Results: The pharmacovigilance program involved 1 general hospital (Ass.2 'Isontina', Gorizia-Italy), 12 pharmacies, and 24 GPs. From March 2012 to March 2013, Medigenia enrolled 2074 patients (52.4% women; mean age, 69 [8]). The system totally administered 62,499 drugs (68.2% prescriptions, 28.4% OTC, and 3.4% herbs), and 3028 were the DDIs identified among them. GPs received 2738 alerts for ADR risk (48% moderate risk, 23.2% high risk); treatment was changed 871 times (31.8%). The most frequent alert among high risk connected with hemorrhage (87.6%), involving primarily acetylsalicylic acid and warfarin. Moderate risk concerned mainly neurologic sequelae (38.2%) and involved in particular antineoplastic agents and phenytoin.

Conclusion: People taking drugs are not always aware of the health risk they are going toward after a multidrug therapy or simply taking a medicine without asking GP, a trend that is increasing in the last years. Medigenia prevents ADR and their health sequel using a cloud-based approach for pharmacovigilance.

Disclosure of Interest: None declared.

PP027—DRUG-INDUCED LIVER INJURY DETECTED THROUGH A PHARMACOVIGILANCE PROGRAM BASED IN LABORATORY SIGNALS

H.Y. Tong1; N. Medrano; C. Zegarra; A. Caparrós; A. Borobia; J. Frias; and E. Ramirez

Clinical Pharmacology Service, La Paz University Hospital, Madrid, Spain

Introduction: Drug-induced liver injury (DILI) is the most frequent reason for withdrawal of approved drugs from the market and accounts for 7% to 15% of the cases of acute liver failure in Europe and the United States. The risk of developing hepatotoxicity involves a complex interplay between the chemical properties of the drug, environment factors, age, sex, underlying diseases, and genetic factors.

Patients (or Materials) and Methods: OBJECTIVES: To determine the incidence of DILI detected through a pharmacovigilance program from laboratory signals in hospitalized patients in La Paz University Hospital from July 2007 to December 2010. Secondary objectives: (1) characterize patients with DILI; (2) determine suspected drugs of DILI according to therapeutic group; and (3) classification of cases according to type of lesion.

Methods: All serum alanine transaminase (ALT) and aspartate transaminase (AST) > 3 upper limit normality (ULN) or > 2 ULN of gamma glutamil transpeptidase (GGT) or bilirubin, detected at admission to the hospital, including those patients who died in the emergency ward or during hospitalization, were monitored prospectively from July 2007 through December 2010. We evaluated each patient to assess alternative causes or confirm DILI. The incidence was calculated by dividing the number of cases by the number of hospitalizations in that period.

Results: We detected 2490 cases of liver enzyme disorders in the study period, with an incidence of 146 cases per 10,000 inpatients (Poisson 95% CI, 123.3–171.1). Of these, 198 cases (7.95%) were secondary to drugs, reporting an incidence of 11.6 cases of DILI per 10,000 inpatients (Poisson 95% CI, 6.2–19.7). The median of age was 47.6 (24.4) years, and 49.6% were female. Most of the DILI (64.6%) occurred during hospitalization and the rest were outpatients. The hospitalization wards with more cases of DILI were Hematology and Internal Medicine (5.7% each one). The main therapeutic groups of suspected drugs of DILI in our study according to the ATC classification system were: J. Antiinfectives for systemic use (34.1%), L. Antineoplastic and immunomodulating agents (20.1%) and N. Nervous system (18.6%). The classification according to the type of lesion: 52.5% was cholestatic, 32.3% had hepatocellular injury, and 15.2% had mix pattern. The median (range) of ALT level was 636.4 (31–14,397 UI/L); AST, 619.8 (12–17,671 UI/L); GGT, 420.6 (14–5708 UI/L); and BT, 2.11 (0.1–38.2 mg/dL).

Conclusion: (1) One case of 11 inpatients with liver enzyme disorders is drug-induced. (2) Most of DILI occur during hospitalization. (3) The main drugs associated with DILI are antibiotics included in group J of the ATC classification system.

Disclosure of Interest: None declared.

PP028—INFLUENCE OF PHARMACOLOGICAL EDUCATION ON AWARENESS OF THE RISK OF ADVERSE DRUG REACTIONS

S. Mugosa1,2*; Z. Bukumiric3; D. Protic4; and Z. Todorovic4

1Clinical Trials Department, Agency for Medicines and Medical Devices of Montenegro; 2Department of Pharmacotherapy, Faculty of Pharmacy, Podgorica, Montenegro; 3Institute of Medical Statistics and Informatics; and 4Department of Clinical Pharmacology, Pharmacology and Toxicology, Faculty of Medicine, Belgrade, Serbia

Introduction: The assessment of the adverse drug reactions risk is an important factor in drug safety monitoring system. The aim of our study was to assess knowledge and attitudes of pharmacologically educated and pharmacologically noneducated students from the University of Montenegro regarding drug safety risk.

Patients (or Materials) and Methods: In this cross-sectional study, a self-completion questionnaire was delivered to 63 pharmacologically educated students (medical students who attended Pharmacology course and passed exams within it), 50 pharmacologically noneducated students (medical students who attended Pharmacology course but did not pass exams within it), and 50 students from other nonmedical faculties at the University of Montenegro.

Results: As expected, pharmacologically educated students are considered to be better informed about ADRs than other participants (P < 0.01). Prescription drugs were ranked as less dangerous than self-medication by all participants. Anticoagulants were considered the most dangerous drugs by pharmacologically educated students (median, 7.5; scale, 1–10; interquartile range, 3.75–8), and antidepressants, anxiolytics, and hypnotics by pharmacologically noneducated students (median, 8, all). Information about drug safety significantly influenced the choice of therapy by both groups of students questioned (median, 8–10, all).

Conclusion: On the basis of the aforementioned results, it can be concluded that when risk of adverse drug reactions is in question, pharmacologically educated students are much better informed than pharmacologically noneducated medical students and students from nonmedical faculties. Additional educational efforts are necessary to build awareness among general population of adverse drug reactions.

Disclosure of Interest: None declared.

PP029—PHARMACOVIGILANCE IN CRIMEA, UKRAINE IN 2012, ANNUAL REPORT

O.V. Matvieiev1;2; O.I. Koniaieva1;3; N.V. Matvieiev1; and P.M. Radzivil1

1Clinical Pharmacology and Pharmacotherapy, Crimea State Medical University named after S.I.Georgevsky, Simferopol; 2Regional Pharmacovigilance Office, State Expert Center of MoH, Kyiv; and 3Sport Medicine, Crimea State Medical University named after S.I.Georgevsky, Simferopol, Ukraine

Introduction: The knowledge of frequency, character, severity, and other peculiarities of adverse reactions (ADR) as well as of dynamic
of their changes in comparison with previous years is very important for effective pharmacovigilance (PV) (eg, taking of regulatory acts, update of instructions for use, revealing of medical mistakes).

Patients (or Materials) and Methods: To analyze structure of ADR, we used search in ARCADE (Adverse Reactions in Crimea Autonomy Database).

Results: In 2012, Regional PV office of State Expert Center of Ukraine in Simferopol (Crimea Autonomic Republic) received 1135 spontaneous reports about ADR from 123 hospitals. As in 2006-2011 period, most frequently ADR were registered in 1-st year children (98 cases) and 46 to 60 year-old adults (259). Sixty-five percent of reports informed about ADR in females, 35% in males. Two reactions were lethal (both in children, uncertain causality), 72 were life-threatening, 102 resulted in hospitalization of patient, and 181 in temporary disability. Most of drugs were used per os (575), others were prescribed intramuscularly (190), intravenously (239), or in topical forms (69 reports). A total of 133 patients had allergy in anamnesis, 73 from them had medicinal allergy. A total of 328 patients took only 1 product (monotherapy), when other took combinations of drugs, from them 113 patients 5 medicines and more. Most frequently drugs were prescribed for treatment of respiratory diseases (269), heart diseases (176), and infections (148). A total of 563 reports informed about skin rush, 115 about dyspeptic disorders, 96 about central neural system symptoms, 53 about fever, 53 about hemopoiesis depression, 37 and 15 about angioneurotic edema and anaphylactic shock, respectively. In 71%, ADRs needed medical correction–prescription of additional drugs. The structure of ADR data according to groups is following: 41% of reactions were caused by systemic antimicrobial drugs (ATC J01-J07), 12% by cardiovascular drugs (C01-C10), 8.3% by drugs influencing on CNS, and 7.5% by nonsteroidal anti-inflammatory drugs. The top 3 of products use of drugs (C01-C10), 8.3% by drugs influencing on CNS, and 7.5% by nonsteroidal anti-inflammatory drugs. The structure of ADR data received from doctors allows to define specific patterns of reactions development, pharmacologic groups of high risk of complications and most frequent medical errors. Knowledge of them let clinical pharmacologists, regulatory agency, and educational societies to focus on the issues really important for effective and safe pharmacotherapy.

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Patients (or Materials) and Methods: French ALFT cases exposed to drugs within 30 days of first symptoms were compared with drug utilization data from the 1/97 sample of the French National Healthcare database (EGB). Event rates were computed per billion DDD dispensed over the period and per million users, compared with the average number of DDD dispensed per user over 3 years. Chronic liver disease, documented clinical causes, and drug overdoses were excluded.

Results: The 65 cases of ALFT identified in France (2005-2007) had been exposed to 235 different drugs. The drug classes most found were paracetamol (47 cases), antihistamines (n = 13), antiepileptic drugs (n = 11), NSAIDs (n = 10), H1 antihistamines (n = 8), proton pump inhibitors (n = 7), and antidepressants (n = 6). Other classes were associated with ≤5 cases. Rates ranged from 1.9 (bromazepam) to 372 cases per billion DDD (prazepam). Per user rates ranged from 0.19 (pantoprazole) to 56 per million (phenytoin). For NSAIDs, PPI, and some H1 antagonists, event rates decreased with increasing average number of DDD dispensed. In these classes, the event rate per user was below 1 per million users. For other drug classes such as antiepileptic drugs, the event rates per billion DDD were similar, and rates per million users increased with increasing average number of DDD dispensed per subject. Drugs fell into 3 main categories: event rates below 1 per million users (NSAIDs, PPI, most antihistamines, some benzodiazepines), from 1 to 10 per million users (paracetamol, benzodiazepines, antiepileptic drugs), and above 10 per million users. Antidepressants were ~1 case per million users. Two antiepileptic drugs had event rates at or above 10 per million users. Overall, drugs with longer duration of use tended to have higher per user event rates.

Conclusion: These results are still tentative because of the small number of cases for individual drugs. SALT should be extended.

Disclosure of Interest: None declared.

PP031—DRUG-ASSOCIATED ACUTE LIVER FAILURE LEADING TO REGISTRATION FOR TRANSPLANTATION IN FRANCE FROM THE STUDY OF ACUTE LIVER TRANSPLANT (SALT)

E. Gulmez1; D. Larrey2; G.-P. Pageaux3; J. Jove1; R. Lassalle1; S. Lignot1; P. Blin2; and N. Moore1
1Pharmacology, Université Bordeaux Segalen, Bordeaux; and 2Hepatogastroenterology, CHU Hôpital Saint-Eloi, Montpellier, France

Introduction: Drug-associated acute liver injury is a common concern in drug safety, especially acute liver failure leading to registration for transplantation (ALFT). SALT was designed to explore drug-associated ALFT.

PP032—ANTIDEPRESSANT PRESCRIPTION BY GAUTENG DISPENSING DOCTORS

S. Moch; S. Laher-Sibda; and J. Miot
Pharmacy and Pharmacology, University of the Witwatersrand, Johannesburg, South Africa

Introduction: In South Africa, mental health services are underresourced, and management of psychiatric disorders is poorly integrated into the primary health care system. Despite the statistic that neuropsychiatric disorders are ranked third in the national burden of disease (following HIV/AIDS and the category “other infectious diseases”), little has been done to document the current services to improve mental healthcare systems. The aim of this research, therefore, was to establish a baseline of antidepressant utilization in various sectors of health service offered in Gauteng, South Africa’s most populous province. This particular segment reports on antidepressant usage in a sample of dispensing doctors prescriptions in 2 geographic locations in Gauteng.

Patients (or Materials) and Methods: Two datasets (A and B) were acquired from different medical data warehousing companies. Each dataset comprised 1 years’ medical records from health care practitioners subscribed to the respective company (Dataset A from 2009, Dataset B from 2011). Data included a unique patient number, age, gender, treatment code, ICD-10 code, and treatment date. Microsoft Excel was used to filter the data and isolate patients treated with an antidepressant and a cluster analysis performed to group antidepressants together. Simple descriptive statistics were determined. Data were analyzed using STATA (v10.0). Statistical significance was determined using Pearson’s chi-squared tests, Mann Whitney U test, and logistic regression. Significance levels were set at P < 0.05.