ISPOR Europe 2023
12 - 15 November

Poster Tour Guide Packet

Poster Session:	**Poster Session 1**
Tour Name:	**Real-World Evidence in Europe**
Tour Date/Time:	Monday, 13 November 2023 | 11:30 - 12:15
Tour Location:	Area B, Poster and Exhibit Hall, Hall C

Acceptance Code:	PT10
Board Number:	1B
Abstract Title:	Opioid Tapering and Its Associations with Risk of Opioid Use Disorder and Mortality Among Older Adults
Presenting Author:	Yi Yang

Abstract Body:

OBJECTIVES: Opioid tapering has increased in recent years, however, evidence regarding its safety profile is lacking. The purpose of this study was to examine the relationships between opioid tapering and subsequent opioid use disorder (OUD) and all-cause mortality among older adults on long-term opioid therapy (LTOT).

METHODS: This study used a nested case-control design. A cohort of older (≥65 years) Medicare beneficiaries with chronic non-cancer pain who were on LTOT was identified from 2012-2018 5% national Medicare claims data. Within this LTOT cohort, cases (beneficiaries who experienced either an OUD or mortality) and controls (identified using incidence density sampling) were identified and matched 1:2 on age (±1 year) and time of cohort entry (±30 days). Opioid tapering was operationalized as a monthly dose change percentage with four levels: steady dose (±10% dose change), tapering (10-40% dose reduction), rapid tapering (> 40% dose reduction), and dose escalation (>10% dose increase). Conditional logistic regression was conducted on the matched samples to evaluate the associations between opioid tapering and OUD and mortality.

RESULTS: A cohort of 42,091 patients met our inclusion criteria. Among them, 2,670 cases of OUD and 4,614 cases of mortality were identified. After controlling for patient socio-demographics and clinical characteristics, compared with steady dose, the odds of OUD were significantly lower (aOR=0.52; 95%CI=0.42-0.64) for rapid tapering and significantly higher (aOR=1.58; 95%CI=1.31-1.90) for dose escalation. Compared to steady dose, significantly higher odds for all-cause mortality were found among patients undergoing tapering (aOR=1.64, 95%CI=1.44-1.86), rapid tapering (aOR=2.33; 95%CI=2.10-2.59), and dose escalation (aOR=2.21, 95%CI=1.95-2.52).

CONCLUSIONS: The results suggest that opioid tapering was associated with increased risk of all-cause mortality but not OUD; opioid dose escalation was associated with both OUD and mortality. Clinicians should evaluate patients on LTOT to weigh the benefits and risks of treatment that incorporates evolving evidence surrounding dose changes.

Tour Guide's Questions for Starting Q&A (Each poster will have ~5 minutes for Q&A with attendees/Tour Guide)

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Acceptance Code:	PT11
Board Number:	2B
Abstract Title:	Overall Survival of Patients with Lung Cancer Newly Diagnosed in the Period of the COVID-19 Pandemic Compared to Patients with an Incident Diagnosis Before the Pandemic: A Retrospective Analysis of German Claims Data
Presenting Author:	Evi Zhuleku *(Non-author Presenter)*

Abstract Body:

OBJECTIVES: This study aimed to compare the overall survival (OS) of patients with incident lung cancer (LC) diagnosed before and during the COVID-19 pandemic in Germany.

METHODS: Using a retrospective, anonymized German claims database, cases with an incident LC diagnosis (=index) were identified during 01/07/2018-30/06/2021. Cases were included if they had at least two confirmed outpatient diagnoses or one inpatient diagnosis of LC (ICD-10-GM code: C34). A case was considered incident if there was a diagnosis-free period of 12 months before above date. Patients were divided into two groups based on their index year (2018/2019 versus 2020/2021) and followed for 12 months or until death (if earlier). OS after incident diagnosis was calculated using Kaplan-Meier estimation and compared between the two groups within a Cox regression model considering main patient characteristics (including metastasis status at index).

RESULTS: The analysis included 4,210 incident LC patients, with 2,323 (55.2%) diagnosed in 2018/2019 (mean age: 69.2 years; male: 66.5%; Elixhauser comorbidity score [ECI]: 9.3) and 1,887 (44.8%) in 2020/2021 (mean age: 69.1 years; male: 66.6%; ECI: 8.9). In 2020/2021, a higher percentage of patients were metastasized at diagnosis (38.8% versus 2018/2019: 33.1%; p<0.001). Significantly more patients diagnosed in 2020/2021 died during the 12-month follow-up (50.2% versus 2018/2019: 46.2%; p=0.011). The median OS for patients diagnosed in 2020/2021 was 11.9 months, whereas the median was not reached for patients diagnosed in 2018/2019. Cox regression confirmed the tendency of shorter OS in patients with incident diagnosis in 2020/2021 but without statistical significance (HR: 1.05; p=0.318).

CONCLUSIONS: This analysis showed that, generally, fewer cases were diagnosed during the pandemic. However, those that were detected were more likely in an advanced stage, which was reflected in worse OS outcomes. Further research is needed to investigate the pandemic's underlying factors and impact on real-world outcomes in LC patients.

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Acceptance Code:	PT12
Board Number:	3B
Abstract Title:	Perceived Financial Burden and Quality of Life Among Patients with Cancer
Presenting Author:	Jarno Ruotsalainen

Abstract Body:

OBJECTIVES: Financial burden perceived by patients with cancer is often underappreciated in countries with universal coverage. This study aimed to characterize the association between perceived financial burden and health-related quality of life (HRQoL) among patients with cancer in Finland.

METHODS: This was a cross-sectional survey of 504 patients with cancer enrolled trough community pharmacies and patient organizations between April 2019 and September 2020. Perceived financial burden was assessed with a question “Has cancer negatively impacted your financial situation?” (answer choices: yes, considerably; yes, to some extent; no; cannot say). HRQoL was measured with the generic 15D HRQoL instrument including the following dimensions: mobility, sight, breathing, sleeping, eating, speaking, secretion, daily activities, mentality, aliments and symptoms, depression, distress, vitality, and sexual activity. The association between perceived financial burden and 15D score was analyzed with linear regression adjusted for gender, time since diagnosis, cancer type and progression, need for assistance, net income, and private cancer insurance.

RESULTS: Of all respondents, 79% were women; 58% had been diagnosed with cancer within the past two years and 8.3% over 10 years ago. Almost every second (47%) respondent perceived that cancer had negatively impacted their financial situation at least to some extent. The mean 15D score was 0.76 (standard deviation [SD]=0.11) in patients perceiving considerable burden (n=135), 0.82 (SD=0.10) in those with some burden (n=220) and 0.89 (SD=0.07) with no burden (n=132). Furthermore, perceived financial burden was inversely associated with the mean 15D score in multivariable regression model (beta coefficient for considerable vs. no burden: -0.09, $p<0.0001$; some vs. no burden: -0.05, $p<0.0001$) and with each dimension of 15D.

CONCLUSIONS: Financial burden is a concern for a significant proportion of patients with cancer. Most importantly, the perceived financial burden seems to be associated with reduced HRQoL independent of the patient’s net income.

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Acceptance Code:	PT7
Board Number:	4B
Abstract Title:	Data Standardization in Brazil: An OMOP Common Data Model Approach in a DATASUS Cohort
Presenting Author:	Guilherme Julian

Abstract Body:

OBJECTIVES: Common data models (CDM), such as Observational Medical Outcomes Partnership (OMOP), are crucial tools to develop quick multi-site and country real world evidence generation. Therefore, this study aims to describe the methods and quality results of the creation of an OMOP dataset with linked outpatient and inpatient information of Brazilian claims data.

METHODS: This study included data from Hospital Information System (SIH) and Outpatient Information System (SIA) from January 2008 until May 2023. The information available in the datasets include all outpatient procedures, consultations, ICD-10 codes of a primary and secondary diagnosis, medicines, and encrypted/anonymized personal data, such as date of birth, residential address, zip code, and sex. All original records from SIA an SIH databases were analyzed to assess the consistency of information for a unique patient key. Patients with inconsistencies in primary key or basic information were excluded from the database. After the cleaning and pre-processing stage, a deterministic linkage algorithm was developed to connect inpatient with outpatient records using the key information of zip code, date of birth, and gender. Subsequently, this dataset underwent transformation into the OMOP CDM. The data quality check was conducted with DataQualityDashboard version 2.1.1

RESULTS: A total of 5.82 million patients were included in the final dataset. In this dataset, there were 3,666 queries tested assessing the quality mapping of the OMOP database. In those queries, the database reached plausibility, conformance and completeness verifications of 99%, 93% and 97%, respectively, reaching an overall pass rate of 98%, indicating a satisfactory index of the mapping quality.

CONCLUSIONS: Our study provides the first results of a high-quality cohort with outpatient and inpatient information in Brazil in OMOP format. CMD approaches in Latin America are very scarce and may be a crucial tool to boost real world evidence generation in the region.

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Acceptance Code:	PT8
Board Number:	5B
Abstract Title:	Five-Year Healthcare Resource Consumption and Direct Costs of Women with a New Diagnosis of Hr+/HER2- Breast Cancer Primary or Advanced: Analysis of a Large Italian Administrative Database
Presenting Author:	Irene Dell'Anno

Abstract Body:

OBJECTIVES: Assess the healthcare resource consumption and direct costs by the Italian National Health Service (INHS) for women newly diagnosed with HR+/HER2- breast cancer (BC), by absence/presence of lymphnode (LNM)/distant metastases (DM).

METHODS: From Fondazione Ricerca e Salute's database (administrative data of ~5 million inhabitants/year), adult women with a new HR+/HER2- BC diagnosis in 2015 (index date) were categorized by absence ("primary")/presence of in-hospital diagnoses of LNM/DM at index date or within the subsequent 60 days. Five-year overall (OS), distant relapse-free (DRFS) and invasive disease-free (IDFS) survivals (Kaplan Meyer analyses), and direct INHS costs were calculated. Among women with LNM, conservative/demolitive surgery and lymphadenectomy were assessed within one-year follow-up.

RESULTS: In 2015, of 2,603 women newly diagnosed with HR+/HER2- BC (incidence: 1.2x1,000 inhabitants), 2,019 had primary BC (mean age 62±14; 39% with ≥2 comorbidities), 420 LNM (60±14; 32%) and 164 DM (67±13; 46%). Within 1-year follow-up, 407/420 women with LNM underwent conservative/demolitive surgery, 170/420 also lymphadenectomy. In 5-year follow-up: OS and IDFS probabilities were 89% and 82% for women with primary BC, 88% and 79% with LNM, and 28% and 17% with DM, respectively ($p<0.01$); the DRFS probability of BC-women with LNM was 86%. The 1st follow-up year resulted the most expensive for the INHS: on average, each patient with primary BC, LNM and DM costed, respectively, € 9,190, € 11,421 and € 16,320 (hospitalizations, including the index one, accounted for 45.1%, 48.8% and 48.3%). The subsequent mean per capita annual expenditures diminished up to € 3,529, € 3,761 and € 7,166, respectively; hospitalization costs halved, while pharmaceuticals almost doubled, and outpatient specialist care slightly reduced for primary BC and LNM and increased for DM.

CONCLUSIONS: This study shows that HR+/HER2- BC-women diagnosed at advanced stages greatly impact on the INHS's resource consumptions and direct costs.

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Acceptance Code:	PT9
Board Number:	6B
Abstract Title:	Harnessing the Potential of Natural-Language Processing and Interconnected Data Streams for Complex Diseases in the Hospital Setting: Lupus Case Study in France (LUPUS REAL)
Presenting Author:	Marc Jouve

Abstract Body:

OBJECTIVES: Efficiently identifying and characterizing with precision patients suffering from a heterogeneous condition with diverse manifestations is complex with traditional data sources. This study assesses the ability of an interconnected hospital-specific natural language processing (NLP)-powered solution (Realli) to identify and characterize patients with lupus in France.

METHODS: Upon Ethics and Scientific Committee approval, we searched native hospital patient electronic medical records ("lupus" or "lupique" text strings) and hospital claims (ICD-10-CM L93.X or M32.X).

RESULTS: Between January 2018 and March 2023, we identified 191 adult patients with lupus (mean age 48.1 years; 88% females), with 95.8%, 20.4% and 4.2% of patients who presented with lupus erythematous, nephritic, and cutaneous, respectively and not mutually exclusive (ICD codes, text strings). Biomarker values on lupus-specific or not, such as anti-DNA antibodies, anti-RNP antibodies, Smith antibodies, and C-reactive protein were retrieved in 63.9%, 4.2%, 12.6%, and 54.5% of patients, while disease activity index (i.e., SLEDAI or BILAG) was reported in 9.4% patients. Most prevalent comorbidities were cardiovascular (56.5%), metabolic (22.5%) and psychiatric (16.8%) disorders and infections (8.9%). In addition, renal impairment was identified in 29.8% (all renal ICD-10 codes) and 24.1% (ICD-10 N17.X to N19.X only or creatinine clearance levels <60 mL/min/1.73 m2). Among those latter, 52% required dialysis. Lastly, 26.7% and 15.2% of patients presented with antiphospholipid antibody syndrome or Gougerot-Sjögren syndrome, respectively. Patients received (not concomitantly) cyclophosphamide (4.7%), immunosuppressants (6.8%), glucocorticoids (47.7%), hydroxychloroquine (73.8%), belimumab (14.7%), and/or rituximab (8.4%). Over the study period, patients were hospitalized on average 7 times (median 3).

CONCLUSIONS: A NLP-powered solution connected to multidata hospital sources is effective in characterizing complex pathologies, with a breadth and granularity of information not available in traditional RWE data sources. Learning from this single-center study will be deployed to multihospital systems in France to test the robustness of the findings.

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