Background and Importance Taking antibiotics weeks before immunotherapy alters the gut microbiota. It is therefore questionable whether the use of antibiotics prior to immunotherapy is associated with decreased effectiveness in cancer patients.
Aim and Objectives To evaluate the influence of the use of antibiotic therapy on the effectiveness of immunotherapy treatment in cancer patients.
Material and Methods Observational, retrospective, 68-month, retrospective study (January 2018 to August 2023) in patients diagnosed with renal cell, non-small-cell lung and head and neck cancers.

The difference in effectiveness was measured by comparing the median progression-free survival (mPFS) and median overall survival (mOS) of patients who received antibiotic therapy 2 months prior to the start of immunotherapy and those who did not receive antibiotic therapy.
Variables age, sex, *Eastern Cooperative Oncology Group* (ECOG) scale, immunotherapy received, number of previous lines, antibiotic prescription 2 months prior to the start of immunotherapy and duration of treatment.
Data source computerised medical records and electronic prescribing programme.
Results A total of 138 patients (71.0% male; median age 67 years) were analysed. Of the patients, 42.0% received antibiotic therapy 2 months prior to the start of immunotherapy.

The group receiving antibiotherapy (56.8% male; median age 68 years): ECOG < 1 (89%), by immunotherapy (pembrolizumab: 58%; atezolizumab: 23%; nivolumab: 19%), number of previous lines (2[1–3] median). mPFS was 5.1 (3.2–7.1) months and mOS was 16.4 (12.7–22.5) months.

The antibiotic-naive group (81% male; median age 65 years): ECOG < 1 (91%), by immunotherapy (pembrolizumab: 54%; atezolizumab: 28%; nivolumab: 18%), number of prior lines (2[1–3] median). mPFS was 5.6 (4.6–9.5) months and mOS was 17.8 (12.6–21.8) months.

The differences in both groups on mPFS and mOS were not statistically significant (p=0.57) and (p=0.78), respectively.
Conclusion and Relevance Despite limitations in sample size, our study reveals that the use of antibiotic therapy 2-months prior to the start of immunotherapy does not make a difference to the effectiveness of immunotherapy.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. No conflict of interest.

Conflict of Interest No conflict of interest.

5PSQ-094 INCIDENCE OF HYPERSENSITIVITY REACTIONS IN PACLITAXEL INFUSIONS FOLLOWING THE DISCONTINUATION OF RANITIDINE

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Background and Importance Current literature supports that the use of H2 antihistamines in paclitaxel-containing regimens is not essential, although publications are scarce.[1]
Aim and Objectives To determine the incidence of hypersensitivity reactions (HRs) during paclitaxel infusion after the withdrawal of ranitidine from the market.
Material and Methods Observational, retrospective and descriptive study in which patients undergoing chemotherapy with paclitaxel-containing schemes for adjuvant (ABC) and neoadjuvant (NBC) breast cancer, cervical cancer (CC), ovarian (OC) and endometrial (EC) were included. The study period was from 2 February 2022 (cessation of marketing of ranitidine) to 31 August 2023.

HRs were analysed after modification of the premedication protocol, which included the same treatment guidelines, excluding ranitidine.
Variables age, sex, type of neoplasm, line of treatment, treatment schedule, administration time, premedication, HRs and measure adopted.
Data source computerised medical records and electronic prescribing programme.
Results A total of 493 administrations of paclitaxel were infused to 68 patients (100% female) with a median age of 64 years [31–89]. 20% corresponded with ABC, 29% OC, 14% CC, 11% EC and 26% NBC. Sixty-seven percent of patients were first-line.

Six HRs were observed during the first or second cycle. Three (50%) were related to paclitaxel administration, one in ABC (paclitaxel 80 mg/m^2 weekly over 1 hour), one in OC (paclitaxel 175 mg/m^2 over 3 hours) and one in EC (paclitaxel 175 mg/m2 over 3 hours). The remaining three were related to the administration of carboplatin in patients on OC.

HRs appeared in patients aged 43–67 years. One required discontinuation of treatment, the rest were given premedication the day before the cycle and increased infusion time.
Conclusion and Relevance The use of premedication protocols without H2 antihistamines appears to be a safe practice. Our study has limitations in terms of sample size. However, it is important to know the role of these drugs and it is necessary to involve the pharmacist in the development of hospital protocols to identify patients to benefit from these drugs.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.
Conflict of Interest No conflict of interest.

5PSQ-095 HOSPITAL PHARMACISTS ENGAGEMENT IN PHARMACOVIGILANCE PRACTICES DURING COVID-19 IN THE NORTH MACEDONIA

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Background and Importance Pharmacists are acknowledged as safety leaders worldwide, since they have high impact of patients' safety, and it was confirmed during COVID-19 pandemic. In the Republic of North Macedonia hospital pharmacists (HPs) were nationally recognised as a key factor for implementation of good pharmacovigilance (PV) practices and since 2017 they are engaged in PV working group in

Macedonian Regulatory Agency (MALMED), actively working on rising the awareness and improvement of Adverse Events (AEs) reporting.

Aim and Objectives The questionnaire-based research aimed to evaluate the curtail role of HPs in implementation of good PV practices during COVID-19 pandemic in overloaded hospitals.

Material and Methods Non-Interventional, questionnaire-based study evaluating the knowledge, attitudes and engagement HPs for pharmacovigilance during COVID-19 pandemic was performed among HPs in the Republic of North Macedonia in July 2022. Obtained data were computed and assessed using statistical software STATGRAPHICS Centurion XVI evaluation (StatPoint technologies Inc., USA).

Results The survey was completed by 35 (representing almost 50%) of HPs in our country. The average age of respondents was 45.4±12.9 years, more than 40% have over 20 years working experience as HPs and almost 70% are working in public hospitals. Although 83% of HPs confirmed that have reported an adverse event (AE) during their working practice and are experienced in implementation of good PV practices, only 13% of HPs strongly agreed and 39.1% agreed, that received the information for AEs associated to COVID-19 treatment and almost the same percentage of HPs reported the AEs to the Agency. Low level of reporting by HPs (17.4%) was observed also for off-label use of drugs during the pandemic. Additionally, only 17.4% of HPs were consulted for the procedure of adverse event reporting to the Agency by other healthcare professionals suggesting that they are still not recognised as safety leaders in hospitals.

Conclusion and Relevance Although HPs are nationally recognised as stakeholders in the improvement of good PV practices, they were not fully engaged in AEs identification and reporting during COVID-19 and appreciation of their PV expertise in hospitals have to be improved. Appropriate PV education alongside with utilisation of contemporary software opportunities is suitable approach for improvement of AEs reporting, medicines safety and public health.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-096 DESCRIPTION OF INMMUNOGLOBULIN REPLACEMENT THERAPY IN MULTIPLE MYELOMA PATIENTS WITH ANTI-BCMA CART

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Background and Importance Multiple Myeloma (MM) is a plasma cell neoplasm. The reduction and dysfunctionality of normal plasma cells together with treatment with anti-BCMA CAR-T leads to a deficit in humoral immunity that manifests as hypogammaglobulinemia and an increase in infections risk, which lead to the need to administer replacement therapy with intravenous polyclonal immunoglobulins (IgRT).

Aim and Objectives The primary objective of this study is to describe the use of immunoglobulins in patients who have received anti-BCMA CAR-T therapy (ide-cel, cilta-cel, ARI0002) for the treatment of MM in a clinical trial or as compassionate use.

Material and Methods This is a single-centre, observational, descriptive and retrospective study to describe the use of immunoglobulins in patients who had hypogammaglobulinemia, defined as IgG levels < 400 mg/dL, or any IgG level along with infectious events that require treatment with immunoglobulins. An institutional review board (IRB) approved the study.

Results 47 patients received an anti-BCMA CAR-T, with Ide-Cel being the CART in 70.21% (n=33) of them. Plasma IgG levels decreased progressively over time (median nadir month 7= 208 mg/dL (range 100–465) presenting a recovery around the eighth month post-infusion. Of these 47 patients, 22 (58.64%) received, at least once, IgRT. In these 22 patients, the median time until the start of treatment with IgRT was 123 days (range: 69 to 799). The rate of infectious events and febrile neutropenia grade 3–4 was 68.18% (15/22) in patients who received IgRT and 56% (14/25) in patients who did not receive IgRT (p=0.391).

Conclusion and Relevance These results reveal a period of hypogammaglobulinemia after anti-BCMA CAR T-cell therapy. The role and when to begin IgRT needs further exploration, as in this study has not improved the rate of grade 3–4 infectious events in patients who received it.

REFERENCES AND/OR ACKNOWLEDGEMENTS

Conflict of Interest No conflict of interest.

5PSQ-097 AN APPROACH TO THE USE OF MACHINE LEARNING TOOLS FOR THE PREDICTION OF ADVERSE EVENTS IN CANCER PATIENTS ON IMMUNOTHERAPY

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Background and Importance The FDA Adverse Reporting System (FAERS) is a tool to voluntary report adverse events (AE), These data can be downloaded and used to apply 'Machine learning'(ML) techniques. The bibliography is limited, although it has already been the subject of a systematic review (Kim et al, 2022). FAERS data set could be useful to elaborate potential predictive modelling.

Aim and Objectives To test a tool of ML to develop a potential predictive model of AE caused by immune checkpoint inhibitors (ICI), using FAERS data set.

To contrast and explain the ML results with a reference model (RM), obtained through conventional processing data (spreadsheet).

Material and Methods All FAERS records from 2022 were downloaded, selecting those of the group ICIs group notified as 'main suspected drug' (inclusion criteria). Collected variables from FAERS data set were:AE, age, drug and sex. The ML decision tree classification algorithm J48 implemented in the Weka application (version 3.8.6) was used to elaborate the ML model. The RM was built using a spreadsheet to tabulate and analyse the data (pivot tables and descriptive statistics).

Results 1,702,222 notifications were downloaded and 86,053 records were selected according to inclusion criteria. The J48 algorithm applied to a subset including 'adverse effect', 'sex'