Detection and analysis of medication errors in the Italian Pharmacovigilance Database

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Medication errors (MEs) are one of the most common types of medical errors (Leape et al., 1991). As defined by Aronson et al. (2009) a medication error is 'a failure in the treatment process that leads to, or has the potential to lead to, harm to the patient'. The treatment process starts after the decision is made to adopt treatment for symptoms or their causes, or to investigate or prevent disease or physiological changes. It includes the prescribing, transcribing, manufacturing or compounding, dispensing and administration of a drug. It also includes the monitoring of therapy because also a faulty monitoring can lead to an erroneous alteration. Prescribing faults and prescription errors are the major problems among medication errors. In fact, prescribing errors account for 60% of medication errors (Schachter et al., 2009). Medication errors can also cause an adverse drug reaction (ADR); the epidemiology of this type of ME depends on the setting in which they are identified.

In 2010, the new European pharmacovigilance legislation included medication errors, but also drug-drug interactions (DDIs), off label use, abuse, professional exposure, misuse and drug overdose, as causes of ADRs to be reported. So, in 2012, the Italian Medicines Agency (AIFA) introduced a new ADR reporting form, which includes 'field seven', where it is possible to specify these above mentioned types of ADR. It is necessary to underline that in September 2009 a dedicated flag to report a medication error has been already introduced by AIFA on the on-line platform.

Our objective was to analyse the ADR caused by medication errors in the Italian Pharmacovigilance Database from 2009 to April 2015. MEs represent 30% of all completed 'field seven' (6,579), obviously in 2009-2011 period MEs represent 100% while in 2013-2015 about 21%. The reports of medication errors were 0,2% in 2009, 0,8 % in 2013 and 1% in 2015 of the annual ADR reports. Until April 2015, the reports of medication errors were 1,965, of these 1,261 (64%) were serious. The number of related suspected drugs were 2,287 and the most involved ones were: insulin (n=177, 8%), warfarin (71, 3%), acetaminophen (61, 3%), oxatomide (59, 3%) and lorazepam (58, 3%). Most of the reports come from hospital physicians (53%) followed by pharmacists (19%). Types of medication errors were specified for 483 reports (24%); in particular 240 errors (50% of 483) caused by a wrong dosage, 215 (45%) by a wrong drug, 22 (5%) by a wrong route of administration and 6 (1%) by an expired drug. The risk factors favouring the errors were: a misinterpretation of a prescription in 52 cases (11% of 483) and the similarity in the drug packaging in 12 cases (2%). As known, a drug-drug interaction can be considered a medication error. The DDIs represent 20% of the total completed 'field seven'. Further investigations are needed to evaluate the role of DDIs in this context.

This study shows that medication errors, together with DDIs, represent the main cause of ADRs reported in the 'field seven'. It is interest to note that ADRs caused by ME are more serious than others present in Italian database. From 2012 to today EMA has continued to promote and improve the reporting, evaluation and prevention of medication errors by regulatory authorities and pharmaceutical industry. So the detection and analysis of medication errors has become of great interest. Although it is difficult to quantify precisely the extent of medication errors, they are clearly frequent, often avoidable and representing a major threat to patient safety. Computerized prescribing and improved training of health professionals could be important in recognizing and preventing medication errors.

Aronson et al. (2009). Br J Clin Pharmacol. 67: 599-604.
Laepe et al. (1991). Engl J Med. 324: 377-84.
Schachter et al. (2009) Br J Clin Pharmacol. 67: 621–23.