2016 in a tertiary care hospital and patients who started treatment with oral urea or tolvaptan during hospitalisation. Variables collected: etiology of hyponatraemia, analytical parameters, dose and duration of treatment.

Results Seven patients treated with tolvaptan: four diagnosed with HF and three with SIADH. Dose ranged from 15 mg/day to 30 mg/day. Median duration: 7 days (2–28). Baseline and final mean natraemia: 119.8 mEq/L and 133 mEq/L respectively. Two patients with SIADH and one with HF had eunatraemia. Three patients were exitus. Six patients were treated with urea, five diagnosed with SIADH and one with adrenal insufficiency. Urea dose ranged from 15 g/day to 30 g/day. Median duration of treatment: 15 days (7–147), three patients continued at home. Baseline and final mean natraemia were 123.4 mEq/L and 133 mEq/L respectively. Three patients with SIADH achieved eunatraemia, two patients were exitus. Only three urea patients had all necessary data for a diagnosis of SIADH. The mean increase in natraemia at 24 hour was 4.57 mEq/L (0–8) in the urea group; 9.9 mEq/L (−3 to 21) in the tolvaptan group (>12 mEq/L in the three cases of SIADH and one case of HF). Deaths were due to complications related to their advanced disease.

Conclusion Off-label use of tolvaptan in HF has not been shown to be effective. Regarding hyponatraemia in SIADH, tolvaptan has shown to be moderately effective, but the correction was too rapid. This result can be related to an incorrect diagnosis of SIADH and/or a too low baseline natraemia. Urea proved to be an alternative of moderate efficacy but safer, allowing its ambulatory use. Therefore, the pharmacy service proposed to establish in our hospital a protocol for the management of severe hyponatraemia to improve the efficacy and safety of tolvaptan and urea.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

5PSQ-028 THE GOVERNANCE OF PCSK9-INHIBITORS FOR THE TREATMENT OF PRIMARY HYPERCHOLESTEROLAEMIA: APPROPRIATENESS ANALYSIS

[1]MR Garreffa*, [1]C Zito, [1]S Esposito, [1]C Monopoli, [2]MD Naturale, [1]AE de Francesco. [1]*Azienda Ospedaliero-Universitaria 'Mater Domini', Unit of Pharmacy, Catanzaro, Italy*; [2]*University of 'Magna Graecia', School of Specialization in Hospital Pharmacy, Catanzaro, Italy*

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Background Recently the European Medicines Agency approved Alirocumab and Evolocumab, two monoclonal antibodies against PCSK9 (PCSK9-inhibitors), a key protein in LDL-receptor degradation. These drugs, as monotherapy or in combination with other lipid-lowering agents, represent an important therapeutic strategy in patients with high cardiovascular risk with severe familial hypercholesterolaemia or intolerance to statins.

In 2017, the Regional Working Group (RWG), using the GRADE method, drafted the guidelines for the identification of the PCSK9-inhibitors prescribing centres and for the prescriptive appropriateness.

Purpose Our goal was to monitor the use of the PCSK9-inhibitors to assess the reliability of the forecasts made by the RWG and the appropriateness.

Material and methods The guidelines for appropriateness have been drawn up using the GRADE method.

The data on therapeutic adherence have been extrapolated from the Health.db, appropriateness analysis tool adopted in our region since 2013.

The pharmaco-utilisation data for the period January 2017 to June 2018 were obtained from the IQVIA database.

Results The pharmaceutical use data showed that about 8.6% of the regional population was treated with statins.

The epidemiological evaluation using Health. db showed that the patients with high adherence to combined statin +Ezetimibe treatment were 0.2%: of these, 0.03% did not reach the therapeutic target. It is expected that only 185 patients (0.01%) present distance from the therapeutic target of more than 30% and, therefore, eligible for treatment with PCSK9-inhibitors.

Also, the pharmaco-utilisation data (real data) demonstrated that the number of patients suitable for treatment with PCSK9-inhibitors in the period July2017 to June 2018 was 190, almost equal to that provided by the epidemiological analysis performed by Health.db according to the GRADE method.

The use of PCSK9-inhibitors at regional level increased significantly in the first half of 2018 compared to 2017 (Δ_{units}= +128%), probably due to the effectiveness and continuity of the treatments.

Conclusion The establishment of the RWG to define the care path for patients with high cardiovascular risk was essential for the epidemiological evaluation and monitoring of PCSK9-inhibitors therapies. This allows us to analyse the cases of suspension of therapy and the eventual occurrence of adverse events. We plan to evaluate the long-term efficacy of these treatments by observing the lowering of LDL-cholesterol.

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No conflict of interest.

5PSQ-029 EFFECTIVENESS AND SAFETY OF EVOLOCUMAB IN REAL CLINICAL PRACTICE

MV Villacañas Palomares*, A Colón Lopez de Dicastillo, I Gutiérrez Pérez, F Uriarte Estefania, R Santos del Prado, S Lorenzo Martin, E Parra Alonso. *Hospital de Sierrallana, Servicio de Farmacia, Torrelavega, Spain*

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Background Monoclonal antibody PCSK9-inhibitor, evolocumab, is a new drug for the treatment of patients with uncontrolled familial hypercholesterolaemia (FH), uncontrolled stable atherosclerotic cardiovascular disease (ASCVD), mixed dyslipidaemia, or in patients who cannot tolerate or cannot be given statins. Evolocumab is used in monotherapy or in combination with statins or another hypolipemiant.

Clinical trials (CT) showed that evolocumab obtained LDL-C reductions of 64% when combined with statins and of 58% in monotherapy, at week 12. No significant adverse events were detected.

In our hospital, pharmacists validate every prescription of evolocumab according to the regional autonomous authorisation criteria.

Purpose To compare the efficacy and safety of evolocumab in the clinical practice with the CT.
Material and methods Retrospective observational study (May 2017 to September 2018) of all evolocumab prescriptions. Demographic, clinical, analytical and treatment variables were collected at baseline and after the first follow-up visit. Efficacy was measured, by the percentage of LDL-C reduction at week 12, using laboratory analysis and medical records. Safety was obtained from medical and pharmaceutical records.
Results Thirty patients (63% male) with a mean age of 62.2 (52–78) were considered for treatment. One of them was not treated because he did not comply with the authorisation criteria (LDL >100 mg/dl). Diagnosis was ASCVD (15/29), statins intolerance (10/29) and FH (4/29). Evolocumab was prescribed in combination with statins in 13 patients, in five with another hypolipemiant and in 11 in monotherapy. The percentage change in LDL-C from baseline in the combination with statins group, was a reduction of 67% ((+7.2%) to (−79.1%)) at week 12 (7–20). In the monotherapy group, it was of 68% ((+24.5%) to (−92.2%)) at week 9 (7–12). Treatment adherence was >96% in all patients. Regarding safety, 20% of patients had an adverse event: itching (2/29), fatigue (1/29), myalgia (1/29), abdominal pain (1/29), diarrhoea (1/29) and glucose alterations (1/29).
Conclusion In clinical practice, the reduction in LDL-C in the monotherapy group was slightly higher than in CT. The adding of statins did not affect the efficacy in our patients, they were similar in both groups. Safety was comparable to CT. It would be interesting to evaluate if these reductions are maintained in the future.

REFERENCES AND/OR ACKNOWLEDGEMENTS
No conflict of interest.

5PSQ-030 DO WE KNOW WHICH ANTIBIOTICS SHOULD BE AVOIDED IN OUR PATIENTS? ANTIBIOTIC ALLERGY SURVEY AMONG HOSPITALISED PATIENTS

R Benko*, T Vivien, M Maria, D Peter, V Reka, B Reka, S Gyongyver. *University of Szeged, Clinical Pharmacy, Szeged, Hungary*

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Background It is known from allergy databases that antibacterials belong to the common sensitising drugs. However, antibacterials are frequently administered in the hospital setting both for prophylactic and for therapeutic purposes. Considering drug allergy is an important drug safety issue, but inadequate allergy labelling can negatively affect drug choice.
Purpose To assess the prevalance and characteristics of antibiotic allergy and to differentiate cases where the allergic nature of drug raction can be excluded/or has weak grounding.
Material and methods A structured interview guide was used for the face-to-face anonymous interviews with hospitalised adult inpatients.
Results During the 19 study days, among the 1522 hospitalised patients 114 mentioned allergy to systemic antibiotics (7.5%). Most of the patients were allergic to one active agent, (100 patients), while 14 patients were polysensitised (allergic to two or more antibacterials). In the majority of cases (81 cases) penicillin products caused the drug reaction, and second, sulfonamides (18 cases) were mentioned. In 24 cases, the patient did not have any information on signs/symptoms of the drug reaction and in 14 cases drug allergy can be excluded (e.g. diarrhoea as the only reaction). Most often drug reactions occured in the hospital setting (30 cases), if not, in 12 cases hospital admission was necessary due to severity. Antibacterials most often resulted in cutaneous reactions (71 cases). Skin reaction/pruritus was the only sign in 48 cases and in 15 cases this reaction happened in childhood. Severe cutaneous drug reaction – EEM and SJ syndrome occured in seven cases. Unintended drug re-exposure occured in eight cases, resulting in reactions similar to the earlier ones (in two cases with severe life-threatening anaphylaxis). Only 12 patients (10.5%) had an allergy 'passport'.
Conclusion Antibiotic allergy was prevalent among the interviewed inpatients. In some of these reactions allergic nature can be excluded by the anamnesis, while other cases had weak evidence due to the complete lack of the anamnesis/childhood occurence of skin reactions. Only very few patients had an allergy passport. Hospital pharmacists can exclude untrue allergic reactions during the reconciliation process and can help in the proper documentation of drug allergy.

REFERENCES AND/OR ACKNOWLEDGEMENTS
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No conflict of interest.

5PSQ-031 A TWO-YEAR RETROSPECTIVE ANALYSIS OF ADVERSE DRUG REACTIONS WITH FLUOROQUINOLONE AND QUINOLONE ANTIBIOTICS

[1]V Borsi*, [2]M Del Lungo, [1]L Giovannetti, [1]MG Lai, [1]M Parrilli. *[1]Azienda Usl Toscana Centro, Pharmacovigilance, Florence, Italy; [2]University of Florence, Dept. of Neurosciences-Psychology- Drug Research and Child Health Neurofarba- Section of Pharmacology and Toxicology, Florence, Italy*

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Background On 9 February 2017, the Pharmacovigilance Risk Assessment Committee (PRAC) initiated a review[1] of disabling and potentially long-lasting side effects reported with systemic and inhaled quinolone and fluoroquinolone antibiotics at the request of the German medicines authority, following reports of long-lasting side effects in the national safety database and the published literature.
Purpose To review the adverse drugs reactions (ADRs) of systemic and inhaled fluoroquinolone and quinolone antibiotics that involved peripheral and central nervous system, tendons, muscles and joints reported from our Pharmacovigilance Department (PVD).
Material and methods Retrospective analysis of ADRs reported in our PVD involving ciprofloxacin, flumequine, levofloxacin, lomefloxacin, moxifloxacin, norfloxacin, ofloxacin, pefloxacin, prulifloxacin, rufloxacin, cinoxacin, nalidixic acid and pipemidic given systemically (by mouth or injection). The period considered was September 2016 to September 2018.
Results Twenty-two ADRs were reported in our PVD involving fluoroquinolone and quinolone antibiotics in the period considered and that affected peripheral or central nervous system, tendons, muscles and joints. The mean patient age was 67.3 years (range: 17–92 years). 63.7% of the ADRs reported were serious, of which 22.7% caused hospitalisation and 4.5% caused persistent/severe disability. 81.8% of the ADRs were reported by a healthcare professional (physician, pharmacist or other) and 18.2% by patients or a non-healthcare professional.