PATIENTS’ PREPARATION FOR REPORTING ADR

*Valentina Petkova, Tatyana Benisheva, Dobriana Sidgimova, Petya Trendafilova

Medical University – Sofia, Bulgaria.

SUMMARY
The aim of this study is to assess the Bulgarian patients’ preparation for reporting ADRs. A questionnaire is applied in order to assess the patient’s attitude. Patient reporting of suspected ADRs has the potential to increase knowledge about the possible harm of medicines.

Key words: ADR, patients, reporting.

INTRODUCTION
Pharmacovigilance studies the safety of drugs as used in clinical practice. The discovery of a new ADR has received much attention, both in the literature and in the legislation.(1)

Adverse drug reactions (ADRs) to medicines can lead to human and economic costs. An earlier systematic review found that ADRs were responsible for 7% of hospital admissions and an estimated one in 10 hospital bed days in the UK. As a result from the thalidomide tragedy, Great Britain has established the yellow card for reporting of ADRs by doctors and dentists 1964.

Patients have positive effects from their drug treatment but they also experience their adverse effects.(1)

The signals of ADRs derived from the experiences of patients using the drugs, and reported by doctors and pharmacists, lie at the heart of pharmacovigilance. The most widely used method is the Spontaneous Reporting System (SRS). The SRS is especially effective for detecting rare and serious ADRs, and includes all drugs during their entire lifetime. It
invites health professionals, and increasingly patients, to report their observations or information to a pharmacovigilance centre. (1)

The direct reporting of adverse drug reactions by patients is of great importance from pharmacovigilance point of view. (2)

The main question is whether patient reports will increase the number and quality of the reports submitted and will help for detection of new adverse reactions, thus contributing to an enhancement of drug safety monitoring. (3) A key question regarding patient reporting is the question of the quality of the reports. Regarding the quality, one should differentiate between the quality of the report and the quality of the clinical judgement. The quality of the report concerns the information given in the report. (2)

Patient reporting has been incorporated into the pharmacovigilance systems in several countries, including the USA, Canada, Australia, New Zealand, Denmark, Sweden and the Netherlands. In 2001, the UK Consumers’ Association called for patient reporting to be introduced after highlighting the fact that doctors were often failing to pass on information about suspected adverse reactions. (2)

There are scientific evidences that a system based on consumer reports could enrich the databases with adverse drug effects by revealing reactions which are important to consumers. Such a system might also have a capacity to generate very early signals of previously unsuspected symptomatic reactions with new drugs. (4)

The authors conclude that we should positively value patients’ involvement in drug therapy and their concern regarding possible adverse effects. As a consequence, patients’ reports on ADRs should be accepted. (1)

That is why the aim of this study is to assess the Bulgarian patients’ preparation for reporting ADRs.

**METHODOLOGY**

A pilot study has been undertaken among 100 patients of pharmacy and hospital living in Bulgaria in order to assess the patients’ awareness about the importance of adverse drug reactions reporting, and the legislative initiatives in the pharmacovigilance area after 2013. Methods applied are:
documentary method;
developed questionnaire of 12 anonymous questions on multiple choice;
sociological method;
methods for analyzing and processing of the data;
graphical, statistical software;
mathematical methods.

A specially developed questionnaire of 12 anonymous questions on multiple choice has been applied among patients with different diseases. The developed questionnaire was completed at different hospitals and pharmacies in Sofia.

A total of 100 patients (response rate: 100%) filled in the questionnaire.

RESULTS

The demographic characterization of the patients, included in the survey show that female prevail (80%) and 52% are up to 40 years. (Figure 1 and Figure 2)

![Figure 1.](image-url)
65% from the patients, included in the survey are with higher education, while 35% are with secondary. All the patients are well educated that grants the possibility to understand correctly the questions in the project from one point of view and to realize their responsibility in the process of pharmacovigilance from other. (Figure 3)

Figure 2.

Figure 3.
Asked “what is drug safety?” the patients give very interesting answers – 55% think that this is a safe, rational and effective drug application, while 41% consider it as system of detection, assessment and prevention of effects/reactions during drug treatment. In fact the two answers cover the real safe and rational drug application so we can consider that the patients know very well the meaning of the “drug safety”. (Figure 4)

Figure 4

What is ADR?

- definition from the Drug Law
- reaction because of misuse of drugs

Figure 5
83% know very well the meaning of adverse drug reaction so it can be expected that when they are reporting it, BDA will receive valuable information. (Figure 5)

The patients from the survey are a little bit confused who can report ADRs. Only 26% know that they can report to the BDA. (Figure 6) But about 70% know that the control organ of ARD is BDA. (Figure 7) and 87% know that the reporting form is localized on the web page of BDA. (Figure 8) So if ADR occurs they can easily find it and if they have a will to report it they can feel the form and send it to BDA for assessment.
Figure 8

DISCUSSION AND CONCLUSIONS

Awareness of ADRs by health professionals and patients can contribute to prudent and sensible prescription practices and compliance, and in this way may decrease the burden of drug side effects (1).

This study discusses the involvement of patients in the reporting of adverse drug reactions (ADRs). Since concerns about the safety of drugs are also patients’ concerns, the patient could also play a part in decreasing the risks of drug therapy. Patient interest in the safety aspects of drugs is evident – great percentage of the patients know what is ADR, how and where to report it. Patient reporting of suspected ADRs has the potential to increase knowledge about the possible harm of medicines.

REFERENCES