Improving the quality of ADR reporting

European Statement:

Patient Safety and Quality Assurance

Author(s):

Sophia Elizabeth Campbell Davies Elena Galfrascoli Tommaso Saporito Gaetana Muserra

What was done?:

Active strategies were implemented by Pharmacists within the Hospital to raise awareness and encourage appropriate detection and reporting of Adverse Drug Reactions (ADRs).

Why was it done?:

Spontaneous reporting is an important tool for the surveillance of drug safety. However, the number of reported ADRs by Hospital healthcare workers and patients was below the gold standard (300 reports/year). Since under-reporting is a major limitation of any Pharmacovigilance system, the causes were analysed by the Pharmacy and a number of actions were put into place.

How was it done?:

Different active strategies have been implemented in the Hospital to increase the number of ADR reports: -Training and educational programs for all healthcare professionals in order to create awareness within the Hospital of the importance of ADR reporting; -Periodic ADR feedback reports to doctors; -Guidelines for monitoring, detecting, preventing and reporting ADRs; -Participation of Clinical Pharmacists in different ward teams (Internal Medicine, Diabetology, Oncology, Paediatrics, Emergency Room, Surgery) allowing Pharmacists to act immediately on problem recognition; -Counseling patients when drugs are dispensed at the Hospital Pharmacy and providing them with "Patient Information Leaflets" containing adherence and ADR diaries. The monitoring tool has been shown to be a crucial element in raising awareness about compliance and ADRs in patients. A successful example has been obtained with DAA treatment in HCV patients showing a 63% compliance to the monitoring tool.

What has been achieved?:

A significant increase has been observed in ADR reporting in the Hospital. Projects implemented by the Pharmacy have almost trebled the number of reports. There has also been an increase in the number of reported severe ADRs.

What next?:

Implementation of different approaches has significantly changed the scenario of ADR reporting in our Hospital. The strategies could be transferred into other healthcare settings by identifying the causes of underreporting ADRs and applying similar strategies both in the Pharmacy and in the ward settings.

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