Abstract 5PSQ-110 Table 3

Final score

Malnutrition (<17 points)	7.23%
At risk of malnutrition (17–23.5 points)	72.29%
Normal status (24–30 points)	20.48%

Conclusion and relevance Screening and serum albumin levels confirmed normal nutritional status. However, when the full MNA test score was obtained, a higher prevalence than expected of patients at risk of malnutrition was noticed. These results show the need to monitor the degree of nutrition of institutionalised patients to develop strategies that can improve the overall status and set new lines of action.

REFERENCES AND/OR ACKNOWLEDGEMENTS

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No conflict of interest.

5PSQ-111 ADVERSE DRUG REACTIONS DUE TO MEDICINES UNDER ADDITIONAL MONITORING

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Background and importance The European list of medicines under additional monitoring (MUAM), identified with a black inverted triangle, includes new active substances, biological medicines, medicines that require a post-authorisation safety study, medicines approved conditionally or authorised under exceptional circumstances, and medicines authorised with specific obligations on the recording or monitoring of suspected adverse drug reactions (ADR). This list is reviewed monthly by the Pharmacovigilance Risk Assessment Committee (PRAC). A drug remains under additional monitoring for 5 years or until the PRAC decides to remove it from the list.

Aim and objectives To describe the ADR produced by MUAM.

Material and methods This was a descriptive, retrospective study in a second level hospital, from 2013 to 2018. The pharmacy service recorded and notified ADR due to MUAM to the pharmacovigilance centre (FC) after their detection spontaneously or from the complex analysis information system (CAIS). Once patients with ADR by MUAM were selected, the electronic medical history was reviewed: age, sex, medicines involved, type of ADR, detection method, admissions due to ADR, description in the data sheet and communication to the FC.

Results Forty-five ADR (from 26 medicines) were detected in 40 patients (57% men), who had a mean age of 65.8 years (26–84). Causative agents were: antineoplastics (80%); antianginals (4.4%); agents acting on the renin–angiotensin system (4.4%); and other (11.2%). The main ADR were febrile neutropenia (lenalidomide (n=2), palbociclib (n=2), ramucirumab (n=2), imatinib (n=1), brentuximab (n=2), nintedanib (n=1)); bradycardia (ivabradine (n=2), fingolimod (n=1)); hepatocarcinoma (ledipasvir/sofosbuvir (n=2)); thrombocytopenia (panitumumab (n=2), ibrutinib (n=1)); oliguric acute kidney injury (sacubitril/valsartan (n=2)); and vomiting (cabozantinib (n=2), alectinib (n=1)). Drugs with a higher incidence of ADR were:

cabozantinib (vomiting (n=2), asthenia (n=1), osteonecrosis (n=1)); nivolumab (myocardial infarction (n=1), cerebral haemorrhage (n=1), pulmonary thromboembolism (n=1)) and regorafenib (hypertension (n=1), skin rash (n=1), hyponatraemia (n=2)). ADR detected by spontaneous notification: 77.8%. ADR caused hospital admission in 62.2% of cases (febrile neutropenia (28.6%)). ADR caused death in 3 patients (oliguric acute kidney injury due to sacubitril/valsartan (n=2) and myocardial infarction due to nivolumab (n=1)). ADR not described in the data sheet: 13.3%. ADR reported to the FC: 93.3%.

Conclusion and relevance Antineoplastic agents were the therapeutic group with the highest incidence of ADR. MUAM caused hospital admission in a high percentage of cases and were the cause of death in three patients. We found that 13.3% of ADR were considered new, so it is essential to continue reporting suspected ADR to gather new information to help define the safety profile of all medicines, especially MUAM.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-112 IMPACT OF HIGH TEMPERATURE AND SHAKING ON CHARGE VARIANTS OF ADALIMUMAB (HUMIRA) ASSESSED BY LIQUID CHROMATOGRAPHY COUPLED TO MASS SPECTROMETRY

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Background and importance Adalimumab (Humira 100 mg/mL) is a monoclonal antibody (mAb) which is used for the treatment of psoriasis, rheumatoid arthritis and Crohn's disease in adults and children. Humira is injected under the skin. The dose for a child is calculated according to the child's weight and the medicine is supplied in prefilled syringes that are self-administered at home. Adalimumab has low stability after the vial is open and therefore it is necessary to study its stability under the usual conditions which the prefilled syringes will be exposed. In this context, the charge variant characterisation allows for the detection of structural changes in the drug.

Aim and objectives The objective of the study was to characterise the charge variants of adalimumab under stress conditions (ie, high temperature (60°C) and smooth shaking) by liquid chromatography coupled to UV and mass spectrometry detection in order to assess the impact of mishandling adalimumab in prefilled syringes.

Material and methods Prefilled syringes were prepared with different volumes of Humira (100 mg/mL) and placed at 60°C for 3 hours (to ensure there was degradation of adalimumab and also validation of the method) or underwent smooth shaking at room temperature for 1 hour. An UHPLC-HESI/MS (Orbitrap) was the platform used for the analysis. The column used for the separation was a MabPac SCX-10 RS 2.1 mm×5 mm column, 5µm (Thermo Fisher Scientific).

Results Several charge variants were characterised for adalimumab (basic and acid variants). Significant differences were