for the delay in indexing of publications, we included all studies with a publication date of 2014 that were indexed in PubMed up to 1 June 2015. **RESULTS:** The search identified 1,870 articles published in 2014. Of these, 975 met the inclusion criteria and were subcategorised according to topic. The greatest number, 13%, were conducted in patients with cardiovascular diseases, with 11% in musculoskeletal disorders, 10% each in cancer and digestive disorders, 8% in mental health disorders, 7% each in infective disease or acute care, and 6% each in respiratory, endocrine and urogenital disorders, and in general populations or healthcare settings. All other disease areas were relatively underrepresented, accounting for 2% or fewer of the relevant publications. **CONCLUSIONS:** Despite product pipelines being weighted towards new cancer drugs and the challenges in demonstrating their cost-effectiveness, cancers are relatively under-represented in recent studies assessing economic burden. The reasons why costs may be less important an outcome in cancer than in cardiovascular or musculoskeletal diseases are unclear, but may reflect a more established, often generic or surgical, therapeutic portfolio.

PHP107

SYSTEMATIC REVIEW OF COST EFFECTIVENESS OF ULTRA-ORPHAN THERAPIES

Aggarwal S[1], Topaloglu H[1], Kumar S[2]
[1]*NOVEL Health Strategies, Chevy Chase, MD, USA,* [2]*GLOBAL ACCESS Monitor, Bethesda, MD, USA*

OBJECTIVES: Ultra orphan therapies are indicated for rare diseases affecting less than a few thousand patients. The annual and lifetime per patient cost of these treatments have generated controversy and policy questions regarding cost effectiveness and reimbursement. The objective of this analysis was to review all available cost effectiveness studies and develop lessons for policy development for ultra orphan therapies. **METHODS:** Fifteen European Medicines Agency (EMA) and Food and Drug Administration (FDA) approved ultra orphan drugs were identified and reviewed for their published cost effectiveness through studies in peer-reviewed journals and Health Technology Assessments (HTAs). Data was collected for: (1) Product (2) Indication (3) Model design and assumptions (4) Author of the analysis (manufacturer, HTA or academic group) (5) Cost effectiveness results and (5) Sensitivity analysis results. All cost effectiveness ratios were converted to 2013 US dollar amounts using historical currency conversion rates. **RESULTS:** For fifteen EMA and FDA approved ultra orphan therapies, eight cost effectiveness studies were identified for seven products (50%). Four of these studies were conducted by the sponsor (as part of the HTA submission), two were conducted by HTAs and two were from academic groups. All models were developed for a life time horizon. In the base case scenario, the median base case incremental cost effectiveness ratio (ICER) was $591,200 per quality adjusted life years (QALYs) (range: $391,120 to $7,425,000). The sensitivity analyses results had a median ICER of $1,958,674 per QALY, with a maximum ICER of $10,395,000. All reported ICERs exceeded the maximum accepted thresholds for end of life care therapies. **CONCLUSIONS:** Review of cost effectiveness studies for ultra orphan therapies shows that none were able to show ICERs within typical thresholds. These results suggest a need for new policy regarding acceptable threshold, or type of models for assessing the cost effectiveness of ultra orphan therapies.

PHP108

OFF-PATENT DRUGS CONSUMPTION AND EXPENDITURES IN ITALY: 2009-2013

Daniel F[1], Aiello A[1], D'Ausilio A[1], Toumi M[2]
[1]*Creativ Ceutical, Milano, Italy,* [2]*Université Aix Marseilles, Marseilles, France*

OBJECTIVES: As in most European countries, spending on pharmaceuticals has also been cut in recent years in Italy through a series of measures, including price reduction and boosting of off-patent drugs prescription. Laws 338/2000 and 405/2001 incentivised the use of generic drugs and introduced patients' co-payment if they preferred a branded vs off-patent drug. The aim of this study was to analyse the consumption and expenditure trend for off-patent drugs in Italy since the introduction of these new measures. **METHODS:** Off-patent (branded and unbranded) drug consumption and expenditure indicators from 2004 (first year in which net expenditure was available) to 2013 (last available year) were analysed from the Observatory on the Use of Medicines (OSMED) published reports. **RESULTS:** In 2004 consumption by defined daily dose (DDD) per 1,000 habitants was 166.8 (21.7% on total DDD), while in 2013, it was 663.0 (64.3% on total DDD) for territorial drugs. Per-capita expenditure was €22 (10.1% of net territorial expenditures) in 2004 and €62.4 in 2013 (41.5% of net territorial expenditure). Such results were mainly due to the higher number of off-patent drugs available on the market and not only to increased use of generic drugs. In 2004, the percentage of unbranded drugs was 1.9% and raised until 14.9% in 2013. Despite such growth, Italy was in 2013 the third European country (behind Greece and Ireland) for expenditure on branded drugs, with a very low uptake vs Germany, France, Spain and UK showing an incidence of generic territorial drug expenditure between 30 and 40%. **CONCLUSIONS:** Consumption and expenditure on off-patent drugs has increased in the last 10 years in Italy, however the unbranded drugs uptake is still very low when compared with other European countries.

PHP109

HOW PHARMACEUTICAL COST INDICATORS ARE AFFECTED WHEN ADJUSTED TO HOSPITALS' CLINICAL WORKLOAD: DATA ANALYSIS FOR GREEK NHS HOSPITALS

Christodoulakis A[1], Karanikas H[2], Billiris A[1], Thireos E[3]
[1]*Datamed SA, Athens, Greece,* [2]*University of Athens, Athens, Greece,* [3]*Athens Medical Society, Athens, Greece*

OBJECTIVES: To examine how hospitals' pharmaceutical cost changes when clinical workload indicators are incorporated in the measurement and provide corrective estimates to the comparative performance assessment of the MoH for Greek NHS hospitals, for 2013. **METHODS:** The study includes annual detailed financial and operational data, as recorded by the MoH's BI system, ESY.net, and analytical data on the type of incidents (based on GR-DRGs) recorded, for 129 Greek NHS hospitals. Several KPIs were examined, but the study focuses on the mean pharmaceutical cost per patient, which was then adjusted to the case mix of the units, by using a hospital clinical weight indicator, estimated as the weighted average of particular incidents, based on GR-DRG data. The results were statistically analysed, in order to group the changes, before and after the indicator's adjustment, per hospital size category and assess hospitals' relative ranking. **RESULTS:** The results reveal that there was a significant -but diminishing as the bed number increases- rise in the mean pharmaceutical cost per patient for three categories (25.49%, 14.23%, 11.74% increase for hospitals with less than 100, 101-250 and 251-400 beds, respectively) after the indicator was adjusted to the hospitals' clinical workload. For hospitals with more than 400 beds, the mean pharmaceutical cost per patient decreased by 15.38%, after the adjustment. The results also indicate significant changes in hospital ranking, even within the 4 categories, ranging from a 34 places ranking rise for Onassis Cardiac Surgery Centre, to a 21 places ranking drop for the G.H. of Thessaloniki 'Agios Dimitrios'. **CONCLUSIONS:** Hospitals with more severe than average incidents, (cancer hospitals, cardiac surgery centres, etc) improved their performance and relative ranking, while small health centres and regional hospitals reported worse results after the indicators' adjustment. The study concludes that clinical workload should be incorporated in hospitals' pharmaceutical cost assessment.

PHP110

ECONOMIC EVALUATION OF FIBRIN SEALANT PATCH: A PROPOSAL TO ASSESS THE ECONOMIC VALUE IN HEMOSTASIS AND AS A SURGICAL SEALANT

Colombo GL[1], Caruggi M[2], Ottolini C[3], Di Matteo S[4], Valentino MC[4], Bruno GM[4]
[1]*University of Pavia, Milan, Italy,* [2]*Azienda Ospedaliera Ospedale di Circolo di Busto Arsizio, Busto Arsizio, Italy,* [3]*Azienda Ospedaliera Sant'Antonio Abate di Gallarate, Gallarate, Italy,* [4]*S.A.V.E. Studi - Health Economics & Outcomes Research, Milan, Italy*

OBJECTIVES: The objective of this work is to set a cost benefit analysis of the use of fibrin sealant patch as supportive treatment in surgery for improvement of hemostasis, to promote tissue sealing and for suture support in surgery in those cases where standard techniques are not adequate. **METHODS:** Efficacy data were obtained from a systematic literature review. The analysis of the costs of hospitalization was conducted on the basis of detection of actual costs, observed from the point of view of the hospital. We performed a cost benefit analysis of the use of fibrin sealant patch valuing the hospitalization and the consequent use of resources. The results of the economic evaluation were subjected to sensitivity analysis, building a stochastic simulation with 1000 repetitions within a normal distribution. **RESULTS:** In the group of patients treated with fibrin sealant patch it was observed the decrease of the duration of hospitalization vs. the group of patients treated with standard techniques: on average 2.66 days, within a range between 0.55 and 11.80 days. The cost per day of hospitalization was estimated at Euro 206.00: this led to a saving in terms of lower costs for the hospital, quantifiable in 549 Euro, from a minimum of 103 Euro and a maximum of 2431 Euro. The use of fibrin sealant patch led then an average savings of about 304.00 Euro per patient with a cost-benefit ratio equal to 2.24 (min. 00.42 - max. 9.93). Overall the results of the sensitivity statistics confirm a lower length of stay associated with fibrin sealant patch than standard care. **CONCLUSIONS:** The analysis shows the positive role of fibrin sealant patch as supportive treatment in surgery where standard techniques are revealed not adequate, with decreased postoperative complications, shorter hospital stays and reducing hospital costs.

PHP111

SYSTEMATIC REVIEW OF ECONOMIC EVALUATIONS IN PERSONALIZED MEDICINE

Lachaine J, Bibeau J, Mathurin K, Miron A, Beauchemin C, Benmouhoub I, Bouchama N, Castonguay A, Charron J, Enckle G I, Lambert-Obry V, Lapierre M, Piché-Richard V
University of Montreal, Montreal, QC, Canada

OBJECTIVES: Personalized medicine (PM) consists of a customized approach considering individual biological and genetic characteristics to prevent, diagnose or treat a medical condition. Although health benefits of PM have been demonstrated, its economic impact is not established. The aim of this review was to explore its cost-effectiveness and summarize the key parameters in every therapeutically health areas. **METHODS:** A systematic review of economic evaluations was performed using the PICO method. Population consisted of patients who might benefit from PM; intervention and comparators were PM and usual care and outcomes were results of economic evaluations. The literature search was performed with the NHS EED filters using Medline, Embase and Pubmed from 2004 to 2014. Eligible articles were economic evaluations, with preventive, diagnostic or therapeutic interventions in PM. **RESULTS:** A total of 76,488 studies were identified and 213 met the inclusion criteria. Cost-utility studies were the most frequent (60.1%), followed by cost-effectiveness studies (32.1%) with a healthcare-payer perspective (67.9%). Time horizon varied between 28 days and lifetime. Cancer was the most evaluated therapeutic field (46.9%) followed by cardiovascular diseases (19.2%) and neurologic and psychological diseases (10.3%). A total of 39.9% of the studies were conducted in the United States. Adjusted 2015USD ICERs varied from dominant to $9,780759 per quality adjusted life year (QALY). Among these, 44% have an ICER of $50,000/QALY or less, while 57% have an ICER of $100,000/QALY or less. Overall, a total of 147 studies compared their ICER to the reference threshold established by their country. Among the ICERs presented, 60.2% were reported as cost-effective (15.3% were dominant) and 39.8% non cost-effective. **CONCLUSIONS:** Despite a high heterogeneity among the studies, most of them suggest that personalized medicine could be cost-effective.

PHP112

ROLE OF PHARMACOECONOMIC ANALYSIS IN PRICING DECISION IN JAPAN

Ikeda S[1], Murata T[2], Kobayashi M[2]
[1]*International University of Health and Welfare, Ohtawara City, Japan,* [2]*CRECON Medical Assessment Inc., Tokyo, Japan*