A gender pharmacovigilance study in Tuscany Region

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Sex and gender are important determinants of drug use and drug response (Franconi et al, 2007). The literature clearly shows that more data on drug response in women are urgently needed (Franconi et al, 2011). Although the regulatory authorities evidenced the importance of including more women in clinical trials, women are still underrepresented in clinical research nowadays especially in phase I and II (Fattinger et al 2000; Zopf et al, 2008). The policies and guidelines set up by the Food and Drug Administration (FDA), and the European Medicines Agency (EMA), have not resolved the under recruitment of women (Kim et al, 2008; Ruiz Cantero et al, 2006; Uhl et al, 2007).
Adverse drug reactions (ADRs) are a major problem for the individual as well as for the public health regularly leading to hospital admission, morbidity or death. Women tend to have a higher risk of ADRs with a 1.5 to 1.7-fold greater risk than men (Fattinger et al, 2000; Zopf et al, 2008).
Our primary aim was to study differences in ADRs between the sexes in Tuscany. Data were obtained from Farmacovigilanza Regione Toscana and we focused our attention on severe ADRs in 2012.
The severe ADRs were more frequent in female than in male (648 versus 515), however the frequency of death was almost the same in the two sexes while hospital recoveries were more frequent in women (540) than in men (428). Death and hospitalization mainly occurred in old age. Notably, after the stratification for age, it emerged that before the 17 year of age, the severe ADRs seemed to be more frequent in young boys than in young girls, while after ADRs were more frequent in women than in men. In young age, the ADRs were mainly associated with the use of antibiotics, whereas in the other classes of age the ADRs were mainly associated with antibiotics and other drug classes. The previous data suggest that also in Italy, the ADRs are more frequent and severe in adult and old women than in adult and old men indicating the need to include women in the clinical studies.

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