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

[1]M Giraldez*, [1]E Mateo, [1]C Garcia Pastor, [2]A Urrutia, [1]M Serrano, [1]E Molins. *[1]Clinica Universidad De Navarra, Pharmacy, Pamplona, Spain; [2]Clinica Universidad De Navarra, Clinical Trials Unit, Pamplona, Spain*

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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

[1]A Paradela Carreiro, [1]L Otero Millan, [1]M Alfonsín Lara*, [1]EY Romero Ventosa, [2]C Veiga García, [3]MJ Villanueva Silva, [1]AM Regueira Arcay, [1]I Agra Blanco, [4]A Romero Rendón, [1]N Martínez López De Castro. *[1]Hospital Álvaro Cunqueiro, Hospital Pharmacy, Vigo, Spain; [2]Fundación Biomédica Galicia Sur, Senior Researcher, Vigo, Spain; [3]Hospital Álvaro Cunqueiro, Oncology, Vigo, Spain; [4]Fundación Biomédica Galicia Sur, Research Fellow, Vigo, Spain*

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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'

and 'drug', allowed us to estimate, for each AE the most likely responsible ICI drug. The metrics of the ML model obtained were satisfactory and compatible with the RM analysis. The J48 algorithm produced a complex tree (to be expected given the large number of AE). The application of J48 on another subset that includes 'adverse effect', 'age' and 'drug', had a lower predictive capacity, due to the lower consistency of the data (age is only recorded as younger or older than 65 years) and that there is a higher proportion of missing values. The RM allows the results obtained with ML to be easily explained and understood.

Conclusion and Relevance The results of the J48 algorithm were useful for the association between AE, sex and drug. Despite the inherent limitations of voluntary AE reporting, this study will serve as a starting point for applying ML techniques in any other group, using FAERS data.

REFERENCES AND/OR ACKNOWLEDGEMENTS

1. Kim, *et al.* 2022. 10.1097/MD.0000000000029387

Conflict of Interest No conflict of interest.

5PSQ-098 ABSTRACT WITHDRAWN

5PSQ-099 DRUG-RELATED PROBLEMS ASSOCIATED WITH THE TREATMENT OF POLYCYSTIC OVARY SYNDROME

T Todorva*, Y Dobreva, N Veleva, S Stoev, H Lebanova. *Medical University Pleven, Pharmaceutical Sciences and Social Pharmacy, Pleven, Bulgaria*

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Background and Importance Polycystic ovary syndrome (PCOS) is a severe public health problem and a major determinant of various reproductive, metabolic, and psychological outcomes. The pharmacological management of PCOS is complex and should be individualised based on the multifactorial manifestation of the disease in the individual patient and her reproductive desires.

Aim and Objectives To identify the most common drug-related problems (DRPs) by reviewing and analysing data from the scientific literature and PCOS treatment guidelines.

Material and Methods A review of international scientific databases, projects, initiatives to improve the therapeutic management of PCOS and normative regulations in the field of pharmaceutical practice was carried out. Both comparative and critical content analysis of therapeutic guidelines and good practice initiatives for the treatment of PCOS, as well as general research methods (historical, internet reference and content review, theoretical deductive analysis method) were used.

Results DRPs related to the lack of sufficient efficacy data to support drug use, as well as inadequate therapy selection to address the complex phenotype of PCOS, and DRPs related to safety and tolerability concerns (mainly associated with metformin and letrozole treatment) are among the main issues identified. The safety profile of oral contraceptives as the primary therapeutic approach for PCOS treatment is also a source of DRPs. The possibility that the choice of therapeutic approach may not be tailored to specific patient characteristics, usually through the selection of subeffective doses and dosage forms, remains a critical concern in the context of PCOS pharmacotherapy. Drug misuse, off-label prescribing or prescribing of repurposed drugs, and DRP due to the long duration of therapy required are other major group of concerns related to the management of PCOS.

Conclusion and Relevance The implementation of complex pharmaceutical care interventions by hospital pharmacists tailored to the specific needs of patients with PCOS and the addressing of the identified DRPs will lead to better control