

The project of active pharmacovigilance 'MEREAFAPS' as a tool to analyze and consequently to improve the use of drugs in the patient pathway between hospital and territory: first ASLTO4 data

S. Bianco¹, M. Aimino², L. Rocatti¹, M. Morello²

¹ASLTO4, Hospital Pharmacy, Ivrea, Italy

²ASLTO4, Hospital Emergency Department, Ivrea, Italy

Pharmacovigilance is an important tool to constantly monitor the relation between risk and benefit of each drug, and to complete its safety profile after its introduction on the market, where the population features are very different from those in the pre-marketing studies.

A lot of projects of active Pharmacovigilance have been activated in Italy to increase the attention on this content such as the "MEREAFaPS" (Epidemiological Monitoring of Adverse Drug Events and Reactions in emergency department), which is the reporting of suspected ADRs that cause access to the emergency department (ED).

ED is a valuable observatory, where the reactions from drugs used in the territory can be intercepted. These ADRs are certainly underestimated considering the growing use of self-medication and multitreatment of the elderly population.

This project, activated in 2006 in Lombardia, was launched in 2012 in Piemonte, and in ASLTO4 from July 2012. The peculiarity of this project is that the reports from all active centers in Italy are included in a single database and this allows a detailed analysis on the impact of ADRs on public health, as well as a careful observation to identify the most reported molecules, the severity of the effects and much more.

This work aims to analyze all the reports from July 2012 to April 2013 in ASLTO4, consisting of three former ASL (Ivrea, Chivasso, Ciriè), but especially in Ivrea, where the Monitor chemist works, assignee of a scholarship.

The ED of Ivrea records approximately 40.000 accesses/year.

The Monitor is constantly in ED to collect the minutes to be converted into reporting forms dispatched to the database and to the national network of pharmacovigilance. A representative specialist was identified in the staff of the ED; she planned operational procedure and constantly collaborates with the chemist Monitor.

The total number of ADRs was 93 (89 from the Ivrea ED and 4 from Chivasso ED): 56% are severe; 94% of these have caused hospitalization/extension of observation in ED and 6% have endangered the life of the patient. 56% of the total are charged to the female gender. 44% of patients are aged ≤ 65 years, 16% are aged 66 to 75 years, 31% are aged 76 to 85 years and 9% are aged over 85 years.

The main drugs reported are: carbamazepine, digoxin, furosemide, amoxicillin/clavulanate potassium, acetylsalicylic acid, ketorolac, levofloxacin, glyburide/metformin, walfarin.

The main terms (Preferred Term) of the international dictionary MedDRA used for the description of ADRs are: hyponatremia, hypoglycemia, itching, drowsiness, confusion, vomiting, erythema, hypokalemia, abuse of drugs.

It should be noted that reports of electrolyte abnormalities in the blood stream is predominant and due to the use of drugs with diuretic action, but also to antiepileptic drugs, which may affect these mechanisms, especially considering concomitant renal failure in elderly patients.

It can be inferred that age is a risk factor because elderly patients are more often affected by simultaneously diseases and receive therefore multitreatments. Therefore risks due to drug interactions are associated with pathophysiological characteristics of patients affected by different morbidity, such as diabetes mellitus, hypertension, renal insufficiency, etc.

Our analysis shows that 11% were avoidable reactions, 17% uncertain and 72% can not be avoided (according to the Naranjo algorithm).

With these important data we can better conduct an "education" to the use of drugs where are involved more professionalism: the General Practitioner, the specialist and the pharmacist. Also the figure of the patient must, where possible, empowered and involved in treatment decisions concerning it.

In summary, the pharmacovigilance, with the contribution of these detailed analysis, acting on the appropriateness of use of drugs, improves the health of the population and consequently produces a potential cost savings.