Adverse Drug Reaction Reporting by Patients in the Netherlands
Three Years of Experience

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Abstract

Background: There has been discussion about the acceptance of adverse drug reactions (ADRs) reported by patients to spontaneous reporting systems. Lack of experience with patient reporting in real life was one of the main drawbacks in this debate. This study covers 3 years of experience with patient reporting in daily practice. We compared patient reports with reports from healthcare professionals. Although patients have the opportunity to report ADRs in several countries, little is published in the literature about the contribution that patient reports have in practice. To our knowledge, this paper is the first to describe long-term experiences with patient reporting as part of a spontaneous reporting system.

Methods: The number of reports received, age and sex of the reporters, characteristics of the most frequently reported drugs and characteristics of the ADRs (most frequently reported ADRs, seriousness, outcome) in a 3-year period (April 2004–April 2007) were compared between patient reports and reports from healthcare professionals.

Findings: During this 3-year period, the Netherlands Pharmacovigilance Centre Lareb received 2522 reports directly from patients, concerning 5401 ADRs. In the same period, healthcare professionals submitted 10 635 reports, concerning 16 722 ADRs. Differences were found in the categories of seriousness and outcome of the reported ADRs between patients and healthcare professionals. Conversely, similarities between patient reports and reports from healthcare professionals were found in age, sex, most frequently reported ADRs and most frequently reported drugs.

Interpretation: Our study highlights clearly that valuable differences between ADR reports from patients and reports from healthcare professionals exist. Differences in interpretation by patients and healthcare professionals may cause the observed disparities in seriousness and outcome of reported ADRs. However, the similarities between patient reports and reports from healthcare professionals in most frequently reported ADRs and most frequently reported drugs are striking. After 3 years of experience with patient reporting, we conclude that patient reporting in spontaneous reporting systems is feasible and that it contributes significantly to a reliable pharmacovigilance.

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