Mean numbers of patients by recommendation type: Standard = 7,838; Special = 3,935; Research Only = 2,423. There is also a clear trend over time: Standard recommendations decrease for all IPGs from 63% in 2003-2009 to 40% in 2014-2018; and the evidence threshold for Standard recommendations increases over time from 56% based on systematic reviews and/or RCTs in 2003-2009 to 85% in 2014-2018; mean numbers of patients per Standard recommendation also increase from 2,002 to 6,098 over this period.

Conclusions. Higher levels evidence and numbers of patients increase the likelihood of the most positive recommendation. However, this evidence might still lack sufficient quality or certainty to answer a policy question. The evidence threshold to achieve a Standard recommendation has also increased markedly over time. As with other NICE committees, factors other than cost and perceived hierarchies of evidence clearly act as drivers of decisions.

VP46 German Claims Data In Rare Disease HTA: Diffuse Large B-cell Lymphoma

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Introduction. In rare disease areas representative data are scarce. Routine sick fund claims data provide a meaningful and reliable base for the in- and outpatient treatment landscape. This real-world data (RWE) from Germany was used to describe treatment patterns for Diffuse Large B-cell Lymphoma (DLBCL), the most frequent and aggressive non-Hodgkin lymphoma type in adults.

Methods. Claims data from several sick funds of 4.8 Million insured were analyzed. Diagnosis of non-follicular Lymphoma (C83) was confirmed in 2.178 patients, DLBCL (C83.3) in 819 patients. The analysis was age- and gender-adjusted, observational period was 2014 and 2015. Treatments were analyzed for hospitalization and medication based on ATC-Code, Pharma Central Number and coded diagnoses (per ICD).

Results. Mean age of DLBCL patients was 60.3 years, with two peaks at 50-54 and 70-74 years. Total costs for patients with DLBCL averaged 25.048 EUR versus 1.259 EUR in healthy insured. Charlson comorbidity index (CCI) of 4.58 indicates clinical relevance and severity. Comorbidities included several psychiatric diagnoses such as depression in every fifth patient. Mean 3.2 hospitalizations with average 31.5 hospital days were observed in DLBCL patients. Forty-seven percent of patients during observational time-frame did not receive oncological treatment, including relapsed / refractory patients. Only few patients received stem cell transplantation (2.6 percent) or radiation (3.9 percent). Most pharmacological treatments were Rituximab (RTX) + CHOP (57 percent), followed by RTX mono therapy (25 percent) or RTX in combination with Bendamustine (8 percent).

Conclusions. Despite limitations in sick fund claims analyses, these provide a reasonable database for rare diseases. They allow standard treatment pathway- and longitudinal analyses. All DLBCL patients frequently required hospitalization and generated significant costs. A high unmet medical need exists for treatments other than palliative care, especially for a tolerable and effective outpatient therapy in elderly relapsed / refractory DLBCL.

VP47 Secondary Prevention For CV Disease: Population And Outcomes Using RWD

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Introduction. The study goal was to estimate prevalence of population in secondary prevention for Atherosclerotic Cardiovascular Disease (ASCVD) stratified by the pharmacological treatment and related outcomes using Health Information Systems (HIS).

Methods. From HIS of Marche and Umbria Regions (1.8 millions of inhabitants) which collect information related to hospitalizations, drugs prescriptions, outpatient visits and results of laboratory tests, we identified all patients aged ≤ 80 years with one or more hospitalization with DRG related to Acute Coronary Syndrome, Peripheral Artery Disease, Ischemic Stroke and Transient Ischemic Attack and discharge date between 2011 and 2014 (study period). Pharmacological treatment for each subject was defined selecting all prescriptions of Statins, Ezetimibe and Simvastatin/Ezetimibe, retrieved between the date of the last prescription in the study period and the previous 90 days. We stratified patient in no-treated, treated with low/medium intensity statins (LMS), high-dose statins (HDS) and other Lipid-Lowering Therapies (LLTs). Furthermore, for Umbria region, we selected the last blood levels test of LDL-cholesterol occurred in period 2011-2016. Starting from test date, we defined the pharmacological treatment in the previous 90 days. Subject were stratified based on LDL-C levels in target (<70) and not at-target (≥70) patients.

Results. Population in secondary prevention for ASCVD in period 2011-2014 in Marche and Umbria was estimated in 23,043 (prevalence: 4.3 x 1,000 inhabitants), corresponding to more than 800,000 subjects in Italian population. Within treated patients: 51.3% received LMS, 38.1% HDS and 10.6% other LLTs. No-treated patients were 27.8%. LDL-C target was achieved by 34.9% of patients treated with LMS and by 46.1% of patients treated with other LLTs.

Conclusions. The study, based on Italian administrative databases, allowed to estimate the very high risk population in secondary prevention for ASCVD. It highlighted a relevant proportion of no-treated patients, and an high proportion of patients that did not achieve recommended LDL-C target.

VP49 Real-world Evidence For Economic Evaluation Of Medical Devices

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Introduction. Randomized controlled trials (RCTs) are considered the gold standard in the hierarchy of research designs for

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