

The following variables were recorded: age, sex, line therapy, location of the primary tumour and metastases, treatment duration and adverse events associated with panitumumab.

Treatment efficacy was assessed according to Response Evaluation Criteria In Solid Tumours (RECIST) ( criteria, progression-free survival (PFS) and global survival (GS).

Panitumumab safety was assessed by adverse events described in the clinical history.

**Results** A total of 33 patients (21 males) were included, whose average age was of  $72 \pm 9.42$  years and the treatment duration was  $6.1 \pm 3$  months.

Patients were treated with panitumumab monotherapy (40%), in combination with FOLFOX (30%), with FOLFIRI (18%) or with other combinations (12%). Panitumumab was used as first-line therapy in 48% of the cases.

Main locations of primary tumour were: colon (36%), sigma (31%), rectum (21%), rectum-sigma (9%) and cecum (3%). Hepatic metastases were developed by 63% of the patients.

According to RECIST criteria, the assessment of efficacy was: partial response (40%), progressive disease (30%), stable disease (21%) and complete response (9%).

Median PFS and GS were 4.5 and 17.3 months respectively. In combination with FOLFOX, 5.3 and 17.4 months, with FOLFIRI 4.6 and 17.1 months and in monotherapy 4.5 and 17.2 months.

The most frequent adverse events were dermal toxicity (97%), diarrhoea (60%), hypomagnesaemia (27%), conjunctivitis (15%) and constipation (6%).

**Conclusion** Panitumumab monotherapy, and in combination with chemotherapy, is effective and well-tolerated in the treatment of patients with mCRC, despite the high incidence of dermal toxicity.

Although the number of patients is limited, results obtained are similar to published studies.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

[https://ejhp.bmj.com/content/24/Suppl\\_1/A99.2](https://ejhp.bmj.com/content/24/Suppl_1/A99.2)

No conflict of interest.

#### 5PSQ-047 NIVOLUMAB FLAT DOSE, CLINICAL-ETHICAL AND ECONOMIC IMPLICATIONS

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**Background** In Italy, on 2 May 2018, the use of nivolumab (Obdivo) was approved in monotherapy in a 240 mg dose every 2 weeks to replace the weight-based dosage (3 mg/kg) for all approved indications (melanoma, non-small cell lung cancer (NSCLC), renal cell carcinoma (RCC)) and a dose of 480 mg every 4 weeks (melanoma and RCC). The dosage change was based on pharmacokinetic data that showed good safety up to a dose of 10 mg/kg. The previous dosage was defined as off-label.

**Purpose** The purpose of this study was to evaluate any change in the drug-related adverse (ADR) events and any additional costs after the transition to the flat dose.

**Material and methods** We collected data from the National Pharmacovigilance Network (NPN) from the 2 May to 15 October in the years 2016, 2017 and 2018. The number of

reported ADRs and the percentage of severe ADR has been compared (deaths were not considered). For the estimation of costs we considered all patients who received nivolumab treatment from 2016. For the naive patients after the 2 May, the dose was calculated with the old scheme of 3 mg/kg. For patients who had already discontinued therapy, the dose difference was calculated with the flat dose. The price ex-factory per mg was € 13.44.

**Results** The reported ADRs in NPN were, respectively: 174 (35.1% serious), 192 (34.4% serious) and 175 (58.3% serious). For the estimation of costs, an average increase of 35.3 mg for a single administration, corresponding to an increase of € 474.43, was measured.

**Conclusion** Since the flat dose was calculated on a hypothetical patient weighing 80 kg, it was easy to view a rapid increase in direct costs related to the drug (11 out of 15 of the patients considered had lower weight). Despite the bias related to the applied methodology, it is possible to think that the costs associated with nivolumab will increase. Furthermore, it is not clear why the 3 mg/kg dosage is to be considered off-label. Furthermore, it is interesting to note that the number of serious ADRs has increased. However, pharmacovigilance monitoring is required to evaluate changes in the safety profile.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 5PSQ-048 REAL-WORLD SAFETY AND TOLERABILITY OF THE RECENTLY COMMERCIALISED PALBOCICLIB

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**Background** Palbociclib was commercialised in November 2017, for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant (in women who had received prior endocrine therapy).

Most common adverse events (AE) described in clinical trials (CT) were: haematological (neutropaenia (80.6%), leucopaenia (45.2%) and anaemia (27.6%)), and no-haematological, above all infections (54.7%). Neutropaenia was the most common AE, experienced in grade (G) 3 or 4 in 55.3% and 10.1% of patients, respectively. Median time for the first neutropaenia episode was 15 days, with a median duration of 7 days.

**Purpose** To evaluate the safety of palbociclib in real-world clinical practice and compare it with the results of CT.

**Material and methods** Prospective observational analysis (February to October 2018) on patients treated with palbociclib, in a regional hospital. Patients' demographics and treatment evolution related to toxicity were analysed. Toxicity grade was classified by CTCAE V5.0. In each visit, the pharmacist revised physician's prescription according to patient's analysis results and made recommendations.

**Results** Nine women (average age of 56) with metastatic breast cancer HR-positive/HER2-negative were included. Five patients had been previously treated: hormonal therapy (3/9), chemotherapy (1/9) or both (1/9). According to prior treatments,