

study because of worsening of psychosis. Functional activity was measured using the resource utilization inventory. Non-adherent patients are those with non-adherence as reason for discontinuation of the antipsychotic medication used at baseline, per physician rating. **RESULTS:** Over the 2-year study, 30% of patients have relapsed and 8% were hospitalized, without significant differences between the two medication formulations. Patients non-adherent before baseline were more likely to be hospitalized (14%) compared to adherent patients (7% hospitalized,  $p < 0.05$ ). Relapse in non-adherent patients was 36% compared to 29% in adherent patients. A logistic regression model on baseline factors associated with relapse found that a greater extent of functional activity was associated with a lower risk of relapse. The risk of subsequent hospitalization was significantly associated only with previous hospitalization. **CONCLUSIONS:** In this 2-year open label study, the rate of relapse and hospitalization was similarly low among patients treated with oral olanzapine or olanzapine-LAI. While prior non-adherence with oral antipsychotics and previous hospitalization were associated with hospitalization, only the latter predicted subsequent hospitalization in the logistic model. Lower risk of relapse was associated with a greater level of productivity.

#### PMH13

##### DIFFERENCES BETWEEN PATIENTS UNDERGOING AUGMENTATION OR SWITCHING OF ANTIPSYCHOTIC MEDICATIONS DURING TREATMENT OF SCHIZOPHRENIA

Ascher-Svanum H<sup>1</sup>, Brnabic AJ<sup>2</sup>, Lawson T<sup>1</sup>, Kinon BJ<sup>1</sup>, Stauffer VL<sup>1</sup>, Feldman PD<sup>1</sup>, Kelin K<sup>2</sup>

<sup>1</sup>Eli Lilly and Company, Indianapolis, IN, USA, <sup>2</sup>Eli Lilly Australia Pty Ltd, Sydney, NSW, Australia

**OBJECTIVES:** Treatment optimization for patients with schizophrenia remains a challenge, and it is often difficult to determine whether augmenting the current medication or switching to another will better benefit a patient. This post hoc analysis compares outcome measures between patients whose antipsychotic medication was either augmented or switched. **METHODS:** Adult outpatients receiving oral antipsychotic treatment for schizophrenia were assessed during a 12-month, multi-country, observational study (F1D-AY-B033). Clinical and functional outcomes were assessed at the time of first treatment switch/augmentation (0–14 days preceding change) and compared between patients undergoing medication augmentation or switching. Due to low numbers of patients with such data, interpretation of findings is based on effect size (ES). **RESULTS:** Data at the time of medication change were available for 87 patients (34 augmented, 53 switched). The primary reason for treatment change in both groups was inadequate response, but lack of adherence was more prevalent in the switched group (26.4% versus 8.8%). Although changes in clinical severity from study initiation to medication change were similar (per the Clinical Global Impressions—Severity scale), patients' physical well being, as measured by physical component scores of the 12-item Short Form Health Survey (SF-12), improved in the augmented group but worsened in the switched group (augmented:  $+7.71 \pm 11.98$ , switched:  $-1.87 \pm 10.98$ , ES=0.85). Similarly, mental health state improved in the augmented group but declined in the switched group, as indicated by SF-12 mental health component scores (augmented:  $+2.41 \pm 13.64$ , switched:  $-1.08 \pm 9.98$ , ES=0.314). **CONCLUSIONS:** Patient's worsening or lack of meaningful improvement may prompt clinicians to switch antipsychotic medications, whereas, when a patient shows improvement, clinicians appear more likely to try to bolster the improvement through augmentation with another antipsychotic medication. Current findings are consistent with physicians' stated reasons for augmenting versus switching antipsychotics in the treatment of schizophrenia. Confirmation of these findings requires further research.

#### PMH14

##### SPEED OF DETECTION OF ADVERSE EVENTS IN SPONTANEOUS ADVERSE EVENT DATABASES COMPARED WITH EPIDEMIOLOGICAL STUDIES: TWO RELATED CASES

Qizilbash N<sup>1</sup>, Méndez I<sup>2</sup>, Sánchez-de la Rosa R<sup>3</sup>

<sup>1</sup>Oxon Epidemiology Limited, London, UK, <sup>2</sup>Oxon Epidemiology Limited, Madrid, Madrid, Spain, <sup>3</sup>TEVA Pharma SLU, Madrid, Spain

**OBJECTIVES:** The risk of bradycardia and its consequences from use of cholinesterase inhibitors (ChI) in dementia was reported in epidemiological studies in 2009 and from a case series for memantine in 2008. We compared the detection and timing of these associations between disproportionality analysis and published epidemiological studies. **METHODS:** We conducted 1) a systematic review of the literature to identify epidemiological studies reporting AEs in patients taking currently prescribed ChI and memantine, and 2) an analysis in the FDA spontaneous Adverse Event Reporting System database (AERS) using the Empirical Bayesian Geometric Mean (EBGM) statistic and 90% credibility intervals (90%CI), to allow for low frequencies of drug-event pairs. A composite event consisted of any of the following: bradycardia, bradyarrhythmia, pacemaker insertion, complete atrio-ventricular block and hip and femoral fracture. AEs from all drugs in AERS was the comparator. **RESULTS:** A total of 246 cases suspected of being associated with ChI and the composite event were identified. A statistically strong signal of disproportionate reporting, adjusted for age, sex and year was observed (EBGM of 6.58, 90%CI: 5.79 – 7.47). Cumulative yearly analyses revealed that the signal became statistically strong in 1997, one year after approval of the first currently used ChI. The first signal was reported in an epidemiological study in 2009. For memantine, 69 suspected cases were identified with the composite event. A statistically strong signal of disproportionate reporting, adjusted for age, sex and year, was observed (EBGM of 1.87; 90%CI: 1.47 – 2.38). Cumulative yearly analyses revealed that the signal became statistically strong and stable two years after the first reported composite event. No epidemiological studies have yet been published. **CONCLUSIONS:** Analysis of suspected events can be followed over time and may detect, confirm or

refute drug-event signals much earlier than epidemiological studies and inform health technology assessments.

#### PMH15

##### MORTALITY IN RELATION TO DISEASE SEVERITY IN SUBJECTS WITH DEMENTIA

Jonsson L<sup>1</sup>, Fratiglioni L<sup>2</sup>, Wimo A<sup>2</sup>

<sup>1</sup>3 Innovus, Stockholm, Sweden, <sup>2</sup>Karolinska Institutet, Stockholm, Sweden

**OBJECTIVES:** The impact on mortality is a major driver in determining the cost-effectiveness of diagnostics and treatment of dementia disorders. We examined the relationship between the degree of dementia severity and mortality in a longitudinal, population-based study in Sweden. **METHODS:** From a total sample of 1810 subjects aged 75 years or older, 211 were identified as having a clinical diagnosis of dementia at baseline and were included in the study. Disease severity was assessed with the Mini-Mental State Examination (MMSE) as well as the Clinical Dementia Rating (CDR), administered at baseline and again at two follow-up visits after approximately 40 and 80 months respectively. Mortality data was obtained from the national death statistics, 10 years post baseline. Survival analysis was conducted using Weibull regression with baseline as well as time-varying covariates. Age and gender were also included as covariates in addition to dementia severity. **RESULTS:** A total of 198 deaths were observed during the observation period, and the time to death was 935 days on median. Annual mortality rates in females were estimated to 12% for mild dementia (MMSE 21–26), 15% for moderate dementia (MMSE 10–20) and 19% for severe dementia (MMSE 0–9) at baseline. The corresponding estimates for males were 19%, 24% and 31% respectively. Each point lower result on the MMSE scale was associated with a decrease in survival by 2.5%. There was no statistically significant relationship between baseline CDR scores and mortality, though a trend was seen towards increasing mortality in more severe CDR states. Similar results were observed in an analysis incorporating changes in disease severity over time. **CONCLUSIONS:** Mortality in subjects with dementia increase with the severity of dementia, as measured by the MMSE. Incorporating differential survival by disease severity has important implications for the long-term cost-effectiveness of diagnosis and therapies for dementia disorders.

#### Mental Health – Cost Studies

#### PMH16

##### BUDGETARY IMPACT ANALYSIS OF BUPRENORPHINE/NALOXONE (SUBOXONE®) IN OPIOID MAINTENANCE TREATMENT IN SPAIN

Martinez-Raga J<sup>1</sup>, Casado MA<sup>2</sup>, González Saiz F<sup>3</sup>, Oñate J<sup>4</sup>

<sup>1</sup>Agencia Valenciana de Salut & Universitat CEU Cardenal Herrera, Valencia, Valencia, Spain,

<sup>2</sup>Pharmacoeconomics & Outcomes Research Iberia (PORIB), Pozuelo de Alarcón, Madrid, Spain,

<sup>3</sup>UGC Salud Mental Hospital de Jerez, Jerez, Cádiz, Spain, <sup>4</sup>Drogodependencias y Salud Mental,

Murcia, Murcia, Spain

**OBJECTIVES:** Prior to the approval of buprenorphine/naloxone (B/N) (Suboxone®) we evaluated its economic impact in the treatment of heroin dependence. Three years since its approval we aimed to reassess the economic impact of B/N considering the availability of data on its actual use in clinical practice and the changing costs of medicines in the current economic crisis. A pharmacoeconomic modeling was applied to evaluate the economic impact of B/N as a maintenance therapy for opioid dependent individuals in the Spanish National Health Care System (NHS) during a three-year period. **METHODS:** We used an interactive budgetary impact analysis model that was developed to calculate the annual costs (drugs and associated costs) to the Spanish NHS of methadone versus B/N depending on the number of patients receiving either medication. Data for the model were obtained from scientific databases and expert panel opinion. **RESULTS:** It was estimated that 81.706 patients would be in agonist opioid maintenance treatment program each of the three-years of the study. More importantly, the introduction of B/N combination has not resulted in an increase in the number of patients receiving treatment for their opioid dependence. The budgetary impact (drugs and associated costs) for opioid maintenance treatment in the first year of the study is expected to be 90,92 million €. In the first year of the pharmacoeconomic modeling the budgetary impact of B/N would rise to 4.85 million € (4.9% of the total impact) to the NHS, with an incremental cost of 0.86 million € (1.0% of the total impact). The mean cost per patient in the first year with and without B/N has been calculated at € 1102 and 1113, respectively. **CONCLUSIONS:** With an additional cost of only € 11 per patient, B/N is an efficient addition to the available pharmacotherapies for opioid dependent patients, particularly when considering the favorable clinical aspects of this novel medication.

#### PMH17

##### THE ECONOMIC AND SOCIAL CONSEQUENCES OF SCHIZOPHRENIA TREATMENT WITH SEROQUEL XR® (QUETIAPINE PROLONGED RELEASE TABLETS) IN POLAND: ANALYSIS OF THE IMPACT ON THE HEALTH CARE SYSTEM

Faluta T<sup>1</sup>, Rdzanek M<sup>1</sup>, Pierzgańska K<sup>2</sup>, Wróbel B<sup>1</sup>

<sup>1</sup>AstraZeneca, Warsaw, Poland, <sup>2</sup>Institute of Psychiatry and Neurology, Warsaw, Poland

**OBJECTIVES:** To estimate the economic consequences of replacing the normal tablets of quetiapine with Seroquel XR® in the treatment of schizophrenia in Poland. **METHODS:** Based on the established model of the economic consequences of schizophrenia treatment, we calculated the cost of treating schizophrenia with quetiapine in Poland. Expenditures for the purchase of medicines, hospital costs and the costs of lost productivity were highlighted. The analysis was performed from a societal perspective, taking into account the Payer's perspective, in one-year time horizon. **RESULTS:** The use of Seroquel XR® will increase the population of patients who comply with the recommended treatment, which will reduce the