that came from the pivotal trials were excluded. Effectiveness was measured as the percentage of patients who remained with undetectable VL on 24 September 2023. To measure safety, the adverse reactions (AR) recorded in the electronic medical records were reviewed.

Results One hundred and seventy-five patients were included: 156 cis-men (89%), 18 cis-women (10%) and one trans-woman (1%), with a median age of 45 years (IQR=36–57). The most common prior treatments were bictegravir/emtricitabine/tenofovir alafenamide (48%) and dolutegravir/lamivudine (23%). One hundred and thirty-seven patients had at least one analysis since the first administration, 15 had two, and the rest had no analysis since the first administration of C/R. Only two patients (1.1%) had detectable VL in their first analysis (log 1.64 and 1.74), but in both, a new analysis was done at 29 and 7 days, respectively, and again had undetectable VL.

The most prevalent AR was pain at the administration site (53.0%), followed by diarrhoea (2.2%), fatigue (1.7%), pyrexia (1.7%), headache (1.7%), and induration (0.6%). The rest of the patients (39.1%) did not present any AR. Two patients (1.1%) discontinued treatment due to AR, one due to pain at the site of administration and another due to fatigue and weight loss [DS1] . The duration of AR had a median of 2 days, and all of them resolved within 7 days of administration.

Conclusion and Relevance The intramuscular association of cabotegravir and rilpivirine effectively maintains VL supressed and it is safe. The most reported adverse reaction is pain at the injection site.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-061 CURRENT PRACTICE OF PAEDIATRIC OFF-LABEL PRESCRIPTIONS IN A PAEDIATRIC HOSPITAL

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10.1136/ejhpharm-2024-eahp.395

Background and Importance Data concerning drugs' dose, efficacy and safety in paediatric are very limited and this gap of knowledge induces the off-label (OL) drug use. A study showed that 60% of paediatric prescriptions were OL and the main OL-drug classes were antibacterials/antiasthmatics/analgesics. Over the last 30 years the Drug-Agency has approved laws to ensure an appropriate use of OL-medications (Law 648/96, Law 94/98, Law 326/03, Law 7/9/2017).

Aim and Objectives The aim of this work was to evaluate the paediatric OL-drug use and safety in our hospital in the last 2 years according to the Law 94/98 and the Law 326/03.

Material and Methods We analysed OL-prescriptions evaluated by the Hospital-OL-Committee (HOLC) (composed by a Hospital-Pharmacist/Pharmacologist/Clinician) from January-2021/December-2022. We calculated how many paediatric patients were involved, which OL-drug was the most prescribed and for what type of disease (if rare disease according to the national-rare-disease-database), how many patients presented an Adverse-Drug-Reaction (ADR). We considered OL all the Intravenous-Immunoglobulins (IgIv) that were not prescribed according to our regional 'Operative-Procedure-for-the-appropriate-use-of-IgIv'.

Results The HOLC evaluated 258 OL prescriptions according to the Law 94/98 and 69 (27%) administered to 49 paediatric patients (two patients received two OL-drugs). 25 different OL-drugs were used to treat 33 conditions (20 rare diseases); seven drugs(28%) did not have the paediatric license. The most prescribed OL drug (second-level ATC) was J06-Immune-Serum-and-Immunoglobulins (20%) represented by IgIv to treat Idiopathic-Dermatomyositis/Giant-cell-Hepatitis with Autoimmune-Haemolytic-Anemia/Chronic-Polyradiculoneuritis (with or without anti-MOG antibodies)/Autoimmune-Encephalitis/Rasmussen-Syndrome/Opsoclone-Myoclone-Syndrome followed by L01-Cytostatic (17,5%) represented by bevacizumab to treat glioma and L04-immunosuppressant (17,5%) represented by adalimumab to treat Bechet-Syndrome/Systemic-Vasculitis. In the same period six patients received OL drugs according to the Law 326/03 and 4(67%) were paediatric. Three OL-drugs were used to treat two rare conditions: two patients received ivacaftor/tezacaftor/elexacaftor+ivacaftor to treat cystic-fibrosis and two fenfluramine to treat Dravet-Syndrome. Four ADRs referred to four OL therapies were reported in four paediatric patients induced by Ponatinib, IgIv, Arsenic-Trioxide, Rituximab.

Conclusion and Relevance The paediatric OL drug use in a common practice and over the last 30 years several strategies were adopted to guarantee an early and safe access to paediatric OL-medications. For example in our hospital, since 2007, all drugs included in the Hospital-Therapeutic-Formulary can be prescribed (without the HOLC's evaluation) if they are on-label for indication but off-label for age/dosage/frequency.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-062 SAFETY EVALUATION OF PEMBROLIZUMAB IN MONOTHERAPY

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10.1136/ejhpharm-2024-eahp.396

Background and Importance Checkpoint inhibition immunotherapy (ICIs) have substantially improved the prognosis for patients with many advanced malignancies. Despite important clinical benefits, ICIs are associated with a unique spectrum of side effects known as immune-related adverse events (irAEs). IrAEs include dermatologic, gastrointestinal, hepatic, endocrine, and other less common inflammatory events. Therefore, prompt recognition and management of irAEs is important.

Aim and Objectives To describe the occurrence of adverse events (AEs) during treatment with pembrolizumab monotherapy, regardless of indication, in routine clinical practice.

Material and Methods We conducted a retrospective, observational study that included all patients treated with pembrolizumab from September 2022 to September 2023 at our centre.

The variables collected were age, sex, previous immunological disease, number of cycles received, AE and degree of toxicity, as well as delays due to toxicity. The computerised clinical history was used for this purpose. Adverse events were classified according to the National Cancer Institute (NCI)