

## The importance of spontaneous reporting in geriatrics: the ViGer Project

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Pharmacovigilance is a cornerstone in elderly's pharmacotherapy since older patients are particularly exposed to adverse drug reactions (ADRs). Half of the deaths due to ADR occurs in patients over 65.

In geriatric patients several factors can be involved in ADRs onset: deficit in hepatic and renal function, comorbidities, non compliance, exclusion of geriatric patients from clinical trials and concomitant therapies. In addition, comorbidities are frequent and can further modify the pharmacokinetic and pharmacodynamic parameters with possible increase in adverse reactions.

The aim of pharmacovigilance in geriatrics (ViGer) project is to encourage voluntary reporting from geriatricians and territorial physicians to better assess the occurrence of ADRs in the elderly.

VIGER project enrolled four Nursing Homes (NH) for elderly in Milan and six Aziende Sanitarie Locali (ASL) in Lombardy.

Alongside collecting information on ADRs, the project pursued several strategies aimed at enhancing high quality spontaneous reporting of ADRs in elderly. Specific attention was paid to continuous education of involved geriatrician and territorial physicians, which was carried out at the beginning of the study but also with a follow up in the third and sixth months. Furthermore, periodic session studies on specific issues of drug safety emerging from the spontaneous reporting system were systematically performed. Finally, an electronic bimonthly report of the data with specific commentaries on relevant issues emerging from the study was generated and delivered to all involved all physicians and health professionals involved.

In the first two years of the project (01/10/2011 - 09/05/2013) 539 reports of suspected ADR has been received. Of these 19% and 12% were classified as serious or unknown respectively. Drugs most frequently related to the onset of serious ADRs were warfarin, allopurinol, ceftriaxone, acetylsalicylic acid, piperacillin/tazobactam, oxaliplatin and vaccines.

Among the 539 ADRs reports, 23 (>4%) were considered preventable. Drugs most involved in these interactions were warfarin, lansoprazole and sulfonylureas. Analysis of the clinical data showed that the therapy (in terms of dosage and indication) was not suitable in many of these patients. In the case of allopurinol this was a significant deviation from the accepted guidelines leading to implementation of appropriate corrective measures by the regional pharmacovigilance authority.

Overall the results of the ViGer project show that a project specifically targeted to ADR monitoring in elderly, if accompanied by continuous education as well as the presence of an active pharmacovigilance system may play an important role in enhancing drug safety and therapeutic appropriateness.