REPORTING SUSPECTED ADVERSE DRUG REACTIONS IN CELJE COMMUNITY PHARMACY

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Background Adverse drug events (ADR) are a growing health problem in Europe. It is widely and falsely believed that ADRs are rare, but this opinion is mostly due to a very low rate of reporting ADRs since only 6% of all expressed adverse drug reactions are reported. Frequent submissions of quality reports is the key factor of providing a rational and safe use of medications.

Purpose With our research we aimed to increase ADR reporting in Celje Community Pharmacy by systematically educating pharmacists and encouraging use of a web-based ADR reporting tool. In addition, we wanted to explore risk factors for ADR in outpatient clinical setting, assess the severity of reported ADRs and evaluate which drugs according to ATC groups were most often suspected of causing the ADRs.

Method We conducted a pilot project on reporting adverse reactions for a year and included 16 pharmacists. Through the total of four meetings pharmacists were informed about the pharmacovigilance system. In order to facilitate the reporting process itself, we used a previously existing web-based online ADR reporting tool (www.nuz.si). Chi-square test, independent t-test and logistic regression were used to examine risk factors for ADRs. Drugs were classified according to anatomic therapeutic chemical classification (ATC) codes and ADRs to CTCAE (Common Terminology Criteria for Adverse Events) classification.

Findings A total of 66 reports of adverse drug reactions were recorded during the study period, and at least one report was submitted by 62.5% of pharmacists involved. The statistical analysis showed that older patients (65 years and older) and patients with polypharmacotherapy (taking 5 medicines or more) had higher prospects for adverse reactions than younger patients (OR=2.2, p=0.050) and patients taking less than 5 medicines (OR=3.5, p=0.002). Gender did not prove to be a statistically significant risk factor. In the study we found that most reported adverse drug reactions were labeled as not serious and were considered moderate in terms of strength. Drugs suspected of causing adverse effects are among the most widely used medicines in Slovenia (alimentary tract and metabolism, cardiovascular and nervous system).

Conclusion Education and use of online reporting proved to significantly improve ADR reporting and their use would be beneficial if it would be systematically used to encourage ADR reporting in a wider scope. Risk factors in our study proved to be similar than in previous research and it once again calls for more careful treatment of the elderly and patients with polypharmacotherapy.