

Forward (Facilitation Of Reporting in hospital WARD) project: an useful tool to improve the detection, evaluation and reporting of ADRs in hospital setting

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Spontaneous reporting is an effective method for early detection of possible adverse drug reactions (ADRs). This system is particularly useful in the identification of rare or unexpected ADR, but, even now, under-reporting is a current problem. The encouragement of active surveillance or intensive monitoring projects is a useful way to sensitize all health professionals about the importance of ADRs reporting in ensuring a positive risk/advantage drugs' ratio in order to increase safety in patient's treatment.

The 'Forward' project, aims at stimulating the reporting of adverse drug reactions, acquiring more information about the Hospital's drug use, improving appropriate prescription. In particular, it consist in a multicentre project involving Internal Medicine, Metabolic Diseases, Geriatrics operative units of Gaetano Martino Hospital in Messina and Internal Medicine operative units of Acireale, Giarre and Caltagirone Hospitals in Catania. For each medical ward a monitor was expected to perform a systematic analysis of the medical records and to support doctors in the identification and collection of the ADR. The number of ADRs, rate of ADRs for hospitalization, average number of Hospitalization days in patients with ADRs, type of ADRs and drugs involved were evaluated.

During the analysis (from January to December 2014) 279 ADRs were detected on 2,093 medical records examined.

The total ADR rate of admission was 11.7/100 compared to 3.5/100 of the previous year, in absence of monitors.

Moreover, the ADR collected accounted for 55% of total Gaetano Martino Hospital ADRs and for 27% of total Acireale, Giarre and Caltagirone Hospitals in Catania.

69.5% (194) of ADRs, led to hospitalization and 30.5%, (85) of ADRs occurred during hospital stay.

In patients who have had ADRs during hospital stay, the average number of hospitalization days increased compared with patients without ADR (13.1 ± 7.3 vs 9.7 ± 5.5).

Conversely, patients hospitalized due to ADR required an average time of hospitalization similar to hospitalization time due to other causes (9.4 ± 4.8 vs 9.7 ± 5.5).

76% of ADRs were serious: 98% required hospitalization or its prolongation and 2% were life-threatening ADRs.

Antithrombotic agents (aspirin, acenocoumarol, enoxaparin) were the drugs mainly involved in the occurrence of ADRs . According to System Organ Class (SOC) MedDRA, 12.2% of the ADRs affected the haemolymphopoietic system, 11.8% involved metabolic disorders and nutrition, 9.7% implied the gastrointestinal tract. Nine ADR were caused by possible drug interaction, 1 case resulted by drug abuse, 3 cases were due to medication errors and 1 case by misuse.

Active surveillance projects in hospital improve the number and quality of ADR reports. The daily presence of a clinical pharmacist in medical ward plays a significant role in stimulating reporting and contributes to monitoring and improving appropriate prescriptions in hospitalized patients. Moreover, the monitors may document important information about the events and exposure to medicinal products.