

Stimulating Spontaneous Reporting of Adverse Drug Reactions by a Patient Directed Incentive

Spontaneous reporting of adverse drug reactions (ADRs) is the most common method used in pharmacovigilance and is especially useful for generating signals of new or rare ADRs. However, the most significant problem with this system is under reporting, since it is dependent upon physicians or pharmacists remembering to report.^[1] Some studies have shown that under reporting is in the range of a 1000-fold phenomenon.^[2,3] Besides, the role of the patient usually remains passive, being the object in which an ADR is detected.

Our idea has been to try to improve spontaneous reporting of ADRs to the Regional Pharmacovigilance Centre in Kragujevac, Serbia, by stimulating patients to report directly to the Regional Centre any suspicion of adverse reactions to drug(s) that they have been taking. Since the foundation of the Regional Centre in 1996, the rate of spontaneous reporting of ADRs has been very low, never exceeding 15 reports per year, for a population of about 200 000. For this reason, we printed 10 000 flyers inviting patients to contact the Regional Centre, and distributed them in the post boxes of 10 000 homes in the city of Kragujevac.

The content of each flyer was as follows:

"Dear fellow citizens,

Taking drugs sometimes may have bad impact on health, since drugs have adverse effects on the human body, too. In the majority of countries up to 10% of all patients actually became sick due to the drugs they were taking. Sometimes the adverse effects were insidious, and could be discovered only after health was seriously and irreversibly affected (e.g. prolonged intake of the drugs against rheumatic diseases could decrease the functioning of the kidneys).

Therefore, if you are taking drugs, and you have any new symptoms, please report them to the physicians of the Regional Centre for Adverse Effects in the Clinical Hospital Centre in Kragujevac, by phone (370060, ext. 224) or in person (the office is located at the entrance of the Clinical Hospital Centre), every working day from 8am to 2pm. The physicians will give you proper advice, of course, free of charge.

Be informed on time!

Prof. Dr Slobodan Jankovic

The pharmacologist"

The printing cost was €30, and medical students distributed the flyers for 1 week. During next 2 months 192 telephone calls and 16 visits were recorded in the Regional Centre, all made by patients suspecting ADRs. Of 208 patient reports, only ten turned out to be real ADRs, with a Naranjo probability score^[4] of ≥ 5 . None of the recorded ADRs was serious. The following ADRs were recorded: aggressive behaviour (maprotiline, two cases), syncope (enalapril, two cases), diarrhoea (ticlopidine), dry cough (cilazapril), rectorrhagia (doxycycline), paraesthesiae (propranolol), skin rash (paracetamol [acetaminophen]), and blurring of vision (pantoprazole). This suggests that for each ADR detected in this way, 1000 flyers were needed.

From the results of this incentive we can conclude that addressing the patient directly is definitely worthwhile when detection and reporting of the ADRs are concerned. The ADRs reported in our study would not have been detected otherwise, because either the patients would not have visited their physicians or the physicians would not take them seriously. However, since the flyers have shown modest effectiveness, some other means of approaching the patients (e.g. messages via mobile phones or e-mail messages, TV advertisements) could give better results.

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Acknowledgements

Professor Jankovic was assisted by the following students from the Medical Faculty, University of Kragujevac,

Kragujevac, Serbia: Nebojsa Aleksic, Ksenija Djokovic, Tanja Macko, Nenad Karapetrovic, Miloje Pantovic, Nebojsa Popadic and Dr Dragan Milovanovic.

Ministry of Science, Technology and Development of Republic of Serbia, supported this work financially, grant no. 1214.

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