

## Analysis of adverse drug reactions for preventability: a focus on psychotropic drug

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### Introduction

Pharmacovigilance (PV) is defined as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problem [1]. The European (EU) PV legislation has been subject to a major review that led to the adoption of new legislation in 2010. The new legislation, Regulation 1235/2010 and a Directive 2010/84/EU, became applicable in July 2012 [2]. Among new changes of particular importance was the extension of the definition of Adverse Drug Reaction (ADR), defined as 'a response to a medicinal product which is noxious and unintended including those arising from therapeutic error, abuse, misuse, off-label use, overdose and occupational exposure'. The new definition also included ADRs, which were "preventable", because they occurred with a not appropriate use of the drug or due to therapeutic errors [3]. The changes introduced, highlight the necessity to identify this type of reaction; they represented a serious public health problem, both for damages to patients and increased the burden on the healthcare system [3]. To date, in Campania Region, no studies have been conducted to assess the impact of preventable ADRs reported through Campania Region spontaneous reporting system. Considering this, we conducted a pilot descriptive study on preventable ADRs to psychotropic drug sent to Campania Pharmacovigilance Regional Centre (CPRC) in fourteen years of post-marketing safety surveillance and both the type of medication error or inappropriate care that caused the preventable ADE, and the type of adverse outcome or patient injury associated with the medication error.

### Methods

Among all reports of suspected ADR sent to CPRC from 1 January 2001 to 31 October 2014 a 1-day trained researcher of CPRC selected those were reported indicated as suspected a drug with Anatomical Therapeutic Code (ATC) N06A, N03A, N05A, N05B, N05C or their combinations. Cases aged less than 17-years old and cases which reported anti-dementia and antiepileptic drugs were excluded. The preventability was determined using Lau modified algorithm from Schumock and Thornton [4].

### Results

During the study period, 421 reports meet the inclusion criteria; 118 reported cases with at least one preventively condition. Cases had an average age of 47.2 years  $\pm$  16.8 (mean  $\pm$  S.D., range 18-99 years). In 29 cases (30%) there was necessary a pharmacological treatment to treat the events. In particular, in 19 cases (20%), drug treatment was stopped and in 10 cases (10%) the patient was hospitalized. In 38 cases (40%), however, there was necessary more than one interventions such to treat the events. The most reported preventively cause (69 cases; 64%) was erroneous administration/use of drugs. Among these reports, 32 cases reported an inappropriate dose or frequency of administration of hypnotic/sedatives drugs, and, in particular, bromazepam, lorazepam, delorazepam, alprazolam and diazepam. In 13 cases, non-therapeutic doses of antipsychotics were administered.

### References

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