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.[1] 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.

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No conflict of interest.

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

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10.1136/ejhpharm-2019-eahpconf.8

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 aflat 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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10.1136/ejhpharm-2019-eahpconf.9

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).