Conclusion and relevance BM expenditure increased by more than 50% in the last five years, with MAB being mainly responsible. The biological active substances with the highest budgetary impact were medicines to treat immune mediated diseases. The incorporation of BS will lead to a reduction of 20% in BM costs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

Section 2: Selection, procurement and distribution

2SPD-029 OFF-LABEL DRUGS: USE ANALYSIS AND PHARMACOEPIDEMIOLOGY IN A COVID CENTRE IN ROME

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Background and importance The coronavirus pandemic has involved the sudden management of innovative therapeutic opportunities to counter it. A drug's off-label use has required a sudden supply and the production of legislation to settle such handling to target real data towards a shareable and objective data collection flow.

Aim and objectives The aim of the study was to analyse the supply process of off-label drugs and reference to the national legislation for each medicinal product, regarding consumption data and the number of COVID-19 patients treated in a COVID centre in Rome, with 200 COVID beds and 40 beds in two intensive care units.

Material and methods For the following products, the supply and handling data were analysed from 1 February 2020 to 31 July 2020: chloroquine, hydroxychloroquine, lopinavir/ritonavir, darunavir/colbicitat, raltegravir and tocilizumab. The AIFA's reference regulations of these drugs were highlighted in the same period. Pharmacoepidemiological data were obtained.

Results The drug's off-label request was first considered. After the AIFA's decision to include in the 648/96 Law (GU 69 17.03.2020) chloroquine, hydroxychloroquine, lopinavir/ritonavir, darunavir/colbicitat, the UOC Pharmacy drafted a specific request form according to the 648/96 Law, to convey the supply and distribution of drugs to the departments through a reporting channel as the regulations required. 10 658 tablets of lopinavir/ritonavir were given to 250 patients, 660 tablets of darunavir/colbicitat to 32 patients, 302 150 tablets of hydroxychloroquine to 350 patients and 330 tablets of chloroquine to 33 patients. Raltegravir tablets were obtained for compassionate use for one patient. Tocilizumab was introduced through an off-label company procedure. Later, the centre was included in the TOCIVID-19 clinical trial (19 March 2020) and patients were moved to the clinical trial. During the off-label use period, 54 therapies were provided and 34 of these required a second dose. From an analysis of the epidemiological data, 80% of patients had at least one comorbidity and age over 75

years; 60% were men. Death occurred in 6% overall, with a 30% death rate for patients over 75 years, according to national data.

Conclusion and relevance The COVID-19 emergency has highlighted the pharmacist's role in the supply of innovative drugs and in the management of National Regulations. A close relationship with physicians has allowed sharing of views, focused on streamlining bureaucracy that often slows down the drug distribution process. Sharing opinions, bureaucratic streamlining and development of communications with online systems, web servers and phone chats can speed up the timing of organisation of the services.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. <https://www.aifa.gov.it/web/guest/-/schede-informative-sui-farmaci-utilizzati-per-emergenza-covid-19-e-relative-modalita-di-prescrizione>

Conflict of interest No conflict of interest

2SPD-030 POSITIONING OF DORAVIRINE IN THE PHARMACOTHERAPEUTIC GUIDE OF A THIRD LEVEL HOSPITAL

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Background and importance Recently, the EMA and AEMPS have approved the use of doravirine (DOR) a non-nucleoside reverse transcriptase inhibitor (NNRTI) for the treatment of adults infected with HIV-1 without past or present evidence of resistance to the NNRTI class. At present, the therapeutic arsenal available in Spain presents various options within each class.

Aim and objectives To position DOR within the antiretroviral therapies (ART) already available in the hospital's pharmacotherapeutic guidelines and assess its incorporation.

Material and methods A bibliographic search was conducted on DOR's positioning in the main national and international guidelines with the following terms: HIV, adults and guidelines; GESIDA (Spain); DHHS (American) and EACS (European). Possible advantages with respect to the ART already available in hospital were analysed. In addition, an economic evaluation was conducted comparing with available ART and the potential patients who would benefit from its use. The official list price was used with the deduction described in the Royal Decree Law 8/2010 as well as 4% VAT.

Results Gesida guidelines (July 2020) recommended the combination DOR+FTC/TAF or DOR/3TC/TDF (not yet marketed in Spain) as an alternative to the preferred regimens (C-I), but never as the initial therapy. On the other hand, the DHHS guidelines (June 2020) recommended DOR as the initial regimens in certain clinical situations. EACS guidelines (2019 update) recommended it as an initial regimen in combination with two NRTIs or as DOR/3TC/TDF.

The main advantages of DOR are: efficacy in high viral loads (rilpivirine (RVP) is not effective), lower potential for drug interactions, lack of food restrictions, fewer adverse effects on the CNS compared with efavirenz (EFV) and a neutral lipid profile (avoiding dyslipidaemia induced by EFV or boosted protease inhibitors).

The number of patients undergoing treatment with NNRTIs in our hospital was 322 (n=1894 total active HIV positive

patients). The potential percentage of use was about 17% of the total. DOR+FTC/TAF or DOR+FTC/TDF represented a cost of 851.55€ and 642.90€/patient/month, respectively. RVP/FTC/TAF, EFV/FTC/TDF or DRV/COBI/FTC/TAF would cost 673.57, 262.58 or 857.51€/patient/month, respectively.

Conclusion and relevance DOR would be beneficial in those patients with CNS disorders due to EFV and high viral load (>100 000 copies) or in polymedicated patients because of the lower profile of interactions. In the remaining cases, there are alternatives already available in the hospital (following recommendations of the GESIDA guidelines).

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

2SPD-031 SUBGROUP ANALYSIS ABOUT EFFICACY OF EARLY USE OF REMDESIVIR IN COVID-19

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Background and importance A greater benefit was suggested with early treatment with remdesivir against COVID-19.

Aim and objectives To develop a systematic review and methodological interpretation of subgroup analyses according to timing of use of remdesivir in COVID-19.

Material and methods A bibliographic review in MEDLINE was conducted up to 10 October 2020. The 'Clinical Queries/Narrow' tool was used with the search strategy: ((Therapy/Narrow[filter]) AND (remdesivir AND COVID)). Randomised clinical trials (RCTs) with subset analysis about early and late use of remdesivir (≤10 vs >10 days from symptom onset, or ≤9 vs >9 days) were selected. The rest of the studies were excluded. All endpoints with subgroup analysis regarding timing of remdesivir use were assessed. Two methodologies were applied. The first considered statistical interaction among subsets, prespecification, biological plausibility and consistency of the subgroup analyses of similar RCTs.¹ The second methodology was a validated tool with preliminary questions to discard subset analysis without minimal relevance, and a checklist.² This checklist assigned a score related to a recommendation for applicability of subgroup analysis in clinical practice.

Results 20 results were found after review; 16 studies were excluded because they were not RCTs and 1 study had no efficacy evaluation of remdesivir. Therefore, three RCTs were selected. Endpoints considered were: time to clinical improvement, mortality, viral load, and clinical status at days 11 and 15. According to the first methodology, no statistical interaction was observed in the outcomes of the RCTs. Prespecification was established in time to clinical improvement, and clinical status at day 15 of an RCT. Biological plausibility was described in the subset analysis of each endpoint of the RCTs. No consistency of subgroup analyses were found. The second methodology discarded the applicability of the subset analysis through preliminary questions in two RCTs because of the absence of minimal relevance. For the third RCT, 'null'

recommendation (score -3 points) of clinical applicability was reached for clinical status at day 11.

Conclusion and relevance No differences were found between early and late use of remdesivir in COVID-19. We developed the first study with a systematic review and methodology about subgroup analysis of timing of use of remdesivir.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Sun X, et al. How to use a subgroup analysis: users' guide to the medical literature. *JAMA* 2014;**311**:405–11.
2. Gil-Sierra MD, et al. Checklist for clinical applicability of subgroup analysis. *J Clin Pharm Ther* 2020;**45**:530–8.

Conflict of interest No conflict of interest

2SPD-032 NETWORK META-ANALYSIS OF THERAPEUTIC ALTERNATIVES IN UNTREATED METASTATIC SQUAMOUS NON-SMALL CELL LUNG CANCER

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Background and importance Multiple therapeutic alternatives are used in untreated metastatic squamous non-small cell lung cancer (umSNSCLC). Paclitaxel-carboplatin-pembrolizumab combination (PC-pembrolizumab) has recently been authorised for this indication.

Aim and objectives To assess the comparative efficacy among different therapeutic alternatives used in mSNSCLC through a network meta-analysis (NMA).

Material and methods A search was conducted on 19 February 2020 with the following inclusion criteria: phase II/III randomised clinical trials (RCT), including drugs used in umSNSCLC, and overall survival (OS) as the efficacy endpoint. Exclusion criteria: mSNSCLC population with EGFR or ALK mutations and RCTs without a comparator common to the evaluated alternatives. Pooled hazard ratios (HR) were calculated by Bayesian methods, through the combination of direct and indirect evidence by the NMA. Fixed and random effects were evaluated. Deviance information criteria (DIC) statistics were used to compare the models. The agreement of direct and indirect estimations was assessed by node splitting models to evaluate the consistency of NMA. Delta value, maximum acceptable difference as clinical criterion of non-inferiority, was set at 0.70 (and its inverse, 1.43), used to calculate the sample size in the PC-pembrolizumab trial.

Results Nine RCTs were selected. PC was the common comparator. The DIC value for the fixed effects model was more favourable. No statistically significant differences between direct and indirect evidence were found, and therefore NMA was consistent. The PC-pembrolizumab combination was considered as the reference (treatment with the greatest magnitude of effect). HR for OS were: 1.4 (95% CI 0.89 to 2.3) versus carboplatin-gemcitabine; 1.6 (1.2 to 2.1) versus PC; 1.5 (1.1 to 2.1) versus nab-PC-attezolizumab; 1.8 (1.3 to 2.5) versus PC-figitumumab; 1.4 (0.96 to 2.0) versus PC-motesanib; 1.3 (0.66 to 2.5) versus PC-necitumumab; 2.1 (0.86 to 5.0) versus PC-olaratumab; 2.9 (1.7 to 4.8) versus PC-sorafenib and 1.2 (0.82 to 1.7) versus pembrolizumab monotherapy. Carboplatin-gemcitabine, PC-motesanib, PC-necitumumab, PC-olaratumab and pembrolizumab did not present statistically