Pharmacovigilance: Spontaneous reporting systems

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Abstract

Introduction: Pharmacovigilance system is consisted of several approaches used for drug safety surveillance. Spontaneous reporting systems in European countries have been established in the second half of the 20th century. Originally, spontaneous collection of adverse drug reactions was designed for healthcare professionals. Under-reporting was in general considered as the main weakness of spontaneous reporting system. To increase the reporting activity, direct patient reporting has been included in spontaneous reporting system at national competent authorities.

Aims: The aim of this work was to characterize spontaneous reporting system. Subsequently, we focused on the evaluation of position of patient-reported outcomes of adverse events (PRO-AE) in established systems of the European countries. In particular, we i) characterized reporting activity within European countries, ii) evaluated the position of adverse drug reaction (ADR) reports directly submitted by patients to national competent authorities, and iii) overviewed of the processing of PRO-AEs.

Methodology: Practical part was based on questionnaires distributed to national competent authorities and literature search of electronic databases with relevant published articles.

Results: Characterization and comparison of national spontaneous reporting systems were based on population based reporting ratio. Increase in reporting activity at national and international level throughout the years was detected. Many factors may influence spontaneous reporting activity, nevertheless legal obligation of healthcare professionals to report any ADR did not correlate with the increase of reporting activity across the European countries.

PRO-AEs became very important in the framework of spontaneous reporting system. Various attitudes to direct patient reporting were detected among respective national competent authorities. Available studies concerned to the comparison reports coming from healthcare professionals or directly from patients reflected various outcomes. After legislation requirement to accept PRO-AEs, which came into force in 2012, issues like medical and reporter validation should be solved.

Conclusion: Spontaneous reporting system is indispensable tool used by national competent authorities to collect ADR reports. Establishment direct patient reporting in the current spontaneous reporting systems brought both opportunities and potential complications due to specific characteristics of patients as reporters.