

Pharmacovigilance in Calabria (Italy): Local experiences resonate international relevance

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Pharmacovigilance and all drug safety issues are relevant for everyone whose life is touched in any way by medical interventions.^[1] Pharmacovigilance is defined by the World Health Organization (WHO) as “the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other problem in the field of medicine.”^[2] The main reason for having a world-wide active and functioning pharmacovigilance system is the need to ensure patients' safety. In all therapeutic protocols patients' wellness is the main objective. Several aspects of drug therapy such as appropriateness of medication prescribing, rationale of choice of the agents, cost-effectiveness of the chosen medications and safety must be considered before starting treatment. Drug related adverse effects threaten patient wellness. In the light of this, pharmacovigilance should be considered a mandatory activity of all countries.^[3]

Though, the history of pharmacovigilance started several years ago its implementation many countries is still found wanting. The international program pursued by WHO has greatly contributed to practice and standards and together with the various national centers, has been seen to improve the quality of pharmacovigilance. Like all other human activities, the dissemination of pharmacovigilance related knowledge and experiences play a crucial role for the development of this

subject. The way to improve is to debate a specific aspect and compare different methodologies and points of view. This special issue fulfills this role by discussing the various aspects of pharmacovigilance in Italy.

CALABRIA'S PHARMACOVIGILANCE CENTRE AND THE UNIVIGIL RESEARCH GROUP

Thanks to the funding of the Italian Medicines Agency (AIFA; Agenzia Italiana del Farmaco), the “regional network of drug information: information, training and pharmacovigilance” under the direction of Prof. Giovambattista De Sarro was created at the University Hospital “Mater Domini” of Catanzaro (Calabria, Italy) by the end of 2010.^[4] Prior to that, reporting of adverse drug reactions (ADRs) from Calabria was very poor with very few reports and was seen to be one of the last region in Italy.^[4] Since then, many protocols have been activated to improve regional knowledge on the relevance of pharmacovigilance and efforts have been taken (i.e., local projects in hospitals; congresses; person-to-person advices etc.) to increase the annual number of reported ADRs. The result was a great participation to a unified regional research group named UNIVIGIL, which has quadruplicated the number of ADRs reported up to 2012^[5] and has already reached the WHO set standard (300 reported ADRs/1 million people) in July 2013.^[5] However, the number of ADRs should not be considered the main result obtained. The main outcome is represented by the great participation and involvement of health-care professionals in pharmacovigilance activities and the number of daily contacts that the center receives by all the health system professionals seeking support in their medical activity.

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In our experience, what was mainly missing was the direct contact with someone giving support and a positive feedback, which made pharmacovigilance closer to all interested persons. The key question on all health professionals' minds was "what happens after I send my report?"^[4] Once this aspect was tackled many reports were filed. Most of the reports are about already known ADRs and in a small region such as Calabria, it is indeed very rare that a new unexpected ADR will be reported or discovered. Reporting should be considered as the dissemination of the observations done during clinical practice and not as research. Indeed, all ADRs are important and the possibility of knowing what others have already done before or after prescribing a therapy and preventing or observing an ADR is helpful in clinical practice.^[6]

Systematic reports to all UNIVIGIL participants and the dissemination of the local acquired knowledge, although important, it is not sufficient to achieve a suitable pharmacovigilance system. Sharing of experiences and comparison with other countries' experiences is necessary to participate in an international platform.

A SPECIAL ISSUE BASED ON LOCAL EXPERIENCE

The aim of this special issue was to bring the pharmacovigilance debate out of our local experience to a wider scientific scenario. Several questions raised in the articles included in this volume should add to the body of knowledge about pharmacovigilance while some others report experts' points of view.

Some general articles on pharmacovigilance on the Italian/European and Asian pharmacovigilance systems are described initially in two articles and then, the pharmaceutical companies approach and European regulation is briefly reported. This is followed by three articles, which critically approach the problems related to ADRs and pharmacovigilance. Pharmacoeconomics is an extremely important issue in several countries. The costs of national health systems have increased exponentially and many countries have created new strategies to monitor their expenses maintaining clinical efficiency.^[7] The cost of drugs' safety and ADRs has also been given importance. The last two general commentaries were directed towards the limitations of the reporting procedure in Italy and the limitations of spontaneous reporting.

All other articles included, discuss safety of drugs starting from the ADRs uploaded into the national database or are related to local projects. Several aspects have been considered, the use of generic drugs and the appearance of reports due to therapeutic failure was analyzed; similarly, the off-label use of drugs in the pediatric age was studied

by a questionnaire-based interview. The safety of biological drugs and their related efficacy is considered including the particular relationship by epidermal growth factor receptor inhibitors dermatological toxicity and their efficacy. A brief review describes the central nervous system side effects of corticosteroids, since despite the fact that corticosteroids are widely used drugs, the number of reported ADRs is very low and often, those ADRs affecting the central nervous system are not recognized. Finally, two case reviews discuss the cases of suicides or attempted suicides and vertigo due to use of drugs. As we all know, at times, the same ADR may be the manifestation of different drugs or may be associated with the disease condition of the patient.

FUTURE DIRECTIONS AND CONSIDERATIONS

Pharmacovigilance has been accepted with great enthusiasm in our region. The feeling of participating in something important with the motivation to improve clinical practice and patients' safety during a period in which the Italian health system is getting reorganized was strikingly surprising. Despite the fact that the most common excuse for not reporting is the lack of time to fill the form,^[4] we have found that when properly informed and supported most of the health-care professionals wish to participate in pharmacovigilance projects. As already indicated by the WHO, the future is the improvement of the world-wide pharmacovigilance system in order to furnish a comprehensive integrated system. This utopistic target, however, obviously faces several limitations. In any case, even if dissimilar systems might become active in different parts of the world, the most important aim should be to diffuse information about drugs' safety to everyone in order to allow every nation to quickly recognize and analyze signals in agreement with the Erice's declaration.^[8] This would be a testament to the ultimate aim of ensuring patient safety as far as possible.

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