were observed. Moreover, prolonged prophylaxis has no benefit on clinical outcomes (LOS: decreased by 37.2%, 11.2 ± 7 to 7.62 ± 3 days, p<0.001; confirmed SSIs: deceased by 1.8%, from 3% to 1.2%, p=0.21).

Conclusion and Relevance Continuous presence of the clinical pharmacist is crucial in optimising antibiotic use. Pharmacist's intervention led to a significant improvement in SAP guideline adherence, that entailed also the significant reduction of antibiotic exposure, length of stay, and costs. Additional research, focusing on empirical and targeted antibiotic therapy and implementation of optimising antibiotic use, is needed.

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Conflict of Interest No conflict of interest

Section 5: Patient safety and quality assurance

5PSQ-002 PHARMACIST IN SECURING DRUG CIRCUIT: FROM PRESCRIPTION TO ADMINISTRATION (ANALYSIS AND ACTIONS)

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Background and Importance In a multidisciplinary hospital with 426 beds, roles of hospital pharmacist are varied and drug circuit presents many risks of medication error. According to the WHO, the roles of pharmacists are 'the Seven star Pharmacist': care giver, decision maker, communicator, leader, manager, lifelong learner and teacher.

Aim and Objectives Objective of this study is to measure effectiveness of actions taken by pharmacists to reduce medication errors: from prescription to administration.

Material and Methods Between 2019 and 2022, a compilation of audits have been made. Various stages of drug circuit were audited using previously validated audit grids. Each audit have been made during 15 days for all new prescriptions. A statistical analysis of proportion comparing the error rate before and after the implementation of improvement actions was carried out. Prescription of all injectable drugs has been formalised, new doctors arriving at the hospital are made aware. Concerning medication reconciliation: in the event of a discrepancy observed, doctor is systematically informed, a pharmacy student has been assigned to the surgery unit. Errors not detected during pharmaceutical validation were presented to all pharmacists. Measures to reduce risk of task interruption were implemented during dispensing (dedicated emergency telephone line, redefining tasks). Concerning administration of medication: training workshop days for nurses have been created by pharmacists.

Results Results showed a statistically significant improvement in certain criteria (statistical analysis of proportion : comparing error rate before and after actions ; alpha = 5%) : medication reconciliation rate increased from 64% in 2019 to 73% in 2021 (64% VS 73%); errors not detected during pharmaceutical validation (2% VS 1%); dispensing error (3% VS 2%); lack of knowledge of the establishment's drug administration procedure (58% in 2019 VS 33% in 2022). On the other hand, certain criteria have deteriorated: prescription compliant in 70% in 2019 and 65% in 2022.

Conclusion and Relevance This study has made it possible to objectify that actions of pharmacists have been beneficial in management of patients. However, we find that actions taken to improve prescription of drugs have not been effective. It would be interesting to set up continuous training for doctors on the use of the prescription software in our establishment.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-003 PERFORMANCE OF A COLD MAINTENANCE DEVICE DURING THE IMPLEMENTATION OF A PNEUMATIC CIRCUIT

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Background and Importance Few information are available about the performance of cold maintenance device.

Within the framework of the implementation of a pneumatic system in a new university hospital, the feasibility of sending different types of medicines, including cold products with a pneumatic system was studied.

Aim and Objectives The objective of this study is to evaluate the compliance of a cold maintenance device within a pneumatic.

Material and Methods The study was led in a French University Hospital with 1495 beds and more than 80 care units between May and September 2022. The analysis was made with kits provided for the cartridges dedicated to cold transport and with qualified electronic temperature recorders Log-tags ® (C.M.I France, Neung-sur-Beuvon). Different conditions were tested, one condition per test, reproduced at least 3 times: kits placed at room temperature, in the fridge (2/8°C) or in the freezer, presence or not of a secondary packaging, eutectic plate or putting the kit in the cartridge. The supplier had certified on his commercial leaflet a duration of 50 min between 2 and 8°C under the following conditions: 500 ml infusion bag stored at 5°C, with thermal recorder inside the bag, placed in the kit then in the cartridge.

Results All the results of the 9 different tests (one condition per test, reproduced at least 3 times) do not meet the 50 min data indicated by the supplier. The method applied by the supplier shows a mean duration between 2 and 8°C of 4.20 min [4;5] Using the same starting conditions: freezing the kit, gave an average of 8.20 min [7;9], using a secondary packaging, the average was 6.40 min [6;7], outside the cartridge, the average was 4.40 min [4;6], and adding an eutectic plate, the average was 29.24 min [11;60] but with a temperature below 0°C. The average for all tests is 8.46 min.

Conclusion and Relevance This study showed that the supplier's device and data did not comply the good practices concerning management of health products subject to cold chain and the patient safety.

Various studies have been undertaken at the level of the Hospital pharmacy and the cold supplier to improve the supplied isothermal enclosure.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest

5PSQ-004 EPCLUSA RELATED SLEEPINESS: A CASE REPORT

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Background and Importance Epclusa is a two-drug combination administered as a single daily pill containing Velpatasvir and Sofosbuvir used to treat de Hepatitis C. The treatment duration is 12 weeks and the cure rates are from 97% to 100% in those patients without cirrhosis or with compensated cirrhosis.

Based on data obtained from phase 3 clinical studies, the percentage of patients experiencing any serious adverse event was 3.2%. The most common adverse reactions observed are headache and fatigue.

Pharmacovigilance collects information, and analyses and notifies case of suspected adverse drug reactions (ADRs) to prevent them occurring in the future

Aim and Objectives To describe a case of sleepiness in a patient treated with Epclusa and establish its possible association.

Material and Methods We describe a case of an 72-year-old woman diagnosed with hepatitis C with compensated cirrhosis and treated with Epclusa. In May 2022, before starting the treatment with Epclusa, her home medication was checked at the Pharmacy Department, which include atorvastatin, enalapril and omperazole; pointing out to separate the intake of omeprazole and Epclusa 4 hours and proving there no were any drug interactions. After 16 days receiving the treatment with Eplcusa, she was referred to the emergency department presenting sleepiness and general deterioration. As a result, she was diagnosed with common cold and treated with amoxicilin. It also coincided with constipation, which spontaneously resolved within two days. Finally Epclusa treatment was stopped.

Results 4 days after, she reported improvement in sleepiness after discontinuation of treatment, although the iatrogenic origin cannot be guaranteed since it has also coincided with catarrhal symptoms and constipation, both situations in resolution. Naranjo's algorithms establish the causality relationship as possible (score of 2). The Spanish pharmacovigilance centre was notified.

Conclusion and Relevance The European Medicines Agency's technical sheet for Epclusa does not describe sleepiness as an ADR. Patient could confuse fatigue with sleepiness in dealing with subjective symptoms. The RPC reported this case as the only Epclusa ADR notified in our country. The reporting of ADRs in hospitals is very important because innovative new drugs are usually used, severe ADRs are most likely to be seen in hospitals and it can be detected early helping others how to act.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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5PSQ-005 ANALYSIS OF ANTI-ANGIOGENESIS-RELATED ADVERSE EVENTS ASSOCIATED WITH VASCULAR ENDOTHELIAL GROWTH FACTOR RECEPTOR-TYROSINE KINASE INHIBITORS (VEGFR-TKIS) IN PATIENTS WITH METASTATIC RENAL CELL CARCINOMA

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Background and Importance Oral vascular endothelial growth factor receptor – tyrosine kinase inhibitors (VEGFR-TKIs) are standard treatments for metastatic renal cell carcinoma. The VEGF pathway plays an important role in the physiological function and homeostasis of the cardiovascular and kidney systems, resulting in anti-angiogenesis-related adverse events (AEs). Limited studies have evaluated anti-angiogenesis-related AEs involving VEGFR-TKIs using real-world data, which may provide important evidence for drug choice and monitoring in the treatment of metastatic renal cell carcinoma.

Aim and Objectives This study aimed to investigate the incidence and patterns of anti-angiogenesis-related AEs associated with the use of VEGFR-TKIs in patients with a metastatic renal cell carcinoma using real-world data.

Material and Methods This cross-sectional study included patients with a diagnosis of metastatic renal cell carcinoma who received axitinib, cabozantinib, pazopanib, sorafenib, and sunitinib at the third level hospital in South Korea between January 2007 and December 2019. Anti-angiogenesis-related AEs were rated 'possible' or higher on the WHO-Uppsala Monitoring Centre (WHO-UMC) causality assessment scale. The severity of AEs was graded using the CTCAE v.5.0. To compare the incidence of AEs associated with different VEGFR-TKIs, we divided the enrolled patients into those who had not previously received a VEGFR-TKI (VEGFR-TKI-naïve) and those who had previously received a VEGFR-TKI (VEGFR-TKI-experienced).

Results A total of 988 patients were included (75% men, median 61 years). 644 patients were VEGFR-TKI-naïve and 314 patients were VEGFR-TKI-experienced. Anti-angiogenesis-related AEs of any grade occurred in 65.1% of VEGFR-TKI-naïve patients and 54.8% of VEGFR-TKI-experienced patients. In addition, severe AEs occurred in 34.6% of VEGFR-TKI-naïve patients and 36.0% of VEGFR-TKI-experienced patients. Regardless of treatment history, the most common AE was hypertension, with a 48.6% of VEGFR-TKI-naïve and 35.0% of VEGFR-TKI-experienced. For VEGFR-TKI-experienced patients, the overall rate of anti-angiogenesis-related AEs for sorafenib (24.3%) was lower than that for other VEGFR-TKIs ($p < 0.05$). Female gender (adjusted hazard ratio [aHR] 1.23, 95% confidence interval [CI] 1.02-1.48) and high blood pressure (aHR 1.47, 95% CI 1.23-1.76) were risk factors for VEGFR-TKI-associated AEs.

Conclusion and Relevance More than half of patients with renal cell carcinoma receiving VEGFR-TKI experienced anti-angiogenesis-related AEs. Any grade of AEs occurred more frequently in VEGFR-TKI-naïve patients, while severe AEs occurred more frequently in VEGFR-TKI-experienced patients.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest