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Effect of pharmacist involvement on patient reporting of adverse drug reactions: first Italian study.

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Abstract

BACKGROUND: Adding **patients** to the range of potential reporters of adverse drug reactions (ADRs) may increase spontaneous **reporting** and contribute to the detection of signals, one of the primary aims of spontaneous **reporting** systems. Community pharmacies could have an important role in this context as a service for promoting **patient reporting** of ADRs.

OBJECTIVES: The main objectives of the present study were to assess the potential impact of an intervention to promote **patient reporting** in community pharmacies in the Veneto region of Italy, and to compare the characteristics of **patients**' and general practitioners' (GPs) reports of ADRs.

METHODS: The study was conducted in the Veneto region of Italy and involved 211 pharmacists working in 118 community pharmacies. Each pharmacist was asked to select, during the study period, about 250 customers who had received at least one drug, and then to present the spontaneous **reporting** form to those who had experienced a suspected ADR. **Patients** were asked to complete the ADR report form and either give it back to the pharmacist, or send it by fax or mail, or else to fill in the form online.

RESULTS: In a 4-month period, 52,495 customers were interviewed by the pharmacists and 4,949 of them (9.4 %) referred a suspected ADR. The Pharmacovigilance Centre of the Veneto region received 2,311 citizen's ADR **reporting** forms related to the study (from 46.7 % of all **patients** interviewed who had experienced suspected ADRs). After quality control 1,794 of these reports were entered into the Italian Pharmacovigilance Database and were compared with the reports (226) sent by GPs in the Veneto region in the same period. **Patients** reported a higher percentage of known and non-serious reactions than did GPs. Drugs widely used in the community setting, and over-the-counter products, were the drugs most frequently reported by **patients**. In contrast, few reports involving reactions to antineoplastic agents or contrast media-drugs mostly used in a hospital setting-were sent by **patients**.

CONCLUSIONS: Our study shows that **patient reporting** has the potential to add value to the pharmacovigilance system. The overall quality of the information provided in **patients**' reports was good. The differences between reports by **patients** and by GPs indicate different points of view that can enrich spontaneous **reporting**.

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