with ADRs to oral anticoagulants. We selected data on hospital admissions due to ADRs to oral anticoagulants (ICD-9-CM code E934.2: coumarin, phenindione, heparin, prothrombin synthesis inhibitors, and warfarin sodium) from any diagnostic field during the study period. We calculated the number of hospitalizations per year, the mean length of stay, the Charlson comorbidity index, and the frequency of atrial fibrillation and thromboembolism **RESULTS:** During the study period, 50,042 patients were hospitalized because of ADRs to oral anticoagulants. The number of cases increased from 10,415 in 2010 to 13,891 in 2013. Women accounted for 52.68% of the patients, and the mean age was 79.45 (SD, 9.54) years. The conditions associated with ADRs to oral anticoagulants included atrial fibrillation (63.16%) and thromboembolism (2.45%). In 2013, the Charlson comorbidity index was >2 in 23.29% of patients. The median hospital stay was 8 days (IQR, 13), and 5,162 patients (10.32%) died during their stay in hospital **CONCLUSIONS:** The number of admissions due to ADRs to traditional oral anticoagulants in Spain increased from 2010 to 2013. Most admissions corresponded to women and elderly people. Of note, atrial fibrillation was a comorbid condition in 63.16% of patients. Appropriate management of these drugs is necessary to improve patient safety

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EVOLUTIONS IN THE PEER-REVIEW PUBLICATION LANDSCAPE AND THEIR IMPLICATIONS FOR SYSTEMATIC LITERATURE REVIEWS

Adkins E, Cadwell K, Pooley N, Fox D, Floyd D
PHMR Ltd, London, UK

OBJECTIVES: Over recent decades the requirement for transparency in data production has led to an explosion in the number of peer review publications. The aim of this research was to evaluate the extent of the literature expansion in three subject areas to highlight challenges posed for performing systematic literature reviews (SLRs). **METHODS:** Colorectal cancer, Clostridium difficile infections, and Crohn's disease were chosen as representative examples of oncology, infectious diseases, and auto-inflammatory diseases, respectively. **S**earches were performed in Medline (via OVID) to identify the size of the literature, broken down by study design and time period (1996–2000, 2001–2005, 2006–2010, 2011–2015). The strategy combined single MeSH index terms for each disease with study design search filters for SLRs, randomised controlled trials, observational studies, and diagnostic studies developed for use in Medline by SIGN (http://www.sign.ac.uk/methodology/filters.html#diag). **RESULTS:** The overall number of published studies and study design type number increased with each 5-year period. For example, in colorectal cancer, clinical trial publications increased two-fold from 2187 (1996–2000) to 4838 (2011–2015). There was a 2.5-fold increase in diagnostic study publications from 1580 (1996–2000) to 4190 (2011–2015), 3.5-fold increase in observational studies from 3298 (1996–2000) to 11554 (2011–2015), and a dramatic 13.5-fold increase in SLRs from 119 (1996–2000) to 1603 (2011–2015). **CONCLUSIONS:** As indicated by the continuing growth of SLR publications, currently there are no signs that the expansion in the literature is slowing down. In particular, publications of observational studies appear to be growing at a faster rate than clinical trials. Over the coming years there is a danger that some SLRs could become unfeasibly large (e.g. those of observational studies), and therefore we suggest how SLR protocols will need to become ever more focussed.

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MCDA APPLICATION IN CENTRAL AND EASTERN EUROPE: SELECTION OF THE MOST IMPORTANT CRITERIA BASED ON EXAMPLES

Nemeth B[1], Piniazhko O[2]
[1]*Syreon Research Institute, Budapest, Hungary,* [2]*Danylo Halytsky Lviv National Medical University, Lviv, Ukraine*

OBJECTIVES: Our study aimed to analyze the use of the different types of criteria in multiple-criteria decision analysis (MCDA) models that are being used in the decision-making process in healthcare while focusing on the potential usability in a Central and Eastern European (CEE) setting. **METHODS:** We reviewed scientific publications and official documents of existing or proposed MCDA models. We identified the criteria and assigned them into nine groups: Economics, Disease description, Intervention description, Health benefits and outcomes, Feasibility, Prevalence, Evidence quality, Social and ethical factors and Other criteria. Taking into account the results of a HTA Implementation Roadmap in Central and Eastern European Countries we aimed to select the most important criteria. Special focus was given to three sources: an MCDA that was introduced for new hospital technologies in Hungary, a published MCDA framework for orphan drugs in Poland and the recently adopted regulation on the development of a National List of Essential Medicines in Ukraine. **RESULTS:** We looked at MCDAs which are aimed to be used for Reimbursement or Investment Decisions (86%) and for Authorization Decisions (14%). Based on our research the four most common criteria mentioned in MCDAs used to support reimbursement decisions outside the CEE region were: Health benefits and outcomes (88%), Economics (80%), Social and ethical factors (76%) and Disease description (68%). Of the MCDA frameworks from CEE countries we focused on, all three considered the Health benefits and outcomes, Disease description, Economics, Social and ethical factors and Evidence. **CONCLUSIONS:** Based on our findings we suggest that the main clusters of criteria that can be the core of Central and Eastern European MCDA models are Health benefits and outcomes, Economics, Social and ethical factors and Disease description, acknowledging that MCDA models should always be adapted to the decision problem and the local settings.

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A CROSS-NATIONAL COMPARISON OF THE EFFECT OF AGE AND GENDER ON HEALTH-RELATED QUALITY OF LIFE (HRQL)

Rendas-Baum R[1], White MK[1], Kosinski M[1], Vietri J[2], Bjorner JB[1]
[1]*Optum, Lincoln, RI, USA,* [2]*Kantar Health, Horsham, PA, USA*

OBJECTIVES: Clinical studies increasingly include multinational assessments of health-related quality of life (HRQL). Age and gender effects on HRQL have been reported but studies are often in small samples of a specific condition and/or country. This study presents a cross-national comparison of age and gender effects on scores of the SF-12v2®, a widely used HRQL measure, using data from a large multinational survey. **METHODS:** Data collected in 2013 and 2014 from participants (18 to 80 years) in the National Health and Wellness Survey were used (N=311,970; US, France, Germany, Italy, Spain, and the UK). The impact of age and gender on HRQL was modelled for each year using multivariate regression with SF-12v2® physical (PCS) or mental (MCS) component score as the outcome and country, age (centered at 45) and gender as explanatory variables. **RESULTS:** Women tended to have lower PCS and MCS scores compared to men ($p<0.01$), with more pronounced differences in the majority of EU countries (PCS: 0.9 to 1.5; MCS: 1.7 to 2.9), while in the US and UK these differences were lower (PCS: 0.1 to 0.5; MCS: 0.3 to 1.4) and often not statistically significant. In the US, age had an impact on HRQL by decreasing PCS by 1.3-1.5 points and increasing MCS by 1.6-2.0 points, with every 10 year increment; statistically significant differences between countries generally indicated small deviations from these values, representing an additional 0.25 decrement in PCS and 0.40 in MCS, on average. **CONCLUSIONS:** This large broad-based study consistently showed significant impacts of age and gender on HRQL, with greater differences on mental health compared to physical health. Variation in the magnitude of these effects tended to be small across countries and consistent across years. This study presents robust findings on the need to apply age and gender adjustments when comparing HRQL scores.

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EQ-5D STUDIES IN NERVOUS SYSTEM DISEASES IN EIGHT CENTRAL AND EASTERN EUROPEAN COUNTRIES

Prevolnik Rupel V[1], Turk E[2], Péntek M[3], Rencz F[3], Golicki D[4], Simon J[5], Brodszky V[3], Baji P[3], Zrubka Z[3], Zavada J[6], Petrova G[7], Rotar A[8], Gulacsi L[3]
[1]*Institute for Economic Research, Ljubljana, Slovenia,* [2]*DNV GL, Hovik, Norway,* [3]*Corvinus University of Budapest, Budapest, Hungary,* [4]*Department of Experimental & Clinical Pharmacology, Medical University of Warsaw, Warsaw, Poland,* [5]*Medical University of Vienna, Vienna, Austria,* [6]*Institute of Rheumatology, Prague, Czech Republic,* [7]*Medical University Sofia, Faculty of Pharmacy, and President, ISPOR Bulgaria Chapter, Sofia, Bulgaria,* [8]*University of Amsterdam, Amsterdam, The Netherlands*

OBJECTIVES: Guidelines for economic analyses of health care technologies require local input data for reimbursement decisions in the Central and Eastern European (CEE) countries. The aim of our study was to systematically review and analyse the available EQ-5D literature in neurology, a clinical area with increasing economic importance. **METHODS:** To identify studies using EQ-5D a systematic literature search was performed using PubMed, EMBASE, Web of Science, CINAHL, PsycINFO, The Cochrane Library and the EuroQol Group database up to July 1, 2015. Local journals were handsearched. The countries included were Austria, Bulgaria, Czech Republic, Hungary, Poland, Romania, Slovakia and Slovenia. Original articles reporting nervous system diseases studies including EQ-5D were analysed by systematic data extraction. **RESULTS:** 143 papers altogether were found in the search, out of which 24 dealt with the diseases of the nervous systems, out of which 12 (50%) were in English. The first study was launched in 1999. Most studies were from Hungary (54%) and none from Bulgaria, Romania and Slovakia. A total of 7834 patients were involved (n=patients/studies: Parkinson's disease 823/9; multiple sclerosis-MS 6300/8; neuropathy 325/2; dystonia 40/1; essential tremor 24/1; Duchenne muscular dystrophy 64/1; epilepsy 100/1 and carpal tunnel syndrome 158/1) in 11 cohorts, 10 cross-sectional studies and 3 other studies. Only 1 study used EQ-5D-5L. EQ-5D utility scores were reported in 18 (75%) papers but the tariff used was not specified in 10. Mean EQ VAS (n=16, 67%) was the lowest in MS and secondary dystonia (32 and 30, respectively). **CONCLUSIONS:** EQ-5D research activity in neurology has been increasing through the years in some CEE countries, but is still absent in others. Data from clinical areas with significant social burden such as migraine or Huntington's disease are lacking. Transferability studies, specific targeted research and strengthening of regional collaboration among neurology centres are encouraged.

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HOW TO SELECT THE BEST COMPARATOR? AN INTERNATIONAL ECONOMIC EVALUATION GUIDELINES COMPARISON

Ziouani S[1], Granados D[2], Borget I[1]
[1]*Univ Paris-Sud, Faculty of Pharmacy, GRADES, Châtenay-Malabry, France,* [2]*Janssen, Issy-les-Moulineaux, France*

Cost Effectiveness Analyses (CEA, including cost-effectiveness and cost-utility evaluations) need to respect international methodological guidelines to provide reliable information in different countries. Cost-effectiveness is a relative concept so if the comparator is inappropriate, then the results will be unsuitable for decision-making purposes. Therefore, one of the most important structural choices of a CEA is the comparator choice.**OBJECTIVES:** The objective of this study was to identify a standard way to define the most appropriate comparators in a CEA according to international guidelines. **METHODS:** We analyzed 29 country-specific economic evaluation guidelines available online, in Chinese, Dutch, English, Portuguese and Spanish, on the ISPOR website section, "Pharmacoeconomic Guidelines around the World" in June 2016. The parts related to the comparator choice were identified by the words "comparator", "compare", "alternatives", and "intervention". The most frequently advised ways to define the appropriate comparators were identified. **RESULTS:** In the 29 countries, the most commonly used comparator was the "standard of care for local practice" (86%). The "watchful waiting or doing nothing" possibility was advised to consider in 45% (N=13) of the guidelines. The "therapy that prescribers would most replace with the proposed drug" was cited to be a good comparator in 38% (N=11) of the guidelines. The "lowest cost alternative" was a comparator of choice in 24% (N=7) of the guidelines. "Unauthorized drug" (i.e. no marketing authorization) used in clinical practice was to consider according to 21% (N=6) of the guidelines. **CONCLUSIONS:** Even if the most commonly advised comparator was the "standard of care for local practice", heterogeneity in the definition of a relevant comparator to consider for a CEA was identified among countries. Further analyses