

Campania Region (Italy) spontaneous reporting system and preventability assessment through a case-by-case approach: a pilot study on psychotropic drugs.

M. Sessa, A. Mascolo, C. Scavone, D. Cimmaruta, C. Rafaniello, L. Sportiello, M.G. Sullo, A. Capuano, F. Rossi.
Department of Experimental Medicine, Section of Pharmacology "L. Donatelli", Second University of Naples, Via de Crecchio 7,
80138 Naples, Italy

Objective: We conducted the first pilot Italian study to assess the preventability of adverse events involving psychotropic drugs reported through spontaneous reporting system from 01/07/2012 to 31/12/2014 in Campania Region.

Research design and methods: Preventability was assessed, case-by-case, using an adapted version of the P-method [1]. The evaluation was performed only for those reports that had, as suspected drug, antipsychotics, mood stabilizers, antidepressants, anxiolytic and/or sedative-hypnotic.

Results: Eighty-one cases (19.2%) out of 421 reported during the study period were preventable. In seventy-seven (95.1%) out of 81 preventable cases, the underlying mechanism of the adverse events was dose-related, in four (4.9%) preventable cases the underlying mechanism of the adverse events was respectively susceptibility- (1; 1.2%), unknown- (1; 1.2%) and time-related (2; 2.5%). In the 81 preventable cases, 97 critical criteria were detected of which 29/97 (29.9%) related to healthcare professionals' practices, 0/97 (0.0%) to drug quality and 68/97 (70.1%) to patient behavior.

Conclusions: We proved that was possible to apply and adapt the P-Method to assess the preventability of the adverse events involving psychotropic drugs, analyzing individual case safety report sent through Campania Region spontaneous reporting system. Information acquired will be used to organize educational activities for both physicians and patients to promote a more appropriate drug use.

Reference:

1. Benkirane R, Soulaymani-Bencheikh R, Khattabi A, et al. Assessment of a new instrument for detecting preventable adverse drug reactions. *Drug Saf.* 2015;38:383-93.