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Objectives: Chronic kidney disease (CKD) is a growing public health issue worldwide. Erythropoiesis stimulating agents (ESAs) are used to treat CKD-related anemia, contributing to CKD management costs. However, 20-30% of ESA costs can be reduced using biosimilars. Our objective was to investigate direct healthcare costs of CKD patients treated with originator or biosimilar ESAs and potential savings achievable by increasing use of biosimilars. ***Methods:*** A multi-center, retrospective (2009-2014), cohort study was conducted using claims databases of five large geographic areas in Italy (8 million residents). Incident CKD-ESA users with at least 1-year ESA use, were included in the study. Yearly mean/patient direct healthcare costs were estimated, by CKD stage. Total annual cost and potential savings due to ESA use were estimated considering 25%, 50% and 75% of ESA substitution with biosimilar epo-alpha. ***Results:*** During the study period 7,810 CKD patients started ESA treatment (epo-alfa reference product: 1,139, 14.6%; epo-alfa biosimilars: 1,204, 15.4%; other still patented ESAs: 5,467, 70.0%). Of these, 2,921 (37.4%) had information on CKD stage (I-III: 40%; IV-V: 27%; dialysis: 33%). ESA-related annual mean cost/patient represented 17% (€1,551; 95% Confidence Interval €1,471-€1,631) of total cost/year in stage I-III, decreasing to 13% (€1,493; €1,413-€1,573) in stage IV-V and 6% (€2,045; €1,946-€2,144) in dialysis patients. 15% of incident ESA users, started ESA biosimilar during the study period (mean ESA cost/patient/year: €1,051). Among ESA-originator users, assuming 25% biosimilar uptake, the annual cost-saving on ESA treatment would represent 10.5% of total ESA costs in CKD stage I-V and 7.7% in dialyzed patients. Assuming 75% biosimilar uptake cost-savings would increase to 31.5% in CKD stage I-V and 23.0% in dialysis. ***Conclusions:*** CKD patients management, especially after initiation of dialysis, is very costly. ESA use contributes partially to the direct healthcare costs of CKD. Larger use of ESA biosimilars would substantially reduce drug expenditure in CKD patients.

PUK38
PATTERN OF TREATMENT AND HEALTHCARE COSTS OF SECONDARY HYPERPARATHYROIDISM IN DIALYSIS PATIENTS: A REAL-WORLD EVIDENCE ANALYSIS

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Objectives: Secondary hyperparathyroidism (SHPT) is a frequent condition in dialysis patients causing mineral bone disease and vascular calcification. Aim of this study was to determine pattern of treatment and healthcare costs related to SHPT in patients underwent renal replacement therapy. ***Methods:*** Administrative datasets of Lombardy Region (about 10 million inhabitants), Italy, were analysed regarding hospitalizations, diagnostic procedures, outpatient and drug prescriptions. Patients in dialysis in year 2011 and already in dialysis in the first 6 months of 2009 were selected. SHPT patients were identified through prescription of cinacalcet and/or paricalcitol and/or hospitalizations (parathyroidectomy and/or SHPT diagnosis) and observed for 4 years (2009-2012). Perspective of the analysis was that of Regional Healthcare Service (RHS). ***Results:*** 8316 patients were in RRT in 2011, of them 4791 were already in dialysis in the first 6 months of 2009 and 1793 had SHPT (37.4%, mean age 63.3 years, females 42.9%). 77% of SHPT patients were treated with cinacalcet and 52% with paricalcitol. Most frequent causes of hospitalizations were complications of renal dialysis device, implant and graft, end-stage renal disease and chronic kidney disease. Patients adherence to SHPT treatments (calculated as percentage of patients with >80% of drugs delivery/time) with cinacalcet were 48.69% while with paricalcitol were 27.99%. Mean per SHPT patient yearly cost accounted at 41,555€/year of which the 64% for dialysis, 12.3% for hospitalizations and 10.1% for drugs. ***Conclusions:*** This analysis of a large dataset confirm usefulness of real-world data for the identification of treatment patterns and costs of a chronic disease highlighting, in this case, the high costs of dialysis patients affected by SHPT and the relevant percentage of patients with sub-optimal adherence. Further investigations are needed in order to identify possible correlation between adherence and costs.

PUK39
URINARY TRACT INFECTIONS (UTIS) AFTER UROGENITAL PROCEDURES AND RELATED OUTCOMES AND COSTS: ANALYSIS OF DATA FROM THE NATIONAL HOSPITAL INFORMATION SYSTEM

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Objectives: The purpose of this study was to evaluate the proportion of Urinary Tract Infections (UTIs) after urogenital procedures and the associations between UTIs and in-hospital mortality, length of stay (LOS) and costs using the Hospital Information System of Italy. ***Methods:*** The National Hospital Discharge Database was retrospectively reviewed for all admissions between 2010 and 2014 with a urogenital procedure in the primary or secondary fields. UTIs were identified according to the presence of primary or secondary diagnosis of pyelonephritis; UTI, site not specified; other post-operative infections; other infections due to medical care; cystitis; and urethritis. The associations between the presence of a UTI and outcomes or costs were assessed with the Mann–Whitney unpaired test and Pearson's Chi-square test, when appropriate, and multivariable generalized linear models. A further sensitivity analysis was performed considering UTIs as only the presence of a primary or secondary diagnosis of a post-operative infection. ***Results:*** Within the 5-year study period, we selected 272,133 acute admitted inpatients with a reported urogenital procedure; the proportion of admitted patients with UTIs was 7.0% (95% CI: 6.9% - 7.4%). The multivariate model showed no association between in-hospital mortality and the presence of a UTI (OR 0.95; 95% CI: 0.83 - 1.10) but indicated a strong association between in-hospital mortality and the diagnosis of a post-operative infection (OR 2.42; 95% CI: 1.26 - 4.66). Compared with patients without UTIs, those with UTIs had significantly longer hospital stays and mean hospitalization costs (IRR_{adj} 1.50; 95% CI: 1.48 - 1.51 and β_{adj} 1.19; 95% CI: 1.18 - 1.21, respectively). ***Conclusions:*** In this study we demonstrated that the presence of UTI after a urogenital procedure is associated with a prolonged hospital stay and elevated mean hospitalization costs. The study may help advance out understanding of the outcomes and costs related to UTIs after urogenital procedures in the Italian context.

Reimbursement & Access Policy Research

RE1
REIMBURSEMENT OF INNOVATIONS IN GERMAN HOSPITALS - FIRST ANALYSIS OF HOSPITAL CLAIMS DATA ON THE DEVELOPMENT OF NEW EXAMINATION AND TREATMENT METHODS

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Objectives: Medical innovations are usually not covered by the German Diagnosis Related Group (DRG) system. In order to address this issue an application system for so called new examination and treatment methods (NUB) has been implemented. Hospitals annually submit NUB specific data to the Institute for the Hospital Remuneration (InEK) to explain why the current DRG remuneration is insufficient. Based on a positive decision by the InEK, an individual fee can be negotiated between hospitals and the statutory health insurances (SHI). Negotiation results are confidential and data is only partly publicly available. This study represents the first analysis of real world data on NUB remuneration. ***Methods:*** Hospital claims data were used to detect all individual fees for NUB billed to SHI between 2013 and 2017 and matched with the annually published InEK database. An analysis of negotiated fees concerning level, quantity and revenue was executed. Analysis also includes a differentiation on the type of NUB (pharmaceuticals, medical devices, medical procedures). ***Results:*** In total, applications for 1,082 NUB were filed to InEK between 2013 and 2017. Individual fees were ultimately billed only for 207 (19.1%) NUB. Of these, 54.1% accounted for pharmaceuticals, 37.2% for medical devices and 8.7% for medical procedures. In 78.4% of all NUB the invoice was based on a positive assessment (status 1) by the InEK. In contrast 38 NUB were invoiced to the SHI based on other legal claims. The total NUB based revenue increased between 2013 and 2017 from 73.3 million to 233.5 million euros. This translates to a 0.2% increased share of the annual SHI expenditures for inpatient services. ***Conclusions:*** Data indicates that just for a low number of NUB individual fees are negotiated and billed to the SHI. Due to the high and rising fees SHI expenditures for NUB increased in the period under review.

RE2
THEMES IN THE DESIGN OF PHARMACEUTICAL VALUE-BASED CONTRACTS IN THE UNITED STATES AND EUROPE

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Objectives: To evaluate themes in contract structures of value-based contracts (VBC) for pharmaceutical products across the US and Europe. ***Methods:*** VBCs in the US and select European nations (UK, Italy, Netherlands, and Spain) were extracted from the University of Washington Performance-Based Risk Sharing Agreement database (1997-2019). Contracts were categorized by the terms of reimbursement (rebate on product, reimbursement for disease sequelae, or coverage with evidence development), and endpoints (clinical, economic, or humanistic (i.e., QALY) with or without patient compliance). Preliminary results for the US and UK are reported. ***Results:*** There were 40 US-based and 21 UK-based VBCs. Most common therapeutic areas for US-based VBCs were endocrinology (32.5%), cardiology (25%), and oncology (20%). The majority of UK-based VBCs were in oncology (48%) and neurology (24%). The majority of US-based contracts were rebates (88%), whereas the majority of UK-based contracts were coverage with evidence development (52%). Outcomes-based assessments were stipulated in the majority of US-based contracts (90%), but not in