## 5PSQ-067 DRUG UTILISATION PROFILES OF ADVANCED THERAPY MEDICINAL PRODUCTS: A REAL-WORLD EVIDENCE STUDY

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10.1136/ejhpharm-2024-eahp.401

**Background and Importance** Advanced therapy medicinal products (ATMPs) represent the forefront of healthcare innovation. Despite the approval of the first ATMP in Italy in 2016, there is currently a lack of scientific evidence concerning the utilisation patterns of ATMPs.

**Aim and Objectives** Study aim was to evaluate the drug utilisation patterns among patients receiving ATMP treatments in Italy.

**Material and Methods** Retrospective study using data sourced from the Monitoring Registries of the Italian Medicine Agency, specifically the Drug Product Registry (DPR) containing information on dispensed treatments and clinical data for patients utilising ATMPs in Campania Region ( ~6 million, 10% of the national population) and residents treated in a different Italian Region. Final cohort included individuals who received at least one prescription for ATMP drugs in the Italian market between 2016 and 2023. We analysed prescription patterns focusing on the index treatment, diagnoses, treatment interruptions, mortality rates and adverse events.

**Results** In total, 92 patients initiated ATMP treatments between 1 January 2016 and 1 September 2023. 21.6% received voretigene neparvovec, 25% onasemnogene abeparvovec, 22.8% tisagenlecleucel and 21.7% axicabtagene ciloleucel. The overall occurrence of adverse events was low (1.1%), primarily associated with autologous human corneal epithelial cells treatments. The overall mortality rate was 12%, affecting only two drugs: 28.6% tisagenlecleucel and 25.0% axicabtagene ciloleucel. Notably, nearly 90% of subjects completed their treatment without experiencing adverse events or mortality.

**Conclusion and Relevance** This study highlights the low occurrence of adverse events and mortality associated with ATMPs, emphasising their potential as a promising frontier for treating severe diseases lacking therapeutic alternatives in real-world scenarios.

### REFERENCES AND/OR ACKNOWLEDGEMENTS

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

## 5PSQ-068 THE HOSPITAL PHARMACIST'S INTERVENTIONS IN THE POST-MARKETING PHARMACOVIGILANCE OF ANTI-ASTHMATIC BIOLOGICS: A REAL-LIFE ANALYSIS

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10.1136/ejhpharm-2024-eahp.402

**Background and Importance** Pharmacovigilance is an important tool for monitoring drug post-marketing safety. Hospital Pharmacist (HP) plays a primary role in the identification of suspected Adverse Drug Reaction (ADRs) due to his direct contact with the patient. In fact, through the application of indirect pharmacovigilance tools in a real-life context, can lead to the identification of hidden or underestimated ADRs.

**Aim and Objectives** The aim of the study was to evaluate the increase of suspected ADRs reports to biological drugs for the treatment of severe refractory hypereosinophilic asthma (omalizumab, dupilumab, mepolizumab and benralizumab) obtained following the interventions of HP.

**Material and Methods** A 7-months (October 2022 to May 2023) post-marketing safety study was conducted. The data were collected via a questionnaire consisting of two sections: general data (sex, age, comorbidities, drugs taken and start of therapy) and list reporting the most common side effects where the patient can indicate one or more suspected ADRs among those reported and/or enter any side effect that is potentially linked to the drug. The questionnaire was illustrated and given to the patients at the time of dispensing. The data were also compared with the clinical trials and all adverse reactions reported by patients were entered into the pharmacovigilance network.

**Results** Initially there were no reports of ADRs for any of the drugs considered. Following the HP's interventions, 55% (55/100) of patients reported one or more adverse reactions (Mepolizumab 65%, 26/40; dupilumab 54.5%, 12/22; omalizumab 53.3%, 8/15; benralizumab 39.1%, 9/23) bringing the number of reports to 122 (76 mepolizumab; 14 dupilumab; 16 omalizumab; 16 benralizumab). The study also highlighted ADRs not reported in the trials; for mepolizumab were found diffuse petechiae, haemorrhagic period and frequent urination problems with recurrent cystitis (3.5%; 1/26) while for dupilumab was found a higher incidence of herpetic development and alopecia (4.5%; 1/22). A higher percentage of pyrexia was found for benralizumab compared to trials (3%; 12/320 vs 13%; 3/26).

**Conclusion and Relevance** The data analysis confirmed the importance of the HP role in pharmacovigilance. The investigation in a real-world context characterised by a high heterogenicity of patient characteristics (age, comorbidity, adherence)

led to an improvement in the incidence of ADRs reports and to the highlighting of side effects not detected during the clinical trials.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
**Conflict of Interest** No conflict of interest.

## 5PSQ-069 COMPARISON OF RENAL GLOMERULAR FILTRATION ESTIMATION FORMULAS IN VANCOMYCIN PHARMACOKINETIC MONITORING

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10.1136/ejhpharm-2024-eahp.403

**Background and Importance** This retrospective study aimed to assess the utility of renal glomerular filtration rate (GFR) estimation formulas, including Cockcroft-Gault (CG), Modification of Diet in Renal Disease (MDRD-4), and Chronic Kidney Disease Epidemiology (CKD-EPI), in the pharmacokinetic monitoring of vancomycin.
**Aim and Objectives** The study aimed to evaluate the correlation between estimated GFR using different formulas and the actual clearance of vancomycin in patients, providing valuable insights for pharmacokinetic monitoring and dosing adjustments.
**Material and Methods** Retrospective study (October 2022 to March 2023) on patients monitored by the Clinical Pharmacokinetics Unit during vancomycin treatment. Inclusion criteria: age $\geq$ 18, $\geq$ two vancomycin trough plasma concentrations (Cmin), and stable serum creatinine (+/- 0.5 mg/dL) during monitoring. Recorded variables: gender, age, weight (kg), height (cm), serum creatinine mg/dL), estimated glomerular filtration rate (eGFR) (mL/min) using various formulas, observed vancomycin Cmin (mcg/mL), and predicted Cmin (mcg/mL) based on Bayesian adjustment (software: Mw-Pharm++®). Linear regression analysed the relationship between initial estimated vancomycin plasma clearance (Clp) using eGFR data and patient's actual Clp obtained through Bayesian estimation (considering monitored vancomycin concentrations).
**Results** A total of 34 patients were recruited (65.70% males, mean age ± standard deviation: 68.06 ± 16.89 years). The mean estimated glomerular filtration rate (GFR) values were: 84.44 ± 49.87mL/min, 116.23 ± 52.95mL/min, 91.53 ± 28.22mL/min for the CG, MDRD-4, and CKD-EPI formulas, respectively. The mean observed vancomycin Cmin in the second analytical determination was 16.13 ± 6.56 mcg/mL. The mean predicted Cmin values were 17.15 ± 8.08 mcg/mL, 14.03 ± 8.26 mcg/mL, and 14.57 ± 7.56 mcg/mL for the CG, MDRD-4, and CKD-EPI formulas, respectively. Based on the coefficients of determination calculated from the regression lines, 83%, 76%, and 86% of the variations found in the actual vancomycin clearance can be explained by variations in the estimated clearance using GFR data obtained with the CG, MDRD-4, and CKD-EPI formulas, respectively.
**Conclusion and Relevance** In this study, the Cockcroft-Gault and CKD-EPI formulas exhibited better correlation with actual vancomycin clearance compared to MDRD-4. The findings suggest a potential risk of overdosing when using MDRD-4. Although initial vancomycin dosing based on estimated GFR formulas provides a reasonable approach, pharmacokinetic monitoring of plasma concentrations remains a safer approach for antibiotic dosing.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
**Conflict of Interest** No conflict of interest.

## 5PSQ-070 DUPILUMAB IS A MONOCLONAL ANTIBODY USED FOR THE TREATMENT OF ATOPIC DERMATITIS. THIS STUDY EVALUATES THE EFFECTIVENESS AND PERSISTENCE. DUPILUMAB PRESENTS GOOD EFFECTIVENESS AND PERSISTENCE

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10.1136/ejhpharm-2024-eahp.404

**Background and Importance** Atopic dermatitis (AD) is a relapsing inflammatory skin disease characterised by severe itching, skin lesions and dysregulation of the immune system. Dupilumab is an anti-IL-4/13 monoclonal antibody approved for the treatment of moderate to severe AD.
**Aim and Objectives** To evaluate the effectiveness and persistence of dupilumab in moderate-severe AD.
**Material and Methods** Observational and retrospective study of patients on treatment with dupilumab for moderate-severe AD from March 2020 to September 2023 in a tertiary hospital. Variables collected: age, sex, previous use of topical (Ct) and systemic (Ci) corticosteroids, topical tacrolimus, antihistamine and cyclosporine, dosage, and duration of treatment. The effectiveness variables are the EASI (Eczema Area and Severity Index) and IGA (Investigator Global Assessment) scales in weeks 16, 24 and 52. Treatment was considered effective when the EASI had been reduced by 50% (EASI50) and when the IGA had been reduced by <2 points. Data were obtained from the electronic medical record (Abucasis®). Quantitative variables were described as mean (minimum and maximum) and qualitative variables as percentages.
**Results** A total of 39 patients were included, mean age 30.7 years (4–64), 58.9% of the patients were male. 100% of the patients have worn Ct and 30% continue to wear them. 69% have taken Ci, 31% tacrolimus, 79% antihistamines, 66% cyclosporine. 56% of patients are on the 300 mg every 2 weeks regimen. The median treatment time with dupilumab in the included patients was 21.7 months (0.9–68.4). At week 16, 89.6% (n=33) of the included patients reached EASI 50, at week 24 EASI 50 was reached by 93% (n=32) and at week 52 it was reached by 100% (n=25). 63% (n=33) of the patients achieved an IGA of 0–1 at week 16, 81% at week 24 and at week 52 the percentage was 100% (n=27) achieving an IGA of 0–1. 10% of patients had treatment failure with Dupilumab, 7% switched to tralokinumab and 3% to upadacitinib.
**Conclusion and Relevance** Dupilumab treatment shows good persistence and effectiveness in AD, although further studies of longer duration are needed to establish the usefulness of dupilumab in long-term clinical practice conditions.

**REFERENCES AND/OR ACKNOWLEDGEMENTS**
**Conflict of Interest** No conflict of interest.