and forty different chronic drugs were prescribed (2.2 ± 2.4 drugs per patient). Twenty-one drugs were classified to have a major interaction with cobicistat, 40 a moderate interaction, five minor, 147 did not have any interaction registered in drugs.com and 27 drugs did not appear in this web. Pharmacists made 87 interventions with 35 different drugs. The most frequent were inhaled budesonide (12) and nasal fluticasone (11). Forty-four (51%) of the pharmaceutical interventions did not need the physician's approval (17 to interrupt chronic treatments, 13 to change treatments, 12 to monitor and one to change dose). The rest (43) required physician approval and these consisted of more varied actions, highlighting six changes in the HIV regimen to eliminate cobicistat. We registered possible/probable toxicities related to the inhibition of metabolism due to cobicistat in eight patients.

Conclusion Pharmacist reconciliation detects numerous potential interactions. Pharmacist intervention helped to modify several treatments and make treatments safer.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None.

No conflict of interest.

4CPS-098 INFLUENCE OF PHARMACOLOGICAL INTERACTIONS IN HEPATITIS C TREATMENT SELECTION IN OPIATE-DEPENDENT PATIENTS

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Background The therapeutic strategy for chronic hepatitis C (CHC) in our health system established that in mono- or co-infected HCV/HIV patients in whom prioritised therapy with glecaprevir/pibrentasvir is contraindicated, their chronic medication (CM) will be changed and/or an alternative therapy for HCV will be used: sofosbuvir/velpatasvir (+7% cost per patient) or elbasvir/grazoprevir (+64% cost per patient).

Purpose To analyse the influence of pharmacological interactions in the selection of HCV treatment in opiate-dependent patients.

Material and methods All treatments started in a Mental Health Network (which opiate-dependent patients attend) from 1 January 2018 to 31 August 2018 were analysed.

Prior to the approval of hepatitis C treatment by the CHC committee, the pharmacist reviewed the treatment and looked for possible pharmacological interactions of the HCV prioritised therapy with the CM. If there was a significant interaction, the pharmacist recommended either to change/stop the CM or to choose an alternative HCV treatment.

Results Approved treatments by the CHC committee: 96. Completed treatments: 73, 98% mono-infected. HCV genotype: 1a: 31 (42%), 3: 22 (30%), 4: 11 (15%), 1b: seven (10%) and 2: two (3%). Forty-seven (64%) patients were $\leq$ F3, 21 (29%) F4 and five (7%) were unknown.

64/73 (88%) patients were treated with glecaprevir/pibrentasvir. A CM change was needed in 14/64 (22%) patients: to avoid metimazole, delay proton-pump inhibitor administration time, to switch to another statin and stop oxcarbazepine.

Only 9/73 patients (12%) received a non-prioritised treatment with sofosbuvir/velpatasvir. In eight of them due to interactions with their CM: antipsychotics (five), HIV protease

inhibitor (one), anti-platelet (one) and ethinylestradiol (one). In another patient the reason was that he was Child-Pugh B.

The sustained viral response is available only in 20% of patients, so the effectiveness has been measured as viral response at the end of treatment (VRE), being 96% (70/73) up to date. Three patients are pending to be determined.

Conclusion The review of pharmacological interactions has allowed the treating of 88% of patients with the prioritised therapy, with an effectiveness in VRE of 96%, according to the results of the clinical trials.

The pharmacological interactions evaluation and pharmaceutical interventions optimize the risk benefit ratio and contribute to the efficient use of HCV therapies.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-099 PALIVIZUMAB OFF LABEL USE IN TERTIARY REFERRAL HOSPITAL

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Background The indication of palivizumab is the prevention of serious lower respiratory tract disease requiring hospitalisation caused by the respiratory syncytial virus (RSV) in children at high risk for RSV disease, but medication assessment in different conditions to the authorised ones is a fairly common situation in our environment, thus the hospital maintain a multidisciplinary pharmacy committee which evaluates this medication for personalised authorisation.

Purpose The purpose of this study is to evaluate palivizumab off-label use (2016–2017).

Material and methods Observational retrospective study of patients receiving palivizumab off-label use. The analysed variables were; base pathology, gestational age, hospitalisation number, costs and evidence degree according to the US Agency for Healthcare Research and Quality scale.

Results Eighteen children (22.2% repeated prophylaxis the second year) were treated with palivizumab with an average age of 24.76 (5–63 months), 44.4% girls. Palivizumab use of off label represented 8.7% of total patients treated with palivizumab (230 patients). 33.3% were diagnosed with cystic fibrosis, 33.3% congenital myopathy and 5.5% respiratory disorders (recurrent pneumonia, pulmonary hypoplasia and respiratory infections secondary to kidney dysplasia, esophageal atresia and interstitial lung disease). According to the evidence level, in children with cystic fibrosis it presents grade Ib, in myopathy prophylaxis the grade is II (cohorts) and for esophageal atresia, pulmonary malformations and serious respiratory diseases the grade is IV (expert opinion). 33.3% of patients had a gestational age under 37 weeks. 11.1% of hospitalisations by RSV infection required oxygen therapy (a patient after having received prophylaxis in previous years and another hospitalisation by VRS in 2016 that was not repeated after the palivizumab treatment in 2017) (7.7 hospitalisation days). Dosage was 15 mg/kg monthly during the 4–5 months of the risk season. The cost/patient/year: €6,255.75 to €7,807.5 (VAT included). The estimated economic impact was €112,603.5 to €140,535 (16.8%–21% of total palivizumab cost).

Conclusion Given the existing low degree of evidence, this study shows that there are no clear advantages of this medication in patients with cystic fibrosis and neuromuscular problems. Consequently, and given the high cost that palivizumab use implies, it would be necessary to establish protocols that define use condition and identification of patients that may benefit better from the treatment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-100

QUALITY OF INTRATECT: IN VITRO EVALUATION OF BIOLOGICAL ACTIVITIES

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Background Human normal immunoglobulin preparations for intravenous application (IVIG) such as Biotest's Intratect were initially developed as substitution therapy for primary and secondary immunodeficiencies. Over time the clinical use has broadened and now additionally includes treatment for a multitude of hyperinflammatory conditions, typically at higher doses.¹ Recently, chronic inflammatory demyelinating polyradiculoneuropathy (CIDP) has become a formally approved indication.

Purpose Due to this change in use which involves increased doses, and in view of adverse events observed with other IVIG brands, we have re-evaluated quality parameters relevant for product safety and efficacy.

Material and methods Since thrombogenicity is a general risk identified for IVIGs, analyses of Intratect with globally-used coagulation tests, such as the thrombin generation Assay, were performed. Additionally, specific tests for the detection of potential impurities (e.g. prekallikrein activator (PKA)) were employed to assess the thrombogenic potential. The tests for anti-A and anti-B hemagglutinins complies with the European Pharmacopoeia (2.6.20).

Results Intratect was found to be free of procoagulant and other impurities. The content of blood group antibodies, which are associated with the risk of haemolysis, can be controlled by the manufacturing process. In Intratect these antibodies are consistently tightly controlled, and their content is far below the isoagglutinin titer threshold. Pathogen antigen recognition is a prerequisite for the anti-infective activity of immunoglobulins. Intratect was found to contain antibody titers against relevant viruses and bacteria. Quality characteristics of IVIG preparations differ from brand to brand but are typically consistent from batch to batch for a single brand.

Conclusion Multiple factors contribute to the quality of the IVIG preparations. Important quality attributes are associated with safety,^{2,3} and adequate antimicrobial activity. Different manufacturing processes determine differences in the quality, safety and efficacy of IVIG brands.

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4CPS-101

INTRAVENOUS IMMUNOGLOBULINS USE FOR CHILDREN'S NEUROLOGICAL AND NEURODEVELOPMENTAL DISORDERS

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Background Intravenous immunoglobulins (IVIG) indications are replacement therapy and as immunomodulatory therapy for several autoimmune disorders. It has been estimated that neurologic indications can account for up to 43% of IVIG used in clinical practice.¹

Purpose To evaluate the use of IVIG in paediatric patients from the neurology service of a children's care reference hospital.

Material and methods Based on medical history records, we collected and analysed retrospective data from January 2013 to December 2017 of all children who received IVIG patients followed by our neurology department.

We classified the patients according to their diagnosis and we contrasted the results with the recent published review about the IVIG use in paediatric neurological and neurodevelopmental disorders.²

Patients diagnosed during an enterovirus encephalitis spread during 2016 in our region were excluded because the patients were assigned to other paediatric departments.

Results A total of 60 patients met the inclusion criteria.

Their diagnostics were: twenty-nine peripheral nervous system indications: Guillain-Barré syndrome (22), peripheral nervous system indications (six) and myasthenia gravis (1).

Fourteen central nervous system indications: acute encephalomyelitis disseminata (four), refractory epilepsy (four), ataxia-telangiectasia (two), acute-cerebellitis (two) and anti-NMDA encephalitis (two).

Seventeen non-neurological specific indications: post-rituximab hypogammaglobulinaemia (four), opsoclonus myoclonus (four), infectious encephalitis (four) and other diagnostics (five).

All patients were treated with a correct dose as per immunomodulatory (1–2 g/kg/dose) or immune-replacement (0.3–0.5 g/kg/dose) therapy. Most of them tolerated well the IGIV administration (three mild-adverse events reported).

Conclusion IVIG are used in a large number of indications not labelled in Spain, although substantiated, in a high percentage, in solid evidence according to the reviews. Other diagnostics not associated with neurological disorders were classified and we need to ensure that other specialists validated the utilisation. Given the significant economic impact of using this therapy, it is necessary to protocolise and adapt its use to the