PCN187
DESIGN INNOVATION FOR EFFICIENT POST-APPROVAL DRUG UTILIZATION AND EFFECTIVENESS STUDIES

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Objectives: Data from electronic medical records are frequently used for retrospective real-world studies of treatment patterns and outcomes. However, site-based retrospective chart review methodology has inherent limitations including extended timelines, greater funding requirements and high site burden. Thus, studies that use electronic medical records for data collection are warranted. The objective was to describe a drug utilization and effectiveness IRB-approved pilot study design and performance metrics, based on data from physician-reported medical charts. Methods: A US-based retrospective chart review pilot study was executed, using an existing on-line physician network. The protocol was centrally IRB-approved and eligible patients were identified from 2016-2019 who had ≥6 months of follow-up. A large panel of physicians, representative of the US market, had been previously screened on factors including years of practice, credentials, scientific publications and location. Stratified sampling, based on diseases treated and number of patients treated with the disease, was used to select physicians. Variables for the study included physician and patient characteristics, treatment patterns and response to treatment. Data were entered by treating physicians into an online platform, including automated, random and tailored edit checks and the subsequent issuing of any queries. Results: Forty-three of the 91 contacted physicians participated (47.3%), of which 24 (26.4%) provided data for patients included in the study. The median chart data of 109/153 (71.8%) screened patients was included in the study. Data was collected (screened and abstracted) efficiently, within 2 months. Queries to the treating physicians on average were answered in 3-5 days. The final dataset had <1% of missing data. Conclusions: This direct-to-physician, online retrospective chart review pilot study was time and cost-efficient, within 2 months. It efficiently, within 2 months. It demonstrated that-Pilot Physician Network combination could be an effective and flexible alternative to traditional site-based chart review studies.

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IDENTIFICATION OF PATIENTS WITH CHRONIC MYELOID LEUKEMIA (CML), MULTIPLE MYELOMA (MM) AND MYELODYSPLASTIC SYNDROMES (MDS) USING REAL-WORLD DATA: FINDINGS FROM THE PRIHTA - EMATOLOGIA PROJECT

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Objectives: The "PRIHTA-EMATOLOGIA" project was developed in collaboration with Veneto Region (Italy) to analyse patients with hematologic malignancies using administrative databases. Within the project, the present study aims to identify patients with CML, MM and MDS, to analyse their prevalence and to evaluate healthcare resource consumption and related costs by using real-world data. Methods: This observational retrospective cohort study was carried out by matching administrative and laboratory data with medical records from the 2007-2012 cohort of CML, MM and MDS patients respectively. Results: 118 CML patients, 240 MM patients and 130 MDS patients were identified. The mean age was 64.6±14.7 in the CML, 69.6±11.4 in the MM and 73.2±9.7 in the MDS cohorts. Proportions of male were 57.6%, 50.4% and 58.5% among CML, MM and MDS patients, respectively. Prevalence was calculated to be 124.7 (CML), 228.8 (MM) and 120.3 (MDS) per 100,000 health-assisted individuals. In each disease, peak prevalence was found between ages 70-79 years. The total annual costs for the last year of study period were €20,042, €30,730 and €11,092 for CML, MM and MDS patients, respectively. Conclusions: This study was the first investigation aiming mainly by prevailing in CML, MM and MDS to compare the economic and the ergonomic burden of hematologic malignancies as CML, MM, and MDS.

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AN ESTIMATE OF NON-SMALL-CELL LUNG CANCER (NSCLC) PATIENTS WITH ALK TRANSLLOCATION (ALK+) IN ITALY ELIGIBLE FOR TREATMENT WITH TYROSINE KINASE INHIBITORS (TKI)

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Objectives: ALK+ NSCLC is an aggressive malignant neoplasm. The prognosis of these patients is rapidly changing due to the availability of the second generation TKI drugs for the second-line treatment post-crizotinib. This study tries to estimate the current number of patients and by ALK+ NSCLC in Italy and provide a future estimate for patients eligible for the treatment with TKI. Methods: a literature review was carried out to identify the most accurate epidemiological parameters aimed to estimate the patients with ALK+ NSCLC in Italy based on the Incidence approach. An epidemiological funnel was designed starting from the Italian population (ISTAT 2019) and the incidence rates of the Italian Cancer Registry Association (AIRTUM 2019) was applied; from the total number of patients with lung cancer, the number of patients with advanced NSCLC was estimated and finally, the number of tested and positive patients for ALK translocation for was identified. Results: in Italy, 42,501 patients are affected by lung cancer is (incidents); 23,562 suffering from advanced (stage III-B/IV) NSCLC. Given the increased awareness of the disease, it is estimated that the number of patients tested for ALK reaches 85% (weighted average percentage for non-squamous and squamous histology). The patients included in the current project was tested. The estimate of patients with ALK+ translocation is 3.8%, for a total amount of approximately 649 eligible patients for first-line treatment. Patients receiving crizotinib are 162 (25%) and the proportion of patients continuing therapy post-crizotinib is 80%, consistent with approximately 130 patients eligible during the year. The KATHERINE trial established a 4-years retrospective follow-up cohort of patients who had initiated a trastuzumab-based neoadjuvant treatment. To complement evidence from this trial, the French observational KADOR study aimed to describe in the real world setting the characteristics and therapeutic management of patients with HER2+ eBC who initiated trastuzumab-based neoadjuvant therapy. Methods: We established a 4-years retrospective follow-up cohort of patients who had initiated a trastuzumab-based neoadjuvant treatment in 2014 followed by surgery and trastuzumab-based adjuvant therapy. This study included 57 active sites. The cohort consisted of 301 patients. Median age was 51 years (IQR: 42.0 – 66.0). Ninety-two out of 267 patients (34.5%) were diagnosed with stage II. Very few patients (3.3%) presented invasive lobular carcinoma. Scarff-Bloom-Richardson (SBR) grade III was observed in 50.3% of the patients. More than half of patients (59.8%) were hormone receptor positive (HR+). Around two thirds of patients (61.5%) received anthracyclines-based chemotherapy followed by concomitant taxane and trastuzumab. Breast conserving surgery was performed for 47.3% patients. Complete pathological response (pCR) was observed in 42.9% patients (37.3% for RH+ and 50.4% for RH- patients). After surgery, the median adjuvant trastuzumab dose administered was 6.0 mg/kg. The median duration of trastuzumab-based therapy (neoadjuvant and adjuvant) was 51.1 weeks (IQR: 48.6 – 54.0). Most HR+ patients (78.0%) also received trastuzumab-based adjuvant therapy. Results: The patients included in this cohort were treated with clinical and therapeutic characteristics consistent with existing literature. This French real world data study confirms that routine practice aligns with the current guidelines for therapeutic management of HER2+ eBC.
Adenoma and Serrated neoplasia pathways (DECAS) was recently developed and calibrated using the German screening colonoscopy registry data, which consist of 5.2 million colonoscopies between 2003 and 2014. The German national cancer registry data. We aimed to use DECAS to estimate the length of protective effects of colonoscopy screening and the amount of colonoscopy needed in the German context. Methods: We used DECAS to simulate a cohort of averaged-risk individuals from age of 20 to 90 for three screening scenarios: (1) no screening; (2) one colonoscopy at age of 55; (3) two colonoscopies at age of 55 and 65. In the base-case analysis, we assumed the adenoma pathway accounting for 85% of the CRC development and the serrated pathway for the other 15%, as well as a 100% uptake of screening and surveillance colonoscopies. Outcomes of interest were hazard ratios (HR) of CRC-specific mortality under each screening scenario comparing to no screening, and the number of colonoscopies required. Results: DECAS predicted HRs of CRC-specific mortality at approximately 0.2 for both screening scenarios after 25 years of follow up, and the trend of both mortality HRs was still decreasing. The average numbers of colonoscopies required were 1,300 and 2,174 per 1,000 for once and twice colonoscopy screening, respectively. We also varied alternative screening and surveillance participation rates for sensitivity analyses. Conclusions: The modeling results from DECAS confirmed the long-term protective effects of colonoscopy screening and provided an estimation of the number of colonoscopies required in the German context. We will further apply DECAS to perform economic evaluations on various CRC screening strategies and policies.

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HOSPITALIZATIONS AND OUTPATIENT VISITS (H&OV) IN MODERATE AND SEVERE ACUTE GRAFT VERSUS HOST DISEASE (aGVHD) PATIENTS IN FINLAND AND SWEDEN
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Objectives: aGVHD is a severe complication, and often very serious, complication of allogeneic Hematopoietic Stem Cell Transplantation (allo-HSCT). The objective of this study was to describe prophylaxis, clinical presentation, and H&OV among patients developing moderate or severe (grade II-IV, Modified Glucksberg or MACIG) aGVHD. Methods: A retrospective chart audit including adult patients diagnosed with grade II-IV aGVHD following the first allo-HSCT (received between January 2016 and June 2017), and that had not experienced disease progression before aGVHD, was conducted in Finland and Sweden. Clinical characteristics, aGVHD prophylaxis treatment, H&OV were collected from clinical records since allo-HSCT (index date) until date of data collection, death or loss to follow up. Results: 55 patients were included. Mean (Standard Deviation, SD) age at transplant was 48.3 (14.4) years; 54.5% were male. At transplant, 61.8% of patients were in complete remission and 49.1% presented intermediate disease risk index. Most donors were unrelated (76.4%). Two unrelated and one related donor were HLA mismatched. Peripheral blood accounted for 96.6% of stem cells sources. Myeloablative (81.8%) and fludarabine-based reduced intensity conditioning (76.4%) were the most frequent conditioning types. aGVHD prophylaxis consisted of calcineurin inhibitors (98.3%), methotrexate (94.6%), and in-vivo T-cell depletion (80.0%). 70.0% and 29.1% of enrolled patients developed grade II or III-IV aGVHD. Forty-nine patients (89.1%) were hospitalized, mean (SD) number of hospitalizations was 2.9 (2.7). Each patient spent in hospital a mean (SD) of 48.4 (47.7) days. Reasons for hospital admission were aGVHD (65.3%) and infections (44.5%). Seven patients (14.3%) were admitted to intensive care units. Patients required on average (SD) 11.7 (11.1) or 3.6 (0.6) emergency visits per year. Conclusions: The present study reports key characteristics, prophylaxis treatment, and H&OV of patients developing moderate and severe aGVHD in Finland and Sweden, showing that aGVHD is associated with considerable healthcare resource utilisation in these populations.

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RESULTS AFTER 10 YEARS OF COLORECTAL CANCER SCREENINGS IN SPAIN: HOSPITAL INCIDENCE AND IN-HOSPITAL MORTALITY (2011-2016)
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Objectives: This study aimed to update colorectal cancer incidence and mortality trends in Spain and provide a detailed analysis of disease management and risk factors involved in in-hospital mortality. Methods: Anonymous primary and specialists’ inpatient admission records from 2011 to 2016 were extracted from a Spanish claims database representative of all Spanish regions. The standardised average expenses of medical procedures determined by the Spanish Ministry of Health were utilised for the calculation of direct medical costs. Results: Primary care files from 37,311 patients and hospitalised care files from 192,048 patients were included. In-hospital mortality rate was 10.07% and remained stable during the study period, similarly to colorectal cancer incidence within the hospitalised population, which was 106 per 10,000 patients. Patients deceased during the hospitalisation presented an increased presence of metastatic tumours. Mean length of hospital stay decreased significantly over the study period, similarly to patients’ 30-day readmission rate, which registered a trend from the 12.9% to 11.5% (p=0.003). In consequence, the direct medical cost measured per patient, of €10,992, decreased over time. The implementation of colorectal cancer screening programmes caused a significant decrease in the number of new diagnoses in patients aged 75 to 79 years; however, hospital mortality rate was not reduced. Metastatic tumours and other conditions as anaemia are associated with higher in-hospital mortality rates. Conclusions: The implementation of colorectal cancer screening programmes in Spain presumably provoked the decrease in the number of new diagnoses in patients aged 75 to 79 years and in-hospital mortality. Such programmes should be promoted to achieve higher participation rates in an effort to reduce incidence and the number of patients presenting manifestations at first admission. The roles of anaemia and overweight in colorectal cancer mortality should be further investigated to determine their value in improving patients’ prognosis.

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PREVALENCE OF MAJOR ADVERSE CARDIOVASCULAR EVENTS (MACE) IN PATIENTS WITH PROSTATE CANCER (PC) RECEIVING ANDROGEN DEPRIVATION THERAPY (ADT) IN THE UNITED STATES
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Objectives: Androgen deprivation therapy (ADT) with gonadotropin-releasing hormone (GnRH) receptor agonists is used to induce castration and prostate cancer (PC) cell death. Studies have shown an association between GnRH agonists and increased cardiovascular disease (CVD) risk; ~30% of men with PC have known CVD; cardiovascular mortality is the leading cause of death. In 2010, the Federal Drug Administration required new safety information to the labels of GnRH agonists warning of increased risk of CVD events in men receiving these medications for PC. We assessed the occurrence of major adverse cardiovascular events (MACE) and associated healthcare resource utilization (HCRU) in men with PC receiving agonist ADT. Methods: Men receiving ADT with ≥2 claims for a diagnosis of PC were identified in the MarketScan Commercial and Medicare Supplemental Database (1/1/2009-12/31/2018). Index date was the first ADT claim; patients had to be continuously enrolled for 12 months pre-index and ≥7 months post-index. The occurrence of MACE (myocardial infarction, cerebrovascular accident, unstable angina, thromboembolism, percutaneous coronary intervention, and/or coronary bypass graft) was assessed over the study period. Post-period all-cause HCRU was evaluated for patients with and without MACE. Results: The study included 41,986 men; mean age was 70.1 (SD:30.3) years, and median duration of follow-up was 22.8 months. A total of 10,402 patients (24.8%) had a MACE during the study period (8.7% pre-index and 26.0% post-index). Patients with a MACE had three times the number of post-index inpatient admissions per-patient-per-month compared to patients without MACE (0.06 [SD:0.10] vs. 0.02[0.06], p<0.001). Conclusions: CVD is a known and important risk for patients with PC treated with GnRH agonists; 20% of patients in this analysis had a MACE following ADT. These patients were more likely to be hospitalized than patients without a MACE. Evaluating CVD history and risk in advanced PC patients when selecting treatment could help to reduce MACE and HCRU.

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IS IT TIME TO PUT CONFIDENTIAL DISCOUNTS FOR HIGH COST ONCOLOGICS ON BACK BURNER? MANAGED ENTRY AGREEMENT (MEA) SHOWS THE WAY FOR FASTER PATIENT ACCESS
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Objectives: Biopharmaceutical manufacturers have traditionally opted for negotiations involving direct confidential discounts to payers in order to gain patient access. However, with higher prices and concomitant clinical uncertainty associated with innovative therapies, manufacturers may be able to expedite time to access by offering MEA upfront during pricing negotiations as contemplation of a fall back option. Methods: A non-systematic review of literature supplemented by DRG's proprietary MEA Database was used to construct a list of MEAs involving high cost oncolgy products implemented in recent years in Italy, Spain, and UK. To access was derived from published literature for each country. Results: We reviewed 17 cases (majority of which were first-in-class products) where high priced oncolgy products reached patients faster than the median time to access in their respective countries based MEAs. Nine products (53%) were launched in UK, six (35%) in Italy, and two (12%) in Spain. All MEAs in UK involved manufacturer-led evidence development element, potentially highlighting the payer uncertainty around the clinical data. On average new reached patients faster than the median time to access by 128 days compared to their respective median time to access, across these countries. For more innovative technologies (such as, cell therapies), access was 125 days faster on average. The greatest number of days saved was 299 days, indicating payer acceptance of MEAs as a critical