structure and mechanism of action, may play a unique role in patients who have limited or no alternative treatment options.
Aim and objectives The aim of this study was to describe the first cases of prescriptions of cefiderocol used in the 5 months following its availability in Italy, and the hospital pharmacist interventions in assisting clinicians from microbiology select a safe and appropriate antibiotic treatment.
Material and methods A standardised prescription form was sent to the infectious disease specialist to collect patients' characteristics, infection type, reasons for cefiderocol use, doses and duration of treatment (concomitant treatments, adverse events and outcome). A susceptibility testing kit (30 µg cefiderocol disc) was provided to the microbiology specialist in order to reserve this new antibiotic for patients with cefiderocol-susceptible isolates. A retrospective study was performed to collect the data of adult patients who received cefiderocol.
Results A total of 30 patients with mean age of 56 (23–90) years received cefiderocol (9 females, 21 males). Of these, 19 patients were treated in intensive care units, with the most common regimen of 2 g three times/day tid (n=6), while 3 patients with acute renal failure required a regimen of 750 mg twice daily. The main sites of infection were respiratory tract (n=16), urinary tract (n=3), intra-abdominal (n=4) and bloodstream (n=5). 5 patients had multisite infections.

The duration of therapy was in the range 6–16 days. The most common pathogens were *Acinetobacter baumannii* (n=13), *Klebsiella pneumoniae* (n= 8), *Pseudomonas aeuroginosa* (n=10) and *Enterobacter* spp (n=5). 10 patients had superinfections. The most concomitant therapy was colistin (n=9). No severe adverse events were reported. 7 patients with septic shock died.
Conclusion and relevance Our study describes real-life experience of the use of cefiderocol as a salvage option in critical patients, providing additional data on its benefit, safety and limits in both empirical and targeted treatment of multidrug-resistant Gram-negative bacteria (MDR-GNB) infections, and it confirms the need for a multidisciplinary team.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

4CPS-111 RUXOLITINIB FOR REFRACTORY GRAFT-VERSUS-HOST DISEASE IN PAEDIATRIC PATIENTS

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Background and importance Ruxolitinib has shown efficacy in the treatment of steroid-refractory graft-versus-host disease (GVHD) after haematopoietic stem cell transplantation (HSCT) in adults, but the evidence in children is still scarce.
Aim and objectives To evaluate the effectiveness and safety of ruxolitinib in paediatric patients with steroid-refractory GVHD.
Material and methods A retrospective observational study including all patients treated with ruxolitinib in our paediatric hospital (January 2017–September 2021) was carried out.

Variables collected from electronic medical records and the pharmacy dispensing program were: age, sex, weight, previous treatments for GVHD, length of treatment, dose, treatment response, reasons for discontinuation and adverse events (AEs) related to ruxolitinib. Effectiveness was assessed by the clinical resolution of GVHD.

Results 31 patients (64.5% male, n=20; median age 13.5 (1–19) years; median weight 36.9 (10–85) kg) received treatment during the period of the study in 34 episodes. In 15 episodes (44.1%) the treatment was for acute GVHD (aGVHD) and in 19 (55.9%) for chronic (cGVHD).

The median number of previous lines was 2 (1–4); all patients had previously received steroids. The median length of treatment was 7.4 (1.4–52.3) months. The median initial dose of ruxolitinib was 11.8% 2.5 mg/12 hours (n=4, weight <15 kg); 58.8% 5 mg/12 hours (n=20, weight 15–60 kg) and 29.4% 10 mg/12 hours (n=10, weight 47–85 kg).

4 episodes of cGVHD were not included in the effectiveness analysis: follow-up was continued in another centre (n=2) and 2 patients died while on treatment from other causes. Complete response rate in aGVHD and cGVHD was 86.7% (n=13) and 60.0% (n=9), respectively. 2 (13.3%) patients with cGVHD showed partial response and treatment was switched to other lines. 2 (13.3%) patients with aGVHD and 1 (6.7%) with cGVHD showed treatment failure. 3 (20.0%) patients were receiving ruxolitinib at the time of the analysis for cGVHD showing stable response (n=2) and improvement (n=1).

AEs related to ruxolitinib were: increased serum alanine aminotransferase and aspartate aminotransferase 8.8% (n=3), herpes zoster infection 5.9% (n=2), hypertension 2.9% (n=1) and anaemia 2.9% (n=1). 1 patient required dose reduction due to grade 4 hepatic toxicity, that was resolved.
Conclusion and relevance In our study, ruxolitinib has shown effectiveness for refractory GHVD in most of the patients. The safety profile in our population is consistent with the literature. Further studies in paediatric patients are warranted.

REFERENCES AND/OR ACKNOWLEDGEMENTS
Conflict of interest No conflict of interest

4CPS-112 VORICONAZOLE THERAPEUTIC DRUG MONITORING: RELATIONSHIP WITH LIVER TOXICITY

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Background and importance Serious fungal infections are a subject of concern in hospital medicine. Voriconazole is one of the most used antifungal agents to treat these situations. Voriconazole therapeutic drug monitoring (TDM) may help to avoid treatment failures or adverse events.
Aim and objectives This study aimed to evaluate the impact of voriconazole TDM in dose or drug changes and seek a relationship between voriconazole plasma levels and liver toxicity.
Material and methods TDM was performed in patients treated with voriconazole. Plasma levels were measured once a steady state was achieved and immediately before administering the drug (though drug concentration).

Voriconazole concentrations were analysed by a validated reverse phase-high performance liquid chromatography-ultraviolet (RP-HPLC-UV) method.

Liver enzymes and cholestasis markers concentrations (aspartate aminotransferase (AST), alanine aminotransferase

(ALT), gamma glutamyl transferase (GGT), alkaline phosphatase (ALP) and total bilirubin (TB)), dose, diagnosis, age and sex were registered.

Microsoft Excel was used for the statistics calculation.

Results 68 determinations in 38 patients (73.75% men; aged 64.84 ±11.29 years).

Diagnosis: probable disease 21 (55.28%), possibility 12 (31.57%), prophylaxis 5 (13.15%).

6 (15.8%) patients needed a change in treatment. 5 (83.33%) had the dose changed in order to maintain plasma levels between 1 and 5.5 µg/mL. In 1 patient (16.66%) voriconazole was substituted.

28 (73.7%) started treatment with the dose of 200 mg/12 hours, whereas the rest (26.3%) has a higher dose. 60% of dose changes were in patients taking 200 mg/12 hours.

A positive correlation existed between plasma levels of voriconazole and liver enzymes as well as with cholestasis markers (AST: r^2=0.1817; ALT: r^2=0.1118; GGT: r^2=0.2528; PA: r^2=0.2444 and TB: r^2=0.4637).

The Chi-square statistic was significant at $p<0.05$ for plasmatic levels over 3 µg/mL and AST/ALT over physiological range (35 U/L).

The relative risk of presenting ALT over the physiological range is 3.12 and for AST 2.31 in patients with plasmatic levels of voriconazole >3 µg/mL respects the ones whose plasmatic levels were <3 µg/mL.

Conclusion and relevance Voriconazole TDM is a tool that can help to avoid treatment failure and adverse events. Its relationship with liver toxicity, which shows our data, TDM would help to prevent these side effects.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of interest No conflict of interest

4CPS-113 REAL-LIFE DATA ON THE USE OF ABIRATERONE/ENZALUTAMIDE IN CASTRATION-RESISTANT PROSTATE CANCER

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Background and importance Abiraterone and enzalutamide are used for treating castration-resistant prostate cancer (CRPC). The lack of direct comparisons makes the selection and positioning of these drugs difficult.

Aim and objectives To compare abiraterone and enzalutamide use in metastatic CRPC, and to provide real clinical data on effectiveness and safety.

Material and methods Retrospective observational study conducted in a tertiary hospital in patients with metastatic CRPC.

Patients evaluated and treatment initiated between January 2015 and September 2021.

The primary effectiveness variable was progression-free survival (PFS). Overall survival (OS) and survival probabilities were also estimated. Survival parameters were estimated with the Kaplan–Meier test and compared by the log-rank test using R-software (v.4 - 2021).

As safety variables, the percentage of patients with adverse events (AE) and grade according to the Common Terminology Criteria for Adverse Events (CTCAE) were collected.

Results 99 patients were included (abiraterone=70 and enzalutamide=29; disproportionality due to the prospective design). No significant differences were observed in the patients' baseline characteristics: mean age (75.6±9.1 years vs 75.8±7.5, respectively) and number of metastases at baseline. These were mainly bone (36.34%) and lung (6%). Gleason at baseline was ≥8 in 45.7% of those treated with abiraterone and 31% with enzalutamide. 92.9% in the abiraterone group had Eastern Cooperative Oncology Group (ECOG) 0–1 and the comparable figure was 89.7% for enzalutamide.

62.9% with abiraterone presented ≥1 AE. Most frequent AE were G1-asthenia (22.3%) and G1-hypertension (12.3%). 8.6% were AE≥G2. In the enzalutamide group, 69% presented ≥1 AE(10.3% ≥G2). Common were G1-asthenia (62.1%) and G1-headache (13.8%).

Median PFS for abiraterone was 31 months (95% CI 20 to NA) and for enzalutamide 42 months (95% CI NA to NA); with no significant differences (p=0.5). Median OS was not reached in either group, with no significant differences (p=0.7). For overall survival, at month 13, 92.2% of patients did not reach the event in the abiraterone group and 81.5% in the enzalutamide group.

The power of the study for PFS was 0.038 and for OS 0.042, indicating that the power to detect differences is low.

Numerical disproportion between individuals makes enzalutamide more sensitive to events; however, the number of events remained proportional, with both curves being practically superimposable.

Conclusion and relevance Statistical differences in PFS were not found. Median OS was not reached in either group; AE were mild to moderate for both groups. We cannot affirm that there are differences in effectiveness and safety between these treatments.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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4CPS-114 INTEGRATION OF A PHARMACIST INTO A GERIATRIC DEPARTMENT

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Background and importance Elderly chronic patients are usually pluripathological and polymedicated, which makes them vulnerable and complex to deal with. The review of their pharmacological treatment and their interactions, deprescribing and managing medications provides safety and improves their quality of life in a context of pharmacotherapy optimisation.

Aim and objectives To create a healthcare resource between the services of geriatrics and hospital pharmacy which facilitates clinical management of arranged patients for a medical consultation in outpatient geriatric clinic.

Material and methods Prospective study which included patients arranged for a geriatric consultation for the first time between May 2021 and August 2021. All these items were considered: pharmacotherapy, adherence to medical treatment, medical history, final analysis and last hospital admission. Treatment optimisation recommendations were mentioned to the geriatric physician. Primary care, specialised and