget impact analysis, based on regional statistics for haemorrhoidal surgery and suggested extra-tariffs for PPH, estimated the need for additional funding ranging 1.7%–16% for Lombardia and 2.2%–20.4% for Toscana, over the current Regional expenditure. **CONCLUSIONS:** Analysis of management courses showed the inadequacy of current regional funding for PPH and MM. Current regionalization of the Italian NHS prompts for implementation of HTA at the Regional level.

**MENTAL HEALTH – Clinical Outcomes Studies**

## PMH1

**COMPLIANCE WITH ANTIPSYCHOTIC DRUGS AND HOSPITALIZATION: A NESTED CASE-CONTROL ANALYSIS IN A COHORT OF PEOPLE WITH SCHIZOPHRENIA**

Moisan J, Grégoire JP

Université Laval, Québec, QC, Canada

**OBJECTIVES:** To assess the association between compliance with antipsychotic drug therapy and mental health-related hospitalization in people with schizophrenia. **METHODS:** A nested case-control study using the Quebec Health Insurance Board databases. The source cohort was made of people with schizophrenia who initiated an antipsychotic treatment between January 1, 2000 and March 31, 2007. Cases were cohort members who were hospitalized for a mental health-related problem during their follow-up period. Five matched (for sex, age and year of treatment initiation) controls were selected using density sampling method thus allowing a control's observation period to equal its case's period. Compliance was assessed using the medication possession ratio (MPR). A paired multivariate logistic regression model was used to calculate adjusted odds ratios (OR). Co-variables included: mental health co-morbidities, patient characteristics at treatment initiation; antipsychotics and other drugs used as well as health services used during the observation period and current use of any antipsychotic at the end of the observation period. **RESULTS:** A total of 2429 cases were identified and matched to 11,988 controls. Compared to individuals with a MPR  $\geq 80\%$ , those with a MPR  $\geq 40\%$  and  $<80\%$  (OR: 1.4; 95% confidence interval (CI): 1.1–1.7) and those with a MPR  $< 40\%$  (OR: 1.9; CI: 1.5–2.4) were more likely to be hospitalized. Were also more likely to be hospitalized: past antipsychotic users (OR: 1.4; CI: 1.1–1.7), those with low SES (OR: 1.3; CI: 1.2–1.4) and those with more medical visits (2<sup>nd</sup> tertile: OR: 1.5; CI: 1.3–1.7, 3<sup>rd</sup> tertile: OR: 2.0; CI: 1.8–2.3). Likewise, having bipolar disorder (OR: 1.7; CI: 1.4–2.0) as well as having another psychosis diagnosis (OR: 1.4; CI: 1.2–1.7) increase the likelihood of hospitalization. **CONCLUSIONS:** Among people with schizophrenia, compliance with antipsychotic treatment does influence the risk of hospitalization.

## PMH2

**EVIDENCE FOR SSRI IN THE TREATMENT OF DEPRESSION: EARLY KNOWLEDGE GAIN—LATE CONSEQUENCES IN ROUTINE CARE?**

Gothe H, Klein S, Storz P, Haeussler B

IGES Institut GmbH, Berlin, Germany

**OBJECTIVES:** This study aims to determine since when the evidence on the two most important groups of antidepressants SSRI and TCA could be valued as a sufficient basis for medical decision making regarding the preference for one of them. Furthermore, it was analyzed whether the utilization of SSRI in Germany from this point onward was adequate and to what extent health gains might have been foregone due

to a limited use of SSRI. **METHODS:** To determine since when the beneficial effect of SSRI was known, cumulative metaanalyses of RCT derived from systematic reviews were conducted. The evidence base was considered as established, when significant (5%-level) results favoring SSRI or TCA regarding two main outcome criteria (antidepressive efficacy and treatment termination due to side-effects) were observed. Utilization figures for SSRI and epidemiological estimates were taken from published sources. **RESULTS:** Findings on  $n = 4031$  patients of 31 studies on the antidepressive efficacy from 1983 to 2001 could be considered. The cumulative metaanalysis showed no significant difference between SSRI and TCA regarding the antidepressive efficacy (RR 0.05; 95%-KI -0.01–0.12). On the other hand, in the course of time, SSRI were consistently superior regarding unwanted side-effects since 1985 (RR 0.69; 95%-KI 0.62–0.77). **CONCLUSIONS:** Regarding the comparison of the efficacy of both substance groups, our findings are in line with the common clinical appraisal. The superiority of SSRI in terms of lower rates of treatment termination has become known in the mid 1980s. The analysis of the utilization data suggests a considerable delay in the consequences of this appreciation for routine care. Factors like cost considerations and lack in knowledge dissemination might have contributed to this phenomenon. Limitations of the present analysis are primarily associated with uncertainties of epidemiological estimates and the application of study results to the entire patient population.

## PMH3

**OVERCOMING THE CHALLENGES OF MODELLING SCHIZOPHRENIA: A UK CASE STUDY OF THE COST-EFFECTIVENESS OF OLANZAPINE LONG-ACTING INJECTION VS. RISPERIDONE LONG-ACTING INJECTION**Carroll SM<sup>1</sup>, Jemai N<sup>2</sup>, Moller J<sup>1</sup>, Novick D<sup>3</sup><sup>1</sup>United BioSource Corporation (UBC), London, UK, <sup>2</sup>Eli Lilly and Company, Erl WoodEl,CL, UK, <sup>3</sup>Eli Lilly and Company, Windlesham, Surrey, UK

**OBJECTIVES:** Schizophrenia is a complex and heterogeneous psychiatric disorder with usual onset in early adulthood leading to a lifetime of morbidity and chronic disability that affects a person's ability to perceive, think and feel. The disease heterogeneity and chronic course presents significant challenges for realistic economic modelling. We present a cost-effectiveness model of schizophrenia applied to the UK, which overcomes the limitations of previous modelling techniques. **METHODS:** Given the heterogeneous and progressive nature of schizophrenia, accurate modelling needs to capture patient history and, in particular, the complex interactions between treatment discontinuation and relapse, and the impact of past relapses on the risk of future relapse. For these reasons, a discrete event simulation (DES) model was built comparing the cost-effectiveness of olanzapine long-acting injection (OLAI) against risperidone long-acting injection (RLAI). The model considered a real-world patient population utilising data from real-world sources such as open-label studies rather than randomised controlled trials. An indirect comparison was used to calculate relapse and treatment discontinuation rates. Key outcomes of interest included relapse, discontinuation, treatment switching, side effects, quality-adjusted life years, and treatment and resource use costs. **RESULTS:** The DES model captured outcomes that other modelling techniques would struggle to achieve. Among these were patient time on/off different treatments, occurrence of side effects including post-injection syndrome, and the number of relapses and treatment discontinuations. By modelling a real-world patient population, the evaluation generated patient-level findings directly relevant to clinical practice and accentuated the benefits of OLAI for reducing the risk of treatment discontinuation and in turn relapses. **CONCLUSIONS:** Key modelling challenges for schizophrenia include capturing patient history and time-dependent variables such as relapse and discontinuation. Real-world modelling to inform decision-making is growing in importance, and therefore requires the application of advanced simulation techniques.

## PMH4

**A SYSTEMATIC REVIEW OF THE REAL-WORLD STUDY EVIDENCE COMPARING THE SAFETY AND TOLERABILITY OF DONEPEZIL, RIVASTIGMINE AND GALANTAMINE FOR THE TREATMENT OF MILD TO MODERATE ALZHEIMER'S DISEASE**Lockhart J<sup>1</sup>, Mitchell S<sup>2</sup>, Kelly S<sup>3</sup><sup>1</sup>Pfizer Limited, Tadworth, UK, <sup>2</sup>Abacus International, Bicester, UK, <sup>3</sup>Pfizer, Tadworth, Surrey, UK

**OBJECTIVES:** The acetylcholinesterase inhibitors (ChEIs) donepezil, rivastigmine and galantamine are recommended for symptomatic treatment of mild to moderate Alzheimer's Disease (AD). Despite AChEI efficacy being demonstrated in randomised clinical trials (RCTs), this study design has limited validity in relation to real-world patient care. Observational studies of routine patient care can be valuable sources of adverse event (AE) data in chronic conditions such as AD. A systematic review was undertaken to compare the safety of the AChEIs in treating AD in routine clinical care. **METHODS:** Cochrane Library, MEDLINE, and EMBASE searches were conducted together with searches of selected bibliographies and conference proceedings to identify head-to-head, non-randomised AChEI studies. Two reviewers independently extracted data from relevant articles. **RESULTS:** Twelve studies ( $N = 6$  prospective;  $N = 6$  retrospective) met the pre-specified inclusion criteria. Due to study design heterogeneity, a narrative data analysis was conducted. Four studies reporting total AE data found consistently fewer AEs in donepezil versus other AChEI patients, the difference being statistically significant in the largest study ( $N = 5462$ ;  $p < 0.001$ ). In three of four studies, fewer donepezil-treated patients withdrew due to AEs compared to patients receiving the other two AChEIs, with a statistically significant difference