to reimbursements, causing a significant growth in costs. Expenses for oncology in 2006–2011 increased by 718% (from €4.15 million in December 2011, a cost/QALY threshold was introduced to legislation, creating a barrier to the inclusion of oncology drugs to the Reimbursement list. Following adoption of this legislation, of the 12 drugs registered by the EMA, only 3 oncology drugs were included. Of the 2009–2012, which were included in the legislation, only 14% of patients were covered under all five categories (brain tumors, cancers, leukemias, lymphomas, and solid tumors). Inclusion of NELSON protocol can lead to a profound impact on current standard of care are often eligible for quicker routes to access. This research sought to investigate how these schemes worked, where they were prevalent, and the outcomes of such schemes. METHODS: The research was conducted through in-depth interviews with payers and clinicians across 10 EMEA markets. RESULTS: Of the 10 markets studied, 5 countries were identified to have either easier or quicker routes to access for new pharmaceuticals (e.g., ATU in France, MRA in Belgium). The most common regulatory reform in Saudi Arabia and the “white list” in Norway). Most often, these routes were reserved for products with orphan indications or products that were believed to significantly impact current standard of care. These regulatory changes and their impact on access to innovative oncological treatment. The health system in Slovakia needs to introduce efficient and transparent mechanisms that enable the treatment of oncology patients in line with the latest medical findings, while keeping expenses for treatment within economic possibilities.

PCN229

INNOVATION MAY DRIVE STREAMLINED ACCESS TO NEW BIOPHARMACEUTICALS ACROSS SOME EMEA MARKETS

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OBJECTIVES:Objectives: Objectives: Approval, pricing, and reimbursement of pharmaceuticals take place under varying timelines with different outcomes. There are some countries that may obtain access to new pharmaceuticals through early access schemes. Breakthrough and innovative products that are thought to have a profound impact on current standard of care are often eligible for quicker routes to access. This research sought to investigate how these schemes worked, where they were prevalent, and the outcomes of such schemes. METHODS: The research was conducted through in-depth interviews with payers and clinicians across 10 EMEA markets. RESULTS: Of the 10 markets studied, 5 countries were identified to have either easier or quicker routes to access for new pharmaceuticals (e.g., ATU in France, MRA in Belgium). The most common regulatory reform in Saudi Arabia and the “white list” in Norway). Most often, these routes were reserved for products with orphan indications or products that were believed to significantly impact current standard of care. These regulatory changes and their impact on access to innovative oncological treatment. The health system in Slovakia needs to introduce efficient and transparent mechanisms that enable the treatment of oncology patients in line with the latest medical findings, while keeping expenses for treatment within economic possibilities.

PCN230

HEALTH ECONOMIC IMPACT OF VOLUME DOUBLING TIME AS BIOMARKER IN LUNG CANCER DIAGNOSIS

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PURPOSE: Aim: Aim: Aim: To determine the health economic impact of volume doubling time as biomarker in suspected lung cancer patients. METHODS: A state-transition model is created to simulate the pathway of lung cancer diagnostic procedures, including x-ray, diagnostic CT, PET-CT, bronchoscopy, mediastinoscopy and more. Hospital registries and data from the National Cancer Registry were used to estimate the amount of diagnostic procedures in a cohort of lung cancer patients. Systematic literature search was performed to estimate the diagnostic performance of different modalities. Patient cohort is defined and the pre-test probability for malignancy is estimated through the Swensen criteria. Probabilistic sensitivity analysis is performed using Monte Carlo Simulations. RESULTS: Diagnostic procedures for patients with suspected lung cancer can count up to almost €3000 per patient. Pathway was modeled in a microsimulated cohort through Swensen criteria, leading to a mean chance of malignancy of 40%. Costly steps in the pathway include cervical mediastinoscopy and mutational analysis. Inclusion of NELSON protocol can lead to a reduction in costs. Decision making per patient can reduce overall of diagnostic modalities. CONCLUSIONS: The diagnostic procedure for suspected lung cancer patients is a costly pathway and can be improved with use of the NELSON screening protocol or personalized selection of diagnostic procedures.

PCN231

HOW SUCCESSFUL HAVE PEDIATRIC INVESTIGATION PLANS BEEN IN STIMULATING RESEARCH FOR PEDIATRIC CANCERS?

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OBJECTIVES: The Drug Review and Pediatric Medical Legislation was created in 2007 to encourage further drug development for pediatric diseases, by requiring pharmaceutical companies to submit pediatric investigation plans (PIPs) when submitting the marketing application for a new drug. The objective of this study was to determine how successful this legislation had been in stimulating research in pediatric cancers. METHODS: Current oncology PIPs were manually extracted from the EMA database. Primary outcomes included investigator applicant, decision, action date, and date of expected completion. Indications for approved PIPs were classified into five categories: brain tumors, diagnostics, leukemias/lymphomas, side effects, and solid tumors. RESULTS: A total of 105 PIPs were found; 32 of which were for pediatric diseases, and 73 for diseases other than pediatric. The study found that 39% (27) of approved PIPs were indicated for solid tumors, including melanomas and malignant tumors; 30% (21) of approved PIPs were indicated for leukemias or lymphomas; 17% (5) of approved PIPs were indicated for side effects, such as anti-nausea and neuropathy medications; 12% (8) of approved PIPs were indicated for brain tumors; and one oncology diagnostic PIP was also approved. The ramp-up of the PIP program was significant. PIPs approved in 2013 and the first half of 2014 accounted for 54% (7) of all PIPs approved during the study period. CONCLUSIONS: Approved PIPs covered a wide range of pediatric cancers, and the number of approved PIPs increased significantly over time. While the ramp-up of the program indicated that it was successful, it is in this area, serious concerns remained regarding the feasibility of the program. For example, there were currently four trials planned for completion between 2015–2020 for extremely rare high grade gliomas. This limitation may compromise the integrity of the PIP program.

PCN232

TREATMENT PATTERNS AND OUTCOMES OF PATIENTS DIAGNOSED WITH OVARIAN CANCER IN THE NETHERLANDS: A REGISTRY STUDY

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OBJECTIVES: Objective: Objective: To provide more information on the patterns of chemotherapy regimens administered for the treatment of ovarian cancer (OC) in the Netherlands. The objective for this study was to describe current chemotherapy patterns for OC in The Netherlands and to describe the processes that led to the use of chemotherapy. METHODS: Data from the Eindhoven Cancer Registry, including data on all newly diagnosed cancer patients, was linked to the PHARMO Database Network including, among other things, information on in- and outpatient drug use. Patients diagnosed between January 2005 and December 2005 were selected. First and subsequent chemotherapy regimens were defined as the start of a different (combination) of chemotherapy agent (s) or a gap >42 days (or >91 or >183 days in sensitivity analysis) between two treatment courses. RESULTS: Of landscape or are active in orphan diseases should take advantage of these schemes. Physicians grasp at the opportunity to use efficacious products as early as possible and companies need to leverage the opportunity for streamlined access to products. The research was performed to estimate the diagnostic performance of different modalities. Patient cohort is defined and the pre-test probability for malignancy is estimated through the Swensen criteria. Probabilistic sensitivity analysis is performed using Monte Carlo Simulations. RESULTS: Diagnostic procedures for patients with suspected lung cancer can count up to almost €3000 per patient. Pathway was modeled in a microsimulated cohort through Swensen criteria, leading to a mean chance of malignancy of 40%. Costly steps in the pathway include cervical mediastinoscopy and mutational analysis. Inclusion of NELSON protocol can lead to a reduction in costs. Decision making per patient can reduce overall of diagnostic modalities. CONCLUSIONS: The diagnostic procedure for suspected lung cancer patients is a costly pathway and can be improved with use of the NELSON screening protocol or personalized selection of diagnostic procedures.

PCN233

THE FDA BLACK BOX WARNING DOES NOT REDUCE THE USE OF ERYthropoietin STIMULATING AGENTS AND INCREASES BLOOD TRANSFUSIONS IN INSURED, LOW INCOME CANCER PATIENTS

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OBJECTIVES: Erythropoietin stimulating agents (ESAs) are useful drugs for treating chemotherapy related anemia to reduce the number of blood transfusions. However, there were unrecognized toxicities of ESAs. These toxicities were finally recognized in 2007 when the FDA issued a black box warning for ESAs. The objective of this study was to determine the effect of the FDA black box warning on ESA use patterns and associated outcomes in insured, low-income cancer patients in South Carolina. METHODS: The merged South Carolina Central Cancer Registry-Medicaid dataset was used to determine the trend of ESA use from 2001-2010. Female Breast, Colon, and Non-Small Cell Lung cancer patients were identified from the registry. Of those, their chemotherapy status was identified along with ESA use from Medicaid medical claims. The major outcome measures were claims for use of ESAs after chemotherapy and the blood transfusion rate. Logistic regression was used as a quantitative method to determine if the likelihood of receiving ESAs treatment was reduced after FDA black box warning. RESULTS: Among 1,645 patients treated with chemotherapy from 2002-2010, the proportion of chemotherapy patients receiving ESAs increased from 56.47% in 2001 to 75.87% in 2010 after black box warning (p < 0.001). The blood transfusion rate per year during 2002-2007 remained around 10-15% and increased to 31% in 2009. The likelihood of ESA use was reduced by 12% after black box warning issued by FDA after adjusting for demographic and clinical variables. CONCLUSIONS: The black box warning may have been effective in reducing overall ESA utilization in cancer patients taking chemotherapy.

PCN234

TREATMENT PATTERNS AND COSTS OF NEOAdjuvANT SYSTEMIC THERAPIES (NAT) FOR EARLY BREAST CANCER (EBC): A RETROSPECTIVE CLAIMS ANALYSIS FROM CANADA, CHILE, MEXICO, SPANISH, ITALY, AND USA

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OBJECTIVES: Retrospective claims analyses are frequently used to determine treatment patterns and costs of specific therapies. This study provides detailed information on the type of chemotherapy regimens administered to OC patients at initial diagnosis and during follow-up and the survival following the various chemotherapy regimens.