A405

#### PND80

#### ADOPTION OF ORAL DISEASE MODIFYING TREATMENTS TO MANAGE PATIENTS WITH RELAPSING REMITTING MULTIPLE SCLEROSIS FROM 2011-2013 IN THE UNITED STATES

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**OBJECTIVES:** New oral Disease Modifying Treatments (DMTs) for Relapsing Remitting Multiple Sclerosis (RRMS) were recently introduced in the US. The objective of this study was to assess trends in adoption of oral DMTs among RRMS patients in the US. METHODS: A multi-center retrospective chart-review study of RRMS patients was conducted in the US in 4Q2011, 4Q2012, 2Q2013, and 4Q2013 to collect de-identified data on diagnosis, clinical status, and treatment patterns. Neurologists were screened for duration of practice (≥3yrs) and patient volume (≥15 MS patients/mo) and recruited from a large panel to be geographically representative. Medical charts of next 10 consecutive MS patients were abstracted by each neurologist. RRMS patients taking oral, injectable, or infusible DMTs were analyzed. **RESULTS:** 2362 eligible RRMS patient charts were evaluated (4Q2011:23%, 4Q2012:25%, 2Q2013:25% & 4Q2013:26%). Use of oral DMTs increased four-fold (4Q2011:7%, 4Q2012:9%, 2Q2013:21% & 4Q2013:31%); use of injectable DMTs decreased (4Q2011:82%, 4Q2012:78%, 2Q2013:71% & 4Q2013:60%), as did use of infusible DMTs (4Q2011:10%, 4Q2012:12%, 2Q2013:7% & 4Q2013:8%). Across timeframes, 61%, 27% & 12% of patients were on 1<sup>st</sup>-line, 2<sup>nd</sup>-line, and 3<sup>rd</sup>-line or subsequent treatment, respectively. Among 3rd-line or subsequent patients, oral DMT use increased from 23% to 59%; use of injectable and infusible DMTs decreased from 34% to 16% and 37% to 25%, respectively. Among  $2^{nd}$ -line patients, oral DMT from 66% to 37% and 21% to 15%, respectively. Among 1<sup>st</sup>, line patients, oral DMT use increased from 3% to 15%, respectively. Among 1<sup>st</sup>, line patients, oral DMT use increased from 3% to 16%; use of injectable DMTs decreased from 96% to 83% and infusible DMT use remained at 1-2%. CONCLUSIONS: Oral DMT use increased between 4Q2011-4Q2013, predominantly in 2<sup>nd</sup> or subsequent lines. The impact of this observed pattern of reserving new treatment options for later lines warrants scrutiny to optimize patient management and alleviate disease burden.

#### **RESEARCH POSTER PRESENTATIONS - SESSION II**

## HEALTH CARE USE & POLICY STUDIES

HEALTH CARE USE & POLICY STUDIES - Consumer Role in Health Care

### PHP1

## AWARENESS AND INTEREST IN THE UNITED STATES HEALTH INSURANCE MARKETPLACE

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OBJECTIVES: To examine the level of awareness and interest in the newly setup Health Insurance Marketplace under Affordable Care Act in West Virginia state of the United States of America. METHODS: Primary survey data were collected in July/August 2013 from a stratified sampling of West Virginians. A mail survey was completed by respondents in a cross-sectional study. Key variables included general awareness of the Health Insurance Marketplace and the availability of subsidies, the individual mandate, interest in using the Marketplace, and perceptions of respondents' ability to qualify for financial assistance. **RESULTS:** Six thousand surveys were mailed with a nine-page questionnaire. A total of 1,198 completed surveys were returned. Two months prior to launch, awareness of the Health Insurance Marketplace was low in WV; yet interest in the Marketplace was higher among those most likely to benefit-the insured and residents likely to qualify for financial subsidies. West Virginians reported being familiar with the individual mandate. **CONCLUSIONS:** Efforts should be increased at the federal, state, and local levels among government and non-government organizations to heighten awareness of the Health Insurance Marketplace in WV and, particularly, the availability of subsidies. Many, once made aware, expressed interest in learning more.

#### PHP2

### ATTITUDES OF PATIENTS TOWARD GENERIC SUBSTITUTION AND IMPLICATION FOR PRACTICE IN SLOVAKIA: FIRST RESULTS FROM ADOPTING THE LAW IN 2012 Babela R, Sajdikova K

St. Elizabeth University, BRATISLAVA, Slovak Republic

OBJECTIVES: Slovakia has from December 2011 new law that defines list of molecules for mandatory generic substitution. It was one of the cost-containment measures applied in the same time at the field of drug policy. We provided research on statistically selected sample of patients in Slovakia to detect current attitude, knowledge and believes toward generic substitution (GS). METHODS: We created special questionnaire for patients and distributed it in selected regions in Slovakia. From 600 questionaires, we evaluated 432. Questionares were distributed among patients visiting pharmacies in 2013/2014 and all patients were older than 20 years. **RESULTS:** There were 57% of women in our sample and only 11% from all patients had lower than college education. 71% of all patients were using prescription drugs regularly and 58% of all patients were familiar with term GS. Suprisingly, only 16% from all patients selected co-payment as the key factor influencing their decision toward GS. Recommendation of GS in pharmacy or by doctor was selected as key factor that influenced patients in choosing GS or generic molecule (40%). Second most influential factor was own experience with generic (27%). Only 8% of patients believed that GS can decrease overall consumption of drugs. We also found out that 36% of patients consider GS as "risky" because of extended number of generics available from various unknown companies. There was also a strong statistical relationship between gender and positives as well as negatives of GS among patients. **CONCLUSIONS:** Based on our research among patients we conclude that generic substitution is most likely effective drug policy tool, but since there are also many negative experiences (own or shared) with generic drugs, GS is still considered as alternative treatment.

#### PHP3

# THE SIMULTANEOUS EFFECTS OF PHARMACEUTICAL POLICIES FROM PAYERS' AND PATIENTS' PERSPECTIVES. ITALY AS A CASE STUDY

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**OBJECTIVES:** The research analyses (i) the individual and interactive effects of three pharmaceutical policies (cost-sharing, prescription quotas, therapeutic reference pricing) on drugs public and private expenditure and volumes, using Italian regional policies as a case-study; (ii) the extent to which the long-run effect of policies on expenditure is mediated by prescribers'/patients' behaviours. METHODS: An enriched difference-in-differences model is used. Firstly, policies impact on public and private expenditure and volume is separately estimated. Then, the hypothesis that the effects of policies on public expenditure are mediated by behaviours (transmission mechanism) is tested. As robustness check, a possible reverse causality and feedback mechanisms is tested, by switching the mediator and the independent variable. RESULTS: The analysis shows (i) that combined policies do not necessarily produce a higher impact than policies alone; (ii) a larger impact of policies in the short-run, whereas in the long-run the trend is often reversed, but not enough to compensate the final impact, which is usually in the expected direction; (iii) as for cost-sharing, that its negative impact on public expenditure is mainly due to a decrease in volumes than to a shift from public to private expenditure. **CONCLUSIONS:** Despite its limitation, this study has shined a light on the impact of policies which are implemented in different time and places, thus covering an information gap and supporting policy-makers. Some empirical findings show also that pharmaceutical policies may have an unintended impact on health: e.g. the volumes decrease due to cost-sharing may imply patients under-treatment.

### PHP4

#### PATIENT, INSUREE AND PUBLIC PARTICIPATION IN HEALTH TECHNOLOGY ASSESSMENT: AN INTERNATIONAL COMPARISON Mühlbacher AC, Juhnke C

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OBJECTIVES: There is a general consensus on the need for a stronger patient-centeredness, even in HTA processes. In international comparison different ways of public participation (citizens, insured and patients) in the decision-making process are discussed and tested. The need was recognized, but not yet fully reflected in practice. This study describes how preferences can be taken into account in different decision situations and shows how methods of preference measurement/ citizens' councils are used in an international context to support decision-making and understand the importance of various decision-criteria that influence these decisions. METHODS: A systematic literature review in PubMed/Medline revealed 95 articles and showed that methods of patients, citizens and policyholder participation are manifold. In order to structure the international approaches further, international HTA-organizations worldwide were questioned via e-mail in the end of 2013 on patients and public participation in their countries. **RESULTS:** 17 out of 126 contacted organizations answered to these questions. In general, the participation efforts extend from qualitative survey of patients' needs up to the science-based documentaries of quantitative patient preferences. The review and the survey of the HTA-agencies show that internationally three mechanisms are used to involve the public in decision-making bodies: membership of at least one patient representative (e.g., Australia, France, Germany), presentation of oral/written comments from patients (e.g., Australia, The Netherlands, Great Britain) and the possibility to check the HTAreports and the corresponding draft recommendations before publication (e.g., France, Germany, Great Britain, New Zealand, USA). CONCLUSIONS: The role of the patients or citizens seems to be limited to an informal or ad-hoc basis and is mostly restricted to consulting activities. In order to achieve a patient-centered health technology assessment two ways to sharing information are relevant: the public needs information on medical and health policy/economic issues and decisionmaker need information on the patient perspective.

HEALTH CARE USE & POLICY STUDIES - Diagnosis Related Group

## PHP5

# THE EFFECT OF DEGRESSIVE FINANCING METHOD ON THE HUNGARIAN DRG BASED HOSPITAL REIMBURSEMENT BETWEEN 2011-2013

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**OBJECTIVES:** Diagnosis Related Groups (DRG) like financing method was introduced in Hungary in 1993. In addition to DRG based reimbursement, an degressive upper ceiling (financial cap) was introduced for hospital reimbursement. The aim of our study was to investigate the financial effects of degressive financing method on the Hungarian DRG-based hospital financing. **METHODS:** The data in our analysis were derived from the nationwide administrative dataset of the National Health Insurance Fund Administration (OEP), the only health care financing agency. We examined the period between 2011 and 2013. In 2011 and 2012 hospital activity over financial cap was reimbursed up to 110% by 30% of DRG base rate, while in 2013 hospital activity over financial cap was reimbursed up to 104% by 25% of DRG base rate. **RESULTS:** In 2011 hospital activity exceeded the financial cap by 4.6% with a monthly variation of 1.5% - 6.6%. In 2012 hospital activity exceeded the financial cap by 4.2% with a monthly variation of 1.1% - 6.5%. In 2013 hospital activity exceeded the financial cap by 1.9% with a monthly variation of 1.1% - 2.6%. Between 2011 and 2013 the DRG base rate remained the same (150000 Hungarian Forint / DRG costweight). **CONCLUSIONS:** Introduction of degressive financing method – in addition to DRG reimbursement – managed to control the activity of hospitals. The soft regulation in 2011 and 2012 resulted in a 4.2-4.6% excess activity of hospitals, while the more rigorous regulation in 2013 managed to decrease the excess hospital activity to 1.9%. Degressive regulation can serve as a cost containment tool for health policy decision makers.

### PHP6

NUB STATUS - A 2014 SITUATION ANALYSIS FOR DRUGS: ONCOLOGY AS LEADING THERAPEUTIC AREA

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OBJECTIVES: In the German hospital landscape NuB's (Neue Untersuchungs- und Behandlungsmethoden) are essentially the precursor for cost-intensive drugs to be reimbursed within the G-DRG system. Hospitals can only start SHI negotiations for reimbursement once drugs have been given a NuB 1 status. The objective of this research was to provide an overview on the proportion of drugs (vs. methods, medicinal products) and their respective indications, which submitted NuB applications for 2014. METHODS: The German DRG database issued by the InEK (Institute for the Hospital Remuneration System) was used to analyse NuB subgroups sorted according to key therapeutic indications. In parallel, the number of NuB 1 status products that went through the AMNOG process was analysed. RESULTS: Out of 618 NuB submissions, only 133 (22%) were classified as drugs. In total, 114 (18%) of all NuB applications received a NuB 1 status, out of these 43 (38%) were drugs. The leading therapeutic area of the NuB 1 status drugs was oncology with 28 drugs (65%), followed by 5 ophthalmic products (12%). NuB 2 status was given to 465 (75%) procedures out of which 82 (18%) were drugs. The analysis reveals that, the success rate to receive the essential NuB 1 status is relatively low. Chances to receive a successfull NuB 1 status approval is one in three for drugs, however only one in six for other procedures. Out of the 43 drugs that were given NuB 1 status, already 24 (55%) passed through the AMNOG process and were given equal proportions from important additional benefit to no additional benefit. CONCLUSIONS: Drug applications are more likely than procedures to be given NuB 1 status and thereby initiate reimbursement negotiations with the SHI. The application quality and support by the scientific societies and treatment centres is essential to make a NuB application successful.

### HEALTH CARE USE & POLICY STUDIES - DISEASE MANAGEMENT

#### PHP8

### MULTICRITERIA DECISION ANALYSIS AND COST ANALYSIS IN HEALTH CARE DECISION MAKING: A LITERATURE REVIEW Ivley I, Landova M

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**OBJECTIVES:** The purpose this literature review is to investigate the application of multicriteria decision analysis and cost analysis methods within health care decision-making. METHODS: A search of the literature was conducted using scintific databases. A combination of the following key words and phrases were inputted into these databases: Analytic Hierarchy Process (AHP), Analytic Network Process (ANP), ELimination and Choice Expressing REality (ELECTRE), Goal programming, Grey relation analysis, Markov process, Technique for Order of Preference by Similarity to Ideal Solution (TOPSIS), CBA, CEA, and related words. The located articles were divided into the following twelve health care topics: evaluation of health information services; evaluation of the product development process; project and technology selection; pharmaceutics; health care management; therapy/treatment; management of medical waste; human resource planning in health care; organ transplantation; evaluation of health care policy; diagnostics; and shared decision-making with the patient. **RESULTS**: Ninety research articles were retrieved and determined relevant. The pertinent articles were published between 1981 and 2013. It was found that the AHP is the most commonly used method in health care decision making (65 articles). AHP is mainly exploited in project and technology selection (22). The ANP method is utilized in the evaluation of health information services, project and technology selection, pharmaceutics and therapy/treatment. For the evaluation of health care policy AHP (11), CBA (1), CEA (1) and Grey relation analysis (1) were used. The TOPSIS, VIKOR, Markov process methods were utilized once in human resource planning in health care, health care management and therapy/treatment respectively. The CBA (4) and CEA (2) methods were especially useful for solving therapy/treatment tasks. CONCLUSIONS: Multicriteria decision analysis and cost analysis offers a scientifically sound evaluation framework for health care management, where stakeholder interests are of crucial concern and complex criteria that cannot easily be reduced to simple monetary expressions, can be assessed in resource limited settings.

### PHP9

# TRENDS IN PHYSICAL AND OCCUPATIONAL THERAPY UTILZIATION IN THE US AND WESTERN EUROPE

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**OBJECTIVES:** Allied health care (AHC) disciplines, such as physical (PT) and occupational therapy (OT), are primarily performed by non-medical health care professionals. Although the budget impact of AHC is generally low, reimbursements are often scrutinized for their financial impact and benefit/risk ratios. To better inform the health care decision making regarding AHC, the aim of this study was to examine trends and utilization of PT and OT. **METHODS**: Data from the 2013 US (N=75,000) and 2013 5EU (France, Germany, Italy, Spain, and UK; N=62,000) National Health and Wellness Survey (NHWS). The NHWS is a patient-reported survey administered to a demographically representative sample of adults (with respect to age, sex, and region) in each country. Overall rates of OT/PT visits were reported. Patients who reported an OT/PT visit in the past six months were compared with those who did not with respect to demographics, health history, and comorbidity variables. Logistic regression models were then conducted to predict OT/PT visits from these variables. RESULTS: Rates of OT/PT visits did not change from 2010 to 2013 but significant differences among countries was observed (p<.05). In 2013, France (0.54%) and the US (4.51%) had the most infrequent visits while Spain (11.13%) and Germany (11.92%) had the most frequent. Being in Germany (OR=3.46), being in Spain (OR=3.24), and having an above the median income (OR=1.14) were the strongest demographic predictors of an OT/PT visit (all p<.05). Although most comorbidities were associated with an increased probability of an OT/PT visit, pain (OR=2.30), arthritis conditions (OR=1.73), and psychiatric conditions (OR=1.73) were most strongly associated (all p<.05). CONCLUSIONS: PT and OT utilization varies significantly across countries, being highest in Germany and Spain where over 10% of adults reported a visit in the past six months. Pain-related (pain, arthritis) and psychiatric comorbidities were among the strongest predictors of PT/OT use.

## PHP10

## A GENDER MEDICINE POST-HOC ANALYSIS: BACKGROUND AND METHODS OF THE METAGEM PROJECT

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**OBJECTIVES:** Gender is a social construct, which is defined by the way people perceive themselves and how they expect others to behave. Gender medicine is the field of medicine that studies the biological and physiological differences between the human sexes and how that affects differences in disease. The progress of research has confirmed that men and women differ not only sexually but also in relationship to factors such as liver enzymes, sex hormones and to variables determined by the environment, education, culture and psychology of the individual [Soldin and Mattison, 2009; Regitz-Zagrosek and Seeland 2012]. The Italian Drug Agency has recognized the importance of gender-specific analysis when evaluating new drug efficacy. The gender-medicine METAGEM project aims to describe gender differences in clinical outcomes, therapeutic approach and safety parameters in real world data. METHODS: Areas of interest were defined regarding Dermatology, Central nervous system, Infectivology, Rheumatology, and Transplantation; data were considered which were collected in ten observational studies conducted between 2002 and 2013 in Italy in routine clinical practice. A post-hoc subgroup analysis is performed by study, during which males are compared with females by statistical tests. A merge of different study data will be performed in order to evaluate safety. As post-hoc analysis all p-values are exploratory. RESULTS: The number of enrolled patients range between 238 to 1746 considering Rheumatology and Dermatology areas respectively, for a total of 3743 male and 3018 female patients. **CONCLUSIONS:** The papers and congress communications which will arise from METAGEM project will make the scientific community more aware of the importance of a gender-dedicated approach in the care of patients.

## HEALTH CARE USE & POLICY STUDIES - Drug/Device/Diagnostic Use & Policy

#### PHP11

HEALTH-ECONOMICS IN CZECH REPUBLIC: CAN FORMAL HEALTH-ECONOMIC METHODOLOGY IMPROVE THE QUALITY OF SUBMITTED ANALYSIS? Hambalek J, Spurna M, Vocelka M, Ballokova A

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OBJECTIVES: Health economic analysis (HEA) has been required since 2008 as a part of drug reimbursement applications submitted to the State Institute for Drug Control (SUKL). In 2013, SUKL introduced a formal health economic guideline, mostly based on the Czech Pharmacoenomic Society's guideline published in 2011. The aim of this study was to assess the impact of guideline implementation on the quality of submitted HEAs. METHODS: We reviewed all (18) applications for new innovative drugs with prescription limited to specialized centers, in which the final decision was issued and came into force between 1/2013-6/2014. The HEAs were described in terms of type of analysis and further confronted with a 'HEA checklist' to identify common deficiencies in submitted HEAs. All check-lists were peer-reviewed to ensure objectivity. Our results were compared with previously published research (assessing HEAs submitted in 2008-2009 before the guideline release). RESULTS: All investigated dossiers contained HEA. Nine of them (50%) were cost-effectiveness analysis (outcome expressed mostly in LYGs) and nine (50%) were cost-utility analyses (outcome in QALYs). In general, the quality of HEAs was higher compared to the previous research, with 'evidence completeness' and 'uncertainty' being the most commonly marked as 'unsatisfactory' in the HEA checklist (less than 50%). Our results showed that 1/3 HEAs fell into the 'best' category (80-100% 'satisfactory' questions), while none of HEAs fell into this category in previous research. CONCLUSIONS: The present analysis showed a trend in higher quality of submitted analyses (1/2013-6/2014) compared with years 2008-2009.

## PHP12

## PRICE COMPARISON IN THE EUROPEAN PHARMACEUTICAL MARKET Ressl S, Walter E

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**OBJECTIVES:** Due to rising health care costs, stricter governmental cost containment measures like international price comparison and external reference pricing, the European pharmaceutical markets will lead to future challenges in pricing. Despite of these prices of pharmaceuticals vary across European countries. Thus, the aim of the analysis was to draw a comprehensive picture of the pharmaceutical price levels and consumption (expenditure per capita) of pharmaceuticals in Europe. **METHODS:** The study analyzed drug prices of the outpatient setting (Rx and OTC) of all countries of the European Union except Denmark plus Switzerland.