index stay and main comorbidities. A cox and a Poisson models were used to estimate the increase risk of death while adjusting on the PS. Sensitivity analyses were performed to explore the robustness of the results. **RESULTS:** Data from 482 ICD and 964 PS matched controls were extracted. The 2 groups were very similar when compared with the variables used to calculate the PS. Significant increase of death rates was found in CDI patients with HRs of 1.65 (CI95%=[1.33;2.04]) unadjusted and 1.58 (CI95%=[1.27;1.97]) adjusted on PS. The PS adjusted RRs were 1.78 (CI95%=[1.18;2.70]) at 28 days, 1.52 (CI95%=[1.17;1.98]) at 3 months, 1.52 (CI95%=[1.20;1.93]) at 6 months and 1.64 (CI95%=[1.32;2.03]) at 12 months. Sensitivity analyses were performed and lead to similar result : patients for whom the CDI infection was coded as the main diagnosis (HR=1.90 (CI95%=[1.27;2.86]) ; Matched controls hospitalized for a disease with diarrhea (HR=1.44 (CI95%=[1.15;1.79])) ; Patients not rehospitalized for CDI after the index stay (HR=1.73 (CI95%=[1.37;2.18])). **CONCLUSIONS:** CDI infection leads to a significant one year increase of death rate when compared to similar patients in terms of age, gender, comorbidities and length of stay.

DB2

A RETROSPECTIVE STUDY ON ASSOCIATION BETWEEN CHANGE IN BMI AND INCIDENCE OF HYPERTENSION USING A HEALTH CARE DATABASE IN JAPAN

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OBJECTIVES: Association between change in BMI over a 1-year period and the incidence of hypertension was examined based on real-world data in Japan. This was a sub-study of the main study which was reported previously (ISPOR Europe, 2015). **METHODS:** This was a retrospective study using a database composed of annual health checkup and claims data (MinaCare Co., Ltd.). A subset of subjects of the main study was selected for this study, which was those with at least 1 year of record prior to 2011, non-missing blood pressure (BP) and body mass index (BMI) values in both years (2011/Baseline, 2012), and aged≥20 years at the 2011 checkup. Diagnosis of hypertension was based on either SBP≥140mmHg/DBP≥90mmHg or prescription of antihypertensive medications based on physician diagnosis (ICD-10 codes I10-I15) within 1 year prior to checkup. **RESULTS:** A total of 251,043 subjects [Female 27.0%; Age 44.0/11.4 (mean/SD); diagnosis of hypertension (HTN) at baseline 18.7%] were analyzed. At baseline, the mean BMI across the age categories ranged between 20.7~22.3 for females and 22.7~24.1 for males. Mean percent change in BMI from 2011 to 2012 decreased with increasing age category for both sexes. Among those without HTN at baseline, the odds of HTN in 2012 increased with increasing BMI change categories for both sexes, after controlling for age, baseline BMI, baseline BP, and 2-way interactions. The association was stronger for males compared to females with the odds-ratio (95%CI) of 0.662 (0.607~0.721), 0.774 (0.719~0.832), 1.284 (1.211~1.362), 1.764 (1.651~1.885) for %BMI change category of ≤-1%, -1%~-0.5%, 0.5%~1%, ≥1%, respectively, where no change (-0.5%~+0.5%) was the reference. **CONCLUSIONS:** Incidence of HTN was positively associated with increasing level of change in BMI over the 1-year period, even after controlling for baseline BMI, BP and other factors. This suggests that controlling weight has impact on HTN even over a short period.

DB3

ACCURACY OF NATURAL LANGUAGE PROCESSING-BASED CLASSIFIERS FOR AUTOMATED IDENTIFICATION OF ABSTRACTS OF STUDIES ON HUMANISTIC AND ECONOMIC BURDEN OF DISEASE

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OBJECTIVES: To determine the sensitivity and specificity of software based on natural language processing to classify PubMed abstracts relevant to the humanistic or economic burden of disease. **METHODS:** We developed an online database of abstracts of over 100,000 studies identified by a systematic search of PubMed on the humanistic and economic burden of disease (www.heoro.com). We manually indexed 10,000 abstracts to one or more study types: PRO study (with subtypes PRO validation study and Utility study), Costs and Resource use studies (Direct and indirect costs, resource use, treatment patterns and adherence), Economic models (cost-effectiveness, cost-utility, cost-benefit and other models) and mortality, as well as geographical location. We used this training set and expert assessment to iteratively develop classifiers from text, MeSH headings and metadata in the abstracts. We then assessed the accuracy of the classifiers on samples of the remaining 90,000 abstracts by expert checking of 200 abstracts scoring positive and 400 negative for each study subtype. **RESULTS:** The classifiers had a sensitivity and specificity of 96% for PRO study identification, sensitivity of 87 to 99% and specificity of 93 to 100% for economic model types, sensitivity of 79 to 99% and specificity of 92 to 98% for costs and resource use study subtypes, and sensitivity of 82% and specificity of 97% for mortality studies. They also identified randomised controlled trials and systematic reviews with 93-95% sensitivity and 99% specificity. Indexing to geographical location was 97% accurate in an analysis of 200 abstracts. **CONCLUSIONS:** With overall accuracy of around 95%, the classifiers compare well with human indexing of study types. As 90,000 abstracts could be indexed accurately within hours, this method facilitates a highly streamlined approach to identifying relevant data for health economics and outcomes research.

DB4

USE OF DATA-MINING TO PERFORM A REAL WORLD COST ANALYSIS OF HER2-POSITIVE BREAST CANCER IN IRAN

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OBJECTIVES: Patient registries play an important role in obtaining real-world evidence of the cost-effectiveness of treatments. However, their implementation is costly and sometimes infeasible in many middle-income countries (MICs). We explored the combination of data-mining and a large claims database to estimate the direct medical costs of HER2-positive breast cancer (BC) treatment in Iran and the fraction of total costs from trastuzumab use. **METHODS:** Data from 21/03/2011-20/03/2014 were examined using data-mining to determine clinical stages. R-based classification algorithms were designed based on medication patterns including drug combinations and/or sequences of drugs in respect of three index dates (early, loco-regional and advanced BC). These algorithms were then validated using patient dossiers from the Cancer Institute of Iran and used to analyze claims data from the Iran Social Security Organization, a health insurer which covers approximately 50% of all Iranians (~40 million). A healthcare perspective was used to calculate the absolute and relative costs of medical services. **RESULTS:** With an 84% (43/51) accuracy rate, 1,295 patients were identified and divided into three BC stages (early (n=802), loco-regional (n=125), advanced (n=218); some patients were categorized into >1 stage (n=177), none (n=284) due to insufficient information, while some were excluded (n=54) due to incomplete follow-up). Mean age per stage was 45, 46 and 48 years, respectively, while mean follow-up in all stages was approximately one year. Average costs of direct medical care in early, loco-regional and advanced stages were €11,796 (95%CI:€9,356-€12,498), €8,253 (95%CI:€6,843-€10,002) and €17,742 (95%CI:€15,720-€19,505), respectively. **CONCLUSIONS:** When comprehensive patient registries are infeasible or costly, validated data-mining algorithms can support real-world cost-effectiveness analyses in MICs and thereby help to optimize reimbursement decisions. The accuracy of data-mining would be improved, if electronic reports of diagnostic tests were generated and included in the classification algorithms as well.

HEALTH CARE EXPENDITURE & REIMBURSEMENT STUDIES

HC1

MODELING THE IMPACT OF REFORM TO THE CANCER DRUGS FUND

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OBJECTIVES: The Cancer Drugs Fund (CDF) was created in 2010 to pay for oncology indications that were not approved by the National Institute for Health and Care Excellence (NICE) and were not routinely available within the NHS in England. After a consultation process, it was agreed that from July 2016, NICE will appraise all new licenced cancer indications and decide whether they are eligible for inclusion in the CDF, which will become a 'managed access fund' This research estimates the number of current CDF indications that may be eligible for the new CDF following its reform. **METHODS:** As of November 2015, there were 48 medicines/indications on the CDF. Information on these products was combined with data from historical NICE technology appraisals (TAs), published October 2007-December 2015, and from other sources. We used a simple set of rules to predict the funding category to which each indication would be assigned: (1) funded for routine commissioning; (2) funded on the new CDF for a limited period; and (3) not funded. **RESULTS:** Of the 48 current CDF medicines/indications, 3 (6%) were likely to receive positive NICE appraisal and therefore enter routine commissioning, and 67% (n=32/48) were judged to fall into the 'not funded' category. The remaining 13 may have the potential to be funded temporarily through the new CDF. **CONCLUSIONS:** This research suggests that the recent reform to the CDF may lead to a substantial decline in the number of cancer medicines available to patients in England. However, it remains to be seen exactly how NICE Appraisal Committees will interpret the new guidance, and the nature of the managed access contracts and data collection processes that will be forged between manufacturers and NHS England.

HC2

ECONOMIC BURDEN OF DISEASES IN FRANCE: ANALYSING THE TRENDS FROM 2012 TO 2014, USING THE FRENCH HEALTH INSURANCE DATABASE (SNIIRAM)

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OBJECTIVES: The aim of this study is to assess and analyze health care expenditure trends by disease between 2012 and 2014, based on a top-down allocation of expenditure using the French health insurance database. **METHODS:** Using information about 56 millions of individuals from the general scheme insurance database (86% of the French population), we identified all people who received care for each of 57 groups of diseases or medical events or treatments, which are frequent, severe and/or costly. Algorithms have been applied to each patient, using ICD-10 diagnoses for long-term chronic diseases or hospital stays, specific drugs or medical procedures. Annual costs of all reimbursed expenditures (outpatient/inpatient care, disability/sickness benefits) were extracted per individual. A top-down method was used to allocate expenditure to each of the 57 diseases based on the average expenditure by disease calculated for individuals with only one disease. This was done for 2012, 2013 and 2014 in order to analyze trends. **RESULTS:** In 2014, among the 155 billion euros of expenditures (all insurance schemes), 33.9 billion were related to isolated hospitalizations with an average annual growth rate of 2%, 22.6 billion to psychiatric disorders and treatments (+1.8%/year), 16.1 to cancer (+3.6%/year), 16.2 to cardiovascular diseases (+.3.1%/year), 7.9 to diabetes (+2.6%/year), 6.9 to neurologic disorders (+3.6%%/year). The highest increase was observed for Liver/pancreas diseases, essentially due to hepatitis C drugs: +864 million € compared to 2012, giving a total of 2.3 billion € in 2014. A more detailed analysis of expenditures by diseases and of main cost drivers will also be presented. **CONCLUSIONS:** Our study provides helpful information to policy makers by monitoring the performance of the health care system at a disease-based level. This tool can also be used to forecast the impact of ageing and epidemiologic patterns on health expenditures.

HC3

THE RELATIONSHIP BETWEEN MEDICAL INNOVATION AND HEALTH EXPENDITURES

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OBJECTIVES: It is widely accepted that medical innovation includes many costly activities, and that it is a key driver of rising health care expenditures. Understanding the relationship between medical innovation and health care expenditures is critical for health policy makers to effectively make resource allocation decisions. This study seeks to investigate the relationship between medical innovation and health care expenditures. **METHODS:** We assessed data from the World Intellectual Property Organization and World Bank statistics for the year 2014, which included data from 72 countries. The number of patent publications in the categories of medical technology, biotechnology, and pharmaceuticals were included as medical innovation indicators; public heath, health care costs per capita, and total health care costs (percentage of gross domestic product [GDP]) were included as indicators of health care-related expenditures. A canonic correlation analysis (CCA) was performed to examine the degree of association between the sets of medical innovation and health care expenditure variables. **RESULTS:** Study results indicate that there is a strong positive correlation between medical innovation and health care expenditure variables (rc= 0.68, p<0.001). **CONCLUSIONS:** In light of this study, health policy makers should manage the relationship between medical innovation and health care expenditures with a focus on accessibility. Improved communication channels in the social system, increased international cooperation, and the determination of a proper balance between the benefits and costs of innovation may help to continue improving medical innovation and enhance health care accessibility. We hope that the study results offer an increased awareness of the relationship and balance between innovation and expenditure, and will help to create an improved health system.

HC4
COMPARISON OF TIME TO REIMBURSEMENT DECISION OF INNOVATIVE PHARMACEUTICALS IN EUROPE
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OBJECTIVES: Knowledge is limited concerning the differences in time-to-decision between marketing authorisation and reimbursement evaluations, and the likelihood of acceptance (and order) for various types of innovative drugs across European countries. In the present study, the decision-making process was evaluated, from EMA approval to reimbursement decisions, in 4 European countries (UK, Scotland, Germany, and France) for innovative drugs (oncology, biological, and orphan drugs). Time-to-decision between EMA approval, HTA dossier submission, and reimbursement recommendation were analysed and compared. Subsequently, we assessed the order of acceptance (i.e., positive decision) across countries and the likelihood of a positive reimbursement decision by drug type after EMA approval. **METHODS:** All innovative drugs approved by EMA between 2010 and 2016 were selected. A database was created containing the dates of EMA approval, HTA dossier submission and reimbursement decisions by the HTA agencies and the actual decision (yes/no). Median time-to-decision was calculated per innovative drug/country. Decision dates, order of approval, and the likelihood for a positive recommendation were analysed and compared at certain time frames using Kaplan-Meier curves. **RESULTS:** In total, 85 drug evaluations were included (52% oncology, 27% biological, and 21% orphan drugs). Median time from market approval until reimbursement decision was 14.5 months. Time to reimbursement decision for orphan drugs was shorter (12.8 months) compared to oncology (14.8 months), and biological drugs (15.3 months). The French agency pioneered reimbursement decisions in 46% of the cases, followed by Scotland (34%; all corrected by number of decisions per country). **CONCLUSIONS:** These results indicate that orphan drugs may receive a reimbursement approval earlier than oncology or biological drugs. The French agency seem to take a leading role in reimbursement decisions. Factors that influence this decision-making process need to be further studied to enhance the understanding of reimbursement trends in innovative products across countries.

BREAKOUTS – SESSION VIII

MEDICAL DEVICE & DIAGNOSTIC RESEARCH STUDIES

MD1
MEDICAL DEVICES: TIMELY ACCESS AND REIMBURSEMENT - CAN NATIONAL HEALTH TECHNOLOGY ASSESSMENT BODIES BE PART OF THE SOLUTION?
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OBJECTIVES: Medical devices are typically reimbursed distinctly to pharmaceuticals due to their relatively greater number, lower cost, shorter life-cycles, and greater difficulties in conducting randomized trials. Most new devices are reimbursed under existing Diagnosis-related Group (DRG) codes but for new higher-cost innovations, reimbursement may be insufficient. Various discretionary funding mechanisms can temporarily reimburse a new device until/if a new DRG code is developed. Prices of medical devices are typically negotiated between hospitals and companies. Such processes can result in significant geographical variation and delays in access. In 2010, the National Institute for Health and Care Excellence (NICE) set up a program (Medical Technologies Evaluation Program [MTEP]) for the appraisal of new/innovative medical devices with claimed patient benefits. This research analyses all MTEP guidance and discusses the optimal role of national payers in device reimbursement. **METHODS:** All publically-available NICE MTEP guidance was screened and key information extracted to 17/06/2016. **RESULTS:** 29 appraisals were identified (annual average: 5.4: 2016 (2), 2015 (5), 2014 (6), 2013 (5), 2012 (3), 2011 (7), 2010 (1)) including cardiovascular (9), general surgery (6), dermatology (4), urology (3), orthopedics (2) and other indications (5). 79% (23/29) were positive recommendations; 96% (22/23) of which included cost-saving claims, with the sole exception being based on comparable resource utilization. Nevertheless, for the 6 not recommended appraisals, the level of clinical evidence was cited as key. **CONCLUSIONS:** To date, relatively few devices have been appraised under MTEP. Outcomes have been mostly positive but, unlike Technology Appraisal Guidance, MTEP guidance is non-binding. Importantly, being cost-saving is a criteria for consideration under MTEP, precluding inclusion of high-cost innovative technologies for which timely access may be particularly challenging. France has a national assessment body (CNEDiMTS) targeted to the appraisal of new/innovative medical technologies, which may form a better model for involvement of national appraisal bodies in device reimbursement.

MD2
TOWARDS IMPROVED CERVICAL CANCER PRIMARY SCREENING IN AUSTRIA - A DECISION-ANALYTIC BENEFIT-HARM ANALYSIS
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OBJECTIVES: To systematically evaluate the benefit-harm trade-off of different cervical cancer primary screening strategies for the Austrian context. **METHODS:** A Markov-state-transition model was applied to evaluate different screening strategies that differ by primary test (cytology, p16/Ki-67-testing, and HPV-testing alone or in combinations), screening interval, age, and follow-up algorithms for test-positive women. We used Austrian clinical and epidemiological data, along with test accuracy data from international meta-analyses and trials. Predicted outcomes were reduction in cervical cancer incidence/-mortality, overtreatment (defined as conization with histological diagnosis of no lesion or a lesion grade CIN1), and incremental harm-benefit ratios (IHBR) measured in numbers of additional overtreatments per prevented cervical cancer death. Comprehensive sensitivity analyses were performed. **RESULTS:** Based on our results, HPV primary screening strategies are more effective compared with cytology or p16/Ki-67-testing alone. Adopting risk-based follow-up algorithms including p16/Ki-67-triage for women with ASCUS/LSIL and colposcopy referral for women with HSIL/p16/Ki-67-positivity can reduce overtreatment. In the base-case analysis (31-43% screening adherence in women below 60 years of age), biennial HPV-based screening achieved an acceptable benefit-harm balance (IHBR: 45 overtreatments per prevented cancer death). Annual screening strategies resulted in much higher IHBRs of 131-355 overtreatments per prevented cancer death. However, the optimal choice of screening depends on a woman's individual benefit-harm trade-off threshold. Based on the IHBRs, the screening interval may be extended to three years in populations with screening adherence of 40%-60% and to 5 years with higher adherence rates. Varying the age at screening initiation from 18 to 24 years reduced overtreatment without significant loss in effectiveness. **CONCLUSIONS:** Based on our analysis, HPV-based screening in women 30 years or older and cytology in younger women at screening intervals of at least 2 years incorporating a risk-based follow-up algorithm can be recommended for the Austrian screening setting. Screening should be initiated in women of the age 20-24 years.

MD3
ADOPTION OF TRANSCATHETER MITRAL VALVE REPAIR IN GERMANY: UTILIZATION PATTERNS AND CASE VOLUMES COMPARED TO MITRAL VALVE SURGERY IN THE PERIOD 2010-2014
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OBJECTIVES: The German healthcare system was among the first markets to introduce transcatheter mitral valve repair (TMVR) in routine care for patients suffering from mitral valve insufficiency. Our objective was to estimate the impact of TMVR availability on overall mitral valve repair volumes and competing therapies in this real-world setting. **METHODS:** Therapy- and age-specific procedure volumes were collected from German Federal Statistics Office databases for TMVR and mitral valve surgery for the period 2010 through 2014. We computed therapy-specific and total procedure volumes and growth stratified by age groups <65, 65-74, 75-84, and >85 years, and in total. **RESULTS:** In the time period 2010 to 2014 overall procedure volumes grew from 17,521 to 24,033 (+37%). This growth was driven by both TMVR (508 to 3,715; +631%) and surgical procedure growth (17,013 to 20,318; +19%). The share of TMVR as percent of total procedures grew from 2.9% to 15.5% over the 5-year period. In 2014, TMVR use reached 4%, 13%, 26%, and 68% in the studied age groups. Absolute TMVR procedure growth was highest in age group 75-84 years (+1,606). Concurrently, surgical volumes grew in all age groups, except for age >85 years, with the highest absolute growth in younger patients (+2,079 in age group <65 years). **CONCLUSIONS:** The availability of TMVR has contributed to pronounced growth in mitral valve repair in Germany, specifically in elderly populations previously left untreated. At the same time, surgical procedure volumes continued to grow substantially in the study period in all age segments, except for the group of very elderly patients.

MD4
DECISION UNCERTAINTY AND THE NEED FOR FURTHER RESEARCH: A CASE STUDY IN FENESTRATED ENDOVASCULAR ANEURYSM REPAIR FOR COMPLEX ABDOMINAL AORTIC ANEURYSMS
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