

subgroup analysis of this phase III trial. In late 2008, the first Gemcitabine generic was commercialised.

**Purpose** Our aim was to highlight the limited evidence of the quality of Pemetrexed's efficacy considered on its approval and its impact on its use.

**Material and methods** The literature was reviewed and a retrospective analysis of the first-line treatment options in non-SC NSCLC in our hospital was made between July 2013 and June/2017.

**Results** An opinion article was published in January 2018 in *JAMA Oncology*.<sup>1</sup> It discussed if an approval based in a subgroup analysis of a clinical trial, predefined but never tested in a phase III trial design for its validation, was strong enough to influence clinical practice. It is well known that any data retrieved from a clinical trial subgroup analysis is indicative and non-conclusive. It is uncertain when a subgroup analysis should influence clinical practice. The non-SC NSCLC treatment guidelines replace Gemcitabine for Pemetrexed as a first option, with evidence level II, using efficacy and not safety as a reason, which could be an argument.

In the 4 years' analysed, 71 patients were treated with Pemetrexed and 22 patients with Gemcitabine, both associated with platin. The cost difference per patient (six cycles considered) was € 10 554 (€ 7 49 334 for the 71 patients).

**Conclusion** Pemetrexed was preferred to Gemcitabine as a first-line treatment of non-SC NSCLC, beside its limited evidence quality. A change in clinical practice should require better evidence levels. In our hospital, this change in clinical practice had a relevant economic impact.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

#### 1ISG-008 FLAT DOSES OF ANTI-PD1: WHAT IS THE ECONOMIC IMPACT?

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**Background** In 2018 the European Summary of Product Characteristics (SPC) of Opdivo (nivolumab) and Keytruda (pembrolizumab) used in monotherapy were modified. The weight-based doses were replaced by flat doses.

**Purpose** We studied the economic impact of these changes in posology at the level of our hospital.

**Material and methods** The data: indications, weight and doses prescribed were extracted from our chemotherapies' prescription and preparation database software.

We selected patients treated by Opdivo for a melanoma or a non-small cell lung cancer (NSCLC) and those treated by Keytruda for a melanoma.

The patients selected were currently treated with a weight-based dose, then with a flat dose after modification of the SPC.

For each patient the economic impact associated with the change of dose was quantified.

**Results** Twenty-eight patients treated by Opdivo were analysed. Before modification of the SPC the average dose prescribed was 233 mg (147 mg; 375 mg). An increase in dose was observed for 18 patients (64%) and a decrease in dose was

observed for 10 patients (36%). The average additional cost per cure per patient with a flat dose was € 73 (€ 10.6/mg of Opdivo) and the estimated additional annual cost for our hospital is € 53 319.

Six patients treated by Keytruda were analysed. Before modification of the SPC the average dose prescribed was 175.4 mg (138 mg; 200 mg). An increase in dose was observed for five patients (80%), and the dose was maintained for one patient (20%).

The average additional cost per cure per patient with a flat dose was € 647€ (€ 26.3/mg of Keytruda) and the estimated additional annual cost for our hospital is € 67 445.

**Conclusion** The flat doses now recommended increase on average the anti-PD1 dose administered to the patients.

This generates an additional estimated cost for the hospital of about € 1 20 000 a year.

The toxicity data with superior doses are reassuring, but no clinical benefit is demonstrated. Benefits on the safety side and on the organisation side with flat doses appear debatable in view of the derived additional costs.

This approach could be applied to the posology of Keytruda as first line of the NSCLC. A weight-based dose would decrease the cost by € 3 78 000 per year for our hospital, with 11 patients currently treated.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

#### 1ISG-009 AVOIDED COST STUDY OF DRUGS IN CLINICAL TRIALS AT A TERTIARY HOSPITAL

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**Background** Clinical trials (CT) in oncology constitute a continued growth area. Besides contributing new molecules which improve patients' prognosis, they also involve a saving measure due to drugs that are supplied by the sponsor.

**Purpose** To determine the avoided cost attributable to supplied drugs by CT in oncology during one year.

**Material and methods** Observational, retrospective study of CT done in an Oncology Department of a tertiary hospital from July 2017 to June 2018. Data were obtained from the Pharmacy's clinical trial programme, PKensayos: number of patients; number of drug units dispensed per clinical trial; avoided cost (supplied drugs by sponsor with label indication and marketed in the European Union (EU)); and total cost (supplied drugs by both sponsor and Pharmacy with label indication and marketed in the EU). More prevalent pathologies were reviewed. Exclusion criteria: investigational, not marketed drugs and blinded samples.

Drugs' prices were collected of average price, purchased in the Pharmacy.

**Results** During the whole period of study, 76 CT were done in the Oncology Department, of which 38 met the requirements of this study. The number of patients was 261. The average of drug units dispensed per CT: 58.5 (1–1512); avoided cost: € 3,482,662; and what supposes € 13,343/patient. Total cost: € 5595 and € 21,438/patient.

Drugs with highest avoided cost: nivolumab (€ 1,336,303), >pemetrexed (€ 543,717), and >ipilimumab (€ 467,006).

Drugs with highest total cost: nivolumab (€ 1,336,303), >ipilimumab (€ 1,336,303), and >pemetrexed (€ 546,026). The most prevalent pathology was lung cancer (19 CT, 14 of which were non-small cell lung cancer) and melanoma (four CT).

**Conclusion** The CT are an opportunity to contain pharmaceutical costs in hospitals. Patients in CT produced a cost saving of € 3,482,662/year. The potential savings justify the need to incorporate as many clinical trials as possible, not just for cost savings but because it would mean better access for patients to these highly effective and/or breakthrough therapies.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

11SG-010

#### REAL-WORLD EVIDENCE OF HIGH-COST DRUGS FOR METASTATIC MELANOMA: EFFECTIVENESS, COMPLIANCE TO CLINICAL PRACTICE GUIDELINES AND ECONOMIC EVALUATION

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**Background** In Italy melanoma is the second most common cancer among men and the third in women. Invasive malignant melanoma accounts for about 1% of all skin cancers, but it is the most deadly. Targeted therapy and immunotherapy have changed the management of metastatic melanoma. Chemotherapy is less effective, but it is still a treatment option.

**Purpose** To analyse drug effectiveness for metastatic melanoma in our hospital, to assess compliance to clinical practice guidelines and to perform an economic evaluation.

**Material and methods** We analysed all patients with metastatic melanoma treated from 1 May 2016 to 30 April 2018 and which drugs were administered. Patients were stratified by age, gender, line of therapy, Eastern-Cooperative-Oncology-Group (ECOG) performance status (PS) and type of cancer treatment (targeted therapy-immunotherapy). We assessed progression-free survival (PFS) and overall survival (OS) with the Kaplan–Meier method. We assessed compliance to Italian clinical practice guidelines and we analysed the drug costs.

**Results** Fifty-three cases of metastatic melanoma were found. The mean age was 66, 58% were older than 65 years and 55% were male. Median PFS was 17.7 months and median OS was 27.5 months. Fifty-eight per cent were treated with immunotherapy (nivolumab or pembrolizumab) and 42% with targeted therapy (dabrafenib +trametinib or vemurafenib +cobimetinib). In the targeted therapy group, median PFS was 9.6 months and median OS was 18.6 months. Median PFS and OS in the immunotherapy group were not reached. Sixty-six per cent were first-line treatments (median PFS 17.6 months, median OS 29.3 months). Beyond first-line therapy median PFS was 6.7 months and median OS was 7.3 months. Seventy-seven per cent had baseline PS of 0. PS was identified as an important prognostic factor for PFS and OS. Female gender and age older than 65 were significant predictors for PFS and OS benefit.

We identified only one case of non-compliance to clinical practice guidelines.

The cost of the drug combination vemurafenib +cobimetinib was higher than the cost of dabrafenib +trametinib. Pembrolizumab was less expensive than nivolumab.

**Conclusion** Our analysis suggests a high level of compliance with clinical practice guidelines.

Dabrafenib+trametinib was a cost-effective regimen in BRAF-mutated patients requiring rapid intervention to avoid disease progression.

Immunotherapy should be the treatment of choice in order to achieve long-term disease control.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

11SG-011

#### REDUCTION OF THE PATIENT WAITING TIME: WHAT COST FOR THE CHEMOTHERAPIES PREPARATION UNIT?

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**Background** Our establishment produces approximately 150 chemotherapies per day for 115 patients. In order to reduce the patient waiting time, we decided to anticipate the chemotherapy prescriptions which permit us to prepare a part of the chemotherapies in advance. To overcome the rise in returns generated by that anticipation, we set up standardised doses (five different types by interval of body surface area in m<sup>2</sup>: <1.49; 1.49–1.69; 1.69–1.89; 1.89–2.1; >2.1) facilitating the reallocation of the chemotherapies returns.

**Purpose** Reduce the cost of returns due to the anticipation of chemotherapy prescriptions.

**Material and methods** From January to June 2018, the returns of chemotherapy prescriptions have been listed and analysed to identify the dose (standardised or not), the cost and the cause of the return. The standardised and reassigned doses prescribed chemotherapies have been counted.

**Results** In a period of 6 months we have counted 852 returns for 18 443 produced chemotherapies, which is 1.6% of the total cost of preparations realised during this period. The return causes were based on the prescription itself (diminution of the dose, alteration of biology report, change of protocol) and on the patient's condition (alteration of the global condition, infection, hospitalisation). Seventy-nine per cent of returns were from anticipated chemotherapies (in order to reduce the patient waiting time), however 16% of these returns could have been reassigned. The standardised dose preparation represented 40% of the returns, 42% of which had been reassigned and it permits a reduction in costs of one-third.

**Conclusion** This standardised work produced a reduction in the return cost of 37%. At the moment, 21% of the prescriptions are standardised. To reduce more the return cost while maintaining the patient care quality, we would like to increase the standardisation and improve the stability of chemotherapy bags.

#### REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.