

44mcg was chosen as comparator since it is the most widely prescribed disease modifying therapy for 1<sup>st</sup>-line treatment in HARRMS patients in Brazil. **METHODS:** We developed a Markov model with 20-year time horizon comparing natalizumab to IFN1a 44mcg. Health states were based on EDSS and relapses (moderate or severe). Since there are no published data evaluating long-term course specifically in HARRMS, we assumed transition probabilities on EDSS states based on natural history studies on unselected RRMS patients, and relapse probabilities based on a post-hoc analysis of the pivotal natalizumab AFFIRM trial. This is a rather conservative approach, since disability progression may be slower in this proposed model than expected for patients with HARRMS and so the benefit from natalizumab could be underappreciated. In each monthly cycle, patients can discontinue treatment, remain stable, progress to higher EDSS state, experience Progressive Multifocal Leukoencephalopathy or die. Patients with EDSS score  $\geq 7.5$  receive best supportive care. Resource use and costs were validated by an expert's panel and valued using Brazilian public official lists (DATASUS and BPS). Costs and outcomes were discounted (5%). Probabilistic sensitivity analyses (PSA) covered variability in efficacy and costs. **RESULTS:** Use of natalizumab was associated with slower EDSS progression and reduced relapse burden. Life years gained with natalizumab and IFN1a 44mcg were 10.90 and 10.54, and costs were USD119,977 and USD132,446, respectively. In the base-case, natalizumab was dominant versus IFN1a 44mcg. PSA has confirmed the consistency of results. **CONCLUSIONS:** For a patient with HARRMS, the model shows that natalizumab was dominant when compared to IFN1a 44mcg in the Brazilian Public Healthcare System.

#### PND13

##### BURDEN OF MULTIPLE SCLEROSIS AND UNMET NEEDS IN BRAZIL: HEALTH CARE RESOURCE UTILIZATION

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**OBJECTIVES:** To assess the health care resource utilization (HRU) of Brazilian multiple sclerosis (MS) patients. **METHODS:** This was a cross-sectional, multicenter study conducted in 8 Brazilian major MS treatment sites. HRU was evaluated as the percentage of patients self-reporting the consumption of resources. The main categories were: hospitalization, consultations, laboratory and imaging tests, disease modifying therapies (DMTs), co-medication, aids and/or home modifications. Frequency and average consumption were annualized. **RESULTS:** The study enrolled 210 MS patients, mean age was 40.7 [standard deviation=11.5] years and 70.7% female. Patients with mild disability (according to self-reported Expanded Disability Status Scale [EDSS]) represented 40.4% of patients, 43.7% had moderate disability and 15.9% had severe disability. Hospitalization was reported by 23%, 33% and 15% of mild, moderate and severe MS patients, with average length of stay of: 7.53, 10.41, and 7.40 days, respectively. Most patients (>96%) had at least one neurologist consultation per year (average 4.94 visits/year in the total sample). Physical therapy was the most consumed non-medical consultation (mild: 11%; moderate: 38%; severe: 64%). Magnetic resonance imaging was reported by 60%, 68%, and 55% of mild, moderate and severe patients. Patients using at least one DMT during the previous year were: 89%, 93%, and 61% of mild, moderate and severe MS patients, respectively. The most prescribed DMT was glatiramer acetate (38%, total sample). The most frequent co-medications were: anti-depressants, anti-spasticity, and analgesics. Home modification was reported by 19% and 45% of patients with moderate and severe disability, respectively. For ambulation, walking stick was used by 35% of moderate patients, while wheelchair was needed by 58% of severe patients. **CONCLUSIONS:** To our knowledge, this is the first Brazilian study investigating the HRU of MS patients. The findings can be useful to better understand MS patients' needs in terms of comprehensive care.

#### NEUROLOGICAL DISORDERS – Patient-Reported Outcomes & Patient Preference Studies

#### PND14

##### WHICH CYSTIC FIBROSIS INHALED ANTIBIOTIC MEDICINE FEATURES MATTER MOST TO ADULT PATIENTS AND PARENTS OF PEDIATRIC PATIENTS?

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**OBJECTIVES:** To quantify patient and parent preferences and adherence for different administration features of inhaled antibiotic medicines for cystic fibrosis (CF). **METHODS:** Adult patients with a self-reported physician diagnosis of CF and parents of pediatric CF patients (6 to 17 years) who had *Pseudomonas aeruginosa* in their lung culture at least twice in one year completed a web-enabled, discrete-choice experiment survey in the United States. Respondents answered 5 treatment-choice questions with known statistical properties. Each question required evaluating a pair of hypothetical CF treatment profiles defined by device type (nebulizer, dry powder inhaler (DPI)), total daily administration and cleaning time, dosing frequency, dry cough side effect, and personal cost per cycle. Lung function measured as forced expiratory volume in one second (FEV<sub>1</sub>) was held constant between the hypothetical CF treatment profiles. Stated adherence questions followed two randomly selected treatment-choice questions. Random-parameters logit models were used to estimate preference weights for all feature levels and the mean relative importance of each feature for both samples. **RESULTS:** A total of 209 adult patients and 271 parents completed the survey. Mean age of adult patients was 32 (SD = 10) years and mean age of pediatric patients was 12 (SD = 3) years. Among all respondents, the average time spent taking inhaled antibiotic medicines was approximately 40 minutes. Relative importance estimates indicated that switching from a 30-minute nebulizer twice daily to a 10-minute DPI twice daily was 6.3 times more important for adult patients and 2.0 times more important for parents than an improvement in dry cough from moderate to mild. Stated adherence for adult and pediatric patients was 20-30% higher for DPIs versus nebulizers. **CONCLUSIONS:**

Treatments administered with more convenient devices such as DPIs and shorter administration times are associated with higher utility and higher stated adherence in adult and pediatric patients.

#### PND15

##### BURDEN OF MULTIPLE SCLEROSIS AND UNMET NEEDS IN BRAZIL: MEASUREMENT OF FATIGUE USING MODIFIED FATIGUE IMPACT SCALE

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**OBJECTIVES:** Fatigue is one of the most frequent symptoms in patients with multiple sclerosis (MS). This study aimed to examine the severity and impact of fatigue in MS Brazilian patients. **METHODS:** This was a cross-sectional, multicenter study conducted in 8 Brazilian major MS treatment sites. Fatigue was assessed using the Brazilian version of the Modified Fatigue Impact Scale (MFIS), which evaluates the impact of fatigue on 3 dimensions of patients' daily life: physical, cognitive and psychosocial. The patient scores 0 (lower impact) to 84 points (higher impact). The final score was classified according to the level of impact: absent (0-38), low (39-58), and high (>58). **RESULTS:** The study enrolled 210 MS patients, of which the mean age was 40.7 [standard deviation = 11.5] years and 70.7% were female. Patients with mild disability (according to self-reported Expanded Disability Status Scale [EDSS]) represented 40.4% of patients, 43.7% had moderate disability and 15.9% had severe disability. In the overall sample, the impact of fatigue was considered absent, low and high in 49%, 32% and 19% of patients, respectively. Any impact (both low and high summed) was reported by 33%, 63%, and 66% of patients with mild, moderate and severe disability, respectively. The mean MFIS total score for mild, moderate and severe patients was 29.3, 45.0, and 45.4 (38.6 in the total sample). The mean impact scores for each domain in the total sample were 20.0 (physical, range 0-36), 14.7 (cognitive, range 0-40), and 3.9 (psychosocial, range 0-8), meaning that fatigue has a proportionally higher impact in the physical than the cognitive or psychosocial domains. **CONCLUSIONS:** Our findings indicate that over 50% of MS Brazilian patients notice some adverse impact of fatigue in their daily lives, particularly related to the physical domain.

#### PND16

##### BURDEN OF MULTIPLE SCLEROSIS AND UNMET NEEDS IN BRAZIL: MEASUREMENT OF HEALTH-RELATED QUALITY OF LIFE USING EQ-5D

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**OBJECTIVES:** To measure the health-related quality of life (HRQL) of multiple sclerosis (MS) patients and examine potential associations between HRQL and patients' characteristics. **METHODS:** This was a cross-sectional, multicenter study conducted in 8 Brazilian major MS treatment sites. HRQL was assessed using the Brazilian version of the EQ-5D and patients self-evaluated their HRQL and health status using five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and a visual analog scale (VAS). The EQ-5D index was calculated based on the value set derived from the UK population, since the Brazilian value set is not available. **RESULTS:** The study enrolled 210 MS patients, of which the mean age (standard deviation [SD]) was 40.7 [11.5] years and 70.7% were female. Patients with mild disability (according to self-reported Expanded Disability Status Scale [EDSS]) represented 40.4% of patients, 43.7% had moderate disability and 15.9% had severe disability. Among the 5 assessed HRQL dimensions, the ones with higher frequency of self-reported severe limitations were usual activities and anxiety/depression (11.0% each). The least impaired dimension was self-care, with 63.0% of patients reporting absence of limitation. The mean [SD] VAS score was 71.6 [18.9]. The mean EQ-5D index for each level of EDSS (mild, moderate or severe disability) was 0.73 [0.21], 0.49 [0.30], and 0.30 [0.34], respectively. In the multivariate analysis, variables related to patients' characteristics were explored and the following were associated with the presence of any limitation in at least one dimension: older age, unemployment/retirement, relapses in the previous year, emergency department visits in the previous 6 months and lower educational level. **CONCLUSIONS:** MS adversely impact patients' HRQL, especially with disability progression and clinical features that can be linked to more severe disease.

#### NEUROLOGICAL DISORDERS – Health Care Use & Policy Studies

#### PND17

##### EVALUATION OF TREATMENT PATTERNS AND CLINICAL TRIALS PUBLISHED ON PATIENTS DIAGNOSED WITH INSOMNIA: A LITERATURE UPDATE

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**OBJECTIVES:** To conduct a systematic review of literature in peer-reviewed journals on real world treatment patterns and clinical trials on patients diagnosed with Insomnia. **METHODS:** A comprehensive literature search was performed using relevant search terms to identify articles published from 2000 to 2010 on the real world treatment patterns and clinical trials conducted on patients with Insomnia. Studies were identified through electronic Embase, Cochrane, Medline, and PubMed databases. Additional parameters were placed on the final search strategy to limit the retrieval to articles written in English, involving human subjects. **RESULTS:** Our search yielded 1,153 articles for treatment patterns and clinical trials on patients diagnosed with Insomnia from PubMed/Medline/Embase/ Cochrane databases. After removing duplicates and non-relevant articles, 65 articles were included for final review. A total of 16 studies had some focus on

real world treatment patterns in Insomnia patients and majority of these studies focused on benzodiazepine users. The rate of medication use in Insomnia patients is fairly low and rates were ranging from 17% to 75%. There were a total of 11 trials published testing Eszopiclone use, 10 trials each on Ramelteon and Zolpidem, 4 trials on Indiplon, 3 trials on Gaboxadol, 3 trials on Doxepin use in patients diagnosed with Insomnia. Several patient reported outcomes measures were used in the assessment of various clinical trials. **CONCLUSIONS:** There were a variety of agents being used to treat insomnia; while benzodiazepines and non-benzodiazepines were largely popular. Products in development need to be studied further to determine whether their new mechanisms of action were truly beneficial for treatment.

#### RESPIRATORY-RELATED DISORDERS – Clinical Outcomes Studies

##### PRS2

#### ACUTE ASTHMA CHARACTERISTICS AND ASTHMA CONTROL IN LATIN AMERICA

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**OBJECTIVES:** To investigate the patient's acute asthma characteristics, and identify predictors of asthma control in a population of asthma patients from five Latin American countries. **METHODS:** Adults and parents of adolescents (12-17 years) with a physician diagnosed asthma and asthma medication use or asthma attacks in the past year were surveyed as part of the 2011 Latin America Asthma Insights and Management (AIM) survey. Using Global Initiative for Asthma (GINA) guidelines as a reference, respondents were categorized into three levels of asthma control: well-controlled, partly-controlled, and uncontrolled. Chi-square tests and adjusted logistic regression were used to determine odds ratios (ORs) to assess the relation of degree of asthma control with frequency of sudden asthma episodes, frequency of asthma symptoms, duration of episodes, day-and night time symptoms, utilization of rescue medications, and asthma episodes seasonality. **RESULTS:** Data from 2168 adults and parents from asthma patients  $\geq 12$  years survey was analyzed. Seven percent (7%) of the patients are controlled, 57% partially controlled, and 36% uncontrolled. Adjusted logistic regression models showed that patients whose asthma was uncontrolled were significantly more likely to have acute sudden asthma episodes compared to patients whose asthma was controlled either partially or fully. Similarly, patients with uncontrolled asthma were significantly more likely to have higher frequency of asthma episodes in most days of the week, increased day and night symptoms than those asthmatics who were controlled. **CONCLUSIONS:** Patients who did not have well-controlled asthma had more acute episodes as compared to patients whose asthma was well-controlled. Our results strongly suggest that the acute asthma requires a significant effort to decrease its severity.

##### PRS3

#### GRAPHIC HEALTH WARNINGS ON CIGARETTE PACKS IN QATAR: PRE-IMPLEMENTATION AWARENESS AND PERCEPTION AMONG THE GENERAL PUBLIC

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**OBJECTIVES:** Graphic health warnings (GHWs) on cigarette packages have been found to be significantly associated with increased awareness of smoking-related health hazards as well as behavior change. Legislations on GHWs have recently been endorsed and GHWs have now been introduced in Qatar. This study aims to evaluate the general public's awareness, beliefs and perceptions on anti-tobacco GHW labels on cigarette packs prior to the introduction of the new law. **METHODS:** A cross-sectional survey using a pretested 23-item questionnaire was conducted among randomly approached adults in Qatar. Data were analyzed using the IBM SPSS<sup>®</sup> version 19. Responses were analyzed by smoking status (ever-smokers vs. never-smokers) to ascertain how these two distinct groups differed in their awareness and perceptions related to health warning messages. The demographic characteristics and other outcomes of interest were compared using  $\chi^2$  or Fishers Exact tests. **RESULTS:** A total of 500 participants (59% male) responded to the survey. Most notably, ever-smokers did not significantly differ from never-smokers on awareness of GHW. About one-third of the respondents had no idea about any specific text warning messages on tobacco products sold and nearly 45% of them did not know what a GHW was. Furthermore, a substantial proportion (more than 20%) of the respondents in both groups did not believe that introducing GHWs will enhance smoking behavior change. Non-smokers generally tended to have more positive attitudes than smokers toward the perceived impact of GHWs ( $p < 0.05$ ). **CONCLUSIONS:** A substantial proportion of the general public in Qatar had poor awareness about GHWs. This study has important implications on the needs to increase awareness about the value of GHWs as well as calls for further research to determine the effectiveness of GHW labels on cigarette packages in Qatar and the greater Middle Eastern region, where legislations on GHWs are still at infancy.

#### RESPIRATORY-RELATED DISORDERS – Cost Studies

##### PRS4

#### IMPACTO DO USO DO MICRODEBRIDADOR NOS DESFECHOS E CUSTOS NAS CIRURGIAS ENDOSCÓPICAS NAS AIS

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**OBJETIVOS:** O objetivo deste estudo foi comparar as técnicas cirúrgicas com uso do microdebridador em relação à técnica convencional nos procedimentos de septoplastia com turbinectomia e sinusectomia, quanto ao tempo de cirurgia, tempo de hospitalização, uso de colas e hemostáticos, escore de dor, taxa de readmissão

hospitalar e custo do procedimento. **MÉTODOS:** A partir do sistema de faturamento do HIAE foram selecionados 538 procedimentos de septoplastia com turbinectomia e sinusectomia realizados no ano de 2011 que utilizaram as técnicas comparadas neste estudo. Foram incluídos na análise 517 pacientes, 56 procedimentos utilizando o microdebridador e 461 utilizando a técnica convencional. Em média, os pacientes que utilizaram o microdebridador possuíam uma faixa etária mais elevada e um percentual maior dos pacientes apresentaram diagnóstico de sinusite crônica. **RESULTADOS:** Em relação à média de tempo de permanência hospitalar esta foi maior no grupo do microdebridador (28 horas versus 22 horas no grupo da técnica convencional,  $p = 0,002$ ). A quantidade média de unidades de cola e de hemostático foi maior no grupo que utilizou o microdebridador. Não houve diferença estatística entre os grupos nos desfechos de tempo de cirurgia e nas taxas de readmissão hospitalar. No desfecho de dor no pós-operatório imediato a diferença entre os grupos foi estatisticamente significativa ( $p = 0,006$ ), indicando um percentual maior de pacientes com escore de dor acima de 5 sendo tratados com o microdebridador, quando comparado com o grupo convencional. Considerando-se o custo do procedimento com a técnica convencional como referência, o uso do microdebridador resultou em um aumento médio de 17,4% em relação à técnica convencional. **CONCLUSÕES:** O uso do microdebridador não se mostrou favorável nos desfechos avaliados, tendo em vista um aumento do tempo de permanência do paciente, uso de colas e hemostáticos em maior quantidade que a técnica convencional e o custo do procedimento foi significativamente mais alto.

##### PRSS

#### COMPARING COPD COSTS BY EXACERBATION FREQUENCY AND DYSPNOEA LEVEL IN A PRIMARY CARE SETTING IN THE UNITED KINGDOM

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**OBJECTIVES:** Economic burden in Chronic Obstructive Pulmonary Disease (COPD) patients with varying levels of dyspnoea is largely unknown. The objective of this retrospective analysis was to estimate the resource use and the associated costs incurred by COPD patients with increasing levels of dyspnoea with or without frequent exacerbations. **METHODS:** A retrospective cohort of prevalent COPD patients was identified in the Clinical Practice Research Datalink (CPRD). All patients who had at least 12 month pre- and post-cohort entry date (1st prevalent COPD diagnosis confirmed by spirometry  $\geq$  April 1, 2009) recorded were included in the analysis. Patients were categorised as having none, 1 or 2+ exacerbations in the 12 months post cohort entry and further classified using Medical Research Council (MRC) dyspnoea scale. Study outcomes included general practitioner (GP) visits, community treated exacerbations (medical dg for exacerbation or ATB+OCS Rx), hospital treated exacerbations and all-cause hospitalisations excluding COPD exacerbations. The costs associated with the estimated resource use were calculated using National Health Service (NHS) reference costs for 2010-11. **RESULTS:** The cohort consisted of 51,641 COPD patients with 27,764 (53.8%), 12,585 (24.4%) and 11,292 (21.9%) having experienced none, 1 and 2+ annual exacerbations post cohort entry. Among all patients, the estimated annual COPD management costs, excluding the costs of medications, were £1,597, £1,849, £2,298, £2,745 and £3,579 with increasing levels of dyspnoea (MRC grade 1-5). The equivalent cost ranges by exacerbation frequency were £1,267-£2,235, £2,021-£3,447 and £2,627-£4,709 for patients with none, 1 or 2+ annual exacerbations, respectively. **CONCLUSIONS:** Increase in COPD management costs with increase in level of dyspnoea occurred in all exacerbation frequency groups. Better symptom control and disease management strategies in primary care setting may help reduce COPD costs significantly.

##### PRSE

#### HEALTH AND ECONOMIC BURDEN OF TOBACCO USE IN SEVEN LATIN AMERICAN COUNTRIES: RESULTS FROM A MICROSIMULATION HEALTH ECONOMIC MODEL (HEM)

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**OBJECTIVES:** Smoking is the single most preventable cause of disease and death all around the world. Our objective was to quantify the disease burden associated with smoking in Argentina, Bolivia, Brazil, Chile, Colombia, Mexico and Peru. **METHODS:** The project began with a survey to health Decision Makers (DM) to explore country-specific information needs. The development stage involved the harmonization of a methodology to retrieve local relevant parameters and develop the model structure. A microsimulation HEM was built considering the availability and quality of epidemiological data and relevant outcomes were conceived to suit the identified information needs of DMs. It considers all tobacco-related diseases: heart, cerebrovascular and chronic obstructive pulmonary disease, pneumonia/influenza, lung cancer and nine other neoplasms. A systematic search on effectiveness, local epidemiology and costs studies was undertaken to populate the model. Calibration and validation was performed for each country. Predicted event rates were compared to the published rates used as model inputs. External validation was undertaken against epidemiological studies not used to provide input data. **RESULTS:** The calibrated model showed all simulated event rates falling within  $\pm 10\%$  of the sources and a high correlation between published data and model results. In these seven LA countries, tobacco is responsible of 259,126 deaths each year. The diseases attributable to smoking cause a total of 1-90 million years of life lost due to premature death, 0-64 million years of life lost due to disability and at least 27 billion dollars (USD dollars 2013) in direct medical costs each year. **CONCLUSIONS:** Tobacco use is