

The development of a Pharmacovigilance Network in Sardinia.

A. Deidda¹, P. Carta¹, C. Chillotti¹, M. Tidore², F. Piras², M. Del Zompo¹, D. Garau², M.E. Stochino¹

¹ Unit of Clinical Pharmacology, Teaching Hospital of Cagliari and Department of Biomedical Sciences, University of Cagliari, Cagliari, Italy

² Assessorato Regionale alla Sanità, Regione Autonoma della Sardegna, Cagliari, Italy

Adverse drug reactions (ADRs) are a major health care dilemma and a common cause for hospital care. According to data collected by the European Commission in 2008, it was estimated that 5% of all hospital admissions are caused by ADRs, that about 5% of hospitalized patients suffer an ADR and that these would be the 5th cause of in-hospital death, with about 197,000 deaths per year in the European Union and a societal economic burden of about € 79 billion a year. Medical literature suggests that at least 30% of ADRs are preventable.

Spontaneous reporting of ADRs is one way of increasing the knowledge of the risks of a drug in clinical practice, and also an important method for detecting signals, which is the number one goal of pharmacovigilance.

Recent years have seen strong growth of spontaneous reporting in Italy, but, in contrast to this national trend, in the years 2005-2010 in the region of Sardinia a significant decrease was observed in spontaneous reports of ADRs. In an effort to raise awareness among health professionals of Sardinia to the spontaneous reporting of suspect ADRs, the regional project 'The development of a Pharmacovigilance Network in Sardinia' was conceived and realized.

The project's objectives included: activation of the ADR pathway, organization of training courses aimed at health professionals and implementation of the website www.farmaci-fc.it.

In the course of one year of activities, 7 Continuing Medical Education courses were organized in various locations in Sardinia, addressed to health professionals involved in the signaling path. The courses have seen a large turnout and a keen interest on behalf physicians, pharmacists and nurses, who have expressed a positive opinion on the efficacy of the initiative. As planned, more than 90% of the reports sent to our unit have been processed and feedback (scientific investigation on the reported ADR) was shipped to the reporting health professionals. The implementation of the website gave positive results, as showed by the relevant increase in the number of visits to the site in 2012 over the previous year.

Through the analysis of the official Italian spontaneous ADR reporting database, we found a growing trend in the number of suspected ADRs submitted by Sardinian Region in 2012, an increase of 15% compared to 2011, and a high improvement in the quality of reporting. Our data highlight the success of the project and the efficacy of the tools used. The recent establishment of the Pharmacovigilance Centre of the Sardinia Region, identified in the Unit of Clinical Pharmacology of the University Hospital of Cagliari, is the main result of our project. The institution of the Regional Centre of Pharmacovigilance in the future will continue and intensify the activities started with the project, for the maintenance and improvement of the results obtained.

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